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November 9, 2015

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

Jocelyn Samuels  
Director, Office for Civil Rights  
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 Health Law Program (NHeLP) is a public interest law firm working to advance access to quality health care and protect the legal rights of low-income and underserved people. NHeLP provides technical support to direct legal services programs, community-based organizations, the private bar, providers and individuals who work to preserve a health care safety net for the millions of uninsured or underinsured low-income people. NHeLP has been an ardent supporter of the Affordable Care Act's (ACA's) section 1557 on which this NPRM is based and we provide the following comments to further strengthen the NPRM.

## § 92.2 Applications

### a. 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 HHS<sup>1</sup> and as such HHS's rulemaking will be given *Chevron* deference.<sup>2</sup>

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 clearly the agency best suited for creating regulations that ensure that Section 1557's intended protections be put into effect. Consistent regulations across all agencies would also promote the equal and uniform application of the provision's protections to all health programs and activities that receive federal financial assistance.<sup>3</sup>

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<sup>1</sup> 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 1681 of this title...”); Age Discrimination Act, 42 U.S.C. § 6103(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....”).

<sup>2</sup> *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842-43 (1984).

<sup>3</sup> 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.”).

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 in its role as coordinating agency for implementation and enforcement of antidiscrimination rules applicable to recipients of federal financial assistance.<sup>4</sup> 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 prioritize those agencies with significant involvement in health care, such as the Department of Veterans Affairs.

*b. Exceptions from the Sex Discrimination Prohibition*

The Department requested comment on whether the final regulation implementing § 1557 should include any specific exemptions to the sex discrimination provision and on the health consequences that would ensue if such an exemption were created. NHeLP strenuously objects to any religious exemption to § 1557, as such an exemption would undermine the right of individuals to access comprehensive health care services, including reproductive health care, free from discrimination, and thwart the objectives of the Affordable Care Act (ACA).

There is nothing in the legislative history or language of the regulation itself that permits exceptions to § 1557's prohibition on sex discrimination. Moreover, existing statutes that allow individuals and entities to refuse to provide certain services are more than sufficient to accommodate religious objections. These statutes are not without extremely harmful consequences. To add additional exemptions would further marginalize and endanger women's health.

Religious exemptions impact health outcomes in negative and sometimes life-threatening ways. Health care should be patient-centered and based on standards of care, but that is often not the case for millions of women who receive treatment from religiously-affiliated providers and institutions. The health consequences of health care refusals are well documented. As the NPRM states,

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<sup>4</sup> Executive Order 12250 (Nov. 2, 1980), available at <http://www.archives.gov/federal-register/codification/executive-order/12250.html> ("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.").

“[e]qual access for all individuals without discrimination is essential to achieving” the ACA’s aim to expand access to health care and health coverage for all, as “discrimination in the health care context can often...exacerbate existing health disparities in underserved communities.”<sup>5</sup>

Women—low income women and women of color in particular—are among these underserved communities who are disproportionately affected by health care refusals which overwhelmingly involve access to reproductive health care, thereby singling out women for unequal treatment. It has long been established that a woman’s ability to control her reproductive life and to become a parent when she has made an affirmative decision to become pregnant is fundamental to her ability to obtain an education and to be economically self-sufficient.<sup>6</sup>

NHeLP urges the Department to fully implement § 1557 without exemption.

- i. Neither statutory nor legislative history supports adding a religious refusal to § 1557, and the only exceptions to § 1557’s broad nondiscrimination mandate are specifically and explicitly contained in Title I of the ACA.

The NPRM specifically requested comment on “whether the regulation should include any specific exemptions for health providers, health plans, or other covered entities with respect to the requirements of the propose rule related to sex discrimination.”<sup>7</sup> There is nothing in the legislative history or language of the regulation itself that permits exceptions to § 1557’s prohibition on sex discrimination. NHeLP first put forth this argument during the Request for Information period and once again we stress that § 1557 furthers a compelling government interest;<sup>8</sup> any exemption to the antidiscrimination mandate of the ACA would undermine the goal of health reform to combat practices that have negatively and profoundly affected women’s health.

Section 1557 bars discrimination “on the ground prohibited under . . . title IX of the Education Amendments of 1972,” which is sex.<sup>9</sup> It is the first federal law to broadly prohibit sex discrimination in health care. In addition, § 1557 must not be misinterpreted to narrow existing interpretations of and protections against sex discrimination. It is critical that regulations issued pursuant to this new statute reflect the long-established jurisprudence of strong protections against sex discrimination in federal law.

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<sup>5</sup> Nondiscrimination in Health Programs and Activities, 80 Fed. Reg. 54,172, 54,194 (Sept. 8, 2015) (to be codified at 45 C.F.R. pt. 2).

<sup>6</sup> See *Planned Parenthood of Se Pa. v. Casey*, 505 U.S. 833, 876-78 (1992) (“The ability of women to participate equally in the economic and social life of the Nation has been facilitated by their ability to control their reproductive lives.”).

<sup>7</sup> Nondiscrimination in Health Programs and Activities, 80 Fed. Reg. 54,172, 54,173 (Sept. 8, 2015) (to be codified at 45 C.F.R. pt. 2).

<sup>8</sup> See NHeLP’s comments on the Section 1557 RFI, <http://www.healthlaw.org/about/staff/mara-youdelman/all-publications/1557-comments#.ViT3TH6rQdU>.

<sup>9</sup> 20 U.S.C. § 1681(a) (2012).

Regulations, guidance, and case law under Title VII of the Civil Rights Act of 1964, the Pregnancy Discrimination Act (PDA), and (most importantly, given § 1557’s statutory language) Title IX of the Education Amendments of 1972 must inform the interpretation of what constitutes sex discrimination in health care under § 1557. We support the NPRM’s explanation that § 1557’s prohibition of sex discrimination includes discrimination based on pregnancy, gender identity, and sex stereotypes.<sup>10</sup>

The NPRM also requested comment on “whether the exemptions found in Title IX and its implementing regulation should be incorporated into this proposed rule.”<sup>11</sup> The § 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>12</sup> Thus, the only exceptions to § 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 § 1557’s antidiscrimination provision must be read strictly and narrowly, and courts have strictly construed such exceptions to give the fullest force to the primary operation of the general rule.<sup>13</sup>

Nothing in § 1557, its language or legislative history, allows for any other limitations or exceptions regarding its application. While it is true that Title IX contains limited exceptions to its protection in certain circumstances, these exceptions are not incorporated into § 1557. First, because those limited exceptions are not explicitly stated in § 1557, they cannot be read to apply to it, therefore, § 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.<sup>14</sup> Since Title IX has codified pregnancy discrimination as a form of sex discrimination, and in light of § 1557’s expansive and unprecedented antidiscrimination provisions, it is clear that refusals that center on reproductive health care—including contraception, sterilization, abortion, and other reproductive health care services—are not protected under § 1557, as they comprise a

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<sup>10</sup> Dep’t of Health & Human Servs., Request for Information Regarding Nondiscrimination in Certain Health Programs or Activities, 78 Fed. Reg. 46,558, 46,559 (proposed Aug. 1, 2013) (“Sex discrimination (including discrimination on the basis of gender identity, sex stereotyping, or pregnancy)”).

<sup>11</sup> Nondiscrimination in Health Programs and Activities, 80 Fed. Reg. 54,172, 54,173 (Sept. 8, 2015) (to be codified at 45 C.F.R. pt. 2).

<sup>12</sup> Patient Protection and Affordable Care Act § 1557, codified at 42 U.S.C. § 18116 (2012).

<sup>13</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)). See also *New York v. Bloomberg*, 524 F.3d 384, 402 (2d Cir. 2008); *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.”)

<sup>14</sup> 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).

kind of sex discrimination. The sex discrimination provision, therefore, limits the scope of permissible health care refusals.

ii. Existing federal statutes offer more than sufficient protection for any health care refusal

Numerous federal and state conscience protections are already in place that allow individuals and institutions to refuse to provide certain reproductive health care services.<sup>15</sup> The first major refusal clauses were adopted in the 1970's shortly after the Supreme Court decision, *Roe v. Wade*.<sup>16</sup> A myriad of federal conscience laws, regulations, and appropriations riders have followed. For example, the Church Amendment, allows certain individuals who receive federal funding to opt out of providing abortions or sterilizations, and prohibits the government from predicating federal funding to institutions on the provision of abortion or sterilization.<sup>17</sup> The Church Amendment also allows individuals to refuse to “perform or assist in the performance of a health care service program or research activity” to which they have a religious or personal moral objection.<sup>18</sup> A 1996 amendment to the Public Service Health Act known as the Coats Amendment further extended conscience protections, stating that medical training programs cannot be denied accreditation based solely on the fact the program does not require, provide, or refer for training in abortions.<sup>19</sup> The Weldon Amendment was first signed into law in 2004 as part of the Department of Labor, Health and Human Services, and Education and Related Agencies Appropriation Act of 2005 spending bill, and it prohibits “discrimination” by any federal agency or state or local government against an entity or individual who refuses to provide, pay for, provide coverage for, or provide referrals for abortion services.<sup>20</sup> Finally, the Religious Freedom Restoration Act (“RFRA”) provides protections for health care refusals.<sup>21</sup> Moreover, state laws provide even more conscience protections, as forty-five states allow individual health care providers to refuse to perform abortion services, forty-three states allow institutional refusals to perform abortion services, twelve states allow some health care providers to refuse to provide contraceptive services, and eighteen states permit health care providers to refuse to perform sterilization procedures.<sup>22</sup> Ultimately, these refusal laws

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<sup>15</sup> See generally <http://www.hhs.gov/ocr/civilrights/faq/providerconsciencefaq.html>.

<sup>16</sup> *Roe v. Wade*, 410 U.S.113 (1973).

<sup>17</sup> 42 U.S.C. § 300a-7. The Church Amendment also prohibits institutions from discriminating against providers who do perform abortions and sterilizations and allows individuals to refuse to “perform or assist in the performance of a health care service program or research activity to which they have a religious or personal moral objection.”

<sup>18</sup> *Id.* § 300a-7(d).

<sup>19</sup> 42 U.S.C. § 238n.

<sup>20</sup> Consolidated Appropriations Act, 2005, Pub. L. No. 108-447, § 508(d)(1), 118 Stat. 2809, 3163 (2004); Departments of Labor, Health and Human Services, Education, and Related Agencies Appropriations Act, 2006, Pub. L. No. 109-149, 119 Stat. 2833, 2851; Consolidated Appropriations Act, 2008, H.R. 2764, 110th Cong. § 508(d)(1) (2007).

<sup>21</sup> Religious Freedom Restoration Act, Pub. L. No. 103-141, 107 Stat. 1488 (codified as amended at 42 U.S.C. §§ 2000bb to 2000bb-4 (2012)).

<sup>22</sup> Guttmacher Inst., *Refusing to Provide Health Services* (Oct. 1 2015), [http://www.guttmacher.org/statecenter/spibs/spib\\_RPHS.pdf](http://www.guttmacher.org/statecenter/spibs/spib_RPHS.pdf).

privilege the personal beliefs of providers and institutions over the well-being of patients and accepted medical standard of care.

Section 1557 does not displace these protections. Section 1557's robust protection of the rights of patients is a corollary and a counterbalance to conscience protections already in place for providers and institutions. While the ACA does not affect current federal refusal laws, Congress consciously rejected efforts to broaden them, most notably when Congress rejected the Brownback Amendment that would have prevented the ACA from requiring "an individual or institutional health care provider to provide, participate in, or refer for an item or service to which such provider has a moral or religious objection, or require such conduct as a condition of contracting with a qualified health plan."<sup>23</sup> Enacting an exemption to the sex discrimination provision would only serve to dismantle the strong antidiscrimination principles contained in the ACA and would run contrary to the legislative history, statutory text, and underlying purpose of § 1557.

- iii. Health care refusals violate evidence-based practice and medical standards of care, undermine women's agency, and lead to worse health outcomes, which could have life-threatening implications

Every patient expects that when she visits a medical professional or enters a hospital that she will receive care that is evidence-based and meets the medical standard of care. Health care refusals seek to substitute personal religious beliefs for medical evidence and quality care, specifically targeting women's reproductive health services.

Examples of medical standards of care overrun by health care refusals abound in the reproductive health context. As one example, preeclampsia and eclampsia are serious pregnancy complications that affect 3.9% of all live births in the United States and were responsible for 17 percent of all maternal deaths in the United States.<sup>24</sup> In addition, significant racial disparities exist in the rate of and complications associated with a preeclampsia and eclampsia diagnoses, and African-American women are more susceptible to preeclampsia and eclampsia. The American College of Obstetricians and Gynecologists ("ACOG") and the American Academy of Pediatrics ("AAP") have longstanding guidelines on the treatment of preeclampsia: in cases of severe preeclampsia and eclampsia, ACOG and AAP recommend abortion as the means of delivery, regardless of fetal age or the potential for survival.<sup>25</sup> Only when a woman suffers from mild preeclampsia should expectant management be considered, and only after a patient and her doctors weigh a variety of factors, including maternal condition, fetal condition, gestational age, and prospect for fetal survival.<sup>26</sup> Even when weighing

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<sup>23</sup> 155 CONG. REC. 13,193-01 (2009).

<sup>24</sup> Am. Coll. of Obstetricians and Gynecologists. ACOG Practice Bulletin No. 33, *Diagnosis and Management of Preeclampsia and Eclampsia* 159-67 (2002), <http://www.pqcnc.org/documents/cmop/cmopresources/PQCNCCMOPAGOGBulletin33.pdf>.

<sup>25</sup> Am. Acad. of Pediatrics; Am. Coll. of Obstetricians and Gynecologists, March of Dimes Birth Defects Foundation. *Guidelines for perinatal care* (6th ed. 2007).

<sup>26</sup> *Supra* note 24, at 165.

these many factors, however, “the woman’s condition will always take priority over the fetal condition.”<sup>27</sup>

Whereas the standards set by ACOG, American Medicaid Association (“AMA”), AAP, and other medical organizations focus on the well-being of the patient and avoiding medical harm, at a religiously-affiliated hospital, and in situations involving reproductive health care, religious tenets take priority over the woman’s condition, the standards of care, and medical guidelines. For example, a doctor must often show several maternal harm or death as a prerequisite to receiving approval for treatment that could result in miscarriage.<sup>28</sup> A large national qualitative study of ob-gyns working in Catholic hospitals across the country found that many of these doctors, when they believed that a woman who was experiencing a pregnancy complication or miscarriage “should be offered a specific intervention to prevent infection or preserve her health or fertility,” hospital administrators often prohibited them from doing so, “citing religious ethics principles,” not the accepted standard of care.<sup>29</sup> One doctor stated that her hospital does not “adher[e] to their original commitment to putting the woman’s health first.”<sup>30</sup>

When health care systems or facilities assert health care refusals, doctors are constrained from offering the quality care they were trained to deliver. Catholic hospitals, medical practices, and insurers are governed by the Ethical and Religious Directives for Catholic Health Care Services (“Directives”) promulgated by the U.S. Conference of Catholic Bishops (“USCCB”), which prohibit, among other things, family planning (even to prevent pregnancy as a result of a rape), sterilization, abortion, assisted reproductive technology, the distribution of condoms even when intended to prevent HIV/AIDS or other sexually transmitted infections, and some end of life decisions.<sup>31</sup>

The prohibition on abortion applies to the direct termination of any stage of any pregnancy and regardless of circumstance; no exceptions exist for rape, incest, the health or life of the woman, or the condition of the fetus because they are not “morally legitimate” in the eyes of the Church.<sup>32</sup> Moreover, treatment options are not subject to patient control or physician recommendation under the Directives; a hospital administrator must ensure that any procedure or treatment complies with religious

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<sup>27</sup> Royal Coll. of Obstetricians and Gynaecologists, *The Management of Severe Pre-Eclampsia/Eclampsia*. Guideline 10A (March 2006).

<sup>28</sup> Lori R. Freedman & Debra B. Stulberg, *Conflicts in Care for Obstetric Complications in Catholic Hospitals*, 4 *AJOB PRIMARY RESEARCH* 1, 6 (2013).

<sup>29</sup> *Id.* at 9.

<sup>30</sup> *Id.* at 5.

<sup>31</sup> U.S. Conf. of Cath. Bishops, *Ethical and Religious Directives for Catholic Health Care Services, Fifth Edition*, (Nov. 17, 2009), <http://www.usccb.org/issues-and-action/human-life-and-dignity/health-care/upload/Ethical-Religious-Directives-Catholic-Health-Care-Services-fifth-edition-2009.pdf>.

<sup>32</sup> Directive 27, *Id.* at 20.



doctrine prior to authorization.<sup>33</sup> For example, some religiously-affiliated hospitals and providers refuse to perform uterine evacuations on women who are miscarrying in the event that there is a detectable fetal heartbeat.<sup>34</sup> Women experiencing ectopic pregnancies—ninety-seven percent of which are not viable—are often forced to undergo painful, invasive surgery to remove the entire fallopian tube rather than treating the pregnancy with medication to end the pregnancy which is the accepted standard of care in many cases.<sup>35</sup> Women also cannot have tubal ligations at a Catholic hospital;<sup>36</sup> cannot receive fertility treatments;<sup>37</sup> and cannot access hormonal contraception or long acting reversible contraceptives, such as IUDs.<sup>38</sup> The Directives even prevent women from receiving contraception in the most urgent situations. For example, rape victims cannot obtain emergency contraception (EC) at many Catholic hospitals, due to the ambiguous and confusingly-worded nature of Directive 36. Only three percent of Catholic hospitals provide EC without restriction, burdening all women and increasing their likelihood of becoming pregnant.<sup>39</sup>

Since unintended pregnancy is linked to worse health outcomes for both mother and infant, these contraception refusals have long-lasting ramifications, and the importance of women's ability to prevent pregnancy for many health-related reasons is well established within medical guidelines across a range of practice areas.<sup>40</sup> Children, for one, benefit from women's control over reproduction. Children born from wanted pregnancies tend to be healthier than those born from unwanted pregnancies, and numerous poor health outcomes – including low birth weight, premature birth, and infant mortality – result when health conditions are not optimized prior to pregnancy.<sup>41</sup>

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<sup>33</sup> Nat'l Women's Law Ctr., *Below the Radar: Health Care Provider's Religious Refusals Can Endanger Pregnant Women's Lives and Health 2* (Jan. 2011), <http://www.nwlc.org/sites/default/files/pdfs/nwlcbelowtheradar2011.pdf>.

<sup>34</sup> Lori R. Freedman, et al., *When There's a Heartbeat: Miscarriage Management in Catholic-Owned Hospitals*, 98 AM. J. PUB. HEALTH 1774, 1774 (2008).

<sup>35</sup> *Supra*, note 30; see also Angel M. Foster, et al., *Assessing Hospital Policies & Practices Regarding Ectopic Pregnancy & Miscarriage Management*, IBIS REPROD. HEALTH & NAT'L WOMEN'S LAW CTR. 5 (2010), [http://www.nwlc.org/sites/default/files/pdfs/ibis\\_rh\\_-\\_nwlc\\_qualitative\\_study\\_report.pdf](http://www.nwlc.org/sites/default/files/pdfs/ibis_rh_-_nwlc_qualitative_study_report.pdf).

<sup>36</sup> Directive 53, *supra*, note 31 at 27.

<sup>37</sup> Directive 41, *id.* at 25.

<sup>38</sup> Directive 52, *id.* at 27.

<sup>39</sup> Catholics for a Free Choice, *Second Chance Denied: Emergency Contraception in Catholic Hospital Emergency Rooms 9* (Jan. 2002), [http://www.catholicsforchoice.org/topics/healthcare/documents/2002secondchancedenied\\_001.pdf](http://www.catholicsforchoice.org/topics/healthcare/documents/2002secondchancedenied_001.pdf).

<sup>40</sup> Ctrs. for Disease Control & Prevention, Dep't of Health and Human Servs., *Unintended Pregnancy Prevention* (Apr. 30, 2010), <http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/index.htm>.

<sup>41</sup> World Health Org., *The World Health Report 2005: Make Every Mother and Child Count 50* (2005), [http://www.who.int/whr/2005/whr2005\\_en.pdf?ua=1](http://www.who.int/whr/2005/whr2005_en.pdf?ua=1); Kay Johnson, et al., Ctrs. for Disease Control & Prevention, *Recommendations to Improve Preconception Health and Health Care—United States: A Report of the CDC/ATSDR Preconception Care Work Group and the Select Panel on Preconception Care*, *MMWR Morbidity & Mortality Weekly Report* (April 21, 2006), <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5506a1.htm>.

Moreover, while refusal clauses and denials of care prevent all women from obtaining complete and accurate contraceptive counseling, devices, and supplies, this burden falls disproportionately and most harshly on low-income women and low-income women of color. Low-income women and low-income women of color already experience severe health disparities in reproductive health, maternal health outcomes, and birth outcomes. Low-income women have higher rates of unintended pregnancy, as compared to higher-income women.<sup>42</sup> Low-income women are the least likely to have the resources to obtain reliable methods of family planning, and yet, they are most likely to be impacted negatively by unintended pregnancy. Further, nearly one out of ten African American women and one in fourteen Latinas of reproductive age experience an unintended pregnancy each year. Low income women have unintended pregnancy rates more than five times the rate for women in the highest income level, and inaccessible and unaffordable contraceptive counseling and services contribute to these health disparities.

Clinicians in Catholic hospitals have discussed with researchers their frustrations with their institution's ethics committees, which one ob-gyn said started to enforce the "the rules of the Church" more strictly once Pope Benedict assumed the papacy.<sup>43</sup> This resulted in her requests to perform tubal ligations denied for patients "that...should never get pregnant, because if they did, it would be risking the mother's life."<sup>44</sup>

Incidents of harm have been publicly reported. The plight of a gravely ill twenty-seven year old woman who was eleven weeks pregnant with her fifth child was well-publicized in 2010.<sup>45</sup> Sister Margaret McBride, a hospital administrator at St. Joseph's Hospital and Medical Center in Phoenix, Arizona, authorized an abortion for the woman to save her life, an action that resulted in her prompt ex-communication for doing "evil," according to the Diocese of Phoenix.<sup>46</sup> St. Joseph Hospital was also stripped of its 115-year religious affiliation with the Church, an action which demonstrated to all Catholic hospitals that ex-communication of providers and administrators and the loss of institutional and financial support are the very real and serious consequences they may face as a result of providing reproductive health care, even in the event of an emergency.<sup>47</sup>

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<sup>42</sup> Lawrence B. Finer & Mia R. Zolna, *Unintended Pregnancy in the United States: Incidence and Disparities*, 2006 GUTTMACHER INST. 8 (2011), <http://www.guttmacher.org/pubs/journals/j.contraception.2011.07.13.pdf>.

<sup>43</sup> Debra B. Stulberg *et al.*, *Tubal Ligation in Catholic Hospitals: A Qualitative Study of Ob-Gyns' Experiences*, 90 CONTRACEPTION 422, 426 (2014).

<sup>44</sup> *Id.*

<sup>45</sup> Nicholas Kristof, *Sister Margaret's Choice*, NY TIMES (May 26, 2010), <http://www.nytimes.com/2010/05/27/opinion/27kristof.html>.

<sup>46</sup> Barbara Bradley Hagerty, *Nun Excommunicated for Allowing Abortion*, NPR (May 19, 2010), <http://www.npr.org/templates/story/story.php?storyId=126985072>.

<sup>47</sup> Ed Pilkington, *US Catholic Hospital's Ties to Church Cut Over Abortion That Saved Mother*, THE GUARDIAN (Dec. 22, 2010), <http://www.theguardian.com/world/2010/dec/22/us-catholic-bishop-hospital-abortion>.

Tamesha Means sued the USCCB over the medical care she received at a Catholic hospital in Michigan—the only hospital in the county—where the doctors at the hospital did not inform her that her pregnancy posed serious risks to her health, that the fetus was in distress and had almost no chance of survival, and that inducing labor immediately and terminating her pregnancy was the safest medical option.<sup>48</sup> The hospital refused to provide this information or any other medical care, and only when “the feet of the fetus breached her cervix and she began to deliver” did the hospital admit her. Nevertheless, the baby died shortly after birth, and Means herself was severely ill with an infection that the hospital left untreated.<sup>49</sup>

These practices unacceptably compromise the health, safety, and autonomy of the women who seek care at religiously-affiliated institutions, and any exemption to § 1557 would only codify these practices and undermine the intent of the ACA.

- iv. Due to the expansion of religiously-affiliated hospitals and health systems, any exemption would further threaten women’s health and perpetuate sex discrimination

The Affordable Care Act has spurred a marked increase in hospital mergers, particularly between Catholic hospitals with non-sectarian hospitals. One health care consulting firm has predicted that the ACA will result in nearly twenty percent of hospitals in the United States merging in the next five to seven years.<sup>50</sup> As a result, it is particularly important to ensure that institutional refusals do not compromise access to health services and reproductive health care in particular. This is because religiously-affiliated providers and institutions impose the greatest number of barriers to care and prohibit the delivery of many reproductive health services on their premises, resulting in interference with the delivery of care that meets accepted medical practice guidelines.

These poor health outcomes affect millions of women across the country. According to the Catholic Health Association, “[t]he Catholic health ministry is present in all 50 states and comprises the nation’s largest group of not-for-profit health care sponsors, systems, and facilities.”<sup>51</sup> Catholic hospitals control more than 15% of the hospital beds in the U.S, and one out of six Americans receives medical care at a Catholic hospital each year.<sup>52</sup> In addition, religiously-affiliated managed care plans, employers, and owners of

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<sup>48</sup> Compl. at ¶ 2, Means v. U.S. Conf. of Catholic Bishops, No. 13-cv-14916, (E.D. Mich. Nov. 29, 2013).

<sup>49</sup> *Id.* at ¶ 3.

<sup>50</sup> See Julie Creswell & Reed Abelson, *New Laws and Rising Costs Create a Surge of Supersizing Hospitals*, N.Y. TIMES (Aug. 12, 2013), <http://www.nytimes.com/2013/08/13/business/bigger-hospitals-may-lead-to-bigger-bills-for-patients.html>; see also David M. Cutler & Fiona Scott Morton, *Hospitals, Market Share, and Consolidation*, 310 JAMA 1964 (Nov. 13, 2013), [http://scholar.harvard.edu/files/cutler/files/jsc130008\\_hospitals\\_market\\_share\\_and\\_consolidation.pdf](http://scholar.harvard.edu/files/cutler/files/jsc130008_hospitals_market_share_and_consolidation.pdf).

<sup>51</sup> See Cath. Health Assoc. of the U.S., *Catholic Health Care in the United States: About Facts & Statistics*, (Jan. 2015), <http://www.chausa.org/about/about/facts-statistics>.

<sup>52</sup> See *id.*

for-profit companies have restricted patient access to care, and reproductive health services in particular.<sup>53</sup>

Despite these myriad of restrictions, however, women often cannot avoid seeking care at a Catholic hospital, either because the name of the facility does not indicate a religious affiliation or because of the strong Catholic hospital presence in rural America.<sup>54</sup> In light of the increased number of mergers between Catholic and non-sectarian hospitals, it is very likely that more women than ever before will have only a Catholic or religiously-affiliated hospital as their only provider option. This practice ensures that the Directives will have an ever expanding impact and govern the health care delivery—or refusal of delivery—of a growing number of individuals in the U.S.<sup>55</sup> If these entities are exempted from § 1557's sex discrimination provision, they will continue to compromise the health of millions of women who require reproductive health care services.

- v. The final rule should contain a provision affirming the right of patients to informed consent, accurate and complete medical information, and the autonomy to make their own health care decisions

Well-established standards of informed consent require that patients have accurate and complete information on which to make their health care decisions. In accordance with AMA and ACOG guidelines, a clinician must provide adequate disclosure and explanation of the full range of medically appropriate treatment options before the patient and clinician settle on a course of treatment.<sup>56</sup> Religious refusals, however, deprive individuals of information about their medical options. The final rule should make clear that religiously-affiliated institutions and providers are not shielded from the obligation to provide information concerning either the status of the patient or the limited number of treatment options that the institution or provider is willing to furnish. This is in line with the current standards of care and current federal commitment to informed consent.<sup>57</sup> Such a requirement would also enable women to seek care in a nonsectarian hospital or from a provider who does not have objections.

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<sup>53</sup> Nat'l Women's Law Ctr., *Health Care Refusals Harm Patients: The Threat to Reproductive Health Care* (May 2014), [http://www.nwlc.org/sites/default/files/pdfs/refusals\\_harm\\_patients\\_repro\\_factsheet\\_5-30-14.pdf](http://www.nwlc.org/sites/default/files/pdfs/refusals_harm_patients_repro_factsheet_5-30-14.pdf).

<sup>54</sup> Thirty-four percent of Catholic hospitals in the United States are in rural settings. See <https://www.chausa.org/about/about/facts-statistics>.

<sup>55</sup> Susan Berke Fogel & Lourdes A. Rivera, *Saving Roe is Not Enough: When Religion Controls Healthcare*, 31 *FORDHAM URB. L.J.* 725, 731 (2004).

<sup>56</sup> Am. Med. Assoc., *Opinion 8.082 Withholding Information from Patients* (Nov. 2006), <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion8082.page>; Committee on Ethics, Am. Coll. of Obstetricians and Gynecologists, *Informed Consent, Committee Opinion* (Aug. 2009), <http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Ethics/Informed-Consent>.

<sup>57</sup> 42 C.F.R. § 482.55 (setting forth the conditions of hospital participation in Centers for Medicare and Medicaid Services).

vi. Conclusion

NHeLP strongly encourages HHS to enact a final rule that has no religious exemption to the sex discrimination provision, makes clear that health care refusals involving reproductive health care constitute impermissible sex discrimination, and contains an affirmative right to access medical information. The ACA's aim to expand access to health care that is free from discrimination cannot be realized without a strong sex discrimination prohibition that applies equally to all providers and institutions. The text and legislative history make clear that the purpose of § 1557 is to eradicate discrimination in health care, and this prohibits the enactment of an exemption.

All women should be able to make their own reproductive health care decisions based on their own beliefs, not the beliefs of providers or institutions, and all women should have access to the care they need. An organization's religious beliefs should not stand in the way of an individual woman's decision to access the health care that she not only wants, but in many cases, that she needs. Religious exemptions authorize health care refusals that have very real and devastating consequences for women. In light of this, the Department should implement § 1557 without an exemption to the sex discrimination provision.

*c. Age Discrimination*

We urge the Department to specify in Section 92.2(b)(1) that Section 1557's application to age discrimination prohibits age-related distinctions in benefit coverage, apart from the exclusions in the Age Act for (1) age distinctions contained in a federal, state, or local statute or ordinance that provides benefits based on age, establishes criteria for participation in age-related terms, or describes intended beneficiaries to target groups in age-related terms, and (2) actions that reasonably take into account age as a factor necessary to the normal operation or the achievement of any statutory objective of such program or activity.<sup>58</sup> Thus, for example, a decision to limit coverage of a service to individuals in a particular age range, even though that service is also effective for individuals of other ages, would violate Section 1557 if the age limitation is not based on a statute or ordinance and is not necessary for the normal operation or achievement of the goals of the service. For example, it should be prohibited to limit services to children below a certain age, even though older individuals could also benefit from those services.

In addition, we urge that the regulations recognize that Medicaid regulations and health plan features may have the effect of discriminating against children, who may need services more intensively and devices more frequently than adults, due to their rapid growth and development.

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<sup>58</sup> See 80 Fed. Reg. 54,173 (Sept. 8, 2015); 45 U.S.C. § 6103(b)(1)(A), (b)(2).

## § 92.4 Definitions

### a. *Language Access and Auxiliary Aids and Services*

We support codification of the definition of “Individual with limited English proficiency” as reflected in the HHS LEP Guidance as an individual whose primary language is not English and who has a limited ability to read, write, speak, or understand English.

We strongly support the requirements for and definition of a “qualified” interpreter. The correlation between oral interpretation by trained professional interpreters and improved access to quality of care is well-documented.<sup>59</sup> We do, however, recommend an addition to the definition as well as a clarification.

With regard to the addition, we suggest that an interpreter who is nationally certified should automatically meet the definition of qualified. While we acknowledge that competency to interpret does not necessarily require formal certification, as HHS recognizes in the LEP guidance, “it may be helpful.”<sup>60</sup> As we have advanced since 2000 to have more formalized competency-based assessments for healthcare interpreters, we believe it is now appropriate for HHS to recognize that a nationally certified interpreter will meet the NPRM’s definition of a “qualified” interpreter. Only in situations when an interpreter is not certified would a covered entity then have to assess whether the interpreter is competent and qualified. This will both encourage the use of certified interpreters and also assist providers who may have little to no ability or knowledge about how to assess an interpreter’s knowledge, skills and abilities refrain from trying to make the determination about whether an interpreter is qualified. Best practices for ensuring competent oral interpretation may be taken from the leading certification entity for health care interpreters, the Certification Commission for Healthcare Interpreters (CCHI).<sup>61</sup> CCHI and the National Board of Certification for Medical Interpreters,<sup>62</sup>

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<sup>59</sup> For example, patients with LEP who are provided with such interpreters make more outpatient visits, receive and fill more prescriptions, and report a high level of satisfaction with their care. Additionally, these patients do not differ from their English proficient counterparts in test costs or receipt of intravenous hydration and have outcomes among those with diabetes that are superior or comparable to those of English proficient patients. Truda S. Bell et al., *Interventions to Improve Uptake of Breast Screening in Inner City Cardiff General Practices with Ethnic Minority Lists*, 4 *Ethnic Health* 277 (1999); Thomas M. Tocher & Eric Larson, *Quality of Diabetes Care for Non-English-Speaking Patients: A Comparative Study*, 168 *WESTERN J. OF MEDICINE* 504 (1998); David Kuo & Mark J. Fagan, *Satisfaction with Methods of Spanish Interpretation in an Ambulatory Care Clinic*, 14 *J. of General Internal Medicine* 547 (1999); L.R. Marcos, *Effects of Interpreters on the Evaluation of Psychopathology in Non-English-Speaking Patients*, 136 *American J. of Psychiatry* 171 (1979).

<sup>60</sup> 68 Fed. Reg. at 47,316 (Aug. 8, 2003), <http://www.gpo.gov/fdsys/pkg/FR-2003-08-08/pdf/03-20179.pdf> (hereinafter HHS LEP Guidance).

<sup>61</sup> Certification Commission for Healthcare Interpreters, <http://www.healthcareinterpretercertification.org>.

<sup>62</sup> The National Board of Certification for Medical Interpreters, *Certified Medical Interpreter Candidate Handbook 2013–2014*,

another certification entity, both use standards established by the National Council on Interpreting in Health Care.<sup>63</sup>

Further, as a clarification, we believe the definition of qualified interpreter is a bit confusing in structure as to what parts of the definition apply to a qualified foreign-language interpreter versus a qualified interpreter for a person with a disability. Thus we suggest dividing out the requirements more specifically.

And while we appreciate the recognition that a qualified interpreter must have knowledge of specialized vocabulary, we also recommend including the additional requirements of knowledge of specialized terminology (which can include phraseology in addition to vocabulary) and concepts, as outlined in the LEP guidance.<sup>64</sup>

**RECOMMENDATION:** Amend the definition of “Qualified Interpreter” as follows:

*Qualified Interpreter.* (1) *Qualified Interpreter* means an interpreter who adheres to generally accepted interpreter ethics principles, including client confidentiality, and who, via a remote interpreting service or an on-site appearance, satisfies at least one of the following paragraphs:

- (i) ***For individuals who are limited English proficient, an interpreter must*** ~~is able, for an individual with a disability, to~~
  - (a) ***be able to*** interpret effectively, accurately, and impartially, both receptively and expressively, using any necessary specialized vocabulary, ***terminology and concepts***, and/or
  - (b) ~~has~~ demonstrated proficiency in, and has above average familiarity with speaking or understanding, both spoken English and at least one other spoken language; and is able, for an individual with limited English proficiency, to interpret effectively, accurately, and impartially, both receptively and expressly, to and from such language(s) and English, using any necessary specialized vocabulary.
  - (c) ***If a foreign-language interpreter is certified by a national non-profit certification entity, the interpreter is deemed to have met the requirements of (a) and (b).***
- (ii) For an individual with a disability, ***an interpreter must*** ~~is able, for an individual with a disability, to~~

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<https://www.certifiedmedicalinterpreters.org/sites/default/files/national-board-candidate-handbook-2013.pdf>.

<sup>63</sup> National Council on Interpreting in Health Care, *National Standards of Practice for Interpreters in Health Care*, <http://www.ncihc.org/assets/documents/NCIHC%20National%20Standards%20of%20Practice.pdf>.

<sup>64</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>.

- (a) be able to interpret effectively, accurately, and impartially, both receptively and expressively, using any necessary specialized vocabulary, terminology and concepts, and/or**
- (b) for sign language interpreters, demonstrate proficiency in, and have above average familiarity with, speaking or understanding, both spoken English and at least one sign language (including American Sign Language); and is able, for an individual who uses sign language, to interpret effectively, accurately, and impartially, both receptively and expressly, to and from such sign language and English, using any necessary specialized vocabulary.**
- (c) Qualified interpreters for individuals with disabilities** can include, for example, sign language interpreters, oral transliterators (individuals who represent or spell in the characters of another alphabet), and cued-language transliterators (individuals who represent or spell by using a small number of handshapes).
- (d) If a sign-language interpreter is certified by a national non-profit certification entity, the interpreter is deemed to have met the requirements of (a) and (b).**

We also recommend that HHS include a definition of a qualified **translator** in the definitions. For the same reason that being bilingual does not necessarily mean an individual has the requisite knowledge, skills and abilities to interpret, it is essential to also recognize that being bilingual alone does not necessarily mean an individual has the knowledge, skills and abilities to translate written documents from English to/from another language. Further, many covered entities may not understand the difference between interpreting and translation. As HHS recognized in the LEP Guidance, “the skill of translating is very different from the skill of interpreting”<sup>65</sup> yet we still hear of many situations where interpreters are translating complex documents such as informed consent documents and discharge instructions.

Additionally, HHS should not encourage the use of less-skilled translators to translate non-vital documents as it recognizes the need for qualified interpreters. Because all documents provided by covered entities tend to have some consequence on the perceptions and actions of people who receive them, it is important to ensure that individuals do not receive erroneous information about available services. We echo HHS’ acknowledgment in its LEP Guidance that “[t]he permanent nature of written translations . . . imposes additional responsibility on the recipient to take reasonable steps to determine that the quality and accuracy of the translations permit meaningful access by LEP persons.”<sup>66</sup>

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

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<sup>65</sup> HHS LEP Guidance, 68 Fed. Reg. at 47,316.

<sup>66</sup> HHS LEP Guidance, 68 Fed. Reg. at 47,317.



automated systems are not sufficiently accurate to be relied upon the healthcare arena.

**RECOMMENDATION:** Add a new definition of “Qualified Translator”

***Qualified Translator. A qualified translator must:***

- (1) be able to translate effectively, accurately, and impartially, using any necessary specialized vocabulary, terminology and phraseology, and/or***
- (2) demonstrate proficiency in, and have above average familiarity with, writing or understanding, both written English and at least one other written non-English language; and is able to translate effectively and accurately to and from such language(s) and English, using any necessary specialized vocabulary.***
- (3) If a translator is certified by a national non-profit certification entity, the translator is deemed to have met the requirements of (1) and (2).***
- (4) Using computer-automated translation services does not meet the definition of a qualified translator.***

Finally, we recommend that the proposed rule require covered entities to document its determination that bilingual or multilingual staff and staff who sign are competent to provide oral assistance and to provide record of that determination upon the Director’s request during an investigation. To that end, we recommend that HHS define “competent” to align with the considerations given in the original HHS LEP Guidance. Specifically, HHS previously cautioned that “Recipients should be aware that competency requires more than self-identification as bilingual.”<sup>67</sup> We further recommend that HHS require a comparable level of competency of bilingual staff as it does for qualified interpreters to provide effective oral assistance under the law.<sup>68</sup> Bilingual staff should have requisite language proficiency, including knowledge of specialized terminology in both English and the non-English language and particular vocabulary and phraseology used by the individual with LEP.<sup>69</sup> For example, a covered entity could require bilingual/multi-lingual staff to undergo a language proficiency examination and keep the record of the exam in a personnel file. Or if the staff has undergone training or other assessment, that information should be recorded and maintained.

**RECOMMENDATION:**

1. Amend the definition of language assistance services as follows:

*Language assistance services* may include but are not limited to:

- (1) Oral assistance including interpretation in non-English languages provided in-person or remotely by a qualified interpreter, and bilingual or multilingual staff ***who the covered entity determines*** competent to communicate, in non-

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<sup>67</sup> HHS LEP Guidance, 68 Fed. Reg. at 47,316.

<sup>68</sup> 80 Fed. Reg. at 54,177.

<sup>69</sup> HHS LEP Guidance, 68 Fed. Reg. at 47,316.

English languages using any necessary specialized vocabulary, directly with individuals with limited English proficiency...

2. Amend the definition of auxiliary aids and services to delete “and” at the end of subsection (3), add new subsection (4) and renumber subsection (4) as subsection (5) as follows:

*Auxiliary aids and services include. . .*

**(4) Staff who sign. A covered entity must determine that staff who sign are competent to communicate in sign language using any necessary specialized vocabulary, directly with individuals who sign; and**

**(5) Other similar devices. . .**

*b. Exclusion for Part B Providers*

We are dismayed that the NPRM 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 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). In the Title VI context, the exclusion of Part B providers arose soon after enactment of Medicare based on two rationales – Medicare Part B is not a “contract of insurance” and Medicare Part B providers are not directly paid by the federal government so no federal financial assistance exists. In 2015, neither of these two explanations apply, particularly to Section 1557.

*i. Contract of Insurance Rationale*

As one rationale for the exclusion, HHS relied on the exclusion in Title VI’s statutory language of “contracts of insurance.” While we believe the original reliance on this exclusion was specious, the statutory language of Section 1557 specifically **includes** contracts of insurance so that this rationale can no longer apply.

The legislative history of Title VI documents that the inclusion of the language “other than contracts of insurance” in Title VI was “clearly designed to assure that programs or activities financed with loans from non-Federal sources were not subject to the prohibitions of the title merely because such loans were not federally insured.”<sup>70</sup> The legislative understanding was focused on a particular concern that Title VI – applicable to all federal financial assistance and not just health programs – should not apply to home mortgages obtained from federally insured institutions or deposits in federally

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<sup>70</sup> *Civil Rights Issues in Health Care Delivery, A Consultation Sponsored by the United States Commission on Civil Rights*, Washington, D.C., April 15-16, 1980 at 855 (hereinafter *Civil Rights Issues*).

insured banks. As Senator Humphrey, the Senate floor leader for the Civil Rights Act, stated:

The exclusion relates to, as the language says, other than a contract of insurance or guarantee. So FDIC (Federal Deposit Insurance Corporation) and all activities pertaining thereto are eliminated. The Federal Housing Administration is eliminated.<sup>71</sup>

The purpose of this exclusion was further reiterated by Senator Pastore, the Senate floor manager for Title VI, who said:

The reason why we have excluded contracts of insurance or guaranty is that we do not want this section to affect, let us say, guarantees of deposits in banks. . . We do not want that section to affect FHA housing. That is precisely why the exception is put in the section.<sup>72</sup>

All historical accounts point to an understanding that the section was limited to banking and housing and that Title VI did apply to federally assisted medical health care programs in existence at the time of its passage let alone to Medicare at the time that program was enacted.<sup>73</sup> So the specific inclusion of “contracts of insurance” in Section 1557 negates this as a rational explanation for excluding Part B providers.

## ii. Direct Payment Rationale

According to an analysis of the exclusion by the U.S. Commission on Civil Rights, HHS’ decision to exclude Part B providers was in part due to the HHS’ Office of General Counsel determination that Medicare Part B did not constitute Federal Financial Assistance because the reimbursement was directly paid to beneficiary and is “limited to 80 percent of the reasonable costs.”<sup>74</sup> Further, payments were made directly to beneficiaries and not to healthcare providers. Yet payments were only made to beneficiaries contingent on their receipt of the health services Medicare was intended to provide.<sup>75</sup>

Yet Medicare currently does provide direct payments, through Medicare Administrative Contractors, to providers with very few opting out of this “assignment” system. Further, any rationale based on the percent of reasonable costs paid by Medicare would not pass muster since other covered programs – such as Medicaid and CHIP – often do not pay providers 100% of their costs but rather lower, negotiated rates.

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<sup>71</sup> *Id.* at 856-7, *citing* 110 Cong. Rec. 13378 (1964).

<sup>72</sup> *Id.* at 857, *citing* 110 Cong. Rec. 13345, 13346 (1964).

<sup>73</sup> Hearing before Subcommittee No. 5 of the House Committee on the Judiciary, 88<sup>th</sup> Cong. 1<sup>st</sup> Sess. 1545-1546 (1963).

<sup>74</sup> Civil Rights Issues, at 854.

<sup>75</sup> *Id.* at 863.

A further explanation for concluding that direct payments are not subject to Title VI arises from the inapplicability of Title VI to Social Security payments. Social Security payments were excluded, however, due to the absence of a program or activity and not due to the method of disbursement.<sup>76</sup> Yet in the educational context, a federal court concluded that the “method of payment. . . does not change the nature of the program or the basic role of the schools participating in the program.”<sup>77</sup> This same statement from the HHS General Counsel’s office concluded that with respect to agreements with contractual obligations, Title VI would apply. Given that in today’s administration of Medicare, HHS directly has contracts with Part B providers (albeit using an intermediary), the prior rationale for excluding them from Title VI no longer applies.<sup>78</sup>

And as HHS notes in the preamble to the NPRM, Title IX payments made either to a student or to an institution both count as Federal Financial Assistance:

This provision was included in the Title IX regulation to make clear that both funds paid to the educational entity on behalf of a student, and funds paid to the student and then remitted to the educational entity, are Federal financial assistance.<sup>79</sup>

Further, the preamble states that Advanced Premium Tax Credits (APTCs) and Cost Sharing Reductions (CSRs) – whether extended to the entity or to the individual for remittance – are Federal Financial Assistance.<sup>80</sup> Thus the explanation that Medicare Part B payments did not constitute federal financial assistance in the 1960’s is outweighed – and indeed overridden – by the subsequent changes in program structure and reimbursement as well as the interpretation of student aid as well as APTCs and CSRs.

Given that we now operate under one unified statutory provision that prohibits discrimination both on the basis of race, color and national origin as well as sex, we should not allow differing standards to continue when the result is that some individuals will be protected from nondiscrimination while others will not.

### iii. Conclusion

As discussed in the Regulatory Impact Analysis for the NPRM, it should not matter whether virtually all Medicare Part B physicians are covered by Section 1557 (and Title VI) as recipients of Federal Financial Assistance. As long as some Part B physicians remain who do not take other federal funds, a strong rationale exists for prohibiting the exemption that has allowed them to effectively partake in discriminatory behavior for

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<sup>76</sup> *Id.* at 862.

<sup>77</sup> *Bob Jones University v. Johnson*, 396 F. Supp. 597, 603 (D.S.C. 1974), *aff’d* 529 F.2d 514 (4<sup>th</sup> Cir. 1975).

<sup>78</sup> Medicare Prescription Drug Improvement, and Modernization Act (MMA) of 2003, section 911.

<sup>79</sup> 80 Fed. Reg. at 54,174, *see also* 45 C.F.R. § 86.2(g)(1)(ii).

<sup>80</sup> *Id.*

over fifty years. As explained above, the initial purported reasons for allowing an exemption no longer exist and certainly cannot be allowed to persist even if only a small number or percentage of Medicare physicians are covered. Indeed, an argument can be made that since the exemption currently only affects such a small number of Medicare Part B physicians that the weight of history is on the side of changing the exemption and explicitly prohibiting **all** Medicare Part B physicians from discriminating even if the underlying assumptions of how Medicare Part B operated had not changed.

As the U.S. Commission on Civil Rights concluded in 1980, Medicare Part B payments are clearly Federal Financial Assistance and should not be excluded from Title VI as either contracts of insurance or by reason of the method of their payment.<sup>81</sup> The passage of time, the change in Medicare payment methods and the specific inclusion of “contracts of insurance” in Section 1557 directly point to the need to change the antiquated policy excluding Medicare Part B providers from Federal Financial Assistance. In the alternative, if HHS does not wish to change its historical policy, the developments over the past twenty-five years as well as the statutory text of 1557 definitively demonstrate that Medicare Part B providers should at least be subject to compliance with Section 1557.

Continuing the exemption effectively recognizes that some healthcare providers are exempt from Section 1557, even if a small “minority.” Further, it perpetuates the myth that providing less care to certain individuals based solely on the color of their skin or the language they speak is someone permissible.

As noted in a 2005 *Health Affairs* article:

Perhaps a more troubling and longer-term consequence of [the Part B] exemption was that no federal effort was ever mounted to collect data and monitor the extent of discriminatory medical treatment. No federal testing program was developed similar to those developed to monitor discrimination in housing and employment. No public reporting requirements have been imposed as have been on lenders for home mortgage applications and approval rates by race as a result of the Home Mortgage Disclosure Act of 1975. Yet, despite repeated calls for such data and the overwhelming role that federal dollars play in financing medical services, the void persists. There has never been a lack of regulatory authority to require such collection and reporting; it has always been a lack of political will.<sup>82</sup> (citations omitted)

HHS’ own Regulatory Impact Analysis concludes that very few healthcare providers only accept Medicare Part B and thus would be exempt from the proposed regulation. Thus changing the policy of HHS to explicitly **include** Medicare Part B providers as covered by Section 1557 would affect a small number of individuals but provide a long-needed correction to ameliorate a harmful, discriminatory policy enacted in a foregone

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<sup>81</sup> Civil Rights Issues, *supra* note 70, at 863.

<sup>82</sup> David Barton Smith, *Racial And Ethnic Health Disparities And The Unfinished Civil Rights Agenda*, *Health Affairs*, 24, no.2 (2005):317-324.

era when it was wrongly regarded as legitimate for healthcare providers to exclude certain patients based on the color of their skin or the language they speak. In the 21<sup>st</sup> century, and with the specific statutory inclusion of contracts of insurance in Section 1557, that longstanding policy no longer has any legs to stand on. Indeed, bringing Medicare Part B providers into compliance with all other federally funded healthcare providers is critical for this Department to correct a wrong and recognize how far this nation has come in seeking to address discrimination.

**RECOMMENDATION:** Delete the exemption for Medicare Part B providers from compliance with Section 1557 (and Title VI).

*c. Definition of Disability*

We support using the definition of disability as it is in the Rehabilitation Act, which incorporates the definition the ADA Amendments Act of 2008. We firmly believe that the broadest definition of disability and the accompanying protections is very important to prevent discrimination in healthcare. We are concerned that entities are already finding ways to actively discourage people with disabilities and/or chronic health conditions through various mechanisms that either punish costly services, e.g., through drug costs or limiting authorizations, or reward individuals for health features or activities that are not always accessible for individuals with disabilities and/or chronic health conditions. This trend toward discriminating toward the healthiest is very troubling. Therefore, we believe it is very important that definition of disability and qualified individual with a disability be as broad as possible. In furtherance of this important goal, we believe OCR should be clear, wherever possible, about the breadth of the definition and the intent that a covered entity not be able to limit who is protected by these regulations by improperly limiting the definitions, such as through vitiating the essential eligibility requirements.

*d. 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. Please see our comments above as 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 trigger 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.<sup>83</sup> 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 regulations must recognize this fact and ensure that these federal funds are not used to finance discrimination.

We were dismayed at the statement in the preamble, however, 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.<sup>84</sup>

It seems this was written in the context of a qualified health plan (QHP) that participates in a marketplace but the result 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 also is bad policy. The result in this case would be a QHP would have to ensure 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 of this statement would to allow a QHP to essentially gut the nondiscrimination requirements of Section 1557.

Indeed, longstanding caselaw in the Medicaid arena prohibits this absurd result. Courts have repeatedly held that the state Medicaid agency cannot disclaim responsibility by contracting away its duties under federal law.<sup>85</sup> For example, these cases have stated:

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<sup>83</sup> 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).

<sup>84</sup> 80 Fed. Reg. at 54174.

<sup>85</sup> *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);

- A State Medicaid agency “may not disclaim its responsibilities under federal law by simply contracting away its duties;<sup>86</sup>
- The need to ensure “accountability for the appropriate operation of the program” and holding Medicaid agency could “diminish[ ] or alter[ ]” its Medicaid responsibilities based on the “action or inaction of other state offices or agencies”,<sup>87</sup> and
- “[T]he state Medicaid agency must oversee and remain accountable for uniform statewide utilization review procedures conforming to bona fide standards of medical necessity.”<sup>88</sup>

Further, since this NPRM will apply to both Medicaid and Medicare in addition to the marketplaces, this interpretation could result in a Medicaid or Medicare fee-for-service enrollee benefitting from the protections of Section 1557 when seeking care while a managed care enrollee would not if the Medicaid Managed Care Organization of Medicare Advantage Plan was allowed to contract away its responsibilities to comply with Section 1557. These enrollees, who may each seek the same service, would be subject to different standards of care merely due whether a fiscal intermediary operates between the enrollee and the healthcare provider.

Given the precedents in Medicaid and the essential need to prevent discrimination in the actual provision of all healthcare services, we strongly recommend that HHS explicitly require subcontractors to Federal fund recipients 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 go out and 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 or the nondiscrimination requirements may have no practical impact.

**RECOMMENDATION:** Rewrite the sentence in the preamble as follows:

A health services provider that contracts with ~~such an issuer~~ **a covered entity** 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.

Further, the proposed rule provides that “[f]or 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.”

<sup>86</sup> *Aff'd sub nom. D.T.M. ex rel. McCartney v. Cansler*, 382 F. App'x 334 (4th Cir. 2010)

<sup>87</sup> *Hillburn v. Maher*, 795 F.2d 252, 261 (2d Cir.1986).

<sup>88</sup> *J.K. ex. rel. R.K. v. Dillenberg*, 836 F. Supp. 694, 699 (D. Ariz. 1993).



The proposed rule does not define what it means to be “principally engaged in providing or administering health services or health insurance coverage.” The preamble states that this phrase is to be interpreted consistently with civil rights laws, and the proposed rule provides examples of entities principally engaged in providing or administering health services or health insurance coverage: “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 a State Medicaid program.”

While these examples are helpful, the Department should include in the text of the rule the statement that “principally engaged” is to be interpreted consistently with civil rights laws and should offer an explanation of that interpretation. The Department should also clarify that a health program or activity applies to all of the operations (including, for example, benefit design, coverage decisions, network establishment, and payment structures) of insurance plans available through the Marketplace, and of a State Medicaid program including the Medicaid expansion.

HHS should clarify that health programs and activities include, among other things, the following aspects of both private and public health coverage, including Medicaid and CHIP programs and Medicaid managed care organizations:

- Setting the terms and conditions of insurance plans including, for example, the scope of services and benefits covered, prior authorization requirements, and other requirements for obtaining reimbursement for services
- Reimbursement for services and benefits under a health insurance plan
- Designing benefits under a health insurance plan
- Determining which providers are covered by health plan networks
- Determining which plans are available through an exchange
- Determining which services and benefits are covered under a state’s “Essential Health Benefits” package
- Administering exchanges
- Administering alternative benefit plans under the Medicaid expansion
- Administering a managed care organization (including a Medicaid managed care organization)

These programs and activities are integral to the ACA's implementation. Conducting them in a non-discriminatory manner is critical to ensure that implementation is effective for all participants and that people with disabilities and other protected groups are afforded equal opportunities to benefit from the ACA.

*e. Definitions of Gender Identity and 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.<sup>89</sup>

HHS' Office for Civil Rights, charged with accepting and investigating complaints under Section 1557, has already received and resolved complaints of sex discrimination based on sex stereotypes.

The current language in the proposed rule, however, could be read to imply that sex stereotyping discrimination only includes discrimination based on gender identity and would therefore not bar other forms of discrimination based on sex stereotyping. The final rule should affirm both that discrimination on the basis of sex stereotypes constitutes sex discrimination, whether or not it also constitutes discrimination on the basis of gender identity, and that Section 1557's protection from sex discrimination, including sex stereotyping, reaches individuals who may also have lesbian, gay, or bisexual sexual orientations.

**RECOMMENDATION:** We recommend revising the definition of sex stereotypes in § 92.4 as follows (incorporating the modifications recommended in the sections discussing gender identity and sexual orientation):

*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 expectation 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 aspects of an**

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<sup>89</sup> See Dep't of Educ., Office of 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](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, L.L.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. Ill. 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).

***individual's sexual orientation identity, such as the sex of an individual's sexual or romantic partners.***

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.<sup>90</sup> In 2012, the Equal Employment Opportunity Commission (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.”<sup>91</sup> The Attorney General affirmed this interpretation in a 2014 memorandum.<sup>92</sup> The Department of Labor has taken the same position in internal guidance and proposed regulations,<sup>93</sup> as has the Office of Personnel Management in its regulations.<sup>94</sup> Similarly, the Departments of Education and Justice have clarified on multiple occasions that, under Title IX, “discrimination based on gender identity, including transgender status, is discrimination based on sex,”<sup>95</sup> as is discrimination based on sex stereotyping.<sup>96</sup> The Department of Housing and Urban Development has similarly concluded that the Fair Housing Act covers claims based on sex stereotypes and gender identity.<sup>97</sup>

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”

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<sup>90</sup> 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).

<sup>91</sup> *Macy v. Holder*, E.E.O.C. App. No. 0120120821, 2012 WL 1435995, \*12 (Apr. 20, 2012).

<sup>92</sup> Attorney General Memorandum, *Treatment of Transgender Employment Discrimination Claims Under Title VII of the Civil Rights Act of 1964* (Dec. 15, 2014).

<sup>93</sup> Department of Labor, *Discrimination on the Basis of Sex*, Proposed Rule, 80 Fed. Reg. 5246 (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).

<sup>94</sup> See 5 C.F.R. §§ 300.102-300.103, 335.103, 410.302, 537.105.

<sup>95</sup> 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, 2015); 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).

<sup>96</sup> See Dep’t of Educ., “Dear Colleague,” 7-8 (Oct. 26, 2010).

<sup>97</sup> *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).

encompasses bias based on gender identity or transgender status.<sup>98</sup> 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.

We support HHS's proposed definitions of gender identity and sex stereotypes. Read together, these definitions 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. The necessity of recognizing non-binary identities in the provision of health care is widely accepted among medical organizations.<sup>99</sup> Further, federal agencies such as the Department of Labor have recognized that sex discrimination protections extend to non-binary individuals as well as to transgender and non-transgender men and women.<sup>100</sup>

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 not familiar with the issue. The proposed definition of gender identity also naturally and necessarily includes non-binary 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 propose language to clarify both definitions.

**RECOMMENDATIONS:** We 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

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<sup>98</sup> *Rumble v. Fairview Health Services*, No. 14–cv–2037, 2015 WL 1197415, \*2 (D. Minn. Mar. 16, 2015).

<sup>99</sup> Am. Psychological Ass'n, *Guidelines for Psychological Practice with Transgender and Gender Nonconforming People* 6 (2015); World Prof. Ass'n for Transgender Health, *Standards of Care for the Health of Transsexual, Transgender and Gender-Nonconforming People* 171, 175 (2012) (requiring physicians to provide affirming care for both binary and non-binary transgender and gender non-conforming patients); Am. College of Obstetricians and Gynecologists, *Committee Opinion No. 512: Health Care for Transgender Individuals*, *Obstetrics & Gynecology* 118(6): 1454 (2011) (same). See also Am. Psychiatric Ass'n, *Diagnostic and Statistical Manual of Mental Disorders, Version 5* 451-53 (2013) (defining gender identity to include identities other than male or female, and specifying diagnostic criteria for gender dysphoria to include such identities); see also, e.g., Institute of Medicine, *The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding* (2011), available at <http://www.iom.edu/Reports/2011/The-Health-of-Lesbian-Gay-Bisexual-and-Transgender-People.aspx>, at 25-26.

<sup>100</sup> See, e.g., Department of Labor, Job Corps Program Instruction Notice No. 14-31, Ensuring Equal Access for Transgender Applicants and Students to the Job Corps Program (May 1, 2015).

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.

We note that further revisions to the definition of sex stereotypes to reflect issues related to sexual orientation are proposed and described below.

*f. Protection from Discrimination on the Basis of Sexual Orientation*

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 gender-nonconforming 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 discrimination 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.<sup>101</sup> 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.<sup>102</sup> 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

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<sup>101</sup> Kellan 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>102</sup> Center for Consumer Information and Insurance Oversight, *Frequently Asked Questions on Coverage of Same-Sex Spouses* (U.S. Department of Health and Human Services, 2014), available at <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/frequently-asked-questions-on-coverage-of-same-sex-spouses.pdf>.

under this section, at 45 C.F.R. § 147.104(e), clarify that this requirement means carriers cannot employ marketing 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.

## **RECOMMENDATIONS:**

1. We 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.

2. Similarly, we recommend that language be added to § 92.4 defining sexual orientation as follows, adapted from the Equality Act<sup>103</sup>:

***Sexual orientation means homosexuality, heterosexuality, or bisexuality.***

Further, 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 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.

**RECOMMENDATION:** We recommend that the definition of sex stereotypes in § 92.4 be revised as follows (incorporating the modifications recommended in the sections above discussing gender identity and gender roles):

*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 expectation ~~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 consistently identify with one and only one of two genders (male or female), and that they act in conformity with the gender-related expressions stereotypically associated**

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<sup>103</sup> H.R. 3185, 114th Cong. § 1101 (2015).

***with that gender. They also include gendered expectations related to the appropriate roles of men and women, such as the expectation that women are primary caregivers, and aspects of an individual's sexual orientation identity, such as the sex of an individual's sexual or romantic partners.***

*g. Intersex Traits*

We also recommend that the proposed rule include “intersex traits” and “the presence of atypical sex characteristics” in the definition of “on the basis of sex.” Intersex traits, also called differences of sex development (DSD), occur when there is atypical development of chromosomal, gonadal, and/or anatomical sex. Stereotypes hinging on the supposed dichotomy of biological sex, like those of the supposed dichotomy of gender, have led to pervasive discrimination against intersex people for decades. For example, intersex people may face discrimination when medical providers follow policies which deem certain medical procedures only to be available to one or the other sex (e.g. ovarian cancer treatment), excluding intersex people who may be registered under another sex. In 2008, an intersex man died of vaginal cancer after he was refused treatment at several health centers due to his sex characteristics.<sup>104</sup> Intersex children face discrimination when they are exposed to risky and medically unnecessary surgical procedures that would not be deemed acceptable for non-intersex children. Recently, several countries have passed laws explicitly protecting intersex people from discrimination. For example, Australia and South Africa have amended their national antidiscrimination laws to explicitly include protections for intersex people.<sup>105</sup> This year, the Council of Europe Commissioner of Human Rights called on all European countries to adopt laws explicitly prohibiting discrimination against intersex people.<sup>106</sup>

*h. Benefit Design*

We strongly support HHS' recognition that § 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 § 1557's non-discrimination protections apply to the full scope of health programs and activities.

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<sup>104</sup> A. Tamar-Mattis, “Report to the Inter-American Commission on Human Rights: Medical treatment of people with intersex conditions as a human rights violation.” (2014), available at <http://www.ushrnetwork.org/sites/ushrnetwork.org/files/07-indiv-aic.pdf>.

<sup>105</sup> Sex Discrimination Amendment (Sexual Orientation, Gender Identity and Intersex Status) Act 2013, No. 98 (Australia, 2013), available at <https://www.comlaw.gov.au/Details/C2013A00098>; Judicial Matters Amendment Act, 2005 (Act 22) (South Africa, 2005), available at <http://www.justice.gov.za/legislation/acts/2000-004.pdf>.

<sup>106</sup> Council of Europe Commissioner of Human Rights, “Human Rights and Intersex People” (April 2015), available at <https://wcd.coe.int/ViewDoc.jsp?Ref=CommDH/IssuePaper%282015%291&Language=lanEnglish&Ver=original>.

**RECOMMENDATION:** 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.***

***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).***

*i. Health Program or Activity*

We support the proposed regulation's reliance on the approach of the Civil Rights Restoration Act in defining "health program or activity." To provide greater clarity in the final rule, we urge that the reference to the Civil Rights Restoration Act be included in the rule itself, and not just the preamble.

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 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>107</sup> 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, 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.

**RECOMMENDATION:** We recommend inserting the following language to the definition of 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. **"Health related" means designed to promote, maintain, or prevent the decline of an individual's or population's physical, mental, or social well-being. Consistent with the Civil Rights Restoration Act.** 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 the operations of other health programs, including public health programs, operated by state and local governments.**

*j. 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

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<sup>107</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.

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>108</sup> Pregnancy discrimination constitutes sex discrimination under Title IX<sup>109</sup> and other civil rights statutes such as Title VII<sup>110</sup> and also necessarily constitutes sex discrimination under Section 1557. These laws prohibit discrimination based on pregnancy itself, as well as pregnancy-related conditions.<sup>111</sup>

*k. Electronic and information technology*

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.<sup>112</sup> As we explained above, 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.

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 2009<sup>113</sup> governing adoption and use of electronic health records and information exchange nationwide:

**RECOMMENDATION:** Add a definition of “health information technology” to § 92.4 as follows

***Health information technology means hardware, software, integrated technologies or related licenses, intellectual property, upgrades, or packaged solutions sold as services that are designed for or support***

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<sup>108</sup> 80 Fed. Reg. at 54,177.

<sup>109</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>110</sup> 42 U.S.C. § 2000e(k) (2012).

<sup>111</sup> 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).

<sup>112</sup> Nondiscrimination in Health Programs and Activities NPRM, 80 Fed. Reg. at 54174.

<sup>113</sup> 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.

***the use by health care entities or patients for the electronic creation, maintenance, access, or exchange of health information.***<sup>114</sup>

## **§ 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 as part of the assurances and to demonstrate compliance with Section 1557.

One tenet of ensuring compliance with nondiscrimination requirements is to ensure strong data collection. Having accurate data ensures that covered entities have the needed information to determine how to provide language services and auxiliary aids and services. 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, gender identity, sexual orientation, disability status, and age. Further, covered entities should be required to assess (and update their assessments) of the population they serve and are eligible to be served so that they can appropriately plan how to meet the needs of their clients/patients. HHS should provide guidelines as to how to conduct an assessment and what data may be readily available to covered entities.

We strongly recommend that HHS require data collection from covered entities as having data on hand is an essential way to ensure and demonstrate compliance with Section 1557. In particular, we recommend collecting data on the groups described in ACA Section 4302, a provision enacted at the same time as Section 1557. Section 4302 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.

We offer our recommendations related to how Section 4302 should interact with Section 1557 to further advance the nondiscrimination provisions in Section 1557. We also believe that any data collection provisions include provisions addressing the following issues:

- ***Train staff in collecting demographic data, including explaining why this data is being collected.*** The Health Research and Educational Trust (HRET) developed a toolkit for collecting race, ethnicity and language data after testing different rationales for collecting this data.<sup>115</sup> Similar training toolkits should be developed and made available for the other demographic categories.
- ***Adopt clear privacy and nondiscrimination protections.*** For a data collection requirement to be impactful, individuals must feel comfortable disclosing personal information that can help to improve the care they receive and foster a broader understanding of health care disparities. We support the language in section

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<sup>114</sup> 42 U.S.C. § 300jj.

<sup>115</sup> See <http://www.hretdisparities.org>.

4302(e)(1)(A)(i) regarding the application of the Health Insurance Portability and Accountability Act (HIPAA) of 1996, and encourage HHS to ensure that the privacy protections applied to demographic data should be not only as broad as HIPAA, but as stringent. Patients should be made aware of their privacy protections and rights – including those granted under applicable state laws as well as HIPAA – and have a clear understanding of why this information is being collected and who will have access to what forms of information.

- **Safeguard that patient/enrollee reporting of demographic data be voluntary.** While health care systems and providers should be required to ask for data of patients/enrollees (and for minors or incapacitated individuals, the language data of their parents/guardians), the responses to data collection requests are (and should be) voluntary for patients/enrollees to report and should be self-reported to ensure accuracy.
- **Support analyses based on multiple demographic variables.** While we recommend several specific demographic variables for data collection to better ensure civil rights compliance it should be emphasized that these variables are neither mutually exclusive nor unrelated. As individuals, each person has a sex, race, ethnicity, primary language, and disability status, and all these demographic identities interact in relevant ways for understanding and addressing health disparities. At the community and population level, these variables, both individually and in combination, can be explanatory for discrimination. For example, racial and ethnic minority women receive poorer quality care than racial and ethnic minority men, who receive poorer care than white men.<sup>116</sup> Spanish-speaking Hispanics experience poorer quality care than English-speaking Hispanics, who experience poorer care than non-Hispanic whites.<sup>117</sup> Compared to women without disabilities, women with disabilities are more likely not to have regular mammograms or Pap tests.<sup>118</sup> Racial and ethnic minorities with disabilities experience greater disparities in diagnoses and utilization of assistive technology.<sup>119</sup> While discrimination investigation

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<sup>116</sup> Correa de Araujo R, Stevens B, Moy E, Nilasena D, Chesley F, McDermott K. Gender differences across racial and ethnic groups in the quality of care for acute myocardial infarction and heart failure associated co-morbidities. *Women's Health Issues* (2006); 16(2): 44-56; Chou AF, Brown AF, Jensen RE, Shih S, Pawlson G, Scholle SH. Gender and racial disparities in the management of diabetes mellitus among Medicare patients. *Women's Health Issues*. (2007); 17(3):150-161

<sup>117</sup> Cheng EM, Chen A, Cunningham W. Primary language and receipt of recommended health care among Hispanics in the United States. *J Gen Intern Med*. (2007); 22 (Suppl 2):283-288; DuBard CA, Gizlice Z. Language spoken and differences in health status, access to care and receipt of preventive services among U.S. Hispanics. *Am J Public Health*. (2008); 98(11):2021-2028.

<sup>118</sup> Diab, M.E. and M.V. Johnston, *Relationships between level of disability and receipt of preventive health services*. *Archives of Physical Medicine and Rehabilitation*, 2004. 85(5): p. 749-757.

<sup>119</sup> Mandell DS, Wiggins LD, Carpenter LA, Daniels J, DiGuseppi C, Durkin MS, Giarelli E, Morrier MJ, Nicholas JS, Pinto-Martin JA, Shattuck PT, Thomas KC, Yeargin-Allsop M, Kirby

sometimes focuses on variations based on a single demographic variable, in our increasingly multicultural society, it is vital that HHS's civil rights enforcement support these types of analyses based on multiple demographic variables. This requires standardized categories and definitions for all these demographic variables.

As suggested in previously submitted comments from The Leadership Conference on Civil and Human Rights governing data collection, 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:

- federally-supported health care providers (at the point of care); and
- publicly administered health programs (at enrollment).

Demographic data collection will be especially important as we move towards a health care payment system that rewards quality rather than quantity. The ACA recognizes the central role of data in quality care, and appropriately includes a condition that demographic data be collected as a component of any federal quality reporting requirements.

Data collection by federally-supported 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. HHS should be cognizant of the interrelationship between sections 4302 and 1557 of the ACA and other civil rights statutes. Thus, requiring data collection enables the enforcement of the civil rights laws that prohibit discriminatory actions by health programs or activities.

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, either voluntarily or because of existing laws and regulations at both the state and federal level. Nationally, 82 percent of hospitals already collect race and ethnicity data and 67 percent collect data on primary language.<sup>120</sup> Twenty-two states have passed regulations requiring hospitals to collect race, ethnicity, and language data.<sup>121</sup> 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.

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RS. Racial/ethnic disparities in the identification of children with autism spectrum disorders. *Am J Public Health*. (2009); 99(3):493-498; Kaye HS, Yeager P, Reed M. Disparities in usage of assistive technology among people with disabilities. *Assist Technol*. (2008); 20(4):194-203.

<sup>120</sup> Hasnain-Wynia, R., Pierce, D., Haque, A., Hedges Greising, C., Prince, V., Reiter, J. (2007) *Health Research and Educational Trust Disparities Toolkit*. Retrieved on 24 January 2011 from <http://www.hretdisparities.org>.

<sup>121</sup> *Id.*

We also believe that requiring data collection at enrollment in publicly administered health programs – including Medicare, Medicaid, and 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 (or create a separate regulatory section governing data collection). Further, as many other federal agencies require data collection and reporting to document compliance with assurances and nondiscrimination, we believe HHS has the distinct authority and indeed the responsibility to mandate data collection. For example, the Department of Education has a robust data collection and reporting requirement.

**RECOMMENDATION:** Add new subsection (d) to 92.5 as follows

***(d) Data Collection.***

- (i) An entity receiving Federal financial assistance to which this part applies shall, as a condition of receipt of such funds, collect demographic data of all of the individuals served;***
- (ii) An entity established under Title I of the ACA that administers a health program or activity and The Department shall collect demographic data of all of the individuals served;***
- (iii) This data shall include, at a minimum, race, ethnicity, language, disability status, sex, sexual orientation and gender identity;***
- (iv) An entity described in paragraph (i) or (ii) must:***
  - (A) collect this data in a form and manner determined by the Secretary which, at a minimum, shall comply with requirements of ACA § 4302 including disaggregated data;***
  - (B) provide this data to HHS at least yearly, in a form and manner determined by the Secretary, to document compliance with this Part; and***
  - (C) disclose this data publicly as determined by the Secretary.***

In addition, we suggest HHS provide detailed information for recipients about how to appropriately collect this data using the following recommendations.

***b. Race and Ethnicity***

- Implement the Institute of Medicine’s (IOM’s) recommendations on the standardization of race and ethnicity data.
- Avoid prioritization schemes or other preference categories for multiracial respondents.
- Utilize multiple sampling strategies to improve the collection and reporting of smaller populations.

***c. Primary Language***

- Implement the IOM's recommendations on the standardization of spoken language need.
- Encourage the collection of written language need in addition to spoken language need.

*d. Disability Status*

- Ensure that standardized disability questions identify people with functional limitations associated with certain cognitive, emotional, or learning impairments.
- Collect activity limitation information at enrollment and point of care (in the electronic health record) and information about accommodations a patient needs to access services and to improve the quality of care.
- Require CMS to retrieve information on locations where people with disabilities receive care who are Social Security Disability Insurance (SSDI) and Supplemental Security Income (SSI) beneficiaries.
- Require identification of the number of providers with accessible facilities and equipment, including medical diagnostic and treatment equipment, as a condition of federal approval of state Medicaid plans and Medicaid waivers.
- Require Federally Qualify Health Centers (FQHCs) to collect data on disability and functional status.

*e. Sex*

- Collect biological sex data at varying points throughout the health care process, in sufficient quantities for useful analysis.
- Ensure sex data is collected alongside other data categories because of interactions between sex and other identities that might affect health care.

*f. Sexual Orientation and Gender Identity*

- Establish standard specifications for collecting sexual orientation and gender identity data, including same-sex relationship status, utilizing existing best practices.
- In all data collection instruments utilized by HHS programs and activities, provide standardized opportunities for participants to disclose their gender identity, sexual orientation, and relationship status, including a same-sex relationship.

**§ 92.7 Designation of responsible employee and adoption of grievance procedures**

HHS asked for comment as to whether all covered entities, and not just those with 15 or more employees, should designate a responsible employee to coordinate its efforts to comply with and carry out the responsibilities under Section 1557 and the regulations. We do believe that the requirement should apply to **all** covered entities given the importance of the Section 1557 protections and need to prohibit discrimination.

We believe that the requirement for a responsible employee and adoption of a grievance procedure is very important to holding covered entities responsible for the protections provided by § 1557. However, we think it is critical that the grievance procedure is effective. We understand that the proposed language in this section is substantially similar to that of the ADA's Title II coordinator and grievance responsibilities. This similarity is what makes us concerned. In our experience, this provision of the ADA is often not effective for individuals with disabilities because there is no clear requirement for response to the individual, nor is there a requirement for a reasonable timeline for any response to the complaining individual. We know of stories of individuals with disabilities who file complaints and never receive a response, or, if they receive a response, that response provides no information as to whether anything changed to address the complaint. We often hear of ADA complaint procedures as "black holes". If there is no additional guidance on what a grievance procedure is supposed to include, we fear that individuals with disabilities will have just another ineffective grievance process by which they complain and hear nothing.<sup>122</sup>

While we firmly believe that, like under the ADA, an individual should not have to exhaust the grievance process before filing elsewhere, we also believe that the § 1557 grievance process needs to be more specific so as to ensure that it is a more meaningful mechanism for complainants and so it fosters resolution of issues without further action. We believe that the basic features of OCR's model 504 Grievance Procedure should be incorporated.<sup>123</sup> These features of a grievance process include: a timeframe for filing complaints, issuance of a written decision on the grievance no later than 30 days after filing; an appeal to a different individual or group with a written response within 30 days after filing the appeal; provision for providing accommodations, if needed, for the involved parties to participate in the grievance process. This model procedure also includes important notice about protection against retaliation and that use of the grievance procedure does not prevent filing a complaint elsewhere. In order to maintain flexibility for entities, we suggest that the basic features be required with the timelines left to the discretion of the entities. We think that having just the model policy that incorporates these provisions is insufficient because so few policies follow the model and setting forth the minimum required features in regulation will at least provide the necessary skeleton for grievance procedures. In suggesting that complaints be resolved within a set timeframe, we envision that most grievances should

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<sup>122</sup> In a recent California decision, a court found that a City's grievance procedure was not flawed because of a failure to specify a definitive timeline for resolution of each access complaint received. The court cited the lack of such a timeline in the DOJ's model grievance policy in its guidance for state and local governments as indicating such a timeline was unnecessary. *Kirola v. City & Cnty. of San Francisco*, 74 F. Supp. 3d 1187, 1231 (N.D. Cal. 2014). In addition, previous court decisions have found that grievance policies and their adequacy are not enforceable. See *Lonberg v. City of Riverside*, 571 F.3d 846 (9th Cir. 2009); *Duffy v. Freed*, No. 09-2978 (JBS/JS), 2010 WL 3740659 (D.N.J. Sept. 17, 2010), *aff'd*, 452 Fed. Appx. 200 (3rd Cir. 2011).

<sup>123</sup> US DHHS OCR, Example of a Section 504 Grievance Procedure that Incorporates Due Process Standards, <http://www.hhs.gov/ocr/civilrights/clearance/exampleofasection504grievanceprocedure.html>.



be able to be resolved promptly but that a resolution could also include informing the individual how and when resolution will occur.

Further, we do not want to require individuals who allege discrimination to have to exhaust any internal grievance or complaint procedures before being allowed to file an administrative complaint or pursue judicial remedies. While we recognize that some individuals may have a positive result when utilizing internal processes, it is likely that for some individuals a covered entity's internal processes will offer no likely positive outcome.

We also suggest that HHS include specific standards for the "prompt and equitable" resolution of complaints. We believe that such standards would include:

1. 72-hour resolution for exigent circumstances, for example if the discrimination places an individual's life or health is at risk;
2. 30-day resolution for non-exigent situations.

Finally, the final rule should clarify the types of information to which an aggrieved party is entitled and that a covered entity is obligated to provide. The proposed rule delineates both informal and formal dispute resolution requirements. Informally, the rule proposes that covered entities adopt grievance procedures and due process standards that "allow for the prompt and equitable resolution of complaints concerning actions prohibited by Section 1557."<sup>124</sup> However, the proposed rule is silent on the types of information that the issuer must provide if they choose to file a grievance based on discrimination or in order to evaluate whether there is a reasonable claim of discrimination in the first instance. A complainant should be entitled to a broad range of plan documents, including internal Sec. 1557 compliance reviews that may be pertinent to their discrimination complaint. While the proposed rule unequivocally clarifies OCR's right to access information, it is unclear what is available to an aggrieved party short of discovery through litigation. Without a defined entitlement to a broad range of plan documents pertinent to the basis for the complaint, the ability to credibly formulate and document a complaint is simply not possible. Transparency is essential to accountability in this regard. Without such transparency on the part of the covered entity, the credibility and probability of resolution is greatly diminished. Therefore, the final rule should clarify entitlement to essential information on the part of a complainant. Access should be defined to include a broad range of plan documents which may be related to the basis for the discriminatory complaint. Section 104b of ERISA, as interpreted by the Department of Labor, is a solid foundation for OCR guidance.

**RECOMMENDATION:** Amend § 92.7 as follows:

- (a) *Designation of responsible employee.* Each covered entity ~~that employs 15 or more persons~~ shall designate. . .
- (b) *Adoption of grievance procedures.* Each covered entity ~~that employs 15 or more persons~~ shall adopt grievance procedures that incorporate appropriate

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<sup>124</sup> Proposed Rule at 54,178.

due process standards and that provide for the prompt and equitable resolution of grievances alleging any action that would be prohibited by Section 1557 or this part. **A grievance procedure must include, at a minimum, the following factors:**

- (1) a timeframe for filing complaints;**
- (2) a timeframe for resolving complaints;**
- (3) a timeframe for issuance of a written decision;**
- (4) an appeal process to an individual or group different from those involved in the original decision;**
- (5) a timeframe for the appeal process that including for filing the appeal and issuing a written response;**
- (6) notice regarding protections against retaliation;**
- (7) notice regarding the availability of accommodations, if needed, for parties involved in the complaint; and**
- (8) notice that the availability and use of the grievance procedure does prevent the person from pursuing other complaint options.**

**At a minimum, a covered entity must resolve grievances within 72-hours for emergency situations, including if an individual's life or health is at stake or within 30 days for non-emergency situations. An individual is not required to exhaust a covered entity's grievance procedures prior to filing a complaint for administrative or judicial relief.**

## **§ 92.8 Notice Requirements**

We commend HHS for requiring that covered entities inform beneficiaries, enrollees, applicants, or members of the public of the availability of language services and that the entity does not discriminate on the basis of race, color, national origin, sex, age or disability.

### **a. § 92.8(a)(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 § 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.

**RECOMMENDATION:** We recommend that § 92.8(a)(1) be revised as follows:

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.

The Appendix to Part 92 (“Sample Notice Informing Individuals about Nondiscrimination and Accessibility Requirements”) should similarly 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.

b. § 92.8(b)

We recommend that HHS adopt the alternative approach and 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>125</sup> The burdens of wall space and use of information technology staff and resources are greatly outweighed by the benefit of having the notice visible and conspicuous so that consumers may see and access the services promised in the notice.

**RECOMMENDATION:** We recommend amending proposed rule § 92.8(b) as follows:

Within 90 days of the effective date of this part, each covered entity shall post, consistent with paragraph (f) of this section, ~~an English language notice~~ **in English with taglines in the top 15 languages in the entity’s service area** that conveys the information in paragraphs (a)(1) through (7) of this section.

c. § 92.8(c) *Translation of sample notices*

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 fail to accurately ensure meaningful access.

We commend HHS for assuming the role of translating the sample notices and agree that this decision maximizes efficiency and economies of scale while minimizing cost burdens for the covered entities.<sup>126</sup> However, we recommend that HHS adopt its proposed alternative and translate the sample notices and taglines to the top 15 languages spoken in each State.<sup>127</sup> A State-based methodology for threshold languages will best account for regional differences, maximize language efficiency, and have the most targeted impact to individuals with LEP. For example, California has 11 written

<sup>125</sup> See 80 Fed. Reg. at 54,179.

<sup>126</sup> 80 Fed. Reg. 54,179.

<sup>127</sup> 80 Fed. Reg. 54,180 (describing statewide versus nationwide determination of top 15 languages).

threshold languages in its Medicaid managed care population, yet only 8 of those are covered in HHS's proposed list of top 15.<sup>128</sup> Many states will have common threshold languages so HHS can still maximize economies of scale. Although the NPRM permits covered entities to provide additional languages, it would be more effective and efficient to have a national standard and require the top 15 languages in each state.

For example, in Illinois, the top 15 languages spoken by limited English proficient individuals would include 5 languages (Gujurati, Serbo-Croatian, Hindi, Urdu, and Greek) that are not part of the top 15 languages nationally.<sup>1</sup> In California, Hmong is one of the top 15 languages spoken by individuals with limited English proficiency in the state, accounting for approximately 33,000 individuals. Similarly, in New Jersey, Gujurati is one of the top 15 languages spoken by individuals with limited English proficiency in the state, representing approximately 30,000 individuals. These additional languages represent significant numbers of individuals with limited English proficiency that must have access to translated notices advising them of their rights. Covered entities should be required to provide these translated notices in the top 15 languages for each state where they provide services. 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.

If a covered entity operates in multiple states, it could either include more than 15 taglines on one document used in multiple states or could have different documents in each state. We do recommend HHS require a minimum font size so that if an entity chooses to have more than 15 languages that it must still use at least a 12 point font or the usefulness of the taglines will be diminished if the font is too small to recognize.

Also, requiring taglines in the top 15 languages in the state would ensure consistency with other HHS regulations. The 2016 Benefit Payment & Parameters final rule requires taglines for the top 15 languages in the state.<sup>129</sup>

Furthermore, we do not believe that Census data is not the most accurate source from which to draw the top 15 languages for all covered entities. HHS should give guidance to covered entities as to the range of available data sources that they should utilize. For example, recipients of federal funds, particularly State Medicaid agencies, have long been required to assess their threshold languages pursuant to the HHS LEP Guidance

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<sup>128</sup> Compare 80 Fed. Reg. 54,179 at fn. 30 with California Department of Health Care Services, All Plan Letter 14-008 (Rev.), "Standards for Determining Threshold Languages" (Aug. 27, 2014), available at <http://www.dhcs.ca.gov/formsandpubs/Documents/MMCDAPLsandPolicyLetters/APL2014/APL14-008.pdf>. California's Medicaid population includes Armenian, Khmer, and Hmong among its threshold languages, which are excluded from HHS's proposed list of top 15 languages.

<sup>129</sup> See 45 C.F.R. § 155.205(c)(3)(i).

and we recommend that Medicaid agencies use those threshold languages to determine their top 15 languages by state.<sup>130</sup>

**RECOMMENDATION:** We recommend amending proposed rule § 92.8(c) as follows:

For use by covered entities, the Director shall make available, electronically and in any other manner that the Director determines appropriate, the content of a sample notice that conveys the information in paragraphs (a)(1) through (7) of this section in English and in the top 15 languages spoken by individuals with limited English proficiency ~~nationally~~ ***in each State***.

d. § 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. For example, Hindi is not one of the top 15 languages nationally for individuals with limited English proficiency. However, when looking at state data, Hindi is one the top 15 languages in at least 7 states, including California, Texas, and Illinois—three of the most populous states in the U.S. We commend HHS for requiring taglines in 15 languages to be included with the notices.

Further, we believe that the proposed rule should clarify that the covered entity has the responsibility to post State-specific taglines if its service area covers more than one state. For example, a health insurance plan based in New Jersey that also operated in New York would have to post taglines for its New York consumers that included Yiddish, French, and Urdu because those languages are in the top 15 non-English languages in New York, even though they are not in New Jersey.

**RECOMMENDATION:** We recommend amending §92.8(d) as follows:

Within 90 days of the effective date of this part, each covered entity shall post taglines in the top 15 languages spoken by individuals with limited English proficiency ~~nationally~~ ***in the State(s) served by the covered entity***.

e. § 92.8(e)

We commend HHS for assuming the role of translating the taglines into the top 15 languages. However, to align this proposed rule with our recommendation for proposed rule § 92.8(c), we recommend that the taglines should be translated into the top 15 languages by state.

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<sup>130</sup> See 42 C.F.R. § 439.10(c)(1) (requiring States to establish a methodology to identify the prevalent non-English languages spoken by enrollees and potential enrollees); 68 Fed. Reg. 47,319-20 (requiring recipients to determine threshold languages).

**RECOMMENDATION:** We recommend changing proposed rule § 92.8(e) as follows:

For use by covered entities, the Director shall make available, electronically and in any other manner that the Director determines appropriate, taglines in the top 15 languages spoken by individuals with limited English proficiency ~~nationally~~ **in each State.**

f. § 92.8(f)

Consistent with our comments and recommendations for proposed rule § 92.8(b), we recommend that HHS adopt the alternative approach and 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>131</sup>

**RECOMMENDATION:** We recommend amending proposed rule § 92.8(f)(1) as follows:

Each covered entity shall post ~~the English language notice~~ required by paragraphs (a) and (b) of this section **in English and the 3 most prominent non-English languages encountered in the entity's geographic service area as well as** and the taglines required by paragraph (d) of this section in a conspicuously visible font size:

g. § 92.8(f)(1) *Location of required notices*

Consistent with Title VI, its implementing regulations and the HHS 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. The HHS LEP guidance has long required that vital documents include, at minimum, taglines and in some cases, should be translated into additional languages to ensure meaningful access.

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. We recommend the below changes to the proposed language.

We believe it would be helpful to explain the difference between a “vital” document and a “significant” document, particularly since “vital” has been used since 2000 in the LEP Guidance. It seems the use of “significant” would be more expansive than “vital” but HHS should clarify its intent. If indeed this is the case, we recommend that HHS maintain a requirement to translate “vital” documents and that while translated vital documents should still include a translated version of the notice, English versions of vital documents should also include both taglines and the notice in case an individual

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<sup>131</sup> See 80 Fed. Reg. at 54,179.

with limited English proficiency either receives the document in English or the document is not translated into that individual's language.

Consistent with 2003 HHS LEP Guidance, “whether or not a document (or the information it solicits) is “vital” may depends upon the importance of the program, information, encounter, or service involved, and the consequence to the LEP person if the information in question is not provided accurately or in a timely manner. Similarly, existing Department of Justice LEP.gov FAQs provide that a document is “vital if it contains information that is critical for obtaining federal services and/or benefits, or is required by law.” Consideration of the “importance” and “consequences” of the document in the current HHS LEP Guidance are a few—and not definitive—factors in determining if a document is “critical,” and therefore, “vital.”

The proposed rule should include examples of what constitutes vital or significant publications. The scope of “vital” documents should align with the definition of vital documents originally listed in the HHS LEP Guidance<sup>132</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. In addition, other vital documents should include publications such as: 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.

Additionally, taglines should be positioned toward the front of these vital and significant publications. These include comprehensive documents such as patient handbooks and other multi-page publications. If taglines are placed at the end of these publications, individuals with limited English proficiency will be less likely to see the taglines and know that they can get language assistance services. For example, during the past two ACA enrollment periods, assistors working with consumers in the Marketplaces reported numerous cases where individuals with limited English proficiency did not see taglines on critical Marketplace notices pertaining to their rights. Consumers received multi-page notices requesting additional documentation or other actions, but individuals often did not see the taglines located at the end of the notice. As a result, they discarded their notices, resulting in termination of coverage and other negative outcomes. This experience underscores the importance of both the content of the notice and location within a communication.

**RECOMMENDATION:** We recommend the following changes to § 92.8(f)(1)(i):

- (i) In ***vital and*** significant publications and ***vital and*** significant communications targeted to beneficiaries, enrollees, applicants, or members of the public; ***If publications are translated into non-English languages, the translated publication must include a translated version of the notice described in paragraph (b);***

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<sup>132</sup> HHS LEP Guidance, 68 Fed. Reg. at 47,322.

*h. § 92.8(f)(2) – Posting notices and taglines in additional publications and communications*

In response to the HHS request for comment on whether the proposed rule should permit covered entities to combine the content of the notice with the content of other notices, and whether the notice could be modified to appropriate for other publications and communication vehicles, we do not recommend that HHS allow such combination and modifications. We believe that any combination or modification would compromise or diminish the primacy of the non-discrimination message of the § 92.8 notice is combined with other messages or notices. To that end, we also believe that to clearly communicate a covered entity's non-discrimination obligations and consumers' right to access services, the notice should be distributed widely, consistently, and in as many formats as possible.

If an entity wants to tailor a tagline for a particular document, to highlight the importance of a particular document or the need to take immediate action, the entity may do so as long as the tagline still begins with the word "ATTENTION" or "IMPORTANT" and the revised tagline is designed to heighten awareness rather than lessen compliance.

**RECOMMENDATION:** Amend § 92.8(f)(2) as follows:

A covered entity may also post the notice and taglines in additional publications and communications, ***but shall not modify or alter the content of the notice.***

*i. § 92.8(g) – Compliance satisfies notice requirements*

We agree that the notice created pursuant to § 92.8 should satisfy the Title VI notice requirement as outlined in 45 C.F.R. § 80.6(d).

*j. Scope of Significant Publications*

The proposed rule seeks comment on how to define the scope of significant publications and communications. We recommend the proposed rule add the following language, providing examples of vital or significant publications or communications. Please see our comments in § 92.201 with regards to recommendations for definitions of vital and significant publications.

**RECOMMENDATION:** We recommend amending § 92.8(f)(1)(i) as follows:

In ***vital and*** significant publications and ***vital and*** significant communications targeted to beneficiaries, enrollees, applicants, or members of the public, ***with taglines placed at the beginning of publications and communications;***



**RECOMMENDATION:** We recommend amending § 92.8(f)(1)(iii) as follows:

***With respect to the English-language notice required by paragraphs (a) and (b) of this section***, in a conspicuous location accessible from the home page of the covered entity's website; ***with respect to the taglines required by paragraph (d)***, in a conspicuous location accessible from on the home page of the covered entity's website.

## § 92.101 Discrimination Prohibited

### a. *Employment Discrimination*

The proposed rule would not apply to discrimination by a covered entity against its own employees except for employee health benefit programs.<sup>133</sup> However no basis exists in the text of Section 1557 that would permit this exclusion. The final rule should eliminate this exclusion and make clear the Section 1557's prohibition against discrimination applies to employment discrimination by a covered entity.

### b. *Strengthening Civil Rights Protections and Ensuring that Families are not Deterred from Securing Coverage*

A unique set of circumstances result in discrimination experienced by mixed-immigration status families or families that include individuals with different immigration statuses, such as undocumented parents with citizen children. As the U.S. Department of Health and Human Services and Department of Agriculture recognized in their "Tri-Agency Guidance," first issued in 2000, application programs and processes for government health programs affecting these mixed-status families may violate Title VI if they have the effect of preventing or deterring eligible applicants from enjoying equal participation in and access to benefits programs.<sup>134</sup> Primary examples involve requests for Social Security numbers, citizenship or immigration status, place of birth, ethnicity, or race, from family members not applying for coverage or benefits for themselves that result in deterring eligible family members from applying.

In mixed-status families where eligible individuals are prevented or deterred from seeking or obtaining assistance, the impact primarily results in low participation rates in programs and decreased access of health services in general. The reach of this impact is potentially quite large: as of 2010, nearly one in four children younger than age 8 has

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<sup>133</sup> Nondiscrimination in Health Programs and Activities, 80 Fed. Reg. 54,172, 54,180 (proposed Sept. 8, 2015) (to be codified at 45 C.F.R. pt. 92).

<sup>134</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*, available at <http://www.hhs.gov/ocr/civilrights/resources/specialtopics/tanf/triagencyletter.html>.

an immigrant parent.<sup>135</sup> Of these children, the vast majority (93 percent) is U.S. citizens and 43 percent live in mixed-status families.<sup>136</sup> Significantly, under the ACA an estimated 3.2 million children with only undocumented parents will be eligible for Medicaid/CHIP or marketplace subsidies.<sup>137</sup> Statistics of coverage rates for children bear out the possible results for these families. Citizen children with non-citizen parents are 38.5 percent more likely to be uninsured than are citizen children with citizen parents.<sup>138</sup> Within every ethnic group, children with immigrant parents were less likely to be insured than children with U.S.-born parents, with the highest rate for uninsured being Hispanic children.<sup>139</sup> In addition to the lower rates of children obtaining access to health insurance, evidence points to a chilling effect on immigrant access to health care more broadly. Although much of the difference between citizens and non-citizens in health care spending can be attributed to the younger population and immigrants' ineligibility for public health insurance programs, an analysis adjusting for health status, race/ethnicity, gender, health insurance coverage, and other factors found that the spending on immigrants' health care was still about 14–20 percent less than U.S.-born citizens.<sup>140</sup>

To be effective, HHS should clarify in the Section 1557 regulations that it has the explicit authority to enforce the statutory and regulatory provisions that are based on the principles articulated in the Tri-Agency Guidance.<sup>141</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

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<sup>135</sup> Karina Fortuny, et al., The Urban Institute, *Young Children of Immigrants: The Leading Edge of America’s Future* at 1 (August 2010), available at <http://www.urban.org/research/publication/young-children-immigrants-leading-edge-america-future>.

<sup>136</sup> *Id.* at 5.

<sup>137</sup> Stacey McMorro, et al., The Urban Institute, *Addressing Coverage Challenges for Children Under the Affordable Care Act* at 6 (May 2011), available at <http://www.urban.org/research/publication/addressing-coverage-challenges-children-under-affordable-care-act>.

<sup>138</sup> Leighton Ku and Brian Bruen, *Poor Immigrants Use Public Benefits at a Lower Rate than Poor Native-Born Citizens*, Cato Institute: Economic Development Bulletin No. 17, at 1, 3 (May 4, 2013), available at <http://www.cato.org/publications/economic-development-bulletin/poor-immigrants-use-public-benefits-lower-rate-poor>.

<sup>139</sup> Donald J. Hernandez, et al., Foundation for Child Development, *Diverse Children: Race, Ethnicity, and Immigration in America’s New Non-Majority Generation 10* (July 2013).

<sup>140</sup> Leighton Ku, *Health Insurance Coverage and Medical Expenditures of Immigrants and Native-Born Citizens in the United States*, 99 Am. J. Pub. Health 1322, 1326–27 (2009).

<sup>141</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.

address disparate, effect-based discrimination resides in the invocation of Title VI and other civil rights statutes.<sup>142</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:** We recommend amending § 92.101(a)(1) as follows:

Except as provided in Title I of the ACA, an individual shall not, on the basis of race, color, national origin, sex, age, or disability, be excluded **or deterred** from participation in, be denied the benefits of, or otherwise be subjected to discrimination under any health program or activity to which this part applies.

**RECOMMENDATION:** We recommend amending § 92.101(b)(1) as follows:

Each covered entity must comply with the regulation implementing Title VI, at § 80.3(b)(1) through (6) of this subchapter, **as well as 42 U.S.C. 18081(g) and 45 C.F.R. § 155.260(a)(1), § 155.260(a)(2), § 155.305(f)(6), § 155.310(a)(2), and § 435.907(e).**

### c. *Benefit Design*

In proposed § 92.101(c), HHS broadly applies exceptions under Title VI, § 504, and the Age Discrimination Act to § 1557. However, not all of the exceptions under these acts apply to § 1557. Notably, § 1557 expressly includes “contracts of insurance” as a “program or activity” subject to non-discrimination protections. By contrast, federal law or regulation exempt “contracts of insurance” from Title VI, § 504, and the Age Discrimination Act. (See 42 U.S.C. § 2000d-1 (2011) [Title VI]; 20 U.S.C. § 1682 (2011) [Title IX]; 45 C.F.R. § 84.3(h) (2011) [§504 regulations]; 42 U.S.C. §6103(a)(4) (2011) [Age Discrimination Act]).

HHS should clarify that the exception for “contracts of insurance” does not apply to § 1557.

**RECOMMENDATION:** We recommend amending § 92.101(c) by adding the following:

(c) ***Except as otherwise provided for under § 1557(a), [F] the exceptions applicable to Title VI apply to discrimination of the basis of race, color, or national***

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<sup>142</sup> Dept. of Justice, *Title VI Legal Manual* (2001), available at <http://www.justice.gov/crt/about/cor/coord/vimmanual.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))).

origin under this part. **Except as otherwise provided for under § 1557(a),** ¶] the exceptions applicable to Section 504 apply to discrimination on the basis of disability under this part. **Except as otherwise provided for under § 1557(a),** ¶] the exceptions applicable to the Age Act apply to discrimination on the basis of age under this part.

#### *d. Language Access*

We agree with HHS's decision to incorporate instead of harmonize the existing Title VI prohibitions on discrimination.<sup>143</sup>

#### *e. Sex Discrimination*

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. 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. We support the comments submitted by the National Women's Law Center on this section.

As we noted above in our comments regarding § 92.4, we strenuously objects to any religious exemption to § 1557, as such an exemption would undermine the right of individuals to access comprehensive health care services, including reproductive health care, free from discrimination, and thwart the objectives of the Affordable Care Act (ACA). Please see our detailed comments on this topic above.

#### *f. Issues related to Disability*

Section 92.101(b)(2)(i) incorporates regulations enacted under Section 504 that pertain to recipients of federal financial assistance, extending these regulations to include State-based marketplaces. In general we support HHS's aim in paragraphs (b)(1-4) to "incorporate into this proposed regulation the specific discriminatory actions prohibited under each civil rights law on which Section 1557 is grounded."<sup>144</sup>

At the same time, the incorporation of existing Section 504 and ADA regulations must be done carefully and in a manner that will not unnecessarily narrow the ambit of Section 1557. In particular, we object to the application of all of Section 504's program accessibility provisions for existing facilities, 45 C.F.R. §§ 84.22 and 85.42, to the many health insurance issuers and managed care organizations that operate health programs and activities in state marketplaces and Medicaid and CHIP programs, in Medicare, and in the federal marketplaces.

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<sup>143</sup> 80 Fed. Reg. at 54,181.

<sup>144</sup> *Id.*

First, the same manner of “confusion and unintended consequences” that HHS foresees in an attempt to harmonize regulatory standards and concepts *between* civil rights statutes is potentially raised by the failure to harmonize regulatory standards and concepts *within* Section 504’s cited regulations. 45 C.F.R. §§ 84.22 and 85.42 differ slightly in their language, but there is no principled reasons that State-based Marketplaces and Federally-facilitated Marketplaces should apply program accessibility in existing facilities in slightly different ways. Each type of marketplace, for example, should have the same obligation to make existing facilities readily accessible to and useable by persons with disabilities unless it can establish a fundamental alteration or undue burden defense. State and municipal entities are, of course, already familiar with that concept under Title II of the ADA and 28 C.F.R. § 35.150, but 45 C.F.R. § 84.22 does not contain this actual language.

Second, both §§.84.22 and 85.42 incorporate a concept of “program accessibility” that was developed specifically for government programs and agencies. We are concerned that incorporating program accessibility in the context of private insurance carriers and managed care organizations may have the unintended consequence of actually diminishing accessibility requirements for health care providers. A key feature of how these large corporate entities appeal to prospective members is through the quality, size and “choice” offered within each entity’s provider networks. At the same time, state insurance and Medicaid agencies and the Centers for Medicare and Medicaid Services work to establish clear guidelines and consumer protections to govern the sufficiency of provider networks. Amidst this backdrop of commercial and regulatory practice, it would be senseless to allow private entities to essentially *decide for themselves* when their provider network is “readily accessible” to people with disabilities. Yet, that is exactly what will happen if such private entities are subject to a program accessibility standard that “does not require a recipient to make each of its existing facilities or every part of a facility” accessible to and useable by persons with disabilities. A large for-profit insurance carrier could arbitrarily decide that, among the great majority of its providers who operate in existing facilities, only 10% need to be physically accessible or have accessible equipment. Moreover those accessible providers could be clustered together in some central location, and whenever a member calls member services and mentions the need for accessibility, that member will be actively directed toward “the accessible provider offices.”

As written and potentially applied, §§84.22 and 85.42 could gut the concept of provider choice for health consumers with disabilities, and also conflict with state and federal regulations that place provider time and distance or provider-member ratio obligations on insurance carrier and managed care provider networks. While the general prohibition of discrimination in §92.101(5) of the proposed rule is supposed to take primacy over the specific forms of discrimination enumerated in §92.101(2)(b)(i) and (ii), the full incorporation of the program accessibility concept will give covered entities an unintended escape hatch, relegating health consumers with disabilities to second-place status every time they try to gain access to their provider network. The fact is, every healthcare provider is already independently subject to Title III of the ADA, and as a recipient of federal financial assistance under Section 1557, is responsible for ensuring that the “entirety” of its program or activity is readily accessible to and useable by

persons with disabilities. It would surely be an unintended consequence if entities that establish extensive provider networks could, by that very fact, escape from their obligations to provide access to people with disabilities.

In light of the above, we recommend that 45 C.F.R. §§ 84.22 and 85.42 be harmonized primarily through the amended language of § 85.42 as follows:

§ 85.42 Program accessibility: Existing facilities.

(a) *General.* The agency shall operate each program or activity so that the program or activity, ~~when viewed in its entirety,~~ is readily accessible to and usable by individuals with handicaps. This paragraph does not—

- ~~(1) Necessarily require the agency to make each of its existing facilities accessible to and usable by individuals with handicaps; or~~
- ~~(2) Require the agency to take any action that it can demonstrate . . .~~

(b) *Methods.*

- (1) The agency may comply with the requirements of this section through such means as redesign of equipment, ~~reassignment of services to accessible buildings,~~ assignment of aides to beneficiaries, home visits, delivery of services at alternate accessible sites, alteration of existing facilities and construction of new facilities, use of accessible rolling stock, or any other methods that result in making its programs or activities readily accessible to and usable by individuals with handicaps. The agency is not required to make structural changes in existing facilities where other methods are effective in achieving compliance with this section. ~~The agency, in making alterations to existing buildings, shall meet accessibility requirements to the extent compelled by the Architectural Barriers Act of 1968, as amended ([42 U.S.C. 4151-4157](#)), and any regulations implementing it.~~
- (2) In choosing among available methods. . .

Please note: We have incorporated comments regarding § 92.101(b)(2)(i)'s discussion of 45 C.F.R. § 84.23(c) and the Uniform Federal Accessibility Standards (UFAS) in our section on § 92.203 on Accessibility Standards for Buildings and Facilities.

### **§ 92.201 Meaningful Access for individuals with limited English proficiency**

As the proposed rule notes, due to 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 and offer additional recommendations. We also emphasize that, 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.<sup>145</sup> Our recommendations are designed to effectuate the text and intent of 1557 and ensure meaningful access in all federally supported health programs and activities and recipients of federal financial assistance.

Visiting health care facilities and agencies that administer health programs and activities are often uncomfortable for individuals with LEP who are “unfamiliar with [the system’s] cultural norms, vocabulary, and procedures.”<sup>146</sup> Unfamiliarity with the health care system often results in inaction that could compromise a basic standard of living for individuals and families. Furthermore, the lack of language assistance services negatively impacts communities at large, not just LEP individuals. When interpreter services are inadequate, children often serve as language brokers for their parents.<sup>147</sup>

Patient experiences that have resulted in malpractice claims are documented in *The High Costs of Language Barriers in Medical Malpractice*, a joint publication by the National Health Law Program and University of California, Berkeley, School of Public Health.<sup>148</sup>

a. *General Comments*

i. Threshold languages

We are dismayed that HHS did not include any thresholds for translating materials.<sup>149</sup> Since the initial promulgation of the HHS LEP Guidance fifteen years ago, federal fund recipients have been on notice that translating materials when certain thresholds are met ensures compliance with Title VI. Given that significant numbers of the entities covered by Section 1557 have already been required to comply with Title VI and the LEP Guidance since at least 2000, we strongly believe that threshold standards for translating documents should be included in the regulation.

Thus 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, thereby dispensing with the “safe harbor” system set forth in the HHS LEP Guidance.<sup>150</sup> Vital documents should be translated for

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<sup>145</sup> Kaiser Family Foundation, *Overview of Health Coverage for Individuals with Limited English Proficiency*, at 3, <http://kff.org/disparities-policy/fact-sheet/overview-of-health-coverage-for-individuals-with/>.

<sup>146</sup> Vikki Katz, *Children as Brokers of their Immigrant Families’ Healthcare Connections*, at 24 (2013) (under review).

<sup>147</sup> *Id.* at 31.

<sup>148</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).

<sup>149</sup> 80 Fed. Reg. at 54,185.

<sup>150</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.

each 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>151</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>152</sup> HHS' long-standing methodology to determine threshold languages—currently a 5% and 1,000 person standard to determine threshold languages<sup>153</sup>—is something that recipients have worked with for years. We recommend that HHS continues this standard and reinforces this language access by requiring written translations in the threshold languages.

While we recognize that the proposed rule covered entities of varying sizes, from the smallest provider office to the largest health insurer, we believe that setting some minimum standards is important to highlight the need to translate documents. Without standards, many entities may forego translating materials entirely as they have no guidelines for when to do so. Having both a numeric and percentage threshold assists both large and small covered entities and having the exemption currently in the HHS LEP Guidance if a language group is smaller than 50 individuals further protects smaller entities from having to translate too many documents.

For larger entities, we would suggest including stronger translation thresholds, as we discuss below regarding “enhanced obligations.” We suggest the same standards apply to any covered entity that has more than 500,000 individuals enrolled or served.

ii. Service Areas

Service areas relevant for the application of translation thresholds should be program-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. The service area may differ depending on the entity. For example, an insurer's service area may spread throughout a state and should include both potential applicants and enrollees. A navigator's service area may be more targeted within a city or county and should include all individuals who may be seeking the navigator's services, not just those actually served. Service areas relevant for the application of the thresholds should be entity-specific, encompassing the geographic area where persons *eligible to be served or likely to be directly or significantly affected* by the entity's program or activity are located.

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<sup>151</sup> See *id.*

<sup>152</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).

<sup>153</sup> HHS LEP Guidance, 68 Fed. Reg. at 47,319.



Where no service area has previously been defined, HHS should permit a covered entity to utilize a service area approved by state or local authorities or allow the covered entity to self-identify the service area as long as the designation does not discriminatorily exclude certain populations.<sup>154</sup> The covered entity could use data gathered by the entity or provided by a listed LEP.gov demographic data source,<sup>155</sup> subject to a showing that the service area does not discriminatorily exclude certain populations. Covered entities should also be able to provide documentation of how the self-identifying determination was made and what data was used.

As discussed in the HHS LEP Guidance, recipients should determine their service areas based on their actual experiences with LEP encounters as well as demographic data on the languages spoken by those who are not proficient in English.<sup>156</sup> HHS should work with LEP.gov to ensure that all of the sources listed on its Demographic Data are as current and accessible as possible.<sup>157</sup>

iii. Timing<sup>158</sup>

Where a covered entity is a federal fund recipient that has already determined the threshold languages in its service area, it should continue to use that demographic information and should be allowed 90 days to come into compliance with the proposed rule, including translation of all vital documents into the threshold languages. Covered entities that have not previously defined a service area and threshold languages in that area should have 90 days to either use an approved demographic data source or self-identify the service area and threshold languages. These entities should have an additional 90 days to come into compliance with the proposed rule, including translation of all vital documents.

b. § 92.201(a) *General requirement*

While we acknowledge HHS's desire to give covered entities flexibility, we urge HHS to eliminate ambiguities and subjective standards for language access. However, we think that the flexibility should be not *whether* to provide meaningful access, but *how* to provide such language assistance. Because "meaningful access" is already a subjective standard, adding a "reasonable steps" adds an excessive layer of ambiguity and therefore makes meaningful language access all the more remote for individuals with LEP. The evaluation of compliance as outlined in subsection (b) should give definition and nuance to "meaningful access" not "reasonable steps," but as written it is unclear

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<sup>154</sup> HHS LEP Guidance, 68 Fed. Reg. at 47,314.

<sup>155</sup> LEP.gov, *Demographic Data*, available at [http://www.lep.gov/demog\\_data/demog\\_data.html](http://www.lep.gov/demog_data/demog_data.html).

<sup>156</sup> HHS LEP Guidance, 68 Fed. Reg. at 47,314.

<sup>157</sup> Many of the government links and data sources listed on LEP.gov's Demographic Data page, [http://www.lep.gov/demog\\_data/demog\\_data.html](http://www.lep.gov/demog_data/demog_data.html), either are not current or have inactive or incorrect links. HHS, in coordination with LEP.gov, should ensure that data sources are properly listed and frequently updated on the LEP.gov website.

<sup>158</sup> 80 Fed. Reg. at 54,185 (requesting comment on time that should be allowed for covered entities to come into compliance).

which the measure of language access is. As HHS has reiterated from the Department of Justice’s LEP Guidance, Title VI policies advance the longstanding principle that “federally assisted programs aimed at the American public do not leave some behind simply because they face challenges communicating in English.”<sup>159</sup> This regulation must do the same.

Further, the proposed section does not include the reference to those “eligible to be served” by an entity. It is insufficient for an entity to only provide language services to those who actually walk in its door (or call its office). Instead, a covered entity must be prepared to provide language services to all those eligible to be served. As recognized in the HHS LEP Guidance:

Ordinarily, persons “eligible to be served, or likely to be directly affected, by” a recipient’s program or activity are those who are served or encountered in the eligible service population . . . . In certain circumstances, it is important in conducting this analysis to include language minority populations that are eligible for their programs or activities but may be underserved because of existing language barriers.<sup>160</sup>

Unfortunately, by not identifying those eligible to be served, a covered entity may actually be discriminating since eligible clients/patients will not go to a covered entity if the client/patient perceives the entity is not prepared to assist the client/patient in his/her language. For example, if a hospital is located in an area with a large Hmong population (e.g. in parts of Minnesota), the hospital likely should have its materials translated into Hmong and have the availability of language services in Hmong. Without having materials and services available, it will be discriminating against Hmong patients who reside in its service area, are eligible to be served, but are not actually served.

**RECOMMENDATION:** Amend § 92.201(a) as follows:

(a) *General requirement.* A covered entity shall ~~take reasonable steps to provide meaningful access to each individual with limited English proficiency~~ **who is eligible to be served** ~~that it serves or~~ **is likely to be affected by** ~~encounters in its~~ **the entity’s** health programs and activities.

c. § 92.201(b) *Evaluation of compliance*

Current HHS LEP Guidance uses a four-factor balancing test to determine the “mix” of language assistance services that should be provided. The balancing test allows covered entities to rely on a flexible and fact-dependent standard to determine what steps are required to ensure meaningful access. The current balancing test is composed of four factors: (1) The number or proportion of LEP persons eligible to be served or likely to be encountered by the program or grantee; (2) the frequency with which LEP individuals come into contact with the program; (3) the nature and

<sup>159</sup> HHS LEP Guidance, 68 Fed. Reg. at 47,312.

<sup>160</sup> *Id.* at 47,314.

importance of the program, activity, or service provided by the program to people's lives; and (4) the resources available to the grantee/recipient and costs. The balancing test, which has been in use since 2003, strives to balance ensuring meaningful access to LEP persons with the cost and resource considerations of the wide variety of covered entities, including smaller providers.

In contrast, the proposed § 92.201(b) provides a modified version of the four-factor balancing test, first focusing on the existing factor of the "nature and importance of the health program or activity" and requires that the Director evaluate and give substantial weight to that factor. 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. Beginning the inquiry with this factor properly balances Title VI obligations with those of § 1557 to ensure LEP persons are meaningfully served by health programs or activities. This approach is consistent with an understanding of the consequences that can result in lack of access to services or information in the health care setting by individuals with LEP.

After consideration of the nature and importance, the proposed rule then requires the Director to take other relevant factors into account, including the five factors denoted in § 92.201(b). Comparing the § 92.201(b) factors to the existing four-factors, we find that § 92.201(b)(2)(iii) is analogous to the current HHS LEP factor "the number or proportion of LEP persons served or encountered in the eligible service population." The proposed § 92.201(b) factors, however, do not include the current HHS LEP factor of "the frequency with which LEP individuals come into contact with the recipient's program, activity or service." Removing this factor from the fact-dependent consideration raises serious concerns for 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. The more frequent the contact with a language group, the more likely a covered entity will need to provide enhanced language. In evaluating this factor, covered entities should also determine the types of contact they may have with a language group, such as whether it is rare or on a daily basis. We recommend amending § 92.201(b) to retain this factor as part of a fact-dependent evaluation of a covered entity's mix of language service options. Doing so supports consistency by codifying a standard that many covered entities have been subject to since 2003 and ensures that the evaluation includes an accurate assessment of need and obligations. This ensures covered entities are best prepared to provide language services that are both necessary and reasonable.

In discussions of resources and costs in § 92.201(b)(iv) and (v), we caution against using these factors as dispositive when federally funded entities must provide language assistance services pursuant to Title VI and Section 1557. As OCR has reiterated from the Department of Justice's LEP Guidance, Title VI policies advance the longstanding principle that "federally assisted programs aimed at the American public do not leave some behind simply because they face challenges communicating in English." Section 1557 policies must do the same. We incorporate our comments to the 2013 Request for Information Regarding Nondiscrimination in Certain Health Programs or Activities and

those submitted by the Asian & Pacific Islander American Health Forum that provide more information on efficient and cost-effective language access practices that covered entities can employ to meet their obligations.

Further, we recommend that the final rule clarify that the 5 factors in (b)(2) are not equally weighted. That is, costs and potentially limited resources cannot outweigh the requirements to provide **some** language access although they may clarify what types of language services should be provided. Thus, the expectation is that Title VI and Section 1557 both require the provision of language access but how it is provided is left up to a fact-dependent analysis. For example, a larger entity may have a need for in-person interpreters for its frequently encountered languages while a smaller entity may be able to provide language services using telephonic interpreting services.

Further, we are concerned that some covered entities use the current four-factor test or proposed 1-plus-5 factor test not as a means of planning how best to provide language services but instead as an individual-specific way to determine if language services should be provided on an individual basis. We do not believe this was the intent of the four-factor test and thus the recognition in § 92.201(b) of a new method of determining compliance should help alleviate some of the misunderstanding of the current four-factor test.

To ensure that the new standards are indeed viewed differently than the current analysis, and to prevent covered entities from attempting to use the new factors to assess language services for individual clients/patients, we strongly recommend that HHS include language in the final rule that both clarifies that the factors should be used by covered entities for language access planning and not individualized compliance.

We support adding a factor that requires analysis of the impact on a consumer if she 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>161</sup>

**RECOMMENDATION:** We recommend amending § 92.201(b) as follows:

- (b) *Evaluation of compliance.* In evaluating whether a covered entity has met its obligation under paragraph (a) of this section, the Director shall:
  - (1) Evaluate, and give substantial weight to, the nature and importance of the health program or activity, including the particular communication at issue, to the individual with limited English proficiency; and
    - (i) ***When evaluating the nature and importance of the health program or activity, consider and give similar substantial weight to the consequences of the contact with individuals with LEP, including whether a denial or delay in access to language assistance services or information could have serious implications, and the***

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<sup>161</sup> HHS LEP Guidance, 68 Fed. Reg. at 47,318.

***urgency of the communication. In addition, the Director shall also consider whether the communication pertains to rights or benefits or requires a response from an individual and the effect on those rights and timing of that effect;***

d. § 92.201(b)(2) *Additional Factors*

We are concerned that many using the current four-factor test believe that each factor is weighed equally in evaluating compliance. We believe the same concern may arise with the new factors outlined in subsection (b). While we appreciate elevating the “nature and importance” factor, we still believe it is important to inform covered entities that the additional factors evaluated as part of compliance do not necessarily have equal weight. That is, as we explain below, costs and resources cannot be a dispositive factor since all covered entities have a responsibility to provide language services in some regard to comply with Section 1557 (and Title VI); it is just the manner and form of the language services that may differ depending on a covered entities’ costs and resources. Thus we suggest including explicit language that the factors outlined in subparagraph (b) may not be considered equally.

**RECOMMENDATION:** We recommend amending § 92.201(b)(2) as follows:

- (2) Take other relevant factors into account. ***Covered entities must recognize that the following factors are not necessarily given equal weight and the Director shall evaluate the relevance and weight of the factors on a case-by-case basis. With regard to the provision of healthcare services, the nature and importance of providing healthcare services is such that an expectation exists that covered entities must provide language services and it is only the form or manner of the services provided that will be evaluated for compliance.***

e. § 92.201(b)(2)(i) – *Length and complexity*

Although the “length and complexity of the communication involved” is one factor to consider, we believe that there should be clarification about this factor because circumstances may exist where it should not be dispositive of the importance of a document. For example, a notice of action denying Medicaid benefits may be short and simple, but it has great consequence in the consumer’s ability to access healthcare. In the reverse, prioritizing long and complex documents may stall a covered entity’s ability to translate other documents that may be simpler but more important. To be sure, we agree with HHS’ reasoning that it is helpful to have lengthy or complicated information in written or audio file format for reference.<sup>162</sup> We support the use of length and complexity as a factor to determine the type and level of services required, i.e., if the communication between the doctor and patient was long and complicated, it would support the use of an in-person or face-to-face interpreter, rather than a remote or telephonic interpreter, not whether language services must be provided. Therefore, if

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<sup>162</sup> 80 Fed. Reg. at 54,183.

this factor is included in the final rule, examples of its use should be provided and length and complexity should never potentially trump or diminish more important considerations, such as the nature and importance of that document.

Furthermore, we recommend adding “the frequency with which LEP individuals come into contact with the recipient’s program, activity or service.” ...” However, length and complexity should not be potentially trump or diminish other considerations, such as the nature and importance of that document.<sup>163</sup>

Thus, we recommend adding to (b)(2) an element of the four-factor test that was elided: “the frequency with which LEP individuals come into contact with the recipient’s program, activity or service.”<sup>164</sup> We believe removing this factor from the fact-dependent consideration raises serious concerns for 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. The more frequent the contact with a language group, the more likely a covered entity will need to provide enhanced language. In evaluating this factor, covered entities should also determine the types of contact they may have with a language group, such as whether it is rare or on a daily basis. We recommend that the § 92.201(b) be amended to retain this factor as part of a fact-dependent evaluation of a covered entity’s mix of language service options. Doing so supports consistency by codifying a standard that many covered entities have been subject to since 2003 and ensures that the evaluation includes an accurate assessment of need and obligations. This ensures covered entities are best prepared to provide language services that are both necessary and reasonable.

While some covered entities may previously have used this factor as a defense to providing language services to a less frequently encountered language group, we believe that indeed the reverse should be true. If a covered entity has a small number of patients/clients of a less frequently encountered language, that language group may not meet the threshold for translating documents but providing telephonic interpretation will not be very costly or resource-intensive. We recognize there may be some particular dialects or languages which are so infrequently encountered that over-the-phone interpreters are not readily available but with advance planning, the needs of most LEP individuals can be met. Again, this points to the need to educate covered entities that the factors defined in § 92.201(b) should not be used to evaluate one individual’s language needs but serve as providing an overall framework for planning and evaluating compliance.

That is, the frequency of contact should point to the need to have more established language services in place for more frequently encountered languages. But it should not offer an “out” to compliance with Section 1557 (or Title VI) for a provider that it only has a few patients who speak a particular language.

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<sup>163</sup> HHS LEP Guidance, 68 Fed. Reg. at 47,314.

<sup>164</sup> *Id.*

**RECOMMENDATION:** We recommend adding new § 92.201(b)(2)(i) and relettering current (i)-(v) as (ii)-(vi):

- (2) Take other relevant factors into account. Such factors may include:
- (i) ***The frequency with which LEP individuals come in contact with the program (covered entities should note that they have an obligation to provide language services to all individuals with limited English proficiency, even patients who speak a less frequently encountered language); this factor relates to an evaluation of the type of language services that should be provided and not to whether language service should be provided such that telephonic interpreting may be the most effective method of providing language services in less frequently encountered languages but the higher the frequency a language is encountered, the higher the expectation of providing additional types of language services;***

**RECOMMENDATION:** We recommend that § 92.201(b)(2)(iii) evaluating the prevalence of the language in which the individual communicates is clarified such that:

- Consistent with HHS LEP Guidance, evaluation of § 92.201(b)(2)(iii) is program-specific, such that those eligible to be served or likely to be encountered will vary by program.
- A covered entity may not rely on current enrollees alone to determine the scope of their service area. A covered entity should consult a variety of data sources including: national data sets such as the U.S. Census/American Community Survey, state and local data sets and other sources, including those provided by community-serving organizations that can accurately describe the prevalence of the language in which the individual communicates among those eligible to be served or likely to be encountered. As discussed in the HHS LEP Guidance, recipients should determine their service areas based on their actual experiences with LEP encounters **and** demographic data on the languages spoken by those who are not proficient in English. HHS should consider equipping recipients with data driven maps that show estimates of eligible individuals with LEP for each service area as well as their approximate location

We recommend combining the cost and resource analysis to codify the existing factor from the original HHS LEP Guidance.<sup>165</sup> As noted in a DOJ memorandum explaining Executive Order 13166 and the agencies' 4 factor tests, DOJ noted:

“Reasonable steps” may cease to be reasonable where the costs imposed substantially exceed the benefits in light of the factors outlined in the DOJ LEP Guidance. The DOJ LEP Guidance explains that a small recipient may not have

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<sup>165</sup> HHS LEP Guidance, 68 Fed. Reg. 47,314.

to take substantial steps “where contact is infrequent, where the total costs of providing language services is relatively high and where the program is not crucial to an individual’s day-to-day existence.” By contrast, where number and frequency of contact is high, where the total costs for LEP services are reasonable, and where the lack of access may have life and death implications, the availability of prompt LEP services may be critical. In these latter cases, claims based on lack of resources will need to be well established.<sup>166</sup>

The same four factors are used in HHS’ LEP guidance, with a combination of costs and resources. Listing costs and resources as separate factors also potentially gives undue importance to two considerations that often interchangeable. If all factors are weighted equally, then almost any other reason to translate could be outweighed by the combination of high costs and few resources. Cost and resources should be a combined element to be weighed against the other factors and covered entities are accustomed to this analysis under the original HHS LEP Guidance.<sup>167</sup> Otherwise, it is critical that HHS provide more guidance as to how resources differ from costs and the different results that may occur in different situations. Is the expectation that an entity may have more resources and thus costs would be lower? Or would a high cost outweigh the need to comply even if the agency has internal resources? It is unclear what result splitting these two factors apart will have on actual evaluations of compliance by covered entities.

It is often difficult if not impossible to ascertain when a seemingly “routine” doctor’s visit may turn into one that affects an individual’s day-to-day existence. How many individuals go to the doctor thinking that they may have high blood pressure, cancer, or heart disease? Only by the ability to effectively communicate with a provider and having a provider take a full health history from a patient is it likely that the provider will gather all the information necessary to actually determine if a patient may have a condition that could affect his day-to-day existence. Thus the importance of even a seemingly “routine” healthcare visit in diagnosing potentially life-threatening conditions should weigh heavily in favor of the provision of language services and likely outweigh any concerns about costs and resources, particularly when over-the-phone interpreting services can offer a wide variety of languages at a relatively low cost.

Perhaps most importantly, cost-benefit analyses fail to evaluate how professional and industry or agency culture contributes to racial disparities in health care.<sup>168</sup> Because language assistance services can be measured in cost or resources—money, time, staffing—the cost-benefit analysis is skewed towards the quantifiable and does not capture the immeasurable benefits of language access, increased access and participation in underserved communities, improved health outcomes, and compliance

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<sup>166</sup> Memorandum from Ralph F. Boyd, Jr. re: Executive Order 13166 (Oct. 26, 2001) at 3, <http://www.lep.gov/13166/Oct26memorandum.pdf>.

<sup>167</sup> HHS LEP Guidance, 68 Fed. Reg. 47,314.

<sup>168</sup> Ikemoto, L. C., Symposium: Racial Disparities in Health Care and Cultural Competency, 48 St. Louis L.J. 75, 119 (2003).



with anti-discrimination laws. The cost-benefit analysis also does not explicitly account for the costs to a consumer who is denied or delayed language assistance.

**RECOMMENDATION:** We recommend combining the cost and resource factors § 92.201(b)(iv) and (v) into a single factor as follows:

- (iv) ~~All resources available to the covered entity;~~ and ***The resources available to the covered entities and costs of language assistance services.***
- (v) ~~The cost of language assistance services.~~

**RECOMMENDATION:** We recommend that HHS add explanatory language to the preamble discussing § 92.201(b)(2)(iv) and (v) evaluating all the resources available to the covered entity and the cost of language services be amended as follows:

Where the Director considers an entity's resources, he or she will evaluate all available resources, including the entity's capacity to leverage resources among its partners or to use its negotiating power to lower the costs at which language assistance services could be obtained. ***Where the Director considers an entity's costs, he or she will evaluate how costs can be reduced by technology and reasonable business practices.***

We also suggest that the regulation incorporate specific language notifying covered entities that the factors outlined in § 92.201(b) should **not** be utilized on an individualized basis to determine if a particular individual who is limited English proficient should receive language services. Rather, these factors must be used in a holistic manner to help a covered entity plan for the types of language services and resources that it will have in place to meet the needs of **all** individuals with limited English proficiency.

**RECOMMENDATION:** Add new subsection (3) to § 92.201(b) as follows:

***(3) A covered entity shall not apply the factors outlined in paragraphs (1) and (2) to determine whether to provide language services to a specific individual with limited English proficiency. A covered entity must provide language services to all individuals with limited English proficiency and should utilize the factors to develop a language access plan that outlines how it will meet its requirements under these regulations.***

f. § 92.201(c) Language assistance services requirements

The proposed rule properly makes clear that language assistance services required under paragraph (a) must be provided free of charge, be accurate and timely, and protect the privacy and independence of the individual with limited English proficiency, consistent with long-standing HHS LEP Guidance. 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.

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. Otherwise, it is left to the entity to determine timely and some documents may not be available.

**RECOMMENDATION:** We recommend modifying § 92.201(c) as follows:

*Language assistance services requirements.* Language assistance services required under paragraph (a) of this section must be provided free of charge, be accurate and timely, and protect the privacy and independence of the individual with limited English proficiency. ***Language assistance services will be timely if they are provided as follows: oral interpretation immediately upon request or determined need, written translations within 30 days after the English version is finalized, and taglines simultaneously with English documents.***

We also 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, thereby dispensing with the “safe harbor” system set forth in the HHS LEP Guidance.<sup>169</sup> Translating vital documents is something that recipients have worked with for years. We recommend that HHS reinforces this language access by making written translations in the threshold languages a mandatory rather than voluntary compliance.

**RECOMMENDATION:** We commend codifying the translation requirement outlined in the original HHS LEP Guidance by adding a new subsection (d) after § 92.201(c) and re-lettering (d), (e) and (f) as (f), (g) and (h) as follows:

***(d) Specific requirement for written translations of vital documents. A covered entity shall provide written translation of vital documents to individuals with limited English proficiency for each language spoken by at least 5% or 1,000 persons, whichever is less, of the population of persons eligible to be served or likely to be affected in the covered entity’s service area. If there are fewer than 50 persons in a language group that reaches the 5% trigger above, the recipient does not translate vital written materials but provides written notice in the primary language of the LEP language group of the right to receive competent oral interpretation of those written materials, free of cost.***

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<sup>169</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.

**(1) Vital publications and communications include, but are not limited to:**

- (a) notices advising LEP persons of free language assistance;**
- (b) applications to participate or renew participation in a covered entity's health program or activity or to receive the covered entity's benefits or services;**
- (c) written notices of eligibility criteria, rights, approval, denial, loss, change in status, or decreases in benefits or services;**
- (d) information and notices related to grievances, appeals, and fair hearings;**
- (e) consent and complaint forms;**
- (f) intake forms with the potential for important consequences;**
- (g) patient handbooks;**
- (h) outreach publications;**
- (i) provider directories;**
- (j) written tests that do not assess English language competency, but test competency for a particular license, job, or skill for which knowing English is not required;**
- (k) actions affecting parental custody or child support, and other hearings;**
- (l) menus;**
- (m) any other documents pertaining to rights or benefits;**
- (n) any document requiring a response from an individual; and**
- (o) any document required by law.**

**(e) Specific requirements for written translation of significant documents. A covered entity shall provide written translation of significant documents to individuals with limited English proficiency for each language spoken by at least 10% or 2,000 persons, whichever is less, of the population of persons eligible to be served or likely to be affected in the covered entity's service area. If there are fewer than 500 persons in a language group that reaches the 10% trigger above, the recipient does not translate vital written materials but provides written notice in the primary language of the LEP language group of the right to receive competent oral interpretation of those written materials, free of cost.**

**(1) Significant publications and communications include, but are not limited to:**

- (a) patient handbooks;**
- (b) marketing materials; and**
- (b) Evidence of Coverage documents.**

*g. § 92.201(d) Specific requirements for interpreter services*

We support the proposed regulation regarding specific requirements for interpreter services. It is critical that individuals understand that language services are available free of charge, are accurate and timely, and protect the privacy and independence of the individual with limited English proficiency. All too often, individuals with limited English proficiency do not understand their rights, and will not know their new rights under Section 1557, and thus believe they have to bring their own interpreter or use a child, other patient, or unqualified individual to interpret. The responsibility for informing individuals must reside with the covered entity. And covered entities should be required to document that this information is provided or it would be assumed the individual with limited English proficiency did not get the information and the covered entity would be not in compliance with Section 1557.

While the current HHS LEP Guidance employs a four-factor balancing test to determine the “mix” of language assistance services that should be provided, this mix must distinguish between when oral interpreting and written translation services are required. Oral interpreting services should **not** be subject to the four-factor test but rather be available “on demand” and free of charge. In contrast, the factors for evaluating compliance provided in § 92.201(b) may be more reasonably employed to determine the type of oral interpreting required and/or the availability of translated documents. We are concerned that the proposed language for interpreter services does not meet existing standards required under Title IV and HHS LEP Guidance. As HHS LEP Guidance notes, oral interpreting “can range from on-site interpreters for critical services provided to a high volume of LEP persons, to access through commercially-available telephonic interpretation services.”<sup>1</sup> In addition, covered entities may, depending on when interpretation is needed and what is reasonable, provide interpretation through: hiring bilingual staff, hiring staff interpreters, contracting for interpreters, using a telephonic interpreter line, using community volunteers or other persons, in limited circumstances.

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. Consistent with HHS LEP Guidance, covered entities may provide oral interpreting services through the range of options that are available and evaluate the type and manner using a fact-dependent inquiry. This avoids an overly prescriptive approach, but provides clarity that some form of oral interpretation services must be provided in all cases where needed to constitute meaningful access. In doing so, this approach provides a reasonable balance and provides covered entities with needed flexibility by codifying existing standards that are already required for some entities. For example, many smaller covered entities may find that contracting with a telephonic interpreter line, such as that required by the Health Insurance Marketplaces and Qualified Health Plans, can provide meaningful access in some cases, while contracting with interpreters or employing staff interpreters may be necessary where communications are likely to

affect the health and well-being of an individual and where the covered entity frequently interacts with LEP persons, such as in a hospital. Lastly, 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:** We recommend amending § 92.201(d) as follows:

Subject to paragraph (a) of this section, a covered entity shall offer a qualified interpreter **services** for an individual with limited English proficiency when oral interpretation is **requested or needed** ~~a reasonable step~~ to provide meaningful access for the individual with limited English proficiency.

*h. § 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 where 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. Research has shown that the ability of a provider to accurately diagnose a patient's condition can be jeopardized by untrained interpreters, such as family and friends, especially minor children, who are prone to omissions, additions, substitutions, volunteered opinions, semantic errors, and other problematic practices.

It is critical that HHS finalize the language prohibiting minors from interpreting in emergencies and prohibiting other adults accompanying an individual can only interpret if the individual specifically requests it. In these situations, we would suggest that HHS should describe the steps that should occur. That is, if an individual wishes to use an adult accompanying her as her interpreter, a series of steps should occur:

1. The covered entity should again inform the individual that language services are available free of charge;
2. The covered entity should inform the individual the accompanying adult may accompany the individual even if the adult is not serving as an interpreter and that the accompanying adult may be better suited to serve as an advocate for the patient rather than interpreter;
3. If the individual still wishes to use the accompanying adult as an interpreter, the covered entity shall:
  - a. Use a qualified interpreter to obtain a signed waiver of language services from the individual;
  - b. Have a qualified interpreter monitor the interaction of the individual, accompanying adult and covered entity staff to assess if the accompanying adult is a qualified interpreter. If the accompanying adult is not able to provide qualified interpreting, the qualified interpreter steps in to ensure effective communication.

And covered entities should be required to document that this information is provided or it would be assumed the individual with limited English proficiency did not get the information and the covered entity would be not in compliance with Section 1557. As we noted in our report on malpractice and language access,

Physicians are taught that if an activity is not documented in the medical record, it did not happen. In reliance on this practice, if the medical chart did not show that a professional interpreter was used, this report concluded that none was used.<sup>170</sup>

We believe the same concept should apply with regards to covered entities documenting compliance with Section 1557. Covered entities must be required to document the provision of language services and an individual's decision to use an accompanying adult or it should be presumed not to have happened.

We also urge HHS to incorporate the statement in the explanatory text of the proposed rule that “a covered entity cannot coerce an individual to decline language assistance services.”<sup>171</sup> As written, subsection (f) does not capture this important concept and covered entities should be explicitly prohibited from discouraging individuals with LEP from exercising their rights, which is a form of discrimination unto itself.

Finally, the covered entity should be informed that if it knows or has reason to know the accompanying adult does not meet the requirements of a qualified interpreter that the covered entity could be found not in compliance with this section.

**RECOMMENDATION:** Amend § 92.201(f) as follows:

(f) *Acceptance of language assistance services is not required.* Nothing in this section shall be construed to require an individual with limited English proficiency to accept language assistance services. ***A covered entity shall not coerce an individual to decline language assistance services. If an individual declines language assistance services, a covered entity shall document the declination in the individual's record.***

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<sup>170</sup> National Health Law Program and University of California, Berkeley School of Public Health, *The High Costs of Language Barriers in Medical Malpractice* (2010) at p. 3, fn. 11, <http://www.healthlaw.org/publications/search-publications/the-high-costs-of-language-barriers-in-medical-malpractice#.Vie5GytFpSE>.

<sup>171</sup> 80 Fed. Reg. at 54,184.

i. *Alternative approaches*

i. Should covered entities be systematically prepared to provide language services?

Many covered entities are already required to evaluate the type of language services they are obligated to provide based on the current HHS LEP Guidance. Doing so ensures that covered entities understand the scope of the populations they serve, the prevalence of specific language groups in their service areas, the likelihood of those language groups coming in contact with or eligible to be served by the program, activity or service, the nature and importance of the communications provided and the cost and resources available. Depending on an entity's size and scope, advance planning need not be exhaustive but is used to balance meaningful access with the obligations on the entity.

We support HHS' experience that entities are in a better position to meet their obligations to provide language assistance services in a timely manner when those entities identify, in advance, the types and levels of services that will be provided in each of the contexts in which the covered entity encounters individuals who are LEP through language access plans. This is also consistent with and a guideline that covered entities already covered by Title VI and HHS LEP Guidance are familiar with.

As such, we recommend that covered entities be required to be systematically prepared to provide language services by developing a language access plan. As noted in the Preamble to the NPRM, in response to a question in the RFI, many organizations already develop such plans based on the model described in HHS LEP Guidance. We recommend that covered entities develop a language access plan based on the evaluation of the factors outlined in §92.201(b). Doing so need not be burdensome and the size and scope of the plan may vary depending on whether the covered entity is a small provider or a Qualified Health Plan issuer. This requirement is consistent with the proposed advanced planning requirement that each covered entity that employs 15 or more persons adopts grievance procedures and designate an individual responsible for carrying out those duties.

**RECOMMENDATION:** We recommend adding the following requirement to §92.201 that covered entities be systematically prepared to provide language services by developing a language access plan:

***A covered entity shall be systemically prepared to provide language services to individuals with limited English proficiency by developing a language access plan.***

ii. Should certain entities have enhanced obligations, and if so, what should those obligations be?

The proposed rule requests comment on whether certain entities should have enhanced obligations, and if so, what should those obligations be. Section 1557 covers a wide

range of covered entities that vary in size, scope and resources and operate in a variety of different service areas. The mix of language services provided by each of these organizations will vary, based on the factors outlined in § 92.201(b). Some entities, however, due to the importance of their programs, size of their programs and business practices (such as marketing and solicitation) will require a more robust range of language assistance services and should thus have enhanced obligations. These entities should include: 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.

We believe these entities have both the resources and means to meet enhanced obligations. Further, requiring these entities to have enhanced obligations will likely relieve smaller entities of some of the challenges they face in meeting language services obligations. For example, when HHS agreed to translate beneficiary-related Medicare forms into 15 languages, this greatly benefitted all Medicare providers across the country who otherwise would have had to translate these documents, depending on their patient population. The economies of scale and efficiencies of having translations done once by a coordinating entity rather than multiple times by different covered entities.

We believe these entities should also be held to a stricter translation threshold and should translate both vital and significant documents when 5% or 500 LEP individuals are present in the entity's state or service area. Having a higher standard for translation will likely result in more documents translated by these entities which then can be used by other covered entities to improve language access. Further, these larger entities both have more resources than smaller covered entities and can likely negotiate better rates for translating documents because of their size, market share, and larger need for translating documents.

Thus, we make the following recommendations regarding enhanced obligations for these entities:

1. Provide oral interpreting in at least 150 languages in their Call Centers and offices (this can be accomplished through telephonic interpreting when in-person interpreters or bilingual staff are unavailable).<sup>172</sup>
2. Translate all vital and significant documents into any language spoken by at least 5% or 500 persons, whichever is less, of the population of persons eligible to be served or likely to be affected in the covered entity's service area.

**RECOMMENDATION:** We recommend adding the following requirement to § 92.201(a):

***The following entities have enhanced obligations to provide language assistance services: U.S. Department of Health and Human Services, State agencies administering Medicaid or CHIP, Health Insurance Marketplaces and Qualified Health Plans. Enhanced obligations include the following:***

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<sup>172</sup> This requirement already applies to qualified health plans, agents and brokers pursuant to the Benefit Payment and Parameters final rule for 2016.



- (1) Provide oral interpreting in at least 150 languages in their Call Centers and offices (this can be accomplished through telephonic interpreting when in-person interpreters or bilingual staff are unavailable).**
- (2) Translate all vital and significant documents into any language spoken by at least 5% or 500 persons, whichever is less, of the population of persons eligible to be served or likely to be affected in the covered entity's service area.**

*j. Additional Guidance*

Given the differences between the NPRM and the current LEP Guidance (as well as the interplay with the CLAS Standards promulgated by the Office of Minority Health), we strongly suggest that HHS issue additional guidance once the NRPM is finalized. Many covered entities who have been operating under the LEP Guidance will need more detailed information and examples about how the Section 1557 rule both parallels and differs from the LEP Guidance so they can ensure their compliance. Further, since the Section 1557 rule implements new requirements (such as the notice, new factors, etc.), all covered entities would benefit from further explanations and examples detailing steps about how to comply with the rule once it is finalized. We thus recommend that HHS issue subregulatory guidance and perhaps even a toolkit to help all covered entities – both those covered by the LEP Guidance and those newly subject to Section 1557 – fully understand how to implement these requirements into practice to ensure compliance.

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

We fully support the provisions regarding effective communication for individuals with disabilities as communication is critical to quality healthcare. Despite the protections afforded individuals with disabilities, we often hear about entities refusing to provide effective communication or relying on communication methods that are the choice of the entity rather than of the individual. Therefore, we support the choice to hold all recipients of Federal financial assistance from HHS to the higher Title II standards. Deferring to the choice of aid or service requested by the individual with a disability helps ensure actual effective communication. We believe that any confusion by the covered entity about their obligations would be minimal and not burdensome when compared to the effect on the individual with a disability and how ineffective communication could affect their healthcare services.

In addition, NHeLP agrees that it makes sense to have one uniform standard for both state and private entities receiving Federal funding and engaged in health programs or activities and supports the use of the Title II standard.

NHeLP believes that the proposed effective communication regulations could be strengthened by including the proposed rules regarding the restricted use of certain persons to interpret or facilitate communication contained in § 92.201(e) for individuals with limited English proficiency in § 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 in regard to individuals with disabilities.

In addition, NHeLP supports the comments submitted by the National Association of the Deaf suggesting the addition of several requirements under this section a policy ensuring that there is not an over reliance on video relay interpreting in meeting the requirements of these regulations.

**RECOMMENDATION:** Amend § 92.202 by adding an “(a)” before the current text and adding new paragraphs (b)-(e) as follows:

- (b) Auxiliary aids and services. Auxiliary aids and services required by individuals with disabilities must be provided free of charge, be accurate and timely, and protect the privacy and independence of the individual with a disability.**
- (c) Specific requirements for interpreter services. If an individual with a disability needs an interpreter, a covered entity shall offer a qualified interpreter for an individual with a disability when interpreting is a reasonable step to provide access for an individual with a disability.**
- (d) Restricted use of certain persons to interpret or facilitate communication. A covered entity shall not:**
  - (1) Require an individual with a disability to provide his or her own interpreter;**
  - (2) Rely on an adult accompanying an individual with a disability to interpret or facilitate communication, except:**
    - (i) In an emergency involving an imminent threat to the safety or welfare of an individual or the public welfare where there is no qualified interpreter immediately available; or**
    - (ii) Where the individual with a disability specifically requests that the accompanying adult interpret or facilitate communication, the accompanying adult agrees to provide such assistance, and reliance on that adult for such assistance is appropriate under the circumstances; or**
  - (3) Rely on a minor child to interpret or facilitate communication, except in an emergency involving an imminent threat to the safety or welfare of an individual or the public where there is no qualified interpreter immediately available.**
- (e) Acceptance of language services is not required. Nothing in this section shall be construed to require an individual with a disability to accept auxiliary aids and services. A covered entity shall not coerce an individual to decline language assistance services. If an individual declines language assistance services, a covered entity shall document the declination in the individual’s record.**

## § 92.203 Accessibility Standards for Buildings and Facilities

While we appreciate that the regulations address accessibility standards for buildings and facilities and strongly support the inclusion of these standards, we have some concerns about the proposed regulations. The delay of implementation of these requirements is questionable when any such building should already have to meet these accessibility requirements either under Title II or Title III of the ADA. Therefore, the accessibility standards should have the same effective date as the rest of the regulations.

We are particularly concerned about the focus on structural accessibility and the absence of language regarding accessible medical diagnostic equipment. We understand that the U.S. Access Board is planning to issue standards for accessible medical diagnostic equipment, but these standards have been expected for years. To wait on these standards with a mere promise that new § 1557 regulations will be promulgated after the standards are issued is insufficient to protect individuals with disabilities from the problems they currently experience with a lack of accessible healthcare due to inaccessible equipment. These problems are exacerbated by more limited networks and other restrictive practices currently on the rise. While we recognize it would be impractical to require covered entities to adhere to certain standards regarding accessible equipment that may then change when the Access Board standards are issued, we strongly object to not having any language about access to accessible healthcare in the meantime.

Overall, we support OCR's plan to enforce the standards for accessible medical diagnostic equipment. We, too, eagerly await the release of final standards from the U.S. Access Board. In the meantime, we encourage OCR to enforce existing anti-discrimination laws and access standards whenever an individual with a disability is denied medical services because of the physical inaccessibility of the equipment. We also encourage OCR to use the Access Board's [Advisory Committee Report](#) and [Proposed Standards](#) as guidelines for this enforcement.

But we believe that language can be added to § 92.203 to require covered entities to provide access to accessible healthcare, including accessible diagnostic equipment that must meet or exceed the accessibility standards for such equipment from the U.S. Access Board. With the language suggested below we are trying to address the problem of restricted access to accessible equipment and ensure that providers who do not have the accessible equipment necessary for an individual will have an obligation to ensure the accessible service is provided rather than flatly deny the individual. We think that providing general language about accessible healthcare will allow there to be enough flexibility such that individuals with disabilities that need to get to accessible providers can be granted the exceptions to network or other limitations and yet the healthcare entities will be able to defend against unreasonable requests.

**RECOMMENDATION:** Add subsection (d) to § 92.203:

***(d) Facilities covered by sections (a)-(c) must also provide accessible medical equipment or make such reasonable accommodations or modifications so as to provide an individual with a disability access to such equipment. Accessible medical equipment must meet or exceed U.S. Access Board standards, or if such standards have not yet been finalized, meet the accessibility needs of the individual.***

Further, we support HHS's position in the draft rule to adopt the 2010 ADA Standards for Accessible Design (2010 Standards) as the relevant standard required in any facility or part of a facility in which health programs or activities are conducted that is constructed or altered by or on behalf of, or for the use of, a recipient or State-based marketplace. We agree with HHS's observation at 80 Fed. Reg. 541(i)(6) that "nearly all of the facilities covered under the proposed rule are already subject to the 2010 Standards." As a result, we are uncertain why the proposed rule gives new construction and alteration an additional time period to come into compliance with the 2010 Standards. That is, the proposed rule applies the 2010 standards to new construction and alteration that is commenced 18 months after publication of the final 1557 rule. However, the 2010 Standards themselves applied to newly constructed State and local government facilities if they were constructed on or after March 15, 2012. The vast majority of facilities covered by this proposed rule were already subject to the 2010 standards as of March 15, 2012. We do not think there needs to be another "safe harbor" period for facilities in which health programs or activities are conducted that are newly constructed or altered between March 15, 2012 and a date that is 18 months after publication of the final 1557 rule.

We recognize that there may be some ADA Title III entities participating in the federal or state marketplaces that arguably did not yet know that specific new construction or alteration standards would apply to them under Section 1557 absent HHS's proposed rule language. Such new construction or alteration would in any event have fallen under Appendix A of the 1991 Title III regulation, which is republished as Appendix D to 28 C.F.R. part 36, containing the ADA Standards for Accessible Design (1991 Standards). We would therefore support, if this were found to be necessary, the tailored recognition that such facilities, where construction or alterations were commenced before 18 months from the final date of the rule, are deemed to comply with the requirements of this proposed rule and with 45 C.F.R. § 84.23 (a) and (b), cross referenced in §92.101(b)(2)(i) with respect to those facilities, if they are in conformance with the 1991 Standards or the 2010 Standards.

An approach which emphasizes the uniform application of the 2010 Standards upon publication of Section 1557 rule will enable greater consistency among implementing agencies, given the overlapping jurisdiction that HHS has with the Department of Justice, which will apply the 2010 Standards to Title II facilities constructed or altered after March 15, 2012. Complainants with disabilities should not be implicitly influenced toward one administrative forum or another by the date on which a healthcare facility's construction or alteration began. More substantively, the 2010 Standards have specific

provisions that apply to “Medical care facilities” which recognize the importance of having accessible patient bedrooms in all areas of a facility in order to facilitate access to needed medical specialty providers and equipment by people with disabilities. Such specificity makes the 2010 Standards especially appropriate for the widest possible adoption in the Section 1557 regulations.

Under a similar rationale, we strongly agree with HHS’s decision in § 92.101(b)(2)(i), with respect to existing facilities, to not adopt “the program accessibility provision at [45 C.F.R.] § 84.23(c), addressing conformance with the Uniform Federal Accessibility Standards for the construction and alteration of facilities, because these standards are outdated.” We do not, however, understand or agree with the ongoing incorporation of the Uniform Federal Accessibility Standards (UFAS) in § 92.203(b), which states that compliance with UFAS shall be deemed to be in compliance with Section 1557 for newly constructed or altered facilities “if the construction or alteration was commenced before [18 MONTHS FROM DATE OF PUBLICATION OF FINAL RULE].”

We object to the ongoing incorporation of UFAS because UFAS is functionally deficient for people with disabilities. Accessibility barriers are permitted under the old standard that particularly affects people with mobility and strength disabilities. In November 2007, the Department of Veteran Affairs (VA) issued *A Barrier Free Design Guide: A Supplement to the Uniform Federal Accessibility Standards*.<sup>173</sup> The purpose of the guide was to tailor UFAS requirements so that health care facilities, in particular, would meet the barrier free needs of the Department of Veterans Affairs (VA).

The VA website currently states that it:

follows GSA [the General Services Administration] and other standard-setting agencies in replacing UFAS with the Architectural Barriers Act Accessibility Standard (ABAAS) for Federal Facilities. In addition, VA uses the Barrier Free Design Guide to meet the needs of the Department of Veterans Affairs in its health care facilities. it has officially adopted the 2010 Standards in place of UFAS.<sup>174</sup>

The VA and other federal agencies were able to replace the UFAS as the relevant standard for recipients of federal financial assistance because of actions taken by the Department of Justice. In a March 29, 2011 memo written by then Assistant Attorney General, Thomas Perez, to Federal Agency Civil Rights Directors, he noted that:

Several federal agencies have asked the Department, pursuant to its coordination authority for Section 504 under Executive Order 12250, if they have the authority to allow their recipients of federal financial assistance to use the 2010 Standards in lieu of UFAS. These agencies recognize that most of their recipients of federal financial assistance are

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<sup>173</sup> Available at

<http://citeseerx.ist.psu.edu/viewdoc/download?rep=rep1&type=pdf&doi=10.1.1.204.2449>.

<sup>174</sup> Available at <http://www.cfm.va.gov/til/accessibility.asp>.

also subject to the ADA and wish to minimize covered entities' need to comply with multiple accessibility standards. In addition, many covered entities would prefer to use the 2010 Standards because they are written using language that is more consistent with the language used in many state building codes.<sup>175</sup>

In light of the above, HHS's retention of the UFAS standards for recipients and State-based Marketplaces appears to reward those few construction or alteration projects that did not have the foresight to take account of the needs of healthcare consumers with disabilities. The proposed rule, after all, only addresses facilities in which health programs or activities are conducted, not for example, a General Services or US Post Office building primarily intended for housing machinery.

Ultimately, this rule reflects the Department of Health and Human Services' commitment to ensuring the accessibility of federally-funded health care programs and activities for people with disabilities. OCR and HHS overall should provide technical assistance to assist those few covered entities conducting health programs and activities in UFAS-only compliant facilities to come into compliance with the 2010 or 1991 Standards.

## **§ 92.204 Accessibility of electronic and information technology**

### *a. People with Disabilities*

We are appreciative of OCR's unequivocal recognition that health-related information and technology must be accessible to and usable by people with disabilities to ensure effective and nondiscriminatory provision of health care services, and we strongly support HHS's inclusion of explicit requirements in the proposed rule for accessible websites and electronic and information technology (E&IT). While it is true that Titles II and III of the Americans with Disabilities Act (ADA) and Sections 504 and 508 of the Rehabilitation Act already provide both strong legal protections for consumers and a wealth of clear guidance for covered entities, we agree with HHS's assessment that an express recapitulation of the general requirement to ensure accessible E&IT and websites is a critical regulatory reaffirmation which should raise the profile of the need for dramatically greater compliance with current law.

We commend HHS for proposing to apply the nondiscrimination requirements to all of a covered entity's E&IT and not to restrict the obligations only to websites or to specific classes or categories of E&IT. All too often, covered entities apply a piecemeal approach to ensuring that consumers of health information with disabilities do in fact have full and equal benefit from their services, programs, and activities. Far too frequently, if access is provided at all, it is limited to a given context, such as accessible informed consent forms, and there is an utter lack of appreciation for the need to provide access at every stage of service delivery where all consumers are expected or invited to interact with online information or specific pieces of equipment. It is essential that covered entities understand that failing to afford access to consumers with

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<sup>175</sup> Available at [http://www.ada.gov/504\\_memo\\_standards.htm](http://www.ada.gov/504_memo_standards.htm).

disabilities at every stage of service delivery – from appointment setting, to in-person check-in, to interaction with any and all devices with which a covered entity expects consumers to use both in the in-patient and out-patient contexts, to review of medical records, billing and insurance data – not only discriminates against people with disabilities, but such failure puts patients at tremendous risk as the patient (or family member of a patient) with disabilities cannot fully understand diagnosis and treatment, to make informed choices about health care providers, or appropriately respond to specific interventions. The risk extends to the consumer's ability to maintain health coverage and needed benefits, or even choose an appropriate health plan in the first place, since billing and procedural coding errors cannot be timely reviewed when billing statements, summary notices, and summary of benefits documents are all too often partially or fully inaccessible, even when provided in an electronic format.

In addition to addressing the range of needs of consumers with disabilities, we anticipate that the proposal to cover *all* of a covered entity's E&IT will assist healthcare professionals with disabilities to achieve greater independence and functional capacity as they exercise their profession. We know of numerous examples where people with disabilities in professions ranging from medical stenographer to licensed psychologists face additional E&IT barriers after they have already undergone rigorous training, educational and testing regimens because a hospital or managed care organization's provider note and record systems are inaccessible to speech-reading software, for example. There is no principled reason for any aspect of a covered entity's E&IT systems to be designed or maintained in a manner that cannot interface with the range of functional human capacities affecting vision, hearing, and speed and range of motion; this holds true for E&IT regardless of whether it is intended primarily or incidentally for public use. We strongly support the proposed rule's requirement that all aspects of a covered entity's E&IT be fully accessible. We also note that training, employing and retaining healthcare professionals with disabilities is a key means of reducing the widely recognized healthcare disparities experienced by people with disabilities.<sup>176</sup>

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 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.

We recommend that § 92.204 include some explicit reference to the effective communication regulations that remain the legal origin point for the obligation to make websites and E&IT technology accessible. While not all of the regulations concerning

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<sup>176</sup> See "CMS Equity Plan for Improving Quality in Medicare." *Centers for Medicare and Medicaid Services, Office of Minority Health*. September 2015. Accessed October 16, 2015. [http://www.cms.gov/About-CMS/Agency-Information/OMH/OMH\\_Dwnld-CMS\\_EquityPlanforMedicare\\_090615.pdf](http://www.cms.gov/About-CMS/Agency-Information/OMH/OMH_Dwnld-CMS_EquityPlanforMedicare_090615.pdf); Krahn, Gloria L, Deborah Klein Walker, and Rosaly Correa-De-Araujo. "Persons With Disabilities as an Unrecognized Health Disparity Population." *American Journal of Public Health*. Vol 105, No. S2 (2015): S198-206.

auxiliary aids and services apply to the E&IT and website context, some are appropriate to incorporate. For example, where a covered entity may give sighted members the option to receive notices through email, a website portal, or electronic CDs, the covered entity may not impose only one of those options upon a member who is blind or visually impaired simply because that option is more convenient for the entity. The explicit incorporation of relevant aspects of 35 C.F.R. § 35.160(b)(2) informs covered entity's that they must consult and work with members with disabilities as part of the entity's effective communication obligation.

**RECOMMENDATION:** Amend § 92.204 as follows

- (a) Covered entities shall ensure that their health programs or activities provided through electronic and information technology are accessible to individuals with disabilities, unless doing so would result in undue financial and administrative burdens or a fundamental alteration in the nature of the health programs or activities. When undue financial and administrative burdens or a fundamental alteration exist, the covered entity shall provide information in a format other than an electronic format that would not result in such undue financial and administrative burdens or a fundamental alteration but would ensure, to the maximum extent possible, that individuals with disabilities receive the benefits or services of the health program or activity that are provided through electronic and information technology. ***In determining what types of electronic and information technology are necessary, a public entity shall give primary consideration to the requests of individuals with disabilities. In order to be effective, electronic and information technology must be provided in a timely manner, and in such a way as to protect the privacy and independence of the individual with a disability.***
  
- (b) State-based Marketplaces and recipients shall ensure that their health programs and activities provided through Web sites comply with the requirements of Title II of the ADA ***in accordance with the standards found at 28 C.F.R. § 35.160(a)(1) and (2), 35.160(d), 35.163, and 35.164. Where the regulatory provisions referenced in this section use the term "public entity," the term "covered entity" shall apply in its place.***

With respect to the application of ADA Title II or Title III standards to § 92.204 covered entities' website obligations, we recommend that the proposed rule require that E&IT comply with a specific set of standards such as Section 508 by the Access Board at 36 C.F.R. part 1194 (Section 508 Standards), or the Worldwide Web Consortium's Web Accessibility Initiative's WCAG 2.0 AA (WCAG Standards). While we appreciate that Section 508 regulations are hopefully being finalized, we think it is important in this proposed rule to reaffirm the rights of people with disabilities, and redress current violations that occur when people with disabilities are given E&IT that fails to meet existing, readily available, and widely accepted standards.



This approach would have the benefit of clarity and consistency, and greater specificity will assist HHS in actual enforcement of the section. It will clearly inform HHS investigators that E&IT that falls short of the 504 or WCAG Standards falls within HHS's jurisdiction and their authority to require correction from covered entities. We appreciate that covered entities will and should continue to engage in an interactive process on how to make E&IT fully accessible to individual consumers and employees, but it will be much more efficient to have compliance with the Section 508 or WCAG standards as the starting point in that discussion. The fact that DOJ is applying WCAG standards in its own Title II and III settlements supports our position that OCR should also adopt the 508 and WCAG Standards as interim standards before final Section 508 regulations are issued. To the extent that there is overlap between the Section 508/WCAG Standards and the Section 508 regulations, and such overlap is likely to be substantial, covered entities will be encouraged to take a head start towards what will eventually be required compliance with the Section 508 regulations.

This approach still leaves room for the expected evolution of E&IT requirements. Even the way in which we talk about categories of technology today, both domestically and internationally, is evolving; the term E&IT has itself fallen out of favor in the policy and other contexts in favor of the term information and communications technology (ICT). We therefore support HHS allowing this evolution to occur while providing, through the interim adoption of Section 508 and WCAG Standards, a specific and currently enforceable statement of law that can only help to improve the full and equal participation of people with disabilities in America's health care marketplace.

#### *b. Other Populations*

We strongly support the requirement that covered entities ensure their health programs or activities provided through electronic and information technology are accessible to individuals with disabilities. Increasingly, healthcare and healthcare communications are reliant on technology and access to technology. Many advances in technology are not inclusive of people with disabilities. Given the long-recognized importance of privacy in healthcare, we believe that technology related to healthcare must be accessible. We completely agree with HHS' statement in the preamble that "without this explicit requirement for accessible electronic and information technology, people with disabilities will not have opportunities to participate in services, programs, and activities that are equal to and as effective as those provided to others, further exacerbating existing health disparities for persons with disabilities."<sup>177</sup>

We do not believe that access to a covered entity's website is sufficient access given that proliferation of technology through various healthcare and healthcare information access points. We believe ensuring access to all of a covered entity's electronic and information technology helps ensure access to the programs and services of the covered entity. We also think that a benefit of such access is that it will help remove current barriers that exist for potential employees of these covered entities, thereby helping to foster inclusion of healthcare providers, which will likely benefit more than just

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<sup>177</sup> 80 Fed. Reg. at 54,187.

those healthcare providers. If the Department strongly believes that a phased in approach is necessary, we ask that this approach not be long-term. Much of the relevant technology is currently evolving and accessibility changes should be incorporated as part of this evolution and not be put off as a far-off requirement.

We are very supportive of the requirement that when determining whether an action would be an undue burden, a covered entity must consider all resources available for use in the funding or operation of the health program or activity. This is consistent with the interpretation of “undue burden” under Section 504 and the ADA and helps prevent defenses that there is insufficient funding in the IT budget as a covered entity provides significant dividends to shareholders. We also appreciate an entity with an undue burden in making the technology accessible continues to have an obligation to provide information in an accessible format that would ensure, to the maximum extent possible, that individuals with disabilities receive the benefits of that health program or activity.

We are concerned, however, that as proposed, § 92.204 on electronic and information technology would focus on nondiscrimination and accessibility for individuals with disabilities only.<sup>178</sup> 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<sup>179</sup> 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.

Thus 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 Office for Civil Rights 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.

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<sup>178</sup> 80 Fed. Reg. at 54,187-88.

<sup>179</sup> 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.

Accordingly, the Office for Civil Rights 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:

**RECOMMENDATION:** Amend § 92.204 as follows:

**§ 92.204 ~~Accessibility of e~~Electronic 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, . . . .

**§ 92.205 Requirements to make reasonable modifications**

We are pleased to see the requirements to make reasonable modifications for individuals with disabilities as proposed and agree that the language is consistent with the ADA. However, we believe this section could be strengthened if additional, clarifying language was added which specifies 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 provides 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.

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

**§ 92.206 Equal program access on the basis of sex**

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. In addition, the final rule should state that access without discrimination on the basis of sex includes equal access without discrimination on the basis of pregnancy. Pregnant women have experienced

considerable discrimination in accessing certain health care services such as mental health care and drug treatment services.<sup>180</sup>

In addition, HHS 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*. 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.

**RECOMMENDATION:** We 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, ***including pregnancy, false pregnancy, termination of pregnancy, or recovery therefrom, childbirth, or related medical conditions*** 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 § 92.206's recognition 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. Denying transgender individuals access to sex-segregated facilities consistent with their gender identity amounts to

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<sup>180</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. DEPT. OF HEALTH AND HUMAN SERV., 2011 NATIONAL SURVEY OF SUBSTANCE ABUSE TREATMENT SERVICES 4 (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).

treating them differently from non-transgender individuals based on a perceived inconsistency between their gender identity and sex assigned at birth—in other words, based on being transgender, and therefore based on sex. In effect, a service provider that denies equal access to services consistent with a person’s lived gender is saying that a transgender man or woman must deny their core identity to access needed services. This is the essence of discrimination based on transgender status: restricting access to services based on an inconsistency between a person’s gender identity and his or her assigned birth sex.<sup>181</sup>

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 associated with another gender, such as a mammogram, a cervical Pap test, or a prostate exam.<sup>182</sup> 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.

**RECOMMENDATION:** Clarify the necessary implications of § 92.206 as follows:

**§ 92.206 Equal program access on the basis of sex.**

**(a)** A covered entity

**(1)** shall provide individuals equal access to its health programs or activities without discrimination on the basis of sex,

**(2)** shall treat individuals consistent with their gender identity, **and**

**(3) in the case of an otherwise lawful gender-specific or gender-segregated facility or program, shall not deny any individual, including an individual who identifies with a gender other than male or female, access to the gender-specific health facility or program that the individual determines is most appropriate for them.**

**(b)** Any health services that are ordinarily or exclusively available to . . .

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<sup>181</sup> See, e.g., *Macy*, *supra* note 91 (holding that under Title VII an employer may not take an adverse action “because the employer believe[s] that biological men should consistently present as men and wear male clothing”).

<sup>182</sup> 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).

## § 92.207 Nondiscrimination in health-related insurance and other health-related coverage

### a. *Benefit Design Generally*

We welcome HHS' recognition that health insurers may seek to circumvent non-discrimination protections in the Affordable Care Act 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 § 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.<sup>183</sup> 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.<sup>184</sup>

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."<sup>185</sup> However, neither the ACA nor its implementing regulations define "significant health needs" and how that may distinguishable from persons with disabilities within the meaning of the Rehabilitation Act. Accordingly, we urge HHS to broadly interpret "disability" to fully encompass the persons with "significant health needs." (See discussion in NHeLP's comments on § 92.4 Definitions, above).

Moreover, the § 1311 certification requirements can be waived beginning in 2017 under a § 1332 waiver. Therefore, the protections from discriminatory benefit designs and marketing under § 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.

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<sup>183</sup> 42 U.S.C. § 300gg-1.

<sup>184</sup> 42 U.S.C. § 300gg-11.

<sup>185</sup> 42 U.S.C. § 18031(c)(1)(a); see also 45 C.F.R. § 156.225(b).

i. Adverse tiering

In 2014, NHeLP and The AIDS Institute filed a still-pending HIV/AIDS discrimination complaint with the HHS Office for Civil Rights (OCR) against four Florida QHPs that placed all HIV medications, including generics, in the highest tier. By placing even generic drugs on the top tier, patients face high up-front costs in the form of expensive co-insurance and co-pays, as well as burdensome prior authorization requirements and quantity limits. These tactics are particularly hazardous for people living with HIV/AIDS. Gaps in anti-retroviral treatment can lead to the development of drug resistance and increased rates of new HIV infections.

In a study published in the *New England Journal of Medicine* in January 2015, *Using Drugs to Discriminate — Adverse Selection in the Insurance Marketplace*, researchers at the Harvard School of Public Health examined 48 ACA health plans and found that a dozen of these plans placed medications used to treat HIV/AIDS in the highest cost-sharing tiers. This practice — known as “adverse tiering” —serves to discourage people with significant health needs from enrolling in the health plan.

The National Alliance on Mental Illness (NAMI) also identified adverse tiering for medications used in the treatment of mental illness in its April 2015 report *A Long Road Ahead – Achieving True Parity in Mental Health and Substance Use Care*. NAMI commissioned a study for formularies for 84 health plans to assess coverage of three classes of psychiatric medications: antipsychotics, antidepressants, and SSRIs/SNRIs used commonly to treat depression. The analysis found that many plans placed these medications on high cost sharing tiers or with restricted access.

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 the NHeLP/TAI complaint, HHS has since recognized that health plans which 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.<sup>186</sup>

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<sup>186</sup> Preamble to the HHS Notice of Benefit and Payment Parameters for 2016 Final Rule, 80 Fed. Reg. 10,750 (Feb. 27, 2015); 2016 Letter to Issuers.

ii. Narrow provider networks

Inadequate provider networks provide another opportunity for health insurers seeking to discriminate or otherwise discourage enrollment of persons with disabilities and other 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.

Plans may have limited or no access to certain providers, such as infectious disease specialists often accessed by persons living with HIV/AIDS, endocrinologists important for the treatment of persons with diabetes, or psychiatrists for persons with behavioral or mental health needs.

A study published in the October, 2015 Journal of the American Medical Association examined specialty provider access in 135 plans sold on HealthCare.gov across 34 states.<sup>187</sup> The specialists included those sought by individuals with common chronic medical conditions or those with high health needs, including in-network specialist physicians in obstetrics/gynecology, dermatology, cardiology, psychiatry, oncology, neurology, endocrinology, rheumatology, and pulmonology. Researchers found that 15% of those plans lacked in-network physicians for at least 1 specialty.

Narrow provider networks may also discriminate against other protected classes. Failure to provide access to child psychiatrists, for example, may constitute discrimination based upon age.

iii. 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 (EOC).

In its analysis of access to mental health benefits in ACA plans, NAMI found high rates of denials of authorization for mental health and substance use care by insurers.<sup>188</sup> Consumers reported that plans routinely denied care found to be reasonable, necessary and appropriate, based on evidence-based clinical standards of care.

In the NHeLP/TAI HIV discrimination complaint, the four Florida issuers required prior authorization for all HIV medications, imposed quantity limits, and restricted access to HIV treatments.

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<sup>187</sup> Stephen C. Dorner, MSc, Douglas B. Jacobs, ScB, and Benjamin D. Sommers, MD, PhD, *Adequacy of Outpatient Specialty Care Access in Marketplace Plans Under the Affordable Care Act*, JAMA, 2015;314(16):1749-1750 (Oct. 27, 2015).

<sup>188</sup> See NAMI, *A Long Road Ahead – Achieving True Parity in Mental Health and Substance Use Care*, at 4 (April 2015).



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 § 1557 protections and enforcement actions.

iv. Specific issues related to individuals with disabilities

Section 92.207(b) states in very general terms that plans shall not “deny or limit coverage of a claim, or impose 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] (2) Employ marketing practices or benefit designs that discriminate on the basis of race, color, national origin, sex, age, or disability in a health-related insurance plan or policy, or other health-related coverage.” While NHeLP applauds the overarching goal of this requirement, we are concerned that absent more specificity, its scope will not be clear.

We urge HHS to provide additional guidance in the final rule concerning what constitutes disability-based discrimination in health insurance, including discriminatory benefit design, discriminatory payment structures, discriminatory network design, and discriminatory coverage decisions. The bare statement in the proposed rule that Section 1557 prohibits discriminatory benefit design offers no information to beneficiaries about their rights under Section 1557 and no information to plan administrators, Medicaid officials, and others about their obligations under Section 1557. In order for Section 1557 to be implemented effectively, covered entities and protected individuals must have more guidance concerning the meaning of disability-based discrimination in health insurance.

This additional guidance is crucial because insurance companies discriminate against people with disabilities in a variety of ways, including through drug formularies, narrow networks, increased cost-sharing, wellness programs, utilization management programs, and limits or caps on certain services. These discriminatory practices are often driven by a desire to reduce costs. However, limiting access to health care for people with disabilities or chronic conditions is pennywise and pound foolish, often resulting in further complications and avoidable hospital admissions and readmissions.

We support CCD's comments with regard to including principles that prohibit coverage that promotes needless segregation; unequal coverage, and disability-based coverage distinctions that are not justified by actuarial data.

v. Arbitrary coverage exclusions

People with developmental disabilities are routinely denied coverage for habilitative services, such as physical therapy, needed to gain skills or improve functioning while an identical service is provided to individuals who would require for a rehabilitative care to

restore functioning. The essential health benefit category of rehabilitative and habilitative services and devices is a broad grouping of services and supports that benefit a wide variety of people with disabilities. The congressional intent of this provision was expressed by Rep. George Miller, Chairman of the House Committee on Education and Labor, a committee with primary jurisdiction over the House health reform bill, when he explained that the term rehabilitative and habilitative services:

“...includes items and services used to restore functional capacity, minimize limitations on physical and cognitive functions, and maintain or prevent deterioration of functioning. Such services also include training of individuals with mental and physical disabilities to enhance functional development.”

[Congressional Record, H1882 (March 21, 2010)].

We have also seen a few states limit the availability of habilitative services and devices to people with autism. Limiting the coverage of habilitative services and devices to people with autism is discriminatory towards people with other disabilities and fails to ensure that coverage decisions focus on the individualized health care needs of each person. We contend that these types of blanket service exclusions should be considered “unlawful on its face” in the same manner that is proposed to apply to gender transition-related care, as excluding habilitation coverage systematically denies services for people with developmental disabilities and is prohibited discrimination on the basis of disability.

Additionally, EHB benchmark packages approved by the Secretary continue to include hard limits on the coverage of habilitative and rehabilitative services and devices, especially in a total number of visits allowed. These limits are a de-facto annual monetary cap on coverage – violating the ACA 1302 and 1557 - because they discriminate against people with more significant disabilities who are the only beneficiaries who need this level of therapy. Limitations on the number of covered visits without regard for medical necessity, best medical practices, or the extent of therapy prescribed to the individual discriminates against people with more significant disabilities who need this extensive habilitation or rehabilitation in order to gain, regain, or maintain functioning.

*b. Benefit design monitoring and enforcement*

We appreciate that monitoring and enforcement of § 1557 and other non-discrimination protections necessarily involved a myriad of activities and multiple agencies within HHS, including the HHS Office for Civil Rights (OCR), the Center for Consumer Information and Insurance Oversight, and the Centers for Medicare & Medicaid Services. 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. We welcome these proposals and urge HHS to employ a

broad, multi-pronged approach to non-discrimination compliance monitoring and enforcement.

In the 2016 Letter to Issuers, CCIIO proposes 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, however, that identifying in advance the conditions to be reviewed 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.

Continual monitoring and enforcement of plan benefit design and marketing is 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 disrupt 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 QHPs compliance with its network adequacy criteria, we urge HHS to require marketplaces to work with their QHPs to monitor compliance more frequently. We ask HHS to codify specific network monitoring requirements in the areas of geo-access mapping, timely access reporting, material network change reporting, secret shopper surveys, internal and external appeals, corrective actions

HHS further states that it will conduct compliance review of plans including examining appeals and complaints (2016 Letter to Issuers, at 35). 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.

However, neither the 2016 Letter to Issuers, the 2016 Payment Parameters Final Rule, nor the proposed § 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 Office for Civil Rights, the Office of Consumer Information and Insurance Oversight, the HHS Office of the Inspector General, the Centers for Medicare & Medicaid Services, the Department of Justice, 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.

c. *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.”<sup>189</sup> 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.

Not all states have been quick to embrace the ACA. Moreover, the lack of clear guidance and coordination has resulted in a patchwork of standards with little or no enforcement of these important non-discrimination protections. We note that a number of 2015 QHPs continue to place all HIV/AIDS medications in the highest cost sharing tier. These plans were approved to participate in the Federally Facilitated Marketplace, despite the clear violation of the ACA’s non-discrimination provisions as described by HHS in the preamble to the Payment Parameters rule. In addition, by relying on state monitoring and enforcement of non-discrimination protections, HHS has created the possibility that the same plan benefit design may be considered compliant by one state, but may be found non-compliant by another state.

While CCIO and state regulators play an important role in plan benefit design certification and compliance, federal non-discrimination standards and enforcement should not be subject to the shifting priorities and exigencies of the annual Letters to Issuers, Benefit Payment & Parameters regulation, and state-level activities. The HHS OCR must remain the primary monitoring and enforcement agency for § 1557 protections against discriminatory plan benefit design and marketing.

We recommend HHS clarify that § 1557 protections apply to marketing practices and materials (see comments on § 92.4 Definitions).

**RECOMMENDATION:** We recommend amending § 92.207(b)(2) as follows:

(2) Employ marketing practices ***or materials***, or benefit designs that discriminate on the basis of race, color, national origin, sex, age, or ~~disability~~ ***mental or physical disability, health status, claims experience, medical history, genetic information, evidence of insurability or geographic location*** in a health-related insurance plan or policy, or other health-related coverage;

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<sup>189</sup> 80 Fed. Reg. 10,823.

#### d. 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.<sup>190</sup>

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.<sup>191</sup> 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.<sup>192</sup>

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 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

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<sup>190</sup> 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](http://www.lambdalegal.org/sites/default/files/publications/downloads/fs_professional-org-statements-supporting-trans-health_4.pdf)).

<sup>191</sup> Wylie C. Hembree et al., *Endocrine Treatment of Transsexual Persons: An Endocrine Society Clinical Practice Guideline*. *J. CLINICAL ENDOCRINOLOGY & METABOLISM*, 3132 (2009).

<sup>192</sup> Dep't of Health and Human Services, NCD 140.3, *Transsexual Surgery*, 12 (2014).

uninsurance such as poverty, in 2013 the uninsured rate among low- and middle-income transgender people was a staggering 59 percent.<sup>193</sup> 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.<sup>194</sup>

The multifaceted nature of insurance discrimination against transgender individuals means that the provisions at § 92.207(b)(3), (4), and (5) are **all** 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.

**RECOMMENDATION:** 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***.

e. *Enforcement*

We further urge HHS to include a more detailed guide for plans of their responsibilities under this section in the final rule. Our experience with coverage offered through state-regulated private plans, state Medicaid programs and Medicaid Managed Care, and Medicare Advantage indicates that plans frequently retain transgender-specific exclusions even once they have been prohibited as discriminatory.

For instance, 45 out of the 51 plans preliminarily identified by the states and the District of Columbia as Essential Health Benefit benchmark plans for 2017—including several

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<sup>193</sup> Laura E. Durso, Kellan E. Baker, and Andrew Cray, *LGBT Communities and the Affordable Care Act: Findings from a National Survey* (2013), available at <http://www.americanprogress.org/wp-content/uploads/2013/10/LGBT-ACA-survey-brief1.pdf>.

<sup>194</sup> See, e.g., Institute of Medicine, *The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding* (2011), available at <http://www.iom.edu/Reports/2011/The-Health-of-Lesbian-Gay-Bisexual-and-Transgender-People.aspx>.

from states that have already prohibited transgender exclusions—include categorical transgender exclusions such as:

- Any procedure or treatment, including hormone therapy, designed to change your physical characteristics from your biologically determined sex to those of the opposite sex. This exclusion applies despite any diagnosis of gender role or psychosexual orientation problems.<sup>195</sup>
- Surgery, sex hormones, and related medical, psychological and psychiatric services to change a Covered Person's sex.<sup>196</sup>
- Sexual identification or gender disorders.<sup>197</sup>
- Sex transformations – Excluded procedures include, but are not limited to: staged gender reassignment surgery, including breast augmentation, penile implantation, facial bone reconstruction, blepharoplasty, liposuction, thyroid chondroplasty, laryngoplasty or shortening of the vocal cords, and/or hair removal to assist the appearance or other characteristics of gender reassignment, and complications resulting from gender reassignment procedures.<sup>198</sup>

**RECOMMENDATION:** To ensure that these and similar categorical coverage exclusions targeting transgender individuals do not persist in plans offered or administered by entities covered under Section 1557, we urge HHS to include the following language in the preamble discussing § 92.207:

***To be considered in compliance with this section, all health coverage programs and plans issued or administered by a covered entity will be required to:***

- ***Revise current health plan documents to remove benefit and coverage exclusions or limitations based on an individual's sex, gender identity, or diagnosis of Gender Identity Disorder, gender dysphoria, or related health condition (e.g., "transsexualism");***
- ***Revise current health plan documents to omit lists of surgeries or other procedures related to gender transition that are universally excluded from coverage, that impose other coverage limitations that are not supported by sound clinical principles, or that create clinically unsupported barriers to receiving medically necessary services related to gender transition;***
- ***Implement protocols for determining medical necessity that are nondiscriminatory and based on the most current version of the recognized professional standard of medical care for transgender individuals; and***

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<sup>195</sup> Priority Health HMO, *Certificate of Coverage (Michigan) 20*, available at [www.priorityhealth.com/member/plans/group-plans/hmo-plan/~media/documents/legal/2015-coverage-docs/2015-priorityhmo-mid-large-coc-pdf](http://www.priorityhealth.com/member/plans/group-plans/hmo-plan/~media/documents/legal/2015-coverage-docs/2015-priorityhmo-mid-large-coc-pdf).

<sup>196</sup> Advantage EPO Silver 100/50 (Horizon Healthcare Services, Inc., New Jersey).

<sup>197</sup> Blue Select Primary PCP/NonPCP Copay Plan (Wellmark of South Dakota).

<sup>198</sup> Preferred Co-Deduct Value 3000+35/70% 0812 (Pacific Source, Oregon).

- **Revise current health plan documents to clarify that transgender individuals seeking coverage for services will be treated in the same manner as other enrollees, including with regard to access to internal and external appeals processes.**

In enforcing Section 1557, we urge OCR to work closely with CMS – including Medicare, Medicaid, and the Center for Consumer Information and Insurance Oversight – 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.

f. § 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 (TPA). 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. Footnote 73 of the proposed rule states that when an entity that acts as a TPA for an employer’s employee health benefit plan is legally separate from an issuer that receives Federal financial assistance for its insurance plans, HHS will engage in a case-by-case analysis as to whether that entity is subject to Sec. 1557.<sup>199</sup> More clarity regarding this assertion is needed. As currently stated, it could encourage discrimination without potential liability, simply because of a corporate structure. A TPA that administers a discriminatory plan should be liable for discrimination. This is not an unusual concept. For example, if an employer were to hire a search firm and in the description of the position said to exclude all women, minorities, and persons with handicaps, the search firm which followed that direction would be liable for discrimination. Likewise, a TPA that administers a discriminatory plan or who applies the plan terms in a discriminatory manner should be liable for that discrimination. At the very least, any TPA which exercises total control and discretion over the provision of benefits should be liable for violations of the law.<sup>200</sup>

Further, 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.”<sup>201</sup> 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

<sup>199</sup> Proposed Rule at 54189, n. 73

<sup>200</sup> *New York State Psychiatric Assn. v. UnitedHealth Group.*, 798 F. 3d 125, 132-133 (2<sup>nd</sup> Cir. 2015).

<sup>201</sup> See, e.g., 34 C.F.R. § 106.31(b)(6) (2015).



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 “tapes” were removed from class before participating in the ceremony.<sup>202</sup> 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 that clarifies that a covered entity may not provide any aid or assistance to discriminatory health-related insurance or coverage. We support the comments from the National Women’s Law Center on this section.

*g. 92.207(b) Discriminatory Actions Prohibited*

We support the Department’s effort to make clear through the proposed regulations 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. We support the comments from the National Women’s Law center regarding waiting periods, harm because of a protected status, categorical exclusions for maternity coverage, and medical management techniques.

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

We are concerned about the inclusion of § 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 from 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.<sup>203</sup> 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.

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<sup>202</sup> *Iron Arrow Honor Soc’y. v. Heckler*, 702 F.2d 549, 561 (5th Cir. 1983) (vacated for mootness by *Iron Arrow Honor Soc’y v. Heckler*, 464 U.S. 67 (1983)) because the President of the University wrote a letter to Iron Arrow’s Chief stating that, regardless of the outcome of the case, the University would not allow Iron Arrow to resume its discriminatory practices on the University campus).

<sup>203</sup> U.S. DEP’T OF HEALTH AND HUMAN SERV., NAT’L INST. OF HEALTH, WHAT ARE THE SIGNS AND SYMPTOMS OF HEART DISEASE? (2014), <http://www.nhlbi.nih.gov/health/health-topics/topics/hdw/signs>.

**RECOMMENDATION:** We recommend amending § 92.207(c) as follows:

- (c) ~~The enumeration of specific forms of discrimination in paragraph (b) does not limit the general applicability of the prohibition in paragraph (a) of this section.~~ ***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.***

*i. Individuals with Disabilities*

Section 92.207(b) states in very general terms that plans shall not “deny or limit coverage of a claim, or impose 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] (2) Employ marketing practices or benefit designs that discriminate on the basis of race, color, national origin, sex, age, or disability in a health-related insurance plan or policy, or other health-related coverage.” While NHeLP applauds the overarching goal of this requirement, we are concerned that absent more specificity, its scope will not be clear.

We urge HHS to provide additional guidance in the final rule concerning what constitutes disability-based discrimination in health insurance, including discriminatory benefit design, discriminatory payment structures, discriminatory network design, and discriminatory coverage decisions. The bare statement in the proposed rule that Section 1557 prohibits discriminatory benefit design offers no information to beneficiaries about their rights under Section 1557 and no information to plan administrators, Medicaid officials, and others about their obligations under Section 1557. In order for Section 1557 to be implemented effectively, covered entities and protected individuals must have more guidance concerning the meaning of disability-based discrimination in health insurance.

This additional guidance is crucial because insurance companies discriminate against people with disabilities in a variety of ways, including through drug formularies, narrow networks, increased cost-sharing, wellness programs, utilization management programs, and limits or caps on certain services. These discriminatory practices are often driven by a desire to reduce costs. However, limiting access to health care for people with disabilities or chronic conditions is pennywise and pound foolish, often resulting in further complications and avoidable hospital admissions and readmissions.

We support CCD’s comments with regard to including principles that prohibit coverage that promotes needless segregation; unequal coverage, and disability-based coverage distinctions that are not justified by actuarial data.

## § 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 rule'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.<sup>204</sup> 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 Section 1557.<sup>205</sup> 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.

**RECOMMENDATION:** We 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 *or deter* 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.*

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<sup>204</sup> 42 U.S.C. §§ 12112, 12182 (2012).

<sup>205</sup> 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").

## §§ 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 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.

### *a. Section 1557 permits judicial claims for disparate impact discrimination*

*Alexander v. Sandoval*<sup>206</sup> held that individuals do not have a private right of action for disparate impact discrimination under Title VI of the Civil Rights Act of 1964.<sup>207</sup> As a result, at the time section 1557 was enacted, 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 Office for Civil Rights.

Section 1557 addresses the *Sandoval* problem by authorizing private enforcement of both disparate impact and intentional discrimination claims. Section 1557 prohibits discrimination on the basis of race, color, national origin, sex, disability and age. It does this by cross-referencing "the grounds" for prohibited discrimination in four pre-existing civil rights statutes--Title VI, Title IX, Section 504, and the Age Discrimination Act. The ACA then provides a single Section 1557 enforcement mechanism for challenging discrimination on the basis of race, color national origin, sex, disability, and age in health care settings. It provides:

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.<sup>208</sup>

The Age Discrimination Act, unlike Title VI, expressly creates a private right of action in federal district court to challenge both disparate impact discrimination and intentional discrimination.<sup>209</sup> The Age Discrimination Act, unlike Title VI, requires individuals to exhaust the administrative review process before going to court, unless that would be futile.<sup>210</sup> Title VI relies primarily on administrative enforcement. The Age Act does not.

By using the disjunctive word "or," section 1557's enforcement mechanism gives individuals the choice of the two types of administrative and judicial review processes authorized by the four listed statutes "for purposes of violations of this subsection."<sup>211</sup>

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<sup>206</sup> 532 U.S. 275 (2001).

<sup>207</sup> *Id.* at 293.

<sup>208</sup> ACA, § 1557 (implemented as 42 U.S.C. § 18116) (emphasis added).

<sup>209</sup> See 42 U.S.C. § 6104.

<sup>210</sup> *Id.* at § 6104(e).

<sup>211</sup> ACA, § 1557 (implemented as 42 U.S.C. § 18116).

Proposed § 92.302 provides that individuals with claims of race, sex, or disability discrimination may only pursue the administrative remedies provided for by Title VI while individuals claiming age discrimination are limited to the administrative remedies provided by the Age Act. However, Section 1557 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.<sup>212</sup>

As a matter of practical application, this parsing of remedies would mean that an elderly, African American woman who wanted to complain of discrimination under the ACA would have to bring separate administrative claims and different court actions.

As its title states, § 1557 is meant to ensure “nondiscrimination” in health care settings; it would make no sense to distinguish the administrative and judicial remedies available if the disability is based on age from the relief available if it is based on race, color, national origin, disability or sex.

Intentional and disparate impact discrimination against any individual, regardless of their protected class, is discrimination under the ACA, and rights and remedies should not vary. Section 1557 does not merely extend Title VI or Title IX or Section 504 or the Age Act to additional activities. It creates a new, health-care-specific civil rights provision that includes its own enforcement provision.

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.”<sup>213</sup>

Section 1557 is not ambiguous. Nevertheless, in a decision pre-dating issuance of the proposed Section 1557 regulations, a district court in Pennsylvania decided that the relief available under Section 1557 depends on the nature of the alleged discrimination, for example age verses disability discrimination.<sup>214</sup> It is important that HHS use the rulemaking process to clarify Section 1557 enforcement procedures and remedies, including specifying a private right of action for disparate impact discrimination.

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<sup>212</sup> See, e.g., *EEOC v. Abercrombie & Fitch Stores, Inc.*, 135 S. Ct. 2028, 2033 (2015) (refusing to impose knowledge requirement for Title VII disparate treatment claim because it would require the Court “to add words to the law to produce what is thought to be a desirable result. That is Congress’s province. We construe Title VII’s silence as exactly that: silence.”).

<sup>213</sup> 80 Fed. Reg. at 54,192.

<sup>214</sup> See *Southeastern Penn. Trans. Auth. v. Gilead Sci.*, No. 14-6978, 2015 WL 1963588 (E.D. Penn. May 4, 2015).

Under Section 1557's clear language, an individual alleging discrimination based upon race, sex, disability, or age has an implied right of action to sue in court to stop intentional discrimination and, possibly receive money damages. Section 1557's clear language also provides that an individual with a disparate impact claim has an express private right of action to bring an action in federal court after exhausting administrative remedies.<sup>215</sup>

*b. Section 1557 broadly prohibits discrimination*

Also, section 1557 prohibits discrimination. It applies to any health program or activity receiving Federal financial assistance, to any Executive Agency, and to any entity established under the ACA. The enforcement regulations must reflect this. It also needs to adhere to the holding of the Supreme Court in *King v. Burwell*<sup>216</sup>, namely that, unless specifically exempted by the ACA, provisions that apply to State-based Exchanges apply when the Exchange is operated by the State or where such Exchange is operated by the federal government for the State.

We recommend that HHS amend § 92.302 and §92.303 to more closely parallel each other. For example, § 92.303 has paragraphs regarding "Access to Sources of Information" and "Intimidatory or retaliatory acts prohibited." We believe these paragraphs should apply to all covered entities, not just health programs and activities administered by the Department. The easiest solution would be to combine § 92.302 and § 92.303 into one section so that no distinction exists in these procedures. In the alternative, paragraphs (c) and (d) should be incorporated into § 92.302 since no individual should suffer intimidation or retaliation when trying to prevent discrimination. Further, during an enforcement activity, OCR should also have access to sources of information held by a covered entity that is not part of the Department.

**RECOMMENDATION:** Combine § 92.302 and § 92.303 into one section (with our line edits below) that applies to all covered entities, including the Department.

**ALTERNATIVE RECOMMENDATIONS:** If HHS does not adopt the above recommendation, we recommend amending § 92.302 and § 92.303 as follows.

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**

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<sup>215</sup> See 42 U.S.C. § 2000d-1 (Title VI); 20 U.S.C. § 1682 (Title IX); 29 U.S.C. § 794(a) (Section 504); see also, e.g., *Sandoval*, 532 U.S. at 293 (regarding Title VI); *Guardians Ass'n v. Civil Serv. Comm'n of New York*, 463 U.S. 582, 582 (1983) (regarding compensatory damages in Title VI intentional discrimination cases). See also Sidney D. Watson, *Section 1557 of the Affordable Care Act: Civil Rights, Health Reform, Race and Equity*, 55 HOWARD L.J. 855, 878 & n. 144 (Spr. 2012) (noting courts read these three statutes in pari materia).

<sup>216</sup> 135 S. Ct. 2480, 2487, 2496 (2015).

- (a) The procedural provisions applicable to Title VI apply with respect to enforcement actions concerning discrimination on the basis of race, color, national origin, sex, disability, **and age** discrimination, under Section 1557 or this part. These procedures are found at §§ 80.6 through 80.11 of this subchapter and part 81 of this subchapter.
- ~~(b) The procedural provisions applicable to the Age Act apply with respect to enforcement actions concerning age discrimination under Section 1557 or this part. These procedures are found at §§ 91.41 through 91.50 of this subchapter.~~  
**Individuals may file complaints of discrimination on the basis of race, color, national origin, disability and age discrimination under Section 1557 or this part pursuant to either Title VI, § 80.7 through 80.11, or the Age Act, § 91.42 through 91.50.**
- (c) An 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. **Claims of disparate impact discrimination must exhaust administrative remedies as required under the Age Act. These procedures are found at §§ 91.41 through 91.50 of this subchapter.**
- (d) **Access to sources of information. A recipient or American Health Benefit Exchange shall permit access by OCR to its books, records, accounts and other sources of information, and facilities as may be pertinent to ascertain compliance with Section 1557 or this part. Where any information requires is in the exclusive possession of any other agency, institution or individual, and the other agency, institution or individual shall fail or refuse to furnish this information, the recipient or American Health Benefit Exchange shall so certify and shall set forth what efforts it has made to obtain the information. Asserted considerations of privacy or confidentiality may not operate to bar OCR from evaluating or seeking to enforce compliance with Section 1557 or this part. Information of a confidential nature obtained in connection with compliance evaluation or enforcement shall not be disclosed except where necessary under the law.**
- (e) **Intimidatory or retaliatory acts. A recipient or American Health Benefit Exchange shall not intimidate, threaten, coerce, or discriminate against any individual for the purpose of interfering with any right or privilege secured by Section 1557 or this part, or because such individual has made a complaint, testified, assisted, or participated in any manner in an investigation, proceeding or hearing under Section 1557 or this part. The identity of complainants shall be kept confidential by OCR, except to the extent necessary to carry out the purposes of Section 1557 or this part.**

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 to challenge a violation of Section 1557 or this part 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...

Finally, the final rule should include a provision that requires the publication of OCR enforcement actions, including the rationale and results of such actions, as well as the compliance correction plans. Published precedent (even if redacted to eliminate specific names) is essential for educating the health insurance industry on what conduct is and is not acceptable under Section 1557. Understanding the rationale for OCR's opinions is helpful to other plans in ensuring that they are compliant and helpful for consumers to understand what conduct is acceptable. Without such precedent, the industry is left only with limited guidance, such as Frequently Asked Questions (FAQs), which, while helpful, are often not sufficiently specific to help companies tailor their behavior in accordance with the law.

Further, in addition to publishing resolved complaints, we recommend that HHS publish a yearly tally of the number of complaints filed disaggregated by the bases for the complaints (e.g. race, color, national origin, sex, disability, age), the number of investigations initiated, the number of complaints resolved, the number of complaints closed without resolution.

**RECOMMENDATION:** Add new § 92.304 as follows:

**§ 92.304 Publication of Complaints and Resolution Agreements**

- (a) ***On at least a yearly basis, OCR shall report the following information:***
  - (i) ***number of complaints filed, disaggregated by the basis of the complaint;***
  - (ii) ***number of investigations initiated;***
  - (iii) ***number of complaints resolved;***
  - (iv) ***number of complaints closed without resolution;***
- (b) ***Within fourteen calendar days of resolving a complaint, OCR shall publicly post on its website a narrative discussion of the resolution and the full document containing the resolution agreement.***



We also are concerned about mandatory arbitration agreements. Insurers could include them in their contracts in an attempt to prevent beneficiaries from using the administrative and enforcement remedies included in Section 1557. A series of recent U.S. Supreme Court decisions has allowed a variety of businesses to restrict claimants to binding arbitration, essentially forcing them to waive their right to file legal claims in court. Binding arbitration greatly favors defendants, particularly when they are large, powerful corporations. In many cases, the arbitrators are beholden to the defendants, who are responsible for paying, hiring, and firing them.<sup>217</sup> Allowing insurance companies to restrict beneficiaries to binding arbitration would subvert the intent of Section 1557. We recommend that HHS include a specific provision prohibiting insurers from requiring binding arbitration as the exclusive means to resolve a complaint arising under Section 1557.

**RECOMMENDATION:** Add new Section 92.305 as follows:

**§ 92.305 Prohibition of Binding Arbitration for Section 1557 Complaints**

***A covered entity is prohibited from requiring an individual to participate in arbitration of a complaint based on Section 1557 or this part. If a covered entity requests that an individual participate in arbitration of a complaint based on Section 1557 or this part, the covered entity must:***

- (a) provide fair, accurate and impartial information about the arbitration, including the limits of arbitration, to the individual;***
- (b) inform the individual that arbitration is voluntary and is not required before the individual files an administrative complaint or judicial action;***
- (c) obtain the individual's written consent to participate in arbitration; and***
- (d) if the individual is limited English proficient or needs auxiliary aids and services to communicate effectively, provide an interpreter or the relevant auxiliary aids and services for the communication required in paragraphs (a) and (b), above; provide the consent form in a language and format that the individual can understand; and, if the individual elects arbitration, provide an interpreter or the relevant auxiliary aids and services during all aspects of the arbitration.***

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<sup>217</sup> For additional discussion, see Public Justice, *Comments to CMS on Proposed Rule Amending 42 C.F.R. § 483.70(n): Binding Arbitration Agreements Between Long-Term Care Facilities and Residents* (Oct. 14, 2015), <http://www.publicjustice.net/sites/default/files/Public%20Justice%20CMS%20Comments%20FINAL%202015.10.14.pdf>.

## Appendices

### a. Appendix A to Part 92 – Sample Notice

We recommend the following edits to Appendix A: Sample Notice. In general, the notice should be written in plain language pursuant to the Federal Plain Language Guidelines.<sup>218</sup> We also recommend the word “first” should be replaced with “primary” because using an ordinal word implies a hierarchy. The idea the notice should convey is that anyone who prefers to communicate in a language other than English can access service. The clause “when needed to communicate effectively with us” is superfluous and unnecessarily complicated. Language assistance should be offered without qualification to anyone who needs it. The words in this clause also increase the complexity and decrease the readability of this sentence.

The interpreter services offered should include the word “qualified” because that is required by the regulations at § 92.201(d) and the word is used in the sign language context in the previous bullet point. It is also important for consumers to be aware of their right to obtain an interpreter who is qualified by the covered entity, and to assert that right if they feel that the interpreter provided does not have sufficient skill to understand and communicate with and for the consumer.

We also think that the phrase “written information in another language” is more informative. For the majority of consumers, the terms “interpretation” and “translation” are virtually synonymous unless used with the qualifiers “oral” and “written.”<sup>219</sup> Only those who are experienced with language access understand the distinction between the two. Therefore, using “written translation” most effectively communicates the nature of the assistance.

**RECOMMENDATION:** Amend the sample notice text as follows:

- Provides free language services to people whose first **primary** language is not English ~~when needed to communicate effectively with us~~, such as:
  - **Qualified** interpreters
  - Information written ~~translated~~ into other languages

### b. Appendix B to Part 92 – Sample Tagline

We recommend the following two changes to improve the readability and to clarify the reader’s rights. First, the conditional phrase “may be available to you” should be deleted because it is inaccurate because the covered entity *must* provide language assistance

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<sup>218</sup> See, e.g., Dep’t of Health & Human Servs., *Preparing Content For Submission: Write in Plain Language*, available at <http://www.hhs.gov/web/building-and-managing-websites/web-requests/write-in-plain-language/index.html>.

<sup>219</sup> See, e.g., 80 Fed. Reg. at 54,176 n. 18 (explaining the terms (interpret and translate) and qualifiers (oral and written) and how each is used in the proposed rule to promote clear understanding of the distinctions).

services. The phrase also implies to the consumer that such assistance is optional therefore increasing the chance that the consumer will not ask for assistance if the covered entity has the discretion to refuse. Second, the original placement of the phrase “free of charge” could also suggest that this provision may or may not be available.

**RECOMMENDATION:** Amend the tagline as follows

ATTENTION: If you speak [insert language] **and you need** language assistance ~~services, free of charge, may be available to you, such as an interpreter,~~ contact 1-xxx-xxx-xxxx (TTY: 1-xxx-xxx-xxxx). **Language services are free of charge.**

## Conclusion

In conclusion, we commend HHS for taking the important step of issuing this NPRM and urge HHS to finalize the rulemaking as quickly as possible to implement this crucial new civil rights protection. It is critical that HHS administers this new law through robust implementation and enforcement mechanisms, and this must be reflected in the final regulations that HHS promulgates. This is essential if Section 1557’s guarantee of protection from discrimination in health care is to be fulfilled and statute’s mandate reflected. If you have any questions regarding these comments, please contact Mara Youdelman ([youdelman@healthlaw.org](mailto:youdelman@healthlaw.org), 202-289-7661).

Thank you for your consideration of our comments.

Sincerely,



Elizabeth G. Taylor  
Executive Director