

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 92

RIN 0945-AA02

Nondiscrimination in Health Programs and Activities

AGENCY: Office for Civil Rights (OCR), Office of the Secretary, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of Health and Human Services (HHS or “the Department”) is issuing this proposed rule on Section 1557 of the Affordable Care Act (ACA) (Section 1557). Section 1557 prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs and activities. Section 1557(c) of the ACA authorizes the Secretary of the Department to promulgate regulations to implement the nondiscrimination requirements of Section 1557. In addition, the Secretary is authorized to prescribe regulations for the Department’s governance, conduct, and performance of its business, including, here, how HHS will apply the standards of Section 1557 to HHS-administered health programs and activities.

DATES: Submit comments on or before November 9, 2015.

ADDRESSES: You may submit comments, identified by RIN Number 0945-AA02, by any of the following methods:

- *Federal eRulemaking Portal:* You may submit electronic comments at <http://www.regulations.gov>. Follow the instructions for submitting electronic comments. Attachments should be in Microsoft Word or Excel; however, we prefer Microsoft Word.

- *Regular, Express, or Overnight Mail:* You may mail written comments (one original and two copies) to the following address only: U.S. Department of Health and Human Services, Office for Civil Rights, Attention: 1557 NPRM (RIN 0945-AA02), Hubert H. Humphrey Building, Room 509F, 200 Independence Avenue SW., Washington, DC 20201. Mailed comments may be subject to delivery delays due to security procedures. Please allow sufficient time for mailed comments to be timely received in the event of delivery delays.

- *Hand Delivery or Courier:* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) to the following address only: Office for Civil Rights,

Attention: 1557 NPRM (RIN 0945-AA02), Hubert H. Humphrey Building, Room 509F, 200 Independence Avenue SW., Washington, DC 20201. (Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the mail drop slots located in the main lobby of the building.)

- *Inspection of Public Comments:* All comments received before the close of the comment period will be available for public inspection, including any personally identifiable or confidential business information that is included in a comment. We will post all comments received before the close of the comment period at <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Claudia Adams, at (800) 368-1019 or (800) 537-7697 (TDD).

SUPPLEMENTARY INFORMATION:

I. Background

Section 1557 of the ACA provides that an individual shall not, on the grounds prohibited under Title VI of the Civil Rights Act of 1964 (Title VI), 42 U.S.C. 2000d *et seq.* (race, color, national origin), Title IX of the Education Amendments of 1972 (Title IX), 20 U.S.C. 1681 *et seq.* (sex), the Age Discrimination Act of 1975 (Age Act), 42 U.S.C. 6101 *et seq.* (age), or Section 504 of the Rehabilitation Act of 1973 (Section 504), 29 U.S.C. 794 (disability), be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any health program or activity, any part of which is receiving Federal financial assistance, or under any program or activity that is administered by an Executive Agency or any entity established under Title I of the Act or its amendments. Section 1557 states that the enforcement mechanisms provided for and available under Title VI, Title IX, Section 504, or the Age Act shall apply for purposes of addressing violations of Section 1557. The Department is responsible for developing regulations to implement Section 1557.

On August 1, 2013, the Office for Civil Rights of the Department (OCR) published a Request for Information (RFI) in the **Federal Register** to obtain information that would assist OCR in drafting the proposed regulation.¹ The RFI solicited information on issues arising under Section 1557. OCR received 402 comments. Of the total comments, one-quarter (99) were from

organizational commenters, with the remainder from individuals. Of the organizational comments, one-third (33) were from civil rights/advocacy groups with over half of these (17) coming from organizations serving lesbian, gay, bisexual, or transgender (LGBT) individuals. Six comments were received from health care providers (including two local government health agencies) and two were from health insurance providers or provider organizations. Of the comments from individuals, 239 were personal testimonies from transgender individuals describing their experiences of discrimination in the health care setting.

OCR has carefully reviewed all comments received, and has referenced them where appropriate and relevant in this preamble. The proposed rule both clarifies and codifies existing nondiscrimination requirements, and also sets forth new standards to implement Section 1557, particularly with respect to the prohibition of discrimination on the basis of sex in health programs other than those provided by educational institutions and the prohibition of various forms of discrimination in health programs administered by the Department and entities established under Title I of the ACA. The Department invites comment on this proposed rule by all interested parties, including comment from Tribes on application of the rule to them.

Subpart A—General Provisions

Purpose and Effective Date (§ 92.1)

Proposed § 92.1 states that the purpose of this part is to implement Section 1557 of the ACA, which prohibits discrimination in certain health programs and activities on the grounds prohibited under Title VI, Title IX, the Age Act, and Section 504, which together prohibit discrimination on the basis of race, color, national origin, sex, age, or disability.

Section 92.1 also establishes that the effective date of the Section 1557 implementing regulation shall be 60 days after the publication of the final rule in the **Federal Register**.

Application (§ 92.2)

Section 1557 applies to all health programs and activities, any part of which receives Federal financial assistance from any Federal agency. In addition, Section 1557 applies to all programs and activities that are administered by an Executive Agency or any entity established under Title I of the ACA.

¹ 78 FR 46558 (Aug. 1, 2013).

OCR proposes in § 92.2(a) to apply the rule, except as otherwise provided in this part, to: (1) All health programs and activities, any part of which receives Federal financial assistance administered by HHS;² (2) health programs and activities administered by the Department, including the Federally-facilitated Marketplaces; and (3) health programs and activities administered by entities established under Title I of the ACA, including the State-based Marketplaces.

Section 92.2(b) provides limitations to the application of the proposed rule. In this section, addressing limitations in the statutes referenced in Section 1557, and in Subpart B, which incorporates exceptions in the regulations implementing the statutes referenced in Section 1557, we have adopted the existing limitations and exceptions that already govern the health programs and activities subject to Section 1557. These limitations and exceptions are found in the Age Act and in the regulations implementing the Age Act, Section 504, and Title VI, which apply to all programs and activities that receive Federal financial assistance.

Thus, § 92.2(b)(1) incorporates the exclusions found in the Age Act, such that the provisions of this proposed rule do not apply to any age distinction contained in that part of a Federal, State, or local statute or ordinance adopted by an elected, general purpose legislative body which provides any benefits or assistance to persons based on age, establishes criteria for participation in age-related terms, or describes intended beneficiaries to target groups in age-related terms.³

By contrast, we are requesting comment on whether the exemptions found in Title IX and its implementing regulation should be incorporated into this proposed rule. Unlike the Age Act, Section 504, and Title VI, which apply to all programs and activities that receive Federal financial assistance, Title IX applies only in the context of education programs and not to the health programs and activities subject to this proposed rule. In addition, many of Title IX's limitations and exceptions do not readily apply in a context that is

grounded in health care, rather than education. For example, Title IX exempts from its prohibitions on sex discrimination certain institutions of undergraduate higher education, military and merchant marine educational institutions, and membership practices of social fraternities and sororities and voluntary youth service organizations.

In the RFI, OCR specifically inquired as to what exceptions, if any, should apply in the context of sex discrimination in health programs and activities. Nearly all commenters who provided a response to this inquiry indicated that Section 1557 includes only one exception—that the statute applies except as otherwise provided in Title I of the ACA. To this end, commenters argued that nothing in the language or legislative history of Section 1557 allows for any other limitations or exceptions regarding its application, highlighting that exceptions to general rules like Section 1557's antidiscrimination provision must be read strictly and narrowly.

We continue to seek comment on whether the regulation should include any specific exemptions for health providers, health plans, or other covered entities with respect to requirements of the proposed rule related to sex discrimination, including the particular requirements that are discussed in this proposed rule.⁴ For example, HHS wants to ensure that the rule has the proper scope and appropriately protects sincerely held religious beliefs to the extent that those beliefs conflict with provisions of the regulation. We note that certain protections already exist with respect to religious beliefs, particularly with respect to the provision of certain health-related services; for example, this proposed rule would not displace the protections afforded by provider conscience laws,⁵ the Religious Freedom Restoration Act,⁶ provisions in the ACA related to abortion services,⁷ or regulations issued under the ACA related to preventive health services.⁸ We seek comment on the extent to which these existing protections would provide sufficient

safeguards for religious concerns in the context of the proposed rule.

At the same time, a fundamental purpose of the ACA is to ensure that vital health care services are broadly and nondiscriminatorily available to individuals throughout the country. As a result, we seek comment on any health care consequences that would ensue were the regulation to provide additional exemptions.

Finally, we seek comment on the scope of additional exemptions, if any, that should be included and the processes for claiming them, including whether those processes should track those used under Title IX, at 45 CFR 86.12.

Relationship to Other Laws (§ 92.3)

Proposed § 92.3 explains the relationship of this part to existing laws. Paragraph (a) provides that Section 1557 is not intended to apply lesser standards for the protection of individuals from discrimination than the standards under Title VI, Title IX, Section 504, the Age Act, or the regulations issued pursuant to those laws. Consistent with the statute, paragraph (b) states that nothing in this part shall be interpreted to invalidate or limit the existing rights, remedies, procedures, or legal standards available to individuals aggrieved under other Federal civil rights laws or to supersede State or local laws that provide greater or equal protection against discrimination on the basis of race, color, national origin, sex, age, or disability. This intent is derived from Section 1557(b) of the ACA. In addition to the statutory references cited directly in Section 1557(b), the proposed rule includes the Architectural Barriers Act of 1968, 42 U.S.C. 4151–4157 (2012), the Americans with Disabilities Act of 1990, 42 U.S.C. 12101 *et seq.* (codified as amended by the Americans with Disabilities Amendments Act of 2008, Pub. L. 110–325, 122 Stat. 3553 (2008)) (ADA), and Section 508 of the Rehabilitation Act of 1973, 29 U.S.C. 794d (Section 508). These laws establish additional Federal civil rights protections for individuals with disabilities, and covered entities must be mindful that the obligations imposed by those laws apply to them independent of the application of Section 1557.

Definitions (§ 92.4)

Section 92.4 contains proposed definitions. Definitions of particular note are set out below.

Auxiliary aids and services. The definition of “auxiliary aids and services” is the same as the definition of this term in the regulations

² Section 1557 applies to all health programs and activities, any part of which receives Federal financial assistance from any Federal Department. However, this proposed rule would apply only to health programs and activities any part of which receives Federal financial assistance from HHS. This narrowed application is consistent with HHS' enforcement authority over such health programs and activities, but other Federal agencies are encouraged to adopt the standards set forth in this proposed rule in their own enforcement of Section 1557.

³ See 42 U.S.C. 6103(b).

⁴ We are also seeking comment elsewhere in this Preamble on a number of possible exceptions to the proposed rule, including with regard to what sex-based distinctions, if any, should be permitted in the context of health programs and activities and the standards for permitting those distinctions. See Preamble discussion of § 92.101(c).

⁵ See, e.g., 42 U.S.C. 300a–7; 42 U.S.C. 238n; Consolidated and Continuing Appropriations Act 2015, Pub. L. 113–235, 507(d) (Dec. 16, 2014).

⁶ 42 U.S.C. 2000bb–1.

⁷ See, e.g., 42 U.S.C. 18023.

⁸ See 45 CFR 147.131.

implementing the ADA, at 28 CFR 35.104, 36.303(b).

Covered entity. The term “covered entity” means: (1) An entity that operates a health program or activity, any part of which receives Federal financial assistance;⁹ (2) an entity established under Title I of the ACA that administers a health program or activity; and (3) the Department.

With regard to the Health Insurance Marketplaces, covered entities include, for example, Navigators that receive Federal financial assistance as defined in this rule. Navigators are entities that carry out the duties identified in the ACA and its implementing regulations, such as informing the public about the health coverage options available through the Health Insurance Marketplaces and facilitating enrollment in health coverage programs.¹⁰ State-based Marketplaces are covered as Title I entities. The Federally-facilitated Marketplaces are covered both as Title I entities and as health programs or activities of the Department.

Director. Director means the Director of the Office for Civil Rights in the Department.

Disability. The definition of “disability” is the same as the definition of this term in the Rehabilitation Act, at 29 U.S.C. 705(9)(B), which incorporates the definition of disability in the ADA, as construed by the ADA Amendments Act of 2008 (Pub. L. 110–325; 42 U.S.C. 12102), as amended. This part uses the term “disability” in place of the term “handicap” used in some previous civil rights statutes and regulations. Throughout this part, where we cross-reference other regulatory provisions, regulatory language that uses the term “handicap” shall mean “disability.” This change in terminology does not reflect a change in the substance of the definition.

Electronic and information technology. The definition of “electronic and information technology” is consistent with 36 CFR 1194.4, the regulation implementing Section 508.

Employee health benefit program. The term “employee health benefit program” means (1) health benefits coverage or health insurance provided to employees and/or their dependents established,

operated, sponsored or administered by, for, or on behalf of one or more employers, whether provided or administered by entities including but not limited to, a health insurance issuer, group health plan (as defined in the Employee Retirement Income Security Act of 1974 (ERISA, at 29 U.S.C. 1191(a)), a third party administrator, or an employer; (2) an employer-provided or -sponsored wellness program; (3) an employer-provided health clinic; or (4) long term care coverage or insurance provided or administered by an employer, group health plan, third party administrator, or health insurance issuer.

Federal financial assistance. The term “Federal financial assistance” includes the standard definition of grants, loans, and other types of assistance in accordance with the definition of “Federal financial assistance” in the regulations implementing Section 504 and the Age Act at 45 CFR 84.3(h) and 91.4, respectively, and also specifically includes subsidies and contracts of insurance, in accordance with the statutory language of Section 1557.

However, consistent with OCR’s enforcement of other civil rights authorities, the definition of Federal financial assistance does not include Medicare Part B.

An additional clause is added to the proposed regulatory provision, modeled on the definition of “Federal financial assistance” in the regulation implementing Title IX at 45 CFR 86.2(g). That Title IX regulatory provision clarifies that Federal financial assistance includes wages, loans, grants, scholarships and other monies that are given to any entity for payment to or on behalf of students who are admitted to that entity or that are given directly to these students for payment to that entity.¹¹ 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. In the health care context, Federal funds are provided to or on behalf of eligible individuals for premium tax credits and advance payments of premium tax credits and cost sharing reductions to ensure the affordability of health insurance coverage purchased through the Health Insurance Marketplaces. To clarify that these funds are Federal financial assistance, we have added language to this proposed definition stating that such funds are Federal financial assistance when extended to the entity

providing the health insurance coverage or services, whether they are paid directly by the Federal government to that entity or to the individual for remittance to the entity providing health insurance coverage or services. Thus, an issuer participating in any Health Insurance Marketplace is receiving Federal financial assistance when advance payments of premium tax credits and/or cost sharing reductions are provided to any of the issuer’s enrollees. 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.

Federally-facilitated Marketplace. The term Federally-facilitated Marketplace has the same meaning as “Federally-facilitated Exchange” defined in 45 CFR 155.20.

Gender identity. The term “gender identity” means an individual’s internal sense of gender, which may be different from an 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. Gender may be expressed through, for example, dress, grooming, mannerisms, speech patterns, and social interactions. For purposes of this part, an individual has a transgender identity when the individual’s 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. The approach taken in this definition is consistent with the approach taken by the Federal government in similar matters.¹²

Health Insurance Marketplace. The term “Health Insurance Marketplace”¹³ means the same as “Exchange” defined in 45 CFR 155.20.

Health program or activity. The term “health program or activity” is defined to include the provision or administration of health-related services or health-related insurance coverage and the provision of assistance in obtaining health-related services or health-related insurance coverage. Similar to the

⁹ As noted *supra* at n.2, this proposed rule would apply to recipients of Federal financial assistance from HHS only. The term “covered entity” is nonetheless defined broadly so that other Federal Departments can readily apply the standards of this rule to their own enforcement of Section 1557.

¹⁰ See, e.g., 42 U.S.C. 18031(i) (authorizing the Navigator program); 45 CFR 155.210 (c), (e) (identifying eligibility requirements for, and responsibilities of, receiving a Navigator grant).

¹¹ See 45 CFR 86.2(g)(1)(ii).

¹² See, e.g., Memorandum from Office of Personnel Management, “Guidance Regarding the Employment of Transgender Individuals in the Federal Workplace” (May 27, 2011); Resource Guide from Office of Personnel Management, the Equal Employment Opportunity Commission, the Office of Special Counsel, and the Merit Systems Protection Board, “Addressing Sexual Orientation and Gender Identity Discrimination in Federal Civilian Employment” (June 2015).

¹³ Health Insurance Marketplaces are also known as “Marketplaces.”

approach of the Civil Rights Restoration Act¹⁴ and except as specifically set forth otherwise in this part,¹⁵ the term further includes all of the operations of an entity principally engaged in providing or administering health services or health insurance coverage, such as a hospital, health clinic, community health center, group health plan, health insurance issuer, physician's practice, nursing facility, or residential or community-based treatment facility.¹⁶ OCR intends to interpret "principally engaged" in a manner consistent with civil rights laws that use this term.

OCR intends the plural "health programs or activities" used in this proposed part to have the same meaning as the term "health program or activity" in the singular. Similarly, this proposed part's use of "health programs and activities," a variation of "health program or activity," does not reflect a change in the substance of the definition of "health program or activity."

Commenters responding to the request in the RFI for examples of programs and activities that should be considered "health programs or activities" generally supported a broad interpretation of the term. We propose to interpret "health programs and activities" to include programs such as health education and health research programs. However, OCR recognizes that health research is conducted to answer scientific questions and advance health through the advancement of knowledge; it is not designed to result in direct health benefits to participants, though individuals may in fact receive health benefits from participation. In addition, and consistent with basic nondiscrimination principles applied in other contexts, OCR notes that individuals have a right to

nondiscriminatory consideration for inclusion in a research project but are not entitled to be selected to participate.

Because Federal civil rights laws already prohibit discrimination on the basis of race, color, national origin, disability, or age in all health research programs and activities that receive Federal financial assistance and prohibit discrimination on the basis of sex in all health research programs conducted by colleges and universities, application of Section 1557 to health research should impose limited additional burden on covered entities. But including health research under Section 1557 would extend the prohibition against discrimination on the basis of sex to Federally assisted health research programs and activities in non-educational institutions, complementing existing initiatives to increase diversity and inclusion in health research. Moreover, applying the requirements of Section 1557 to Department-conducted health programs and activities, including health research, would hold HHS components to the same standards as recipients of Federal financial assistance, prohibiting discrimination on all bases covered by Section 1557.

OCR also recognizes that research projects are often limited in scope for many reasons, such as the principal investigator's scientific interest, funding limitations, recruitment requirements, and other nondiscriminatory considerations. Thus, criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research. OCR does not intend for inclusion of health research within the definition of health program or activity to alter the fundamental manner in which research projects are designed, conducted, or funded; nor is OCR proposing to systematically review health research protocols. For example, a medical research institution that is a covered entity may exclude individuals who are a deaf from a clinical trial to investigate a new brain imaging technology for assessing cognitive functioning that relies on auditory stimulation as the test stimulus. This research design would not be discriminatory on the basis of disability because there is a nondiscriminatory justification for excluding individuals who are deaf.

OCR continues to seek comment on programs and activities that should be considered health programs or activities.

Individual with a disability. The proposed definition of "individual with a disability" is the same as the definition of this term used for the purpose of Section 504 of the Rehabilitation Act, found at 29 U.S.C. 705(20)(B)–(F), as amended. The Rehabilitation Act, at 29 U.S.C. 705(20)(B)–(F), incorporates the definition of "individual with a disability" from the ADA. This part uses the person-first term "individual with a disability" in place of the outdated terms "handicapped person" and "individual with handicaps" which are found in earlier civil rights laws and regulations. Throughout this part, where we cross-reference Section 504, regulatory language that uses "handicapped person" and "individual with handicaps" shall mean "individual with a disability." This change in terminology does not reflect a change in the substance of the definition.

Individual with limited English proficiency. The term "individual with limited English proficiency" codifies the Department's long-standing definition reflected in guidance interpreting Title VI's prohibition of national origin discrimination, entitled Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons¹⁷ (HHS LEP Guidance). Under this definition, an individual whose primary language for communication is not English is an individual with limited English proficiency under this part as long as the individual has a limited ability to communicate in one of the following ways: Reading, speaking, writing, or understanding. Consequently, an individual whose primary language for communication is not English and who has some ability to speak English is an individual with limited English proficiency under this part if the individual has a limited ability to read, write, or understand English.

Language assistance services. The term "language assistance services" identifies types of well-established methods or services used to communicate with individuals with limited English proficiency, including oral language assistance, written translation, and taglines. A covered entity has flexibility to provide language assistance services in-house or through commercially available options. To maximize covered entities' flexibilities

¹⁴ 102 Stat. 28, Pub. Law 100–259 (1988).

¹⁵ Employee health benefits programs are discussed elsewhere in this proposed rule. See *infra* discussion of proposed § 92.208.

¹⁶ A health program or activity also includes all of the operations of a State Medicaid program. Where a State Medicaid program resides in an agency that is principally engaged in providing health services or health insurance coverage, or is primarily engaged in providing assistance in obtaining health services or health coverage, all of the operations of the agency will be a health program or activity. Where a State Medicaid program is operated by a State agency that operates many other programs that provide services other than health-related services, health related insurance coverage, or assistance in obtaining health-related services or health-related coverage, the agency as a whole may not be principally engaged in providing health services, health insurance coverage, or assistance in obtaining health services or health coverage; in such cases, only the agency's Medicaid program and other health-related programs will meet the definition of health program and activity. The same is true for local Medicaid agencies.

¹⁷ Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons, 68 FR 47311, 47313 (Aug. 8, 2003) (hereinafter HHS LEP Guidance).

and to account for the likelihood of future innovations, we decline to offer an exhaustive list of available methods. However, given the range of methods available specifically for oral language assistance, proposed paragraph (1) identifies the following as available methods to communicate orally with individuals with limited English proficiency: Oral interpretation (in-person or remotely)¹⁸ and direct communication through the use of bilingual and multilingual staff competent to communicate directly, in non-English languages using any necessary specialized vocabulary, with individuals with limited English proficiency.

On the basis of sex. The term “on the basis of sex” is defined to include, but is not limited to, discrimination on the basis of pregnancy, false pregnancy, termination of pregnancy, or recovery therefrom, childbirth or related medical conditions, sex stereotyping, or gender identity.

Section 1557 extends the grounds for discrimination found in nondiscrimination laws (*i.e.*, race, color, national origin, sex, age, or disability) to certain health programs and activities. The HHS Title IX regulation explicitly includes discrimination on the basis of pregnancy as a form of discrimination on the basis of sex, and the definition in this section mirrors that regulation. See 45 CFR 86.40(b) (prohibiting discrimination on the basis of “pregnancy, childbirth, false pregnancy, termination of pregnancy or recovery therefrom”).

The proposed inclusion of sex stereotyping reflects the Supreme Court’s holding in *Price Waterhouse v. Hopkins*, 490 U.S. 228, 250–51 (1989), that discrimination based on stereotypical notions of appropriate behavior, appearance or mannerisms for each gender constitutes sex discrimination.

We propose that discrimination on the basis of sex further includes

¹⁸ We use the terms “oral interpretation” and “written translation” for clarity but we note that the term “interpretation” used without the preceding descriptor of “oral” refers to the communication of information orally and the term “translation” used without the preceding descriptor of “written” refers to the communication of information in writing. See, e.g., U.S. Dep’t of Justice, Commonly Asked Questions and Answers Regarding Limited English Proficient (LEP) Individuals and Translators, available at http://www.lep.gov/faqs/042511_Q&A_EO_13166.pdf (differentiating between interpreters and translators in FAQ 11); Interpreters and Translators, U.S. Department of Labor, Bureau of Labor Statistics, Occupational Outlook Handbook, 2014–15, available at <http://www.bls.gov/ooh/media-and-communication/interpreters-and-translators.htm> (explaining that interpreters convert information in a spoken language and translators convert information in written language).

discrimination on the basis of gender identity. OCR has previously interpreted sex discrimination to include discrimination on the basis of gender identity.¹⁹ Other Federal agencies have similarly interpreted the meaning of sex discrimination.²⁰ In addition, courts, including in the context of Section 1557, have recognized that sex discrimination includes discrimination based on gender identity.²¹ We thus propose to formally adopt this well-accepted interpretation of discrimination “on the basis of sex.”

As a matter of policy, we support banning discrimination in health programs and activities not only on the bases identified previously, but also on the basis of sexual orientation. Current law is mixed on whether existing Federal nondiscrimination laws prohibit discrimination on the basis of sexual orientation as a part of their prohibitions of sex discrimination. To date, no Federal appellate court has concluded that Title IX’s prohibition of discrimination “on the basis of sex”—or Federal laws prohibiting sex discrimination more generally—prohibits sexual orientation discrimination, and some appellate

courts previously reached the opposite conclusion.²²

However, a recent EEOC decision concluded that Title VII’s prohibition of discrimination “on the basis of sex” precludes sexual orientation discrimination because discrimination on the basis of sexual orientation necessarily involves sex-based considerations. The EEOC relied on several theories to reach this conclusion: A plain interpretation of the term “sex” in the statutory language, an associational theory of discrimination based on “sex,” and the gender-stereotype theory announced in *Price Waterhouse*.²³ The EEOC’s decision cited several district court decisions that similarly concluded that sex discrimination included sexual orientation discrimination, using these theories.²⁴ The EEOC also analyzed and called into question the appellate decisions that have concluded that sexual orientation discrimination is not covered under Title VII. The EEOC decision applies to workplace conditions, as well as hiring, firing, and promotion decisions, and is one of several recent developments in the law that have resulted in additional protections for lesbian and gay individuals against discrimination.²⁵

¹⁹ See Letter from Leon Rodriguez, Director, U.S. Department of Health & Human Services, Office for Civil Rights, to Maya Rupert, Federal Policy Director, National Center for Lesbian Rights (Jul. 12, 2012).

²⁰ See regulations issued by the Office of Personnel Management, clarifying that the discrimination on the basis of sex includes discrimination on the basis of gender identity, 79 FR 43919 (Jul. 29, 2014); Directive 2014–02, U.S. Department of Labor, Office of Federal Contract Compliance Programs (Aug. 19, 2014), available at http://www.dol.gov/ofccp/regs/compliance/directives/dir2014_02.html; Statement of Interest of the United States, *Jamal v. SAKS & Co.*, No. 4:14–CV–2782 (S.D. Tex. 2015); Statement of Interest of the United States, *Tooley v. Van Buren Public Schools*, No. 2:14–cv–13466–AC–DRG (E.D. Mich.) (Feb. 24, 2015), Mediated Settlement Order, *United States v. Toone*, No. 6:13–CV–744 (E.D. Tex. 2014); Memo from Eric Holder, Att’y Gen., to U.S. Att’y’s & Heads of Dep’t Components (Dec. 15, 2014); U.S. Dep’t of Educ., Questions and Answers on Title IX and Sexual Violence at B–2 (<http://www2.ed.gov/about/offices/list/ocr/docs/qa-201404-title-ix.pdf>) Resolution Agreement Between Arcadia Unified Sch. Dist., U.S. Dep’t of Educ., Office for Civil Rights, & the U.S. Dep’t of Justice, Civil Rights Div., OCR Case No. 09–12–1020, DOJ Case No. 169–12C–70, at 1 (Jul. 24, 2013); *Macy v. Holder*, EEOC Appeal No. 0120120821, Agency No. ATF–2011–00751 (Apr. 20, 2012) 2012 WL 1435995, at *11.

²¹ See, e.g., *Rumble v. Fairview Heath Services*, 2015 WL 1197415 (D. Minn. 2015) (order denying motion to dismiss); *Barnes v. City of Cincinnati*, 401 F.3d 729 (6th Cir.), cert. denied, 546 U.S. 1003 (2005); *Smith v. City of Salem, Ohio*, 378 F.3d 566 (6th Cir. 2004); *Schroer v. Billington*, 577 F. Supp.2d 293 (D.D.C. 2008). But see *Johnston v. University of Pittsburgh*, Civ. Action No. 3:13–213 (W.D.Pa. Mar. 31, 2015) (interpreting Title IX, among other authorities).

²² See, e.g., *Kiley v. Am. Soc’y for Prevention of Cruelty to Animals*, 296 Fed. App’x 107, 109 (2d Cir. 2008); *Vickers v. Fairfield Med. Ctr.*, 453 F.3d 757, 759 (6th Cir. 2006); *Bibby v. Philadelphia Coca Cola Bottling Co.*, 260 F.3d 257, 260 (3d Cir. 2001); but cf. *Latta v. Otter*, 771 F.3d 456 (9th Cir. 2014) (Berzon, J., concurring) (in striking down State law prohibition on same sex marriage, observing that “the same sex marriage laws treat the subgroup of men who wish to marry men less favorably than the otherwise similarly situated subgroup of women who want to marry men” and therefore constitute sex discrimination); see also *Muhammad v. Caterpillar*, 767 F.3d 694 (7th Cir. 2014), 2014 WL 4418649 (7th Cir. Sept. 9, 2014, as Amended on Denial of Rehearing, Oct. 16, 2014) (removing statements from previously issued panel decision that relied on outdated precedents about coverage of sexual orientation discrimination under Title VII as requested in EEOC Amicus Brief).

²³ *Baldwin v. Foxx*, EEOC Appeal No. 0120133080, Agency No. 2012–24738–FAA–03, at 5–6 (July 15, 2015) (finding that sexual orientation is inseparable from and inescapably linked to sex and thus that an allegation of discrimination based on sexual orientation is necessarily an allegation of sex discrimination).

²⁴ See e.g., *Centola v. Potter*, 183 F. Supp. 2d 403, 410 (D. Mass. 2002); *Heller v. Columbia Edgewater Country Club*, 195 F. Supp. 2d at 1212 (D. Or. 2002); *Koren v. Ohio Bell*, 894 F. Supp. 2d 1032, 1038 (N.D. Ohio 2012); *Terveer v. Billington*, 34 F. Supp. 3d 100, 116, 2014 WL 1280301 (D.D.C. 2014); *Boutillier v. Hartford Public Schools*, 2014 WL 4794527 (D. Conn. 2014); *Deneffe v. SkyWest, Inc.*, 2015 WL 2265373, at *6 (D. Colo. May 11, 2015).

²⁵ For example, in 1996, the Supreme Court struck down an amendment to the Colorado constitution that prohibited the State government from providing any legal protections to gay, lesbian, and bisexual individuals. Seven years later, in 2003, the Supreme Court invalidated a Texas law that criminalized same-sex sodomy. And just this year,

The final rule should reflect the current state of nondiscrimination law, including with respect to prohibited bases of discrimination. We seek comment on the best way of ensuring that this rule includes the most robust set of protections supported by the courts on an ongoing basis.

Qualified individual with a disability. The definition of “qualified individual with a disability” is the same as language in the ADA and the regulation implementing Title II of the ADA, at 42 U.S.C. 12131(2) and 28 CFR 35.104, respectively, except that the definition has been modified to apply in the context of a health program or activity.

Qualified interpreter. The term “qualified interpreter” means an individual who has the characteristics and skills necessary to interpret for an individual with a disability, for an individual with limited English proficiency, or for both. The language in paragraph (1) applicable for interpreting for an individual with a disability is the same as language in the regulations implementing the ADA, at 28 CFR 35.104, 36.104. The language in paragraph (2) applicable for interpreting for an individual with limited English proficiency reflects a synthesis of the attributes, described in the Department’s LEP Guidance, that are necessary for an individual to interpret competently and effectively under the circumstances and thus to provide the effective oral language assistance services required under the law.²⁶ The fact that an individual has above average familiarity with speaking or understanding a language other than English does not suffice to make that individual a

qualified interpreter for an individual with limited English proficiency.

The definition of “qualified interpreter” includes criteria regarding interpreter ethics, including client confidentiality. Because the definition of a qualified interpreter includes adherence to generally accepted interpreter ethics principles, bilingual or multilingual staff who are competent to communicate directly with individuals with limited English proficiency nonetheless may not satisfy a requirement to adhere to such principles. For instance, a bilingual nurse who is competent to communicate in Spanish directly with Spanish-speaking individuals with limited English proficiency may not be a “qualified interpreter” if serving as an interpreter would pose a conflict of interest with the nurse’s treatment of the patient.

Recipient. The term “recipient” is the same as language in the regulation implementing Title IX at 45 CFR 86.2(h), except that it has been modified to apply in the context of a health program or activity.²⁷

Sex stereotypes. The term “sex stereotypes” refers to stereotypical notions of masculinity or femininity, including expectations of how individuals represent or communicate their gender to others, such as behavior, clothing, hairstyles, activities, voice, mannerisms, or body characteristics. These stereotypes can include expectations that gender can only be constructed within two distinct opposite and disconnected forms (masculinity and femininity), and that gender cannot be constructed outside of this gender construct (individuals who identify as neither, both, or a combination of male and female). This definition is consistent with the approach taken by the Federal government in similar matters.²⁸

State-based Marketplace. The term “State-based Marketplace” means an Exchange operated by a State with the approval of the Department pursuant to 45 CFR 155.105.

Taglines. Taglines are short statements written in non-English languages to alert individuals with limited English proficiency to the availability of language assistance services free of charge.²⁹ For instance, a

tagline in Tagalog appearing on an English language document serves to notify Tagalog-speaking individuals with limited English proficiency that language assistance services, such as oral interpretation services through a qualified interpreter, are available and how they can be obtained.

Title I Entity. Title I of the ACA established Health Insurance Marketplaces, including the State-based Marketplaces and Federally-facilitated Marketplaces. The Federally-facilitated Marketplaces are also a health program or activity operated by the Department.

Assurances Required (§ 92.5)

Section 92.5 proposes that each entity applying for Federal financial assistance, each issuer seeking certification to participate in a Health Insurance Marketplace, and each State seeking approval to operate a State-based Marketplace be required to submit an assurance that its health programs and activities will be operated in compliance with Section 1557 and this part. The regulations implementing Title VI, Title IX, Section 504, and the Age Act all require similar assurances. We modeled the assurance, duration of obligation, and covenants language on the Section 504 regulation, at 45 CFR 84.5. To reduce burden on covered entities, OCR is revising the Assurance of Compliance HHS–690 Form to include all civil rights laws, including Section 1557, with which covered entities must comply.

Remedial Action and Voluntary Action (§ 92.6)

Section 92.6 proposes provisions addressing remedial action and voluntary action by covered entities. Paragraph (a) proposes that a recipient or State-based Marketplace that has been found to have discriminated on any of the bases prohibited by Section 1557 be required to take remedial action as required by the Director to overcome the effects of that discrimination. The Department, including the Federally-facilitated Marketplaces, like recipients and State-based Marketplaces, is also obligated to address discrimination, but is subject to a different remedial process than recipients and State-based Marketplaces. See proposed § 92.303.

Proposed paragraph (b) permits, but does not require, all covered entities to take voluntary action in the absence of a finding of discrimination to overcome the effects of conditions that result or

the Supreme Court ruled that States may not prohibit same-sex couples from marrying and must recognize the validity of same-sex couples’ marriages.

²⁶ See HHS LEP Guidance, *supra* n. 17, 68 FR at 47316 (explaining that an individual’s proficiency in another language, knowledge of specialized terminology, and adherence to interpreter ethics are considerations in determining competency to interpret); *id.* at 47317–18 and 47323 (discussing why family members, friends, and ad hoc interpreters may not be competent to interpret); see also, e.g., Voluntary Resolution Agreement between U.S. Dep’t of Health & Human Servs., Office for Civil Rights and Mee Memorial Hosp., OCR Transaction Nos. 12–143846, 13–1551016, & 13–153378, pt. II.J. (2014), available at <http://www.hhs.gov/ocr/civilrights/activities/agreements/mee.html> (defining qualified interpreter); Voluntary Resolution Agreement between U.S. Dep’t of Health & Human Servs., Office for Civil Rights and Montgomery County Dep’t of Soc. Servs., OCR Transaction No. 08–79992, pts. II.E (defining qualifications of an “interpreter” under the agreement), IV.H (requiring timely, competent language assistance); & IV.L (identifying interpreter standards), available at <http://www.hhs.gov/ocr/civilrights/activities/examples/LEP/mcdssra.html>.

²⁷ See *supra* n. 2.

²⁸ See Brief of the U.S. Equal Employment Opportunity Commission as Amicus Curiae in Support of Rehearing, *Muhammad v. Caterpillar Inc.*, No. 12–1723 at 4 (7th Cir. filed Oct. 9, 2014).

²⁹ The HHS LEP Guidance, *supra* n. 17, describes the practice of tagging non-English statements in “brochures, booklets, and in outreach and recruitment information” informing individuals

with limited English proficiency of the availability of language assistance services. See *id.* at 47,320 (explaining how statements in non-English languages “could be ‘tagged’ onto the front of common documents.”).

resulted in limited participation by persons based on race, color, national origin, sex, age, or disability. The provisions at § 92.6(a) and (b) are modeled after the Title VI, Title IX, Section 504, and Age Act regulations.

Designation of Responsible Employee and Adoption of Grievance Procedures (§ 92.7)

Proposed § 92.7 outlines the requirement for covered entities that employ 15 or more persons to designate a responsible employee and adopt grievance procedures. The implementing regulations for Section 504 and Title IX contain such requirements. Moreover, through its case investigative experience, OCR has observed that the presence of a coordinator and a grievance procedure help to bring concerns to prompt resolution within the entity, leading to lower compliance costs and more efficient outcomes. We thus propose in this provision to apply these requirements to all bases of prohibited discrimination.

Paragraph (a) proposes that covered entities that employ 15 or more persons designate at least one employee to coordinate compliance with the requirements of the rule. A covered entity that has already designated a responsible employee pursuant to the regulations implementing Section 504 or Title IX may use that individual to coordinate its efforts to comply with Section 1557 or this part, provided that the scope of the individual's responsibilities is modified to include all prohibited bases of discrimination included in Section 1557 and other duties as required by Section 1557 or this part. For the Department, including Federally-facilitated Marketplaces, OCR will be deemed the responsible employee.

Paragraph (b) proposes that covered entities that employ 15 or more persons be required to adopt grievance procedures and appropriate due process standards that would allow for the prompt and equitable resolution of complaints concerning actions prohibited by Section 1557 and this part. Covered entities that already have a grievance procedure in place pursuant to the regulation implementing Section 504 may use that procedure to address claims under Section 1557 or this part, provided that the existing procedure meets the standards established under the Section 504 regulation. In addition, covered entities may use that procedure to address all other Section 1557 claims, provided that that procedure meets the standards under the Section 504 regulation and that the procedure is

modified to apply to race, color, national origin, sex, and age discrimination claims. For the Department, including Federally-facilitated Marketplaces, the procedures for addressing complaints of discrimination on the grounds covered under Section 1557 will be deemed grievance procedures.

OCR is considering requiring that all covered entities, not just those that employ 15 or more persons, designate a responsible employee and establish grievance procedures. While Section 504 limits these requirements to recipients with 15 or more employees, Title IX applies them to all recipients that operate educational programs or activities, regardless of the size of the recipient. Following the approach of Title IX would lead to a broader application under Section 1557 that would benefit more individuals by reaching more covered entities and allowing covered entities to address any potential compliance issues at an earlier stage and in a less formal manner than an OCR investigation. We invite comment on this proposal, including any associated costs and benefits.

Notice Requirement (§ 92.8)

Section 92.8 proposes that each covered entity take initial and continuing steps to notify beneficiaries, enrollees, applicants, or members of the public of certain important information. We modeled this section generally after the notice requirements found in regulations implementing Title VI, Title IX, Section 504, and the Age Act, which require covered entities to have a notice in place.

Paragraphs (a)(1)–(7) of § 92.8 propose the components of the notice that each covered entity is required by § 92.8(b) and (f) to post.

Paragraph (a)(1) proposes that the notice include that the covered entity does not discriminate on the basis of race, color, national origin, sex, age, or disability.

Paragraphs (a)(2) and (a)(3) propose that the notice include a statement that the covered entity provides auxiliary aids and services, free of charge, in a timely manner, to individuals with disabilities, when such aids and services are necessary to provide an individual with a disability an equal opportunity to benefit from the entity's health programs or activities; and language assistance services, free of charge, in a timely manner, to individuals with limited English proficiency, when those services are necessary to provide an individual with limited English proficiency meaningful access to a covered entity's health

programs or activities. These provisions are necessary to ensure that individuals are aware of their rights under the law, and are grounded in OCR's experience that failures of communication based on the absence of auxiliary aids and services and language assistance services raise particularly significant compliance concerns. In addition, such failures of communication often are a primary contributor to limitations in access to health programs and activities for individuals with disabilities and individuals with limited English proficiency. Apprising individuals of the availability of communication assistance under Section 1557 will promote both compliance with the law and better health outcomes.

Paragraph (a)(4) proposes that the notice include information on how an individual can access the aids and services referenced in (a)(2) and (a)(3).

Paragraph (a)(5) proposes that the notice provide contact information for the responsible employee, where such a responsible employee is required by § 92.7(a).

Paragraph (a)(6) proposes that the notice include the availability of the grievance procedure, where such a grievance procedure is required by § 92.7(b), and information on how to file a grievance.

Paragraph (a)(7) proposes that the notice provide information on how to file a complaint with OCR. Inclusion of this requirement ensures that covered entities inform individuals about the enforcement mechanisms outside of the covered entity's internal process.

Paragraph (b) provides that within 90 days of the effective date of this part, each covered entity shall post the notice, consistent with paragraph (f) of this section, that conveys the information in English in paragraph (a)(1) through (7) of this section.

Paragraph (c) provides that the Director shall make available an electronic sample notice in English that contains the content listed in, and meets the requirements of, paragraphs (a)(1) through (7). Covered entities may use this sample notice or may develop their own notices that meet the requirements of paragraphs (a)(1) through (7). We request comment on the sample notice included in Appendix A to this proposed rule.

OCR also invites comment on whether this proposed rule should permit covered entities to combine the content of the notice required under the proposed rule with the content of other notices that covered entities may be required to disseminate or post under Federal laws and, if so, what steps covered entities may or should take to

ensure that the content of the notice required by the proposed rule is sufficiently conspicuous and visible to beneficiaries, enrollees, applicants, or members of the public that they are able to become aware of the content of the notice. In addition, OCR invites comment on whether this proposed rule should allow the notice to be modified to be appropriate for publications and other communication vehicles that may not have sufficient space to accommodate the full notice, *e.g.*, postcards, trifold brochures, and social media platforms and, if so, what information such a modified notice should include.

Paragraph (c) also proposes that the Director shall translate the sample notice into the top 15 languages³⁰ spoken by individuals with limited English proficiency nationally and make the translated notices available to covered entities electronically and in any other manner the Director determines appropriate. Assigning to OCR the responsibility to translate the sample notice maximizes efficiency and economies of scale. This approach means covered entities will receive the benefits of having multi-language notices available without incurring the associated translation costs. We expect that making the sample notice available in non-English languages will substantially increase the value and utility of the notice required in paragraphs (a) and (b) of § 92.8.

Under our proposed approach, covered entities are encouraged, but not required, to post one or more of the translated notices, particularly in the most prevalent languages spoken by individuals with limited English proficiency in the covered entities' geographic service areas, as determined by the covered entities. Covered entities also may make the notice available in

non-English languages other than the top 15 languages for which translated notices are provided by the Director. We encourage covered entities to make the content of the notice available in additional non-English languages to inform national origin groups within covered entities' geographic service areas of their rights under Section 1557 and this proposed rule.

In lieu of this approach, OCR considered requiring, rather than merely encouraging, covered entities to post one or more of the notices in the most prevalent non-English languages frequently encountered by covered entities in their geographic service areas, such as Spanish. This option would leverage the OCR-translated notices and improve, for certain national origin populations, access to the information in the notice in a language that those individuals with limited English proficiency could understand. The main disadvantage of this option is the burden of using physical wall space to post notices and using information technology staff/resources for web posting of notices and printing of notices. For the purposes of this proposed rule, we believe the availability of the taglines that § 92.8(d) of this proposed rule requires covered entities to post strikes an appropriate balance. We seek comment on the alternate approach.

With regard to the proposal that the Director provide translations of the sample notice, we selected the top 15 languages spoken by individuals with limited English proficiency nationally as a data driven policy. This scope reaches nearly 90 percent of individuals with limited English proficiency in the United States based on the U.S. Census Bureau's 2011 to 2013 data—the most recent three-year data available—that estimates the prevalence of foreign-language speakers who speak English less than “very well.” We will review U.S. Census Bureau data more recent than 2011 to 2013, as the data becomes available, to determine if and when the top 15 languages spoken nationally by individuals with limited English proficiency change, warranting the Director to make available notices translated in additional non-English languages.

Paragraph (d) proposes that within 90 days of the effective date of this part, each covered entity shall post, consistent with paragraph (f) of this section, taglines in the top 15 languages spoken nationally by individuals with limited English proficiency.

Paragraph (e) proposes that the Director shall make available taglines in the top 15 languages spoken nationally

by individuals with limited English proficiency for use by covered entities. Taglines have a high utility as a gateway to language assistance services: They are written in non-English languages that individuals with limited English proficiency can understand, inform those individuals how to access language assistance services, and encourage those individuals to identify themselves and the languages in which they communicate.³¹ The Department's LEP Guidance describes the practice of tagging non-English statements in publications and informational materials.³²

We request comment on the content of the sample tagline included in Appendix B to this proposed rule. As with our approach to making available translated notices, assigning to OCR the responsibility to provide translated taglines maximizes efficiency and economies of scale. This approach means that covered entities will receive the benefits of having multi-language taglines available without incurring the associated translation costs. For this reason, we anticipate covered entities will use the translated taglines that the Director makes available. Covered entities are not limited to posting taglines in the 15 languages made available by the Director; covered entities may provide taglines in as many other non-English languages as appropriate to alert national origin groups in the covered entity's geographic service area of language assistance services that may be available.

Paragraph (f) of this section prescribes the location for posting both notices and taglines. Specifically, the proposed rule requires that covered entities post the English-language notice required by § 92.8(a) and (b) and the taglines required by § 92.8(d) in a conspicuously-visible font size in: Significant publications or significant communications targeted to beneficiaries, enrollees, applicants, or members of the public, which may include patient handbooks, outreach publications, or written notices pertaining to rights or benefits or requiring a response from an individual; in conspicuous physical locations; and in a conspicuous location on the home page of a covered entity's Web site. Section 92.8(f) specifically states that a

³⁰ See U.S. Dep't of Commerce, U.S. Census Bureau, American FactFinder, Language Spoken at Home by Ability to Speak English for the Population 5 Years and Older, 3-Year American Community Survey (ACS), Estimates (2011–2013), http://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ACS_13_3YR_B16001&prodType=table (last visited Mar. 27, 2015). The most recent ACS data available are the 2013 estimates. OCR chose the three-year data set (as opposed to the one-year or five-year data) because it best balances the currency and stability of the data. The top 15 languages in which OCR plans to translate the notice excludes bundled language groups, such as “other Indo-European languages” and “other Pacific Islander languages.” The top 15 foreign languages, ordered from high to low estimates of number of individuals speaking English less than “very well,” are Spanish (or Spanish Creole), Chinese, Vietnamese, Korean, Tagalog, Russian, Arabic, French Creole, French (including Patois and Cajun), Portuguese (or Portuguese Creole), Polish, Japanese, Italian, German, and Persian (Farsi).

³¹ See, *e.g.*, HHS LEP Guidance, *supra* n. 17 at 68 FR at 47320 (discussing ways to identify the primary languages in which individuals with limited English proficiency communicate and considerations for notifying individuals with limited English proficiency of language assistance services).

³² See HHS LEP Guidance, *id* at 68 FR at 47320.

covered entity may post the notice and taglines in additional publications and communications beyond those listed in paragraphs (f)(1) through (3) of § 92.8. We seek comments on additional ways to define the scope of the significant publications and significant communications.

We propose to require the notice and taglines on a covered entity's Web site to be located conspicuously on the home page so that individuals, generally, are aware of their rights, and individuals with limited English proficiency do not have to navigate English-only text to find information in the individual's language. Covered entities may satisfy the requirement to post the notice on the covered entity's Web site by including a link in a conspicuous location on the covered entity's home page that immediately directs the individual to the content of the notice on the covered entity's Web site. Covered entities may satisfy the requirement to post taglines on the covered entity's Web site by including web links conspicuously on the home page that identify each of the 15 non-English languages, written "in language," and that direct the individual to the full text of the tagline indicating how the individual may obtain language assistance services. For instance, a tagline web link directing a Spanish-speaking individual with LEP to a Spanish-language tagline should appear as "Español" rather than "Spanish." Similarly, a tagline directing an individual to a Web site with the full text of a tagline written in Haitian Creole should appear as "Kreyòl Ayisien" rather than "Haitian Creole." Providing tagline web links and the text of taglines in their respective non-English languages is of particular importance for languages that do not use a Latin script.

Covered entities that distribute general or major publications targeted to beneficiaries, enrollees, applicants, or members of the public will need to update these publications to include the new notice. However, we propose allowing entities to exhaust their current stock of hard copy publications, rather than requiring a special printing of the publications to include the new notice. When covered entities restock their printed materials, they will be expected to include in those printed materials the notice that we are promulgating with the final rule.

Because the top 15 languages spoken by individuals with limited English proficiency nationally may be over-inclusive or under-inclusive of the languages spoken by individuals with limited English proficiency within the

areas served by covered entities' health programs and activities, OCR considered a State-based methodology for identifying the languages in which covered entities would be required to post taglines. For instance, we considered proposing a requirement for entities to make available taglines in the top 15 languages spoken statewide, rather than nationwide, by individuals with limited English proficiency. Identifying a State-based threshold aligns with Federal regulations governing the Health Insurance Marketplaces and qualified health plan³³ issuers.³⁴ Under this approach, OCR would make available to covered entities translated taglines for the non-English languages constituting the top 15 languages spoken statewide by individuals with limited English proficiency. We seek comment on this alternate methodology, specifically regarding the geographic areas or service areas that should apply for determining a threshold number of languages in which the Director should translate and make available, or for which covered entities should post, taglines.

To reduce the burden on covered entities, proposed subsection (g) of this section states that a covered entity's compliance with § 92.8 satisfies the notice requirements under HHS' Title VI, Section 504, Title IX, and Age Act regulations. We request comment on OCR's proposal to treat compliance with § 92.8 as satisfying the notice requirements under the regulations implementing Title VI, Section 504, Title IX, and the Age Act.

Subpart B—Nondiscrimination Provisions

Subpart B of the proposed rule incorporates regulatory provisions implementing the civil rights statutes referenced in Section 1557(a): Title VI, Title IX, the Age Act, and Section 504.

Discrimination Prohibited (§ 92.101)

Proposed § 92.101 of subpart B prohibits discrimination on the basis of race, color, national origin, sex, age, or disability under any health program or activity to which Section 1557 or this part applies. Paragraphs (a) and (b) of § 92.101 follow the structure of the implementing regulations for Title VI, Section 504, Title IX, and the Age Act by including a general nondiscrimination provision in paragraph (a) followed by a provision identifying specific discrimination prohibited in paragraph (b). Exceptions

to discrimination prohibited under the Title VI, Section 504, and Age Act regulations are addressed in paragraph (c). Paragraph (d) effectuates technical changes in terminology to apply the provisions incorporated from other regulations to the covered entities obligated to comply with this proposed rule.

General Discriminatory Actions Prohibited § 92.101(a)

In paragraph (a)(1) of § 92.101, we restate the core objective of Section 1557(a), which prohibits discrimination on the grounds prohibited under Title VI (race, color, or national origin), Title IX (sex), the Age Act (age), or Section 504 (disability) in any health program or activity to which this part applies.

In paragraph (a)(2), we propose to limit the ways in which the proposed rule applies to employment. Except as provided in § 92.208, which addresses employee health benefit programs, this proposed rule does not apply to discrimination by a covered entity against its own employees. Thus, this proposed rule would not extend to hiring, firing, promotions, or terms and conditions of employment outside of those identified in § 92.208; such claims would continue to be brought under other laws, including Title VII of the Civil Rights Act of 1964,³⁵ Title IX, Section 504, the ADA and the Age Discrimination in Employment Act,³⁶ as appropriate. We believe that this approach is consistent with the purpose of the ACA and with Section 1557's focus on discrimination in health programs and activities.³⁷ We invite

³⁵ 42 U.S.C. 2000e *et seq.*

³⁶ 29 U.S.C. 621 *et seq.*

³⁷ This approach is consistent with the coverage of the Age Act and Title VI, which explicitly exclude discrimination in employment, subject, in the case of Title VI, to certain exceptions not applicable here. See 45 CFR 91.3(b)(2) (excluding employment from application of the regulation implementing the Age Act); 80.2(d) (excluding employment from application of the regulation implementing Title VI); 80.3(c), (d)(3) (exceptions to the exclusion of employment discrimination under the regulation implementing Title VI). Moreover, while Section 504 and Title IX, which are silent on the question, have been interpreted to bar discrimination in employment, those interpretations were based on analyses of the purposes underlying the Rehabilitation Act and on extensive discussion of employment in the legislative history of Title IX. *Consolidated Rail Corp. v. Darrone*, 465 U.S. 624, 626 (1984) (promoting and expanding employment opportunities for handicapped individuals is a stated purpose of the Rehabilitation Act, 29 U.S.C. 701(8), and legislative history demonstrates that Congressional intent to bar employment discrimination was a focus of the Act); *North Haven Bd. of Ed. v. Bell*, 456 U.S. 512, 522–530 (1982) (statutory language favors inclusion of employment discrimination and legislative history corroborates Congressional intent to prohibit sex discrimination in employment in Title IX). Our approach in the

³³ Qualified health plan means the same as "Qualified health plan" defined in 45 CFR 155.20.

³⁴ See 45 CFR 155.205(c)(2)(iii)(A) through (C).

comment on our proposal to exclude these forms of employment discrimination from the scope of this proposed rule.

Specific Discriminatory Actions Prohibited § 92.101(b)

Proposed paragraph (b) incorporates into this proposed regulation the specific discriminatory actions prohibited by each civil rights statute which Section 1557 references. We considered harmonizing each of the specific discriminatory actions prohibited across each civil rights law addressed by Section 1557. Although harmonization could reduce redundancy in the specific discriminatory actions incorporated that are similar to one another, harmonization would likely lead to confusion and unintended differences in interpretation that are subtle yet significant. For example, with respect to the separate or different treatment prohibited under the Title VI regulation, such as at 45 CFR 80.3(b)(1)(iii) and (vi), the Section 504 regulation at 45 CFR 84.4(b)(1)(iv), 85.21(b)(1)(iv) requires separate or different treatment in some instances where it is necessary to provide persons with disabilities with aids, benefits or services that are as effective as those provided to others. To avoid confusion and unintended differences in interpretation, therefore, paragraphs (b)(1)–(4) incorporate into this proposed regulation the specific discriminatory actions prohibited under each civil rights law on which Section 1557 is grounded. Thus, for example, the specific discriminatory actions listed under Title VI are incorporated here to govern the obligations of covered entities not to discriminate based on race, color, or national origin. We seek comments on this proposed approach.

Proposed paragraph (b)(1) of § 92.101 adopts the specific discriminatory actions prohibited by the Title VI implementing regulation, which appear in 45 CFR 80.3(b)(1) through (6).

Proposed paragraph (b)(2)(i) of § 92.101 addresses the specific prohibition of discrimination on the basis of disability with which recipients and State-based Marketplaces must comply. This paragraph adopts relevant provisions in the Section 504 implementing regulation for Federally assisted programs and activities at 45 CFR part 84. The provisions incorporated are the specific discriminatory actions prohibited at

§ 84.4(b); the program accessibility provisions at §§ 84.21 through 84.23(b); and the provisions governing education, health, welfare, and social services at §§ 84.31, 84.34, 84.37, 84.38, and 84.41–84.55. We do not propose adopting the program accessibility provision at § 84.23(c), addressing conformance with the Uniform Federal Accessibility Standards for the construction and alteration of facilities, because these standards are outdated. Section 92.203 of this proposed rule requires compliance with more contemporary standards.

Paragraph (b)(2)(ii) of § 92.101 addresses the specific prohibitions of discrimination on the basis of disability with which the Department, including the Federally-facilitated Marketplaces, must comply. This paragraph adopts relevant provisions in the Section 504 implementing regulation for Federally administered programs and activities at 45 CFR part 85. The provisions adopted are the specific discriminatory actions prohibited at § 85.21(b) and the program accessibility provisions at §§ 85.41 through 85.42 and 84.44 through 84.51.

Paragraph (b)(3) of § 92.101 adopts the specific discriminatory actions prohibited by the Title IX implementing regulation, which appear at 45 CFR 86.3(b)(1) through (8).

Paragraph (b)(4) of § 92.101 adopts the specific discriminatory actions prohibited by the Age Act implementing regulation, which appear at 45 CFR 91.11(b).

Paragraph (b)(5) of § 92.101 states that the specific discriminatory actions prohibited in § 92.101(b)(1) through (4) do not limit the general prohibition of discrimination in § 92.101(a). This statement is consistent with regulatory provisions in the implementing regulations for Title VI at 45 CFR 80.3(b)(5) and the Age Act at 45 CFR 91.11(c).

Paragraph (c) of § 92.101 incorporates the exceptions to the general prohibition of discrimination that appear in the implementing regulations for Title VI, Section 504, and the Age Act, as these exceptions have applied to health programs and activities for nearly 40 years. Generally, the exceptions in the Title VI, Section 504, and Age Act implementing regulations provide that it is not discriminatory to exclude a person from the benefits of a program that Federal law or executive order limits to a protected class. For instance, we incorporate the exceptions in the Age Act implementing regulation which address, among other things, age distinctions in Departmental

regulations, and actions based on age where age is a factor necessary to the normal operation or achievement of a statutory objective of a program or activity. This would include allowable age rating under the ACA where issuers may vary premium rates based on age within a 3:1 ratio.³⁸

Paragraph (c) of § 92.101 does not address the sex-based distinctions authorized in Title IX and its implementing regulation in the context of education programs or activities. As discussed previously, given Title IX's limitation to education programs and activities, these distinctions do not necessarily apply in the health care context.

Title IX and its implementing regulation allow some single-sex education programs (e.g., separate toilet, locker room, and shower facilities in education programs and activities; contact sports in physical education classes; classes on human sexuality; and choruses) when certain requirements are met. Thirty organizations that filed comments in response to the RFI indicated that, to the extent single-sex programs are permitted under Section 1557 or this part, they should be narrowly tailored and necessary to accomplish an essential health purpose. Some commenters also indicated that single-sex programs should be permissible when they are necessary to serve the disadvantaged sex or to comply with constitutionally protected rights to privacy. Nearly 20 organizational commenters urged that, in the very narrow circumstances where single-sex programs or activities are permitted, Section 1557 should require equal access for all individuals in a manner consistent with their self-identified gender.

HHS does not propose to prohibit separate toilet, locker room, and shower facilities where comparable facilities are provided to individuals, regardless of sex. However, we continue to seek comment on what other sex-based distinctions, if any, should be permitted in the context of health programs and activities and the standards for permitting the distinctions (see also the previous discussion of § 92.2 regarding the application of this proposed rule). Examples of sex-based distinctions include a women's health clinic or a counseling program limited to male victims of domestic violence.

proposed rule is not intended to alter the scope of either Section 504 or Title IX in this regard.

³⁸ 45 CFR 147.102(a)(1)(iii). This is also consistent with language in the Section 1557 provision, which states that a person is protected from discrimination "[e]xcept as otherwise provided for in this title."

Finally, paragraph (d) of § 92.101 effectuates technical changes to apply the provisions incorporated in § 92.101(b) and (c) to covered entities obligated to comply with this proposed rule by, among other things, replacing references to “recipient” in the incorporated provisions with “covered entity.”

Subpart C—Specific Applications to Health Programs and Activities

Section 1557 is unique among Federal civil rights laws in that it specifically addresses discrimination in health programs and activities. To provide additional specificity regarding nondiscrimination requirements in this setting, Subpart C builds upon pre-existing civil rights regulations referenced in Subpart B. Due to the nature and importance of health care, health-related insurance, and other health-related coverage to individuals and communities, OCR is proposing these additional specific requirements to ensure that covered entities have clear instruction in areas where OCR, through its enforcement work, has seen significant discrimination issues and complaints. We believe that these specific requirements will best assist covered entities in meeting their obligations and explain to individuals the scope of some of the protections afforded by Section 1557. We seek comment on this approach.

Meaningful Access for Individuals With Limited English Proficiency (§ 92.201) Overview of § 92.201

Proposed § 92.201 effectuates Section 1557’s prohibition of national origin discrimination as it affects individuals with limited English proficiency in health programs and activities of covered entities. About 25 million individuals in the United States, or about 8.5 percent, have limited proficiency in English.³⁹ These individuals may have been born in other countries or in the United States, such as some Native Americans or children of immigrants.⁴⁰ For purposes of this proposed part, an individual with

limited English proficiency is a person whose primary language for communication is not English and who has a limited ability to read, write, speak, or understand English.

For individuals with limited English proficiency, lack of proficiency in English—and the use of non-English languages—is a direct outgrowth of, and is integrally tied to, their national origins.⁴¹ As the Department of Justice explains, in its role coordinating Federal Departments’ enforcement of Title VI, language serves as an identifier of one’s national origin by “‘permit[ing] an individual to express both the personal identity and membership in a community. . . .’”⁴² OCR’s experience enforcing Title VI further demonstrates that disadvantaging an individual on the basis of his or her limited English proficiency is inextricably linked to discrimination on the basis of national origin.

It is thus well-established under Title VI and its implementing regulation that a prohibition on national origin discrimination requires covered entities to take reasonable steps to provide meaningful access to individuals with limited English proficiency.⁴³ As the Supreme Court recognized 40 years ago, the provision of language assistance services is essential to ensure the equality of opportunity promised by nondiscrimination laws. As the Court

stated in *Lau v. Nichols*, which arose in the context of education,

[T]here is no equality of treatment merely by providing [limited English proficient] students with the same facilities, textbooks, teachers, and curriculum [as their English speaking peers]; for students who do not understand English are effectively foreclosed from any meaningful education. . . . We know that those who do not understand English are certain to find their classroom experiences wholly incomprehensible and in no way meaningful.⁴⁴

Based on these principles, OCR proposes § 92.201 to require covered entities to take reasonable steps to provide meaningful access to health programs and activities for all persons regardless of national origin. Specifically, proposed paragraph (a) of § 92.201 incorporates the Title VI standard, and paragraph (b) identifies requirements for the Director’s evaluation of a covered entity’s compliance with paragraph (a). Proposed paragraph (c) contains requirements for language assistance services, and proposed paragraph (d) includes specific requirements for oral interpretation. Proposed paragraph (e) sets forth restrictions on covered entities’ use of certain persons to interpret for, or facilitate communication with, individuals with limited English proficiency. Proposed paragraph (f) provides that no individual with limited English proficiency shall be required to accept language assistance services. Each paragraph is described further as follows.

General Requirements (§ 92.201(a), (b) and (c))

Proposed § 92.201(a) adopts the well-established principle that covered entities must take reasonable steps to provide meaningful access to health programs and activities for all individuals with limited English proficiency that they serve or encounter in their health programs or activities.⁴⁵ Consistent with our longstanding enforcement of Title VI, we intend the general obligation in paragraph (a) to be a flexible standard that the Director

⁴¹ See, e.g., 29 CFR 1606.1 (defining an individual’s national origin in Equal Employment Opportunity Commission regulations as his or her ancestor’s place of origin and an individual’s “physical, cultural or linguistic characteristics”).

⁴² DOJ Policy Guidance 2000, 65 FR at 50124 & n.8 (citing *Hernandez v. New York*, 500 U.S. 352, 370 (1991) (plurality opinion)). See also 29 CFR 1606.1 (Equal Employment Opportunity Commission’s definition of national origin, which includes an individual’s linguistic characteristics); *Garcia v. Gloor*, 618 F.2d 264, 269 (“To a person who speaks only one tongue or to a person who has difficulty using another language when spoken in his home, language might well be an immutable characteristic. . . .”).

⁴³ See, e.g., HHS LEP Guidance, *supra* n. 17 at 68 FR at 47313 (“[T]he failure of a recipient of [F]ederal financial assistance from HHS to take reasonable steps to provide LEP persons with [a] meaningful opportunity to participate in HHS-funded programs may constitute a violation of Title VI and HHS’s implementing regulations”); Policy Guidance, Title VI Prohibition against National Origin Discrimination As It Affects Persons with Limited English Proficiency, 65 FR 52762, 52765 (August 30, 2000) (explaining the requirement to take reasonable steps to provide meaningful access and to provide the “language assistance services necessary to ensure such access. . . .”). See also E.O. 13166, *Improving Access to Services for Persons with Limited English Proficiency*, (Aug. 11, 2000) (requiring each Federal Department to improve access to Federally assisted programs and activities by persons with limited English proficiency and to implement a system by which individuals with limited English proficiency can meaningfully access the Departments’ Federally conducted programs and activities).

³⁹ U.S. Dep’t of Commerce, U.S. Census Bureau, American FactFinder, Language Spoken at Home by Ability to Speak English for the Population 5 Years and Older, *supra* n. 30 (serving as data source to calculate that 25 million of the 294 million individuals in the United States speak English less than “very well”). OCR chose the three-year ACS data (as opposed to the one-year or five-year data) because it best balances the currency and stability of the data.

⁴⁰ Dep’t of Justice, Enforcement of Title VI of the Civil Rights Act of 1964—National Origin Discrimination Against Persons with Limited English Proficiency; Policy Guidance, 65 FR 50123, 50124 (Aug. 16, 2000) [hereinafter DOJ Policy Guidance, 2000].

⁴⁴ *Lau v. Nichols*, 414 U.S. 563, 566 (1974) (requiring a school district with students with limited English proficiency of Chinese origin to take reasonable steps to provide the students with a meaningful opportunity to participate in Federally funded educational programs).

⁴⁵ The Department’s LEP Guidance provides an in-depth explanation of Title VI’s prohibition against national origin discrimination as it affects limited English proficient populations and how recipients can determine what steps are reasonable to provide all individuals with limited English proficiency meaningful access. HHS LEP Guidance, *supra* n. 17 at 68 FR 47311.

considers in light of the particular facts.⁴⁶

Because it incorporates long-standing principles under Title VI, the standard we propose in paragraph (a) provides familiarity and consistency for covered entities about the scope of their obligations. As we stated in the Department's initial policy guidance released in 2000 on the Title VI prohibition of national origin discrimination with respect to persons with limited English proficiency:

The key to providing meaningful access for LEP persons is to ensure that the recipient/covered entity and LEP person can communicate effectively. The steps taken by a covered entity must ensure that the LEP person is given adequate information, is able to understand the services and benefits available, and is able to receive those for which he or she is eligible. The covered entity must also ensure that the LEP person can effectively communicate the relevant circumstances of his or her situation to the service provider.⁴⁷

Further, the standard balances two core principles critical in effectuating Section 1557's prohibition of national origin discrimination.

The first principle is that the Department must "ensure that [health programs and activities] aimed at the American public do not leave some behind simply because they face challenges communicating in English."⁴⁸ Safe and quality health care requires an exchange of information between health care provider and patient for the purposes of diagnoses, treatment options, the proper use of medications, obtaining informed consent, and insurance coverage of health-related services, among other myriad purposes.⁴⁹ This exchange of information is jeopardized when the provider and the patient speak different languages and may result in adverse health consequences and even death.⁵⁰ Indeed, the provision of health care services, by its "very nature[.], requires the establishment of a close relationship with the client or patient that is based on sympathy, confidence and mutual

trust."⁵¹ Provider-patient communication is essential to the concept of patient centeredness, which is a core component of quality health care and has been shown to improve patients' health and health care.⁵²

The second principle is that the level, type and manner of language assistance services required under paragraph (a) should vary based on the relevant facts, which may include the operations and capacity of the covered entity.

For these reasons, proposed § 92.201(b) identifies how the Director will evaluate whether a covered entity has met the requirement in paragraph (a).⁵³ Proposed § 92.201(b)(1) requires the Director to consider, and give substantial weight to, the nature and importance of the health program or activity, including the particular communication at issue. Proposed § 92.201(b)(2) requires the Director to take other relevant factors into account and lists some of the type of factors that the Director is required to consider, if relevant.

Section 92.201(b)(2)(i) and (ii) identify the length, complexity, and context of the communication as potentially relevant factors in a particular case. Where a communication is particularly long or complex, for example, a covered entity might be required to provide a means for an individual with limited English proficiency to be able to refer back to the information communicated through, for instance, a document written in the individual's primary language or an audio file of the information conveyed orally in the individual's primary language.

The prevalence of the primary language, among those eligible to be served or likely to be encountered by the health program or activity, in which the individual with limited English proficiency communicates, identified in paragraph (b)(2)(iii) of § 92.201, might also be relevant in a particular case. Where an individual with limited English proficiency speaks a language that has a low prevalence among those eligible to be served or likely to be encountered by the health program or activity, the covered entity might, for example and depending on other relevant factors, satisfy its obligations by

providing, rather than a written document translated verbatim, a qualified interpreter who reads the brochure and provides an oral interpretation of the brochure into the non-English language.

The resources available to the covered entity and the costs of language assistance services might also be relevant in a particular case. 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.

Proposed § 92.201(c) 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.⁵⁴ Consistent with the observation in the Department's LEP Guidance that there is no one definition for "timely" that applies to every type of interaction with every type of recipient at all times, a determination of whether language assistance services are timely will depend on the specific circumstances of each case. However, the LEP Guidance makes clear that language assistance is timely when it is provided 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."⁵⁵

Specific Requirements for Interpreter Services § 92.201(d)

Proposed § 92.201(d) addresses standards applicable to oral interpretation. In particular, this paragraph provides that when a covered entity is required by proposed § 92.201(a) to provide oral interpretation as a reasonable step to provide meaningful access to an individual with limited English proficiency, the covered entity must offer that individual a qualified interpreter. As defined in § 92.4, a qualified interpreter for an individual with limited English proficiency possesses certain characteristics and skills necessary for him or her to interpret competently and effectively under the circumstances and

⁴⁶ Under Title VI, OCR investigates each complaint and conducts its compliance reviews on a case-by-case basis and tailors each case resolution to the particular facts of each case. For highlights of OCR's Title VI enforcement specific to the prohibition of national origin discrimination as it affects individuals with limited English proficiency, see Enforcement Success Stories Involving Individuals with Limited English Proficiency, Office for Civil Rights, U. S. Department Of Health And Human Services, <http://www.hhs.gov/ocr/civilrights/activities/examples/LEP/index.html> (last visited Jul. 20, 2015).

⁴⁷ 65 FR at 52765.

⁴⁸ 68 FR at 47312.

⁴⁹ See, e.g., 65 FR at 52763.

⁵⁰ See, e.g., *id.*

⁵¹ *Id.*

⁵² Dep't. of Health & Human Servs., Agency for Health Care Research & Quality, Chapter 6, Patient Centeredness, National Healthcare Quality Report, 2013, available at <http://www.ahrq.gov/research/findings/nhqdr/nhq13/chap6.html>.

⁵³ The Department's LEP Guidance takes a similar approach of identifying the factors that OCR will consider, in determining the extent of a recipient's obligations to individuals with limited English proficiency. See 68 FR 47314–16.

⁵⁴ This principle is consistent with long-standing concepts reflected in the HHS LEP Guidance *supra* n. 17. See 68 FR at 47318, 47323 (with respect to privacy), 47316–19, 47322 (with respect to timeliness), and 47317–20, 47322 (with respect to services free of charge).

⁵⁵ *Id.* at 47316. Additionally, the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care (the National CLAS Standards) also emphasize the importance of timely language assistance.

adheres to generally accepted interpreter ethics principles, including client confidentiality.

Restricted Use of Certain Persons To Interpret or Facilitate Communication § 92.201(e)

Proposed § 92.201(e) identifies restrictions on the use of certain persons to provide language assistance services for an individual with limited English proficiency. This paragraph applies in addition to, and regardless of, the appropriate level, type or manner of language assistance services a covered entity is required to provide. As some RFI commenters shared, the use of incompetent or ad hoc interpreters, such as family members, friends, and children, is not uncommon and can have negative implications. Thus, proposed paragraph (e)(1) of § 92.201 prohibits a covered entity from requiring an individual with limited English proficiency to provide his or her own interpreter. Proposed paragraphs (e)(2)(i) and (ii), however, identify narrow and finite situations in which a covered entity may rely on an adult accompanying an individual with limited English proficiency to interpret. Proposed paragraph (e)(3) prohibits a covered entity from relying on a minor child to interpret or facilitate communication and identifies an exception to this prohibition that is narrower in scope than the exception identified in (e)(2)(i) and (ii).

The provisions of § 92.201(d) and (e) codify standards described in the Department's LEP Guidance regarding the use of family members or friends as interpreters or to facilitate communication.⁵⁶ These standards account for the issues of competency, confidentiality, privacy, and conflict of interest that arise as a result of relying on an informal (or ad hoc) interpreter. The provisions of § 92.201(d) and (e) are consistent with oral interpretation standards that OCR has advanced through its resolution of Title VI cases and compliance reviews.⁵⁷

⁵⁶ HHS LEP Guidance, *supra* n. 17 at 68 FR at 47317–18.

⁵⁷ See, e.g., Voluntary Resolution Agreement between U.S. Dep't of Health & Human Servs., Office for Civil Rights and Mee Memorial Hosp., OCR Transaction Nos. 12–143846, 13–1551016, & 13–153378, pt. II.J. (2014), available at <http://www.hhs.gov/ocr/civilrights/activities/agreements/mee.html> (defining qualified interpreter); Voluntary Resolution Agreement between U.S. Dep't of Health & Human Servs., Office for Civil Rights and Montgomery County Dep't of Soc. Servs., OCR Transaction No. 08–79992, pts. II.E (defining qualifications of an “interpreter” under the agreement), IV.H (requiring timely, competent language assistance); & IV.L (identifying interpreter standards), available at <http://www.hhs.gov/ocr/civilrights/activities/examples/LEP/mcdssra.html>.

In lieu of the approach we propose in § 92.201(d) and (e), OCR considered proposing that all covered entities have the capacity to provide, in their health programs or activities, qualified interpreters for individuals with limited English proficiency through telephonic oral interpretation services available in at least 150 non-English languages. We considered proposing this requirement to ensure that every covered entity could provide a base level of cost-effective language assistance services to the nation's increasingly linguistically diverse populations. This alternate approach, relative to the approach we propose in § 92.201(d) and (e), likely would improve access to health programs and activities for individuals with limited English proficiency; would improve the clarity of covered entities' obligations when communicating orally with individuals; and would mirror the requirement for Health Insurance Marketplaces and qualified health plan issuers to provide telephonic oral interpretation services described further below.⁵⁸

Despite these benefits, we were concerned with proposing an overly prescriptive approach that regulated the manner in which covered entities take reasonable steps to provide meaningful access to individuals with limited English proficiency, given the range in the types, sizes, and service areas of covered entities' health programs and activities regulated by Section 1557 and this proposed rule. We seek comment on what oral interpretation services, if any, we should require and how such approaches appropriately balance the provision of meaningful access to individuals with limited English proficiency while preserving covered entities' flexibilities to identify the means of providing such access.

Even without a requirement in this proposed rule to provide telephonic oral interpretation services, OCR expects that most entities will, at a minimum, have the capacity to provide individuals with limited English proficiency with qualified interpreters remotely, given the widespread commercial availability of relatively low-cost language assistance services such as remote oral interpretation via telephone, as well as the nature and importance of covered entities' health programs or activities.

Acceptance of Language Assistance Services Is Not Required § 92.201(f)

Proposed paragraph (f) provides that no individual with limited English proficiency shall be required to accept language assistance services, consistent

with an individual's right to self-determination. Paragraph (f) also demonstrates the corollary that a covered entity cannot coerce an individual to decline language assistance services. If an individual with LEP voluntarily declines an offer of language assistance services from the covered entity, a covered entity could denote, in the individual's file or records, the language assistance services offered and the declination.⁵⁹

Covered entities, including Health Insurance Marketplaces, Medicaid programs, and qualified health plan issuers, are reminded that independent of proposed § 92.201, they must comply with any applicable language access requirements in other laws and regulations.⁶⁰ For instance, Marketplaces and qualified health plan issuers must provide language assistance services for applicants and enrollees who are limited English proficient,⁶¹ free of charge, including telephonic oral interpretation services in at least 150 non-English languages.⁶² Moreover, under Public Health Service Act Section 2719, as added by the ACA and incorporated by reference into ERISA and the Internal Revenue Code,

⁵⁹ See HHS LEP Guidance, *supra* n. 17 at 68 FR at 47318 (identifying recordkeeping of language assistance services offered in provided as a best practice).

⁶⁰ See, e.g., 42 U.S.C. 18031(e)(3)(B) (requiring health plans seeking certification as qualified health plans to provide information on certain claims payment and rating practices, cost-sharing, and enrollee and participant rights in plain language, which means language that the intended audience, including individuals with limited English proficiency, can readily use and understand); 42 U.S.C. 18031(i)(3)(E) (statutorily requiring Navigators to provide culturally and linguistically appropriate services); 45 CFR 155.210(e)(5) (requiring Navigators to provide culturally and linguistically appropriate services), 42 CFR 431.905 (requiring State agencies providing Medicaid programs to provide language assistance services for applicants and beneficiaries who are limited English proficient).

⁶¹ See, e.g., 45 CFR 155.205(c)(2) (requiring accessibility of information provided to individuals with limited English proficiency); 155.205(a) (requiring Marketplace toll-free call center to be accessible to individuals with limited English proficiency), 155.205(b) (requiring Marketplace Web site to be accessible to individuals with limited English proficiency), 155.205(d) (requiring Marketplace consumer assistance functions, including the Navigator program in 45 CFR 155.210, to be accessible to individuals with limited English proficiency), 155.205(d) (requiring Marketplace outreach and education activities to be accessible to individuals with limited English proficiency), 155.230(b) (requiring applications, forms, and notices to be accessible to individuals with limited English proficiency), 156.250 (requiring meaningful access to qualified health plan information). Starting in benefit year 2017, 45 CFR 155.205(c)(2)(iii) requires Marketplaces and QHP issuers to provide taglines in 15 non-English languages into translate Web site content in certain languages.

⁶² 45 CFR 155.205(c)(2)(i)–(iii).

⁵⁸ See 45 CFR 155.205(c)(2)(i)(A).

non-grandfathered group health plans and health insurance issuers offering non-grandfathered health coverage are required to provide relevant notices in a culturally and linguistically appropriate manner.⁶³ We invite comment on whether and, if so, to what extent and how, the requirements under these different authorities should be harmonized.

Alternative Approaches

Although we believe that the approach of the proposed rule best serves the purposes of the law, we considered a regulatory scheme requiring covered entities to provide meaningful access to each individual with limited English proficiency by providing effective language assistance services, at no cost, unless such action would result in an undue burden or a fundamental alteration of the health program or activity. Under this approach, a covered entity would be able to raise an undue burden or fundamental alteration defense but would be required, if it made this showing successfully, to take another action to provide meaningful access if there was one that was less burdensome or that did not fundamentally alter the nature of the health program or activity.

We also considered a regulatory scheme that would require a predetermined range of language assistance services in certain non-English languages. The language assistance services required and the

languages required would vary based on certain factors, such as whether the covered entity is of a certain type or size, has frequent contact with individuals with limited English proficiency, or operates particularly important health programs or activities, among other potential factors. Under this approach, instead of requiring the Director to evaluate each case on its particular facts, the Director would evaluate a covered entity's compliance based on whether the entity provided the range of language assistance services in the non-English languages specified. Potential categories of covered entities that could have enhanced obligations to provide language assistance services under this alternative approach could include State agencies administering Medicaid or CHIP, Health Insurance Marketplaces, or the Department in its operation of its health programs or activities. Other potential categories could include the following types of covered entities that have a minimum number of beds, employees, or locations: Hospitals, nursing homes or skilled nursing facilities, home health agencies, and retail pharmacies (including mail-order pharmacies). We seek comment on whether certain categories of covered entities should have enhanced obligations to provide language assistance services and, if so, what characteristics of covered entities should define these categories.

We also considered a regulatory scheme requiring covered entities to provide a range of language assistance services in the non-English languages spoken by State-wide populations with limited English proficiency that meet defined thresholds. Such thresholds would provide a minimum number of non-English languages covered entities would be required to provide in delivering oral interpretation services; requirements for written translation of vital documents and Web site content; and requirements for including taglines on vital documents and on Web sites. For instance, we considered thresholds triggering a requirement to translate standardized vital documents based on number of languages (e.g., top ten languages spoken by individuals with limited English proficiency); percentage of language speakers (e.g., languages spoken by at least 5% of individuals with limited English proficiency); the number of language speakers (e.g., languages spoken by at least 5,000 individuals with limited English proficiency); and composite thresholds mixing and matching these approaches. For example, we considered a composite threshold requiring the

translation of standardized vital documents in the top ten languages spoken State-wide by individuals with limited English proficiency and the languages spoken by at least 10,000 individuals with limited English proficiency State-wide. We also considered a composite threshold that would require the translation of vital documents in the top five languages spoken State-wide by individuals with limited English proficiency and the languages spoken by at least 5,000 individuals with limited English proficiency State-wide.

We seek comment on whether OCR should require thresholds, and if so, what thresholds should be required, and to what geographic areas or service areas the thresholds should apply. If thresholds should be required, we seek comment on the time that should be allowed for covered entities to come into compliance with the thresholds, including whether this proposed rule should permit covered entities to implement their obligations with a phased-in approach. We also seek comment on other methodologies for formulating language access thresholds that would result in meaningful access for individuals regardless of national origin, while being mindful of the potential burden on covered entities.

We further considered adopting a requirement for covered entities to be systematically prepared to provide language assistance services in their health programs or activities, such as through the establishment of policies and procedures or through other advanced planning mechanisms. In OCR's experience, covered entities are in a better position to meet their obligations to provide language assistance services in a timely manner to individuals with limited English proficiency 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 with limited English proficiency. Thus, the Department's LEP guidance encourages covered entities to conduct advanced planning through the establishment and implementation of language access plans.⁶⁴

An advanced planning requirement could require each covered entity to identify all resources for providing language assistance services; to annually assess the frequently-encountered or highly prevalent languages in the

⁶³ The Department of Labor, HHS and the Department of Treasury issued interim final rules implementing the Internal Claims and Appeals and External Review Processes under the Public Health Service Act Section 2719, as added by the ACA, which describes the "culturally and linguistically appropriate" standard requirements. See 29 CFR 2590.715–2719(e); 45 CFR 147.135 (e). See also 80 FR 34292, 34310 (June 16, 2015) (Summary of Benefits and Coverage and Uniform Glossary Final Rule), extending the culturally and linguistically appropriate standards set forth in the internal claims and appeals and external review to the requirements of the Summary of Benefits and Coverage and Uniform Glossary requirements. That standard requires language assistance services for individuals who speak primary languages other than English and reside in a county that meets the threshold under the rules. Specifically, the rules establish a threshold with respect to the percentage of people residing in a particular county who are literate only in the same non-English language (currently 10%) based on American Community Survey data published by the United States Census Bureau. See 29 CFR 2590.715–2719(e)(3). For individuals residing in counties that meet this threshold, the plan or issuer must provide oral language assistance services (such as a telephone customer assistance hotline) that include answering questions in any applicable non-English language and providing assistance with filing claims and appeals in any applicable non-English language. The plan or issuer must also provide, upon request, notices in any applicable non-English language and taglines must be included in the English versions of all notices provided to such individuals.

⁶⁴ See HHS LEP Guidance, *supra* n. 17 at 68 FR at 47319–21 (encouraging recipients to develop a language access plan (called an "LEP plan" in the guidance)).

service area of the health program or activity; to establish written procedures to which frontline staff could refer when encountering individuals with limited English proficiency; and to monitor and oversee the quality of language assistance services provided. An advanced planning requirement could also require each covered entity to build its inventory of translated materials and capacity to provide oral language assistance to meet the needs of the national origin populations that the entity frequently serves.

OCR solicited information in its Request for Information about covered entities' experience with one mechanism for advanced planning—developing and implementing language access plans. Nearly all of the commenters who responded to the question regarding language access plans had experience developing and implementing plans themselves or providing technical assistance to other organizations that were doing so. Commenters identified benefits, such as: Increasing the likelihood of ensuring nondiscrimination on the basis of national origin with respect to individuals with LEP; facilitating consistent and appropriate language assistance services; and defining clear staff obligations and roles. Most commenters who responded to this question described language access plans or the institution of organizational policies and procedures as simple and non-burdensome. We seek comment on whether § 92.201 should include a requirement for covered entities to be systematically prepared to provide language assistance services in their health programs or activities, and if so what advanced planning mechanisms should be required and why.

Covered entities that are already developing or implementing language access plans, or otherwise assessing their language assistance needs, are encouraged to continue such efforts. Covered entities should be aware, however, that engaging in such planning is not a defense for failing to provide language assistance services to any particular individual, at all or in an untimely manner, if such services are reasonable steps to provide meaningful access. Covered entities that are conducting advanced planning should consider how they can ensure that language assistance services are available in their health programs and activities as they simultaneously improve their operational capacities to provide effective language assistance services into the future.

Effective Communication for Individuals With Disabilities (§ 92.202)

Proposed § 92.202 incorporates the provisions governing effective communication with individuals with disabilities found in the regulation implementing Title II of the ADA, which applies to State and local government entities.⁶⁵ OCR typically looks to the ADA for guidance in interpreting Section 504 as the two laws contain very similar standards. The Title II implementing regulation and the regulation implementing Title III of the ADA, which applies to places of public accommodation and commercial facilities, were amended in 2010. The updated regulations provide clear, specific, and current guidance in understanding rights and responsibilities respecting effective communication with individuals with disabilities.

The amended regulations incorporate longstanding Department of Justice interpretations regarding effective communication with individuals with disabilities under the ADA, which are consistent with OCR's enforcement of Section 504 and are a sound set of standards for incorporation into the Section 1557 regulation.

OCR considered whether to incorporate the standards in the regulation implementing Title II of the ADA or in the regulation implementing Title III of the ADA, or the standards in both regulations. As summarized by the Department of Justice,⁶⁶ standards regarding effective communication under both regulations are very similar. There are, however, limited differences between the Title II and Title III regulations, regarding limitations on the duty to provide a particular aid or service and the obligation under the Title II regulation to give primary consideration to the choice of an aid or service requested by the individual with a disability.

OCR proposes to apply the Title II standards to entities covered under the proposed rule. First, State or local government entities that are covered under the proposed rule are already subject to the Title II standards. Second, the other entities covered under the proposed rule are health programs and activities that either receive Federal financial assistance from HHS or are conducted directly by HHS. Although OCR could apply Title II standards to

States and local entities and Title III standards to private entities, we believe it is appropriate to hold all recipients of Federal financial assistance from HHS to the higher Title II standards as a condition of their receipt of that assistance. OCR also believes it appropriate to hold HHS itself to the same standards to which the Department subjects the recipients of its financial assistance.

Where the regulatory provisions referenced in § 92.202 use the term "public entity," that term shall be replaced with "covered entity."

Accessibility Standards for Buildings and Facilities (§ 92.203)

The Section 504 regulatory provisions incorporated into Subpart B in this proposed regulation contain program accessibility requirements that apply to existing facilities as well as new construction and alterations. This proposed provision establishes specific accessibility standards for new construction and alterations. OCR notes that these standards are consistent with existing standards under the ADA.

Under § 92.203(a) of the proposed rule, each 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 shall comply with the 2010 ADA Standards for Accessible Design (2010 Standards), as defined in 28 CFR 35.104, if construction or alteration was commenced on or after [18 MONTHS FROM DATE OF PUBLICATION OF FINAL RULE]. All newly constructed or altered buildings or facilities subject to this section shall comply with the requirements for a "public building or facility" as defined in Section 106.5 of the 2010 Standards.

Under § 92.101(b)(2)(i) of the proposed rule, new construction and alterations of such facilities are also subject to the new construction standards found in the Section 504 implementing regulation at 45 CFR 84.23(a) and (b). OCR is not incorporating 45 CFR 84.23(c), which treats compliance with the Uniform Federal Accessibility Standards as compliance with 45 CFR 84.23(a) and (b) because the 2010 Standards are more current than the Uniform Federal Accessibility Standards. Moreover, nearly all of the facilities covered under the proposed rule are already subject to the 2010 Standards. This provision will require facilities subject to the ADA and Section 1557 to comply with the same accessibility standards for new construction or alterations.

⁶⁵ Comments received during the RFI period illustrate that, despite longstanding existing Federal civil rights laws, individuals with disabilities continue to face inequality and discrimination in health care.

⁶⁶ <http://www.ada.gov/effective-comm.htm>.

However, under § 92.203(b) of the proposed rule, each 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 before [18 MONTHS FROM DATE OF PUBLICATION OF FINAL RULE] in conformance with the Uniform Federal Accessibility Standards, the 1991 Standards, or the 2010 Standards shall be deemed to comply with the requirements of this section and with 45 CFR 84.23 (a) and (b), cross referenced in § 92.101(b)(2)(i) with respect to those facilities. Thus, if the construction or alteration of facilities began prior to the effective date of paragraph (a) of this section, the facilities shall be deemed in compliance if they were constructed or altered in conformance with applicable standards at the time of their construction or alteration.

Under § 92.203(c) of the proposed rule, each building or part of a building that is constructed or altered by or on behalf of, or for the use of, the Department must be designed, constructed, or altered so as to be readily accessible to and usable by individuals with disabilities. The definitions, requirements, and standards of the Architectural Barriers Act, as established in Appendices C and D to 36 CFR part 1191, apply to buildings and facilities covered by this section.

OCR considered adding specific language regarding accessibility standards for medical diagnostic equipment. However, we are aware that the United States Access Board is currently developing standards for accessible medical diagnostic equipment and, therefore, are deferring on proposing specific accessibility standards for medical equipment at this time. Once the United States Access Board standards are promulgated, OCR intends to issue regulations or policies that require covered entities to conform to those standards. We request comment on this proposal. We note that a health program or activity's use of medical diagnostic equipment is covered by Section 1557 and this proposed rule under the general prohibition of discrimination on the basis of disability in § 92.101.

Accessibility of Electronic and Information Technology (§ 92.204)

Section 92.204(a) of the proposed rule requires covered entities to ensure that their health programs or activities provided through electronic and information technology are accessible to individuals with disabilities, unless doing so would impose undue financial

and administrative burdens or would result in a fundamental alteration in the nature of an entity's health program or activity.⁶⁷ For example, a Health Insurance Marketplace creating a Web site for application for health insurance coverage must ensure that individuals with disabilities have an equal opportunity to benefit from the Web site's tool that allows comparison of health insurance coverage options, quick determination of eligibility, and facilitation of timely access to health insurance coverage by making its new Web site accessible to individuals who are blind or who have low vision.

This provision is consistent with existing standards applicable to covered entities. Specifically, Section 508 of the Rehabilitation Act requires that electronic and information technology developed, procured, maintained, or used by Federal agencies be accessible for individuals with disabilities. Section 508 applies to HHS administered health programs or activities, including the Federally-facilitated Marketplaces. Section 504 and the ADA, which apply to recipients of Federal financial assistance, and to State and local government entities and places of public accommodation, respectively, similarly have been interpreted to require that covered entities' programs, services, and benefits provided through electronic and information technology be accessible to individuals with disabilities.⁶⁸

Section 92.204(b) proposes to require State-based Marketplaces and recipients of Federal financial assistance to ensure that their health programs and activities provided through Web sites comply with the accessibility requirements of Title II of the ADA. OCR has decided to adopt Title II requirements for a number of reasons. First, State-based Marketplaces, as State entities, are already subject to the ADA Title II requirements. Second, even though recipients of Federal financial assistance from HHS include both entities covered by Title II of the ADA, as State and local government entities, and entities covered by Title III of the ADA, as places of public accommodation and commercial facilities, we believe it is appropriate to apply one uniform standard to all recipients of Federal

financial assistance from HHS under the proposed rule. Further, it is reasonable to hold recipients of Federal financial assistance from HHS to the Title II ADA requirements (rather than those of Title III of the ADA), since Title II is modeled on Section 504, which applies to recipients of Federal financial assistance. Our proposed regulatory text cross-references the Title II regulations as a whole, which would therefore incorporate any future changes to the Title II regulations.

These requirements are informed by this Department's extensive experience with web-based technology through Federal grant-making programs, including programs that provide funds for State infrastructure changes to allow electronic applications for participation in the Medicaid program and the Health Insurance Marketplaces, provider adoption of electronic health records, and the development of web-based curricula for health care professionals.

Based on the Department's prior experience in this field, we believe that including an explicit requirement for electronic and information technology is necessary to clarify the obligations of covered entities to make this technology accessible. In addition, we are concerned that without an 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. The RFI yielded numerous comments and concerns about the lack of accessibility of electronic and information technology and the incidents of and potential for discrimination, for example with respect to health information.

OCR initially considered whether to limit the explicit accessibility requirements to a covered entity's Web site only, rather than all of a covered entity's electronic and information technology. However, given the existing requirements under Section 504, Section 508, and the ADA applicable to information provided through electronic and information technology as a whole, and given the importance of such technologies, such as kiosks and applications, to access to health care, health-related insurance and other health-related coverage, we have decided to include an explicit accessibility requirement that applies to all of a covered entity's electronic and information technology. We seek comment on this proposal.

⁶⁷ The terms "undue financial and administrative burdens" and "fundamental alteration" as used in this part have the same meaning that they have under the ADA.

⁶⁸ See, e.g., discussion in Dep't of Justice, Advanced Notice of Proposed Rulemaking: Accessibility of Web Information and Services of State and Local Government Entities and Public Accommodations, 75 FR 43460, 43462–67 (Jul. 26, 2010) discussing Section 504 and Title II of the ADA).

In addition to proposing that Web sites of recipients of Federal financial assistance and State-based Marketplaces comply with the accessibility requirements of Title II of the ADA, OCR also considered requiring all covered entities to ensure that all their electronic and information technology comply with specific accessibility standards, such as standards developed pursuant to Section 508 by the Access Board at 36 CFR part 1194, the Worldwide Web Consortium's Web Accessibility Initiative's WCAG 2.0 AA, or other standards that provide equal or greater accessibility to individuals with disabilities. As part of this alternative, OCR considered whether a phased-in approach to accessibility similar to the one recently taken by the Department of Transportation might be appropriate.⁶⁹ Most States already apply, to State agency Web sites, a standard based on Section 508 or WCAG, thereby reducing any regulatory burden from such a requirement.⁷⁰ In addition, obligating covered entities to make their electronic information and technology comply with the accessibility requirements of Title II of the ADA should facilitate their compliance with any accessibility standards adopted in the future. Further, the Department of Justice is applying WCAG standards to municipal and public accommodations entities in publicly announced settlements.⁷¹ Finally, this alternative would provide more clarity for those covered entities and enhance access for individuals with disabilities.

However, this alternative could potentially place a greater burden on recipients of Federal financial assistance and Title I entities. In addition, we are

aware that the Access Board is in the process of amending and updating the Section 508 standards applicable to electronic and information technology. Given these developments and circumstances, we are proposing a general accessibility performance standard for electronic and information technology, rather than a requirement for conformance to a specific set of accessibility standards. The application of this general accessibility performance standard will be informed by future rulemaking by the Access Board and the Department of Justice. We seek comment on whether the regulation should impose a general accessibility performance standard for electronic and information technology or require that electronic and information technology comply with a specific set of standards, such as the Section 508 or WCAG standards.

As noted, under the proposed rule, covered entities must make their health programs and activities provided through electronic and information technology accessible, unless doing so would impose undue financial and administrative burdens or would result in a fundamental alteration in the nature of the health program or activity. In 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.

When undue financial and administrative burdens or a fundamental alteration are determined to exist, the covered entity is still required to provide information in a format other than an accessible 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.

Requirement To Make Reasonable Modifications (§ 92.205)

Section 92.205 of the proposed rule provides that a covered entity shall make reasonable modifications in policies, practices, or procedures when necessary to avoid discrimination on the basis of disability, unless the covered entity can demonstrate that the modification would fundamentally alter the nature of the health program or activity. This provision is consistent with the U.S. Supreme Court's decision interpreting Section 504 in *Alexander v. Choate*, 469 U.S. 287 (1985), Title II of

the ADA, and OCR's longstanding interpretation of Section 504.

Equal Program Access on the Basis of Sex (§ 92.206)

Section 92.206 proposes that covered entities be required to provide individuals equal access to their health programs or activities without discrimination on the basis of sex and proposes that covered entities treat individuals consistent with their gender identity. This provision applies to all health programs and activities, and prohibits, among other forms of adverse treatment, the denial of access to facilities administered by the covered entity. This proposed approach is consistent with the principle that discrimination on the basis of sex includes discrimination on the basis of gender identity and that failure to treat individuals in accordance with their gender identity may constitute prohibited discrimination. It is also consistent with recent guidance issued and enforcement actions taken by the U.S. Department of Education, the U.S. Department of Justice, and the Equal Employment Opportunity Commission.⁷²

The limited exception to the requirement that covered entities treat individuals consistent with their gender identity is that a covered entity may not deny or limit health services that are ordinarily or exclusively available to individuals of one gender based on the fact that the individual's sex assigned at birth, gender identity, or gender otherwise recorded in a medical record or by a health insurance plan is different from the one to which such health services are ordinarily or exclusively available. The exception applies only in limited circumstances. For example, a covered entity may not deny an individual treatment for ovarian cancer where the individual could benefit medically from the treatment, based on the individual's identification as a transgender male.

⁷² See, e.g., U.S. Dep't of Educ., Questions and Answers on Title IX and Single-Sex Elementary and Secondary Classes and Extracurricular Activities (2014); U.S. Dep't of Justice, Office of Justice Programs, Office for Civil Rights, Frequently Asked Questions, Nondiscrimination Grant Condition in the Violence Against Women Reauthorization Act of 2013 (2014); Resolution Agreement Between the Arcadia Unified School District, the U.S. Dep't of Educ., Office for Civil Rights, and the U.S. Dep't of Justice, Civil Rights Division, OCR Case Number 09-12-1020, DOJ Case Number 169-12C-70 (July 24, 2013); *Complainant v. McHugh*, EEOC Appeal No. 0120133395 (Apr. 1, 2015). See also U.S. Dep't of Educ., Questions and Answers on Title IX and Sexual Violence at B-2, available at <http://www2.ed.gov/about/offices/list/ocr/docs/qa-201404-title-ix.pdf>.

⁶⁹ See Nondiscrimination on the Basis of Disability in Air Travel: Accessibility of Web sites and Automated Kiosks at U.S. Airports, 76 FR 59307 (Sept. 26, 2011).

⁷⁰ The following states apply WCAG 2.0 (AA) to State agency Web sites: Alaska (<http://doa.alaska.gov/ada/resources/web.html>) (note that Alaska's standard for training, authoring, and procurement of accessible electronic and information technology is currently consistent with Level A Success Criteria and Conformance Requirements and Alaska is migrating toward WCAG 2.0 AA compliance as tools, training and resources permit; Georgia (<http://georgia.gov/accessibility>); Hawaii (<https://portal.hawaii.gov/page/accessibility/>); Minnesota (mn.gov/mnrit/images/Std_State_Accessibility.pdf); Virginia and Oklahoma have statutory requirements to apply Section 508 to State agencies (<http://section508.gov/state-policy>), and many others have adopted similar policies (<http://www.ssbartgroup.com/reference/laws-and-standards/state-and-local-laws/>). In addition, States may utilize third party test software programs, which may utilize a Section 508/WCAG or a higher standard, to determine the accessibility of its Web sites.

⁷¹ ADA Enforcement Activities—Settlements (Department of Justice) http://www.ada.gov/enforce_activities.htm#settlements.

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

Section 92.207 of the proposed rule emphasizes and provides specific details regarding the prohibition of discrimination on the basis of race, color, national origin, sex, age, or disability in the provision and administration of health-related insurance or other health-related coverage. This prohibition applies to all covered entities that provide or administer health-related insurance or other health-related coverage, including health insurance issuers and group health plans that are recipients of Federal financial assistance and the Department in the administration of its health-related coverage programs. This section is independent of, but complements, the nondiscrimination provisions at 45 CFR 155.120(c)(1) and (2) that apply to the Health Insurance Marketplaces and 45 CFR 156.200(e) that apply to issuers of qualified health plans through the Health Insurance Marketplaces with respect to their qualified health plans. These provisions prohibit discrimination on the basis of race, color, national origin, disability, age, sex, gender identity or sexual orientation, and entities covered under them and Section 1557 are obligated to comply with both sets of requirements.

Based on the longstanding civil rights principles discussed in connection with the definition of “health program or activity” in § 92.4 of this proposed rule, we propose to apply this part to all issuers that receive Federal financial assistance, whether those issuers’ products are offered through the Marketplace, outside the Marketplace, in the individual or group health insurance markets, or as an employee health benefit program through an employer-sponsored group health plan. Thus, for example, an issuer that participates in the Marketplace and thereby receives Federal financial assistance, and that also offers plans outside the Marketplace, will be covered by the proposed regulation for all of its health plans, as well as when it acts as a third party administrator for an employer-sponsored group health plan.⁷³

Paragraph (a) of the proposed rule provides a general nondiscrimination requirement, and paragraph (b) provides specific examples of prohibited actions.

Paragraphs (b)(1) and (2) address the prohibition on denying, cancelling, limiting, or refusing to issue or renew a health-related insurance plan or policy or other health-related coverage on the basis of an enrollee’s or prospective enrollee’s race, color, national origin, sex, age, or disability, and the use of marketing practices or benefit designs that discriminate on these bases.

The proposed rule does not require plans to cover any particular benefit or service, but a covered entity cannot have a coverage policy that operates in a discriminatory manner. For example, a plan that covers inpatient treatment for eating disorders in men but not women would not be in compliance with the prohibition of discrimination based on sex. Similarly, a plan that covers bariatric surgery in adults, but excludes such coverage for adults with particular developmental disabilities would not be in compliance with the prohibition on discrimination based on disability.

Paragraphs (b)(3) through (5) of the proposed rule specifically address discrimination faced by transgender individuals in accessing coverage of health services. We propose in paragraph (b)(3) that to deny or limit coverage, deny a claim, or impose additional cost sharing or other limitations or restrictions, on any health service is impermissible discrimination when the denial or limitation is due to the fact that the individual’s sex assigned at birth, gender identity, or gender otherwise recorded by the plan or issuer is different from the one to which such services are ordinarily or exclusively available.⁷⁴ For example, although many sex-specific preventive care services (e.g. pelvic or prostate exams or mammograms) are routinely covered by covered entities, RFI commenters stated that individuals are routinely denied coverage for medically appropriate sex-specific health services due to their gender identity or because they are enrolled in their health plans as one sex, where the health service is generally associated with another sex. Under our proposed rule, coverage for medically appropriate health services must be made available on the same terms for all individuals, regardless of sex assigned at birth, gender identity, or recorded gender. Thus, for example, coverage cannot be denied for an individual for whom a pelvic exam is medically appropriate based on the fact that the individual either identifies as a

transgender man or is enrolled in the health plan as a man.⁷⁵

In addition, many health-related insurance plans or other health-related coverage, including Medicaid programs, currently have explicit exclusions of coverage for all care for beneficiaries related to gender dysphoria or associated with gender transition. Historically, covered entities have justified these blanket exclusions by categorizing transition-related treatment as cosmetic or experimental.⁷⁶ However, such across-the-board categorization is now recognized as outdated and not based on current standards of care. For example, a May 2013 decision of the HHS Departmental Appeals Board invalidated Medicare’s National Coverage Determination 140.3, which disallowed coverage of “transsexual surgery” because the record indicated that the blanket denial of coverage was not reasonably based on the state of current medical science.⁷⁷

For similar reasons, an increasing number of states, including, California,⁷⁸ Colorado,⁷⁹ Connecticut,⁸⁰ Illinois,⁸¹ Massachusetts,⁸² Nevada,⁸³

⁷⁵ OCR recognizes that insurers may use computer systems, that at times, flag a gender mismatch for services requested; such flagging, by itself, would not be impermissible where it does not result in a denial of services or a claim for services.

⁷⁶ Liza Khan, *Transgender Health at the Crossroads*, 11 Yale J. Health Pol’y L. & Ethics 375,377 (2011).

⁷⁷ U.S. Dep’t of Health and Human Serv. Departmental Appeals Board. Appellate Division NCD 140.3, Docket No. A–13–87, Decision No. 2576 (May 30, 2013). The board cited to the World Professional Association for Transgender Health (WPATH), an international multidisciplinary professional association that publishes Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People (7th ed. 2012), which provides clinical guidance for health professionals.

⁷⁸ State of California Department of Managed Health Care. (2013). Gender Nondiscrimination Requirements, Letter No. 12–K, available at <https://www.dmh.ca.gov/Portals/0/LawsAndRegulations/DirectorsLettersAndOpinions/dl12k.pdf>.

⁷⁹ Colorado Department of Regulatory Agencies. (2013). Division of Insurance Bulletin No. B–4.49, available at <http://www.one-colorado.org/wp-content/uploads/2013/03/B-4.49.pdf>.

⁸⁰ Connecticut Insurance Department. (2013). Bulletin IC–34, available at http://www.ct.gov/cid/lib/cid/Bulletin_IC-37_Gender_Identity_Nondiscrimination_Requirements.pdf.

⁸¹ Illinois Division of Insurance. (2014). Company Bulletin 2014–10, available at <http://insurance.illinois.gov/cb/2014/CB2014-10.pdf>.

⁸² Massachusetts Office of Consumer Affairs and Business Regulation. (2014). Division of Insurance Bulletin 2014–03, available at <http://www.mass.gov/ocabr/docs/doi/legal-hearings/bulletin-201403.pdf>.

⁸³ Nevada Division of Insurance. (2015). 15–002—Prohibition of Denial, Exclusion, or Limitation of Medically Necessary Health Care Services on the Basis of Gender Identity or Expression, available at http://doi.nv.gov/uploadedFiles/doinvgov/_public-documents/News-Notices/Bulletins/Bulletin%2015-002.pdf.

⁷³ Where an entity that acts as a third party administrator for an employer’s employee health benefit plan is legally separate from an issuer that receives Federal financial assistance for its insurance plans, we will engage in a case-by-case inquiry to evaluate whether that entity is appropriately subject to Section 1557.

⁷⁴ Under Section 207(a), a covered entity would be barred from denying coverage of any claim (not just for sex-specific services) on the basis that the enrollee is transgender.

New York,⁸⁴ Oregon,⁸⁵ Vermont,⁸⁶ Washington State,⁸⁷ and the District of Columbia,⁸⁸ have laws and policies providing that exclusions and denials of coverage for treatment for gender identity disorder are or are likely to be discriminatory in at least some circumstances.⁸⁹ Likewise, the Office of Personnel Management issued a letter on June 23, 2015, to health insurance carriers participating in the Federal Employees Health Benefits Program indicating that “no [such] carrier may have a general exclusion of services, drugs or supplies related to gender transition or ‘sex transformations.’”⁹⁰ Additionally, a significant number of public and private employers are offering coverage to employees that includes coverage for transition-related services.⁹¹

OCR proposes to apply basic nondiscrimination principles in evaluating whether a covered entity’s denial of a claim for coverage of treatment related to transition-related care is the product of discrimination. Based on these principles, an explicit, categorical (or automatic) exclusion of coverage for all health services related to gender transition is unlawful on its face under paragraph (b)(4); in singling out the entire category of services and treatments for transition-related care, such an exclusion systematically denies

services and treatments for transgender individuals and is prohibited discrimination on the basis of sex.

Moreover, we propose in § 92.207(b)(5) to bar a covered entity from denying or limiting coverage, or denying a claim for coverage, for specific health services related to gender transition where such a denial or limitation results in discrimination against a transgender individual. In evaluating whether it is discriminatory to deny or limit a request for coverage of a particular service for an individual seeking the service as part of transition-related care, OCR will start by inquiring whether and to what extent coverage is available when the same service is not related to gender transition. If, for example, a health plan or State Medicaid agency denies a claim for coverage of a hysterectomy that a patient’s provider says is medically necessary to treat gender dysphoria, OCR will evaluate the extent of the plan’s coverage of hysterectomies under other circumstances. OCR will also carefully scrutinize whether the covered entity’s explanation for the denial or limitation of coverage for transition-related care is legitimate and not a pretext for discrimination.

These provisions do not, however, affirmatively require covered entities to cover any particular procedure or treatment for transition-related care; nor do they preclude a covered entity from applying neutral standards that govern the circumstances in which it will offer coverage to all its enrollees in a nondiscriminatory manner.

We invite comment as to whether the approach of § 92.207(b)(1)–(5) is over or under inclusive of the types of potentially discriminatory claim denials experienced by transgender individuals in their attempts to access coverage and care, as well as on how nondiscrimination principles apply in this context.

Paragraph (c) of § 92.207 provides that 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. Paragraph (d) of the proposed rule provides that nothing in § 92.207 is intended to determine, or restrict a covered entity from determining, whether a particular health care service is medically necessary or otherwise meets applicable coverage requirements in any individual case.

Employer Liability for Discrimination in Employee Health Benefit Programs (§ 92.208)

Proposed Section 92.208 addresses the application of Section 1557 to

employers that offer health benefit programs to their employees. Under our proposed approach, where an entity that receives Federal financial assistance provides an employee health benefit program to its employees, it will be liable for discrimination in that employee health benefit program under this part only in the following circumstances:

(a) The entity is principally engaged in providing or administering health services or health insurance coverage;

(b) The entity receives Federal financial assistance the primary objective of which is to fund the entity’s employee health benefit program; or

(c) The entity is not principally engaged in providing or administering health services or health insurance coverage but operates a health program or activity (which is not an employee health benefit program) that receives Federal financial assistance; except that in such cases, the entity is accountable under this part with regard to the provision or administration of employee health benefits only to the employees in that health program or activity.

Under § 92.208(a) of the proposed rule, where an employer is principally engaged in providing or administering health services or health coverage and receives Federal financial assistance, the employer will be subject to Section 1557 in its provision or administration of employee health benefit programs to its employees. Thus, if a hospital provides health benefits to its employees, it will be covered by Section 1557 not only for the services it offers to its patients or other beneficiaries but also for the health benefits it provides to its employees.⁹²

Under proposed § 92.208(b), where an entity receives Federal financial assistance the primary objective of which is to fund an employee health benefit program, that entity’s provision or administration of the health benefit program will be covered by Section 1557 regardless of the business in which the entity is engaged. Where, for example, an entity receives Federal financial assistance that is specifically designated to support its employee wellness program, this part will apply to the entity’s administration of that wellness program.

Proposed § 92.208(c) seeks to clarify that an employer that is not principally

⁹² This approach is consistent with the basic principle underlying the proposed rule and derived from longstanding civil rights interpretations: where an entity that receives Federal financial assistance is principally engaged in providing or administering health services or health insurance coverage, all of its operations will be covered by Section 1557.

⁸⁴ New York State Department of Financial Services. (2014). Insurance Circular Letter No. 7, available at http://www.dfs.ny.gov/insurance/circular/2014/cl2014_07.pdf.

⁸⁵ Oregon Department of Consumer and Business Services. (2012). Insurance Division Bulletin INS 2012–1, available at <http://www.oregon.gov/DCBS/insurance/legal/bulletins/Documents/bulletin2012-01.pdf>.

⁸⁶ Vermont Department of Financial Regulation. (2014). Division of Insurance Bulletin No. 174, available at http://www.dfr.vermont.gov/sites/default/files/Bulletin_174.pdf.

⁸⁷ Washington Office of Insurance Commissioner. (2014). Letter to Health Insurance Carriers in Washington State, available at <http://www.insurance.wa.gov/about-oic/newsroom/news/2014/documents/gender-identity-discrimination-letter.pdf>.

⁸⁸ District of Columbia Department of Insurance, Securities, and Banking. (2014). Bulletin 13–IB–01–30/15 (Revised), available at <http://www.insurance.wa.gov/about-oic/newsroom/news/2014/documents/gender-identity-discrimination-letter.pdf>.

⁸⁹ <http://www.transhealthcare.org/states-that-have-banned-anti-transgender-discrimination-in-health-insurance/>.

⁹⁰ U.S. Office of Personnel Management. FEHB Program Carrier Letter, Letter No. 2015–12 (Jun. 23, 2015), available at <http://transequality.org/sites/default/files/images/blog/FEHB%20CL%202015-12%20Covered%20Benefits%20for%20Gender%20Transition%20Services.pdf>.

⁹¹ Kellan Baker & Andrew Cray, Center for American Progress, FAQ: Health Insurance Needs for Transgender Americans (Oct. 12, 2013), available at <http://www.americanprogress.org/issues/lgbt/report/2012/10/03/40334/faq-health-insurance-needs-for-transgender-americans/>.

engaged in providing or administering health services or health insurance coverage, but that operates a health program or activity (that is not an employee health benefit program) that receives Federal financial assistance will be covered by this part for its provision or administration of an employee health benefit program, but only with regard to employees in the health program or activity. Thus, when a State receives Federal financial assistance for its Medicaid program, the State is governed by Section 1557 in the provision of employee health benefits for its Medicaid employees, but not for its transportation department employees, assuming no part of the State transportation department operates a health program or activity.

In summary, unless the primary purpose of the Federal financial assistance is to fund employee health benefits, we propose to not apply Section 1557 to an employer's provision of employee health benefits where the provision of those benefits is the only health program or activity operated by the employer. If, for example, a community organization that exclusively offers a legal clinic receives Federal financial assistance, and the organization uses grant funds to support personnel costs, including employee health benefits, Section 1557 would not apply to the organization's provision of employee health benefits.⁹³

Absent the limitations this rule proposes in § 92.208, employers that receive Federal financial assistance for any purpose could be held liable for discrimination in the employee health benefit programs they provide or administer, where those employers are not otherwise engaged in a health program or activity and where the use of Federal funds for employee health benefits is merely incidental to the purpose of the assistance. We believe that claims of discrimination in such benefits, brought against employers that do not operate other health programs or activities, are better addressed under other applicable laws.

We propose to apply the same analysis of employer liability under Section 1557 whether the employee health benefit program is self-insured or

fully-insured by the employer. Where an employer that would otherwise be covered under this section creates a separate legal entity to administer its employee health benefit plan, the employer continues to be liable for the nondiscriminatory provision of employee health benefits to its employees; the employer, as a recipient, may not, through contractual or other arrangements, discriminate on a prohibited basis against its employees.⁹⁴

Nondiscrimination on the Basis of Association (§ 92.209)

Section 92.209 of the proposed rule specifically addresses discrimination faced by an individual or an entity 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 is believed to have a relationship or association. The language of Section 1557 makes clear that individuals may not be subject to any form of discrimination "on the grounds prohibited by" Title VI and other civil rights laws; the statute does not restrict that prohibition to discrimination based on the individual's own race, color, national origin, age, disability or sex. Further, a prohibition on associational discrimination is consistent with longstanding interpretations of existing civil rights laws that prohibit discrimination on identified bases, whether the basis is a characteristic of the harmed individual or an individual who is associated with the harmed individual.⁹⁵ A prohibition

⁹⁴ With regard to the liability of the legal entity that an employer creates to administer its employee benefit plan, by contrast, we propose to analyze questions related to the application of Section 1557 to the issuer or group health plan on a case by case basis consistent with longstanding principles of nondiscrimination law. We will ask, for example, whether the plan itself receives Federal financial assistance, such as through receipt of Medicare Part D payments. If it does not, we will evaluate the plan's relationship with the employer in assessing whether Section 1557 applies to the plan.

⁹⁵ See *McGinest v. GTE Service Corp.*, 360 F.3d 1103, 1118 (9th Cir. 2004) (case involving indirect comments in the workplace that crossed racial lines, noting that "Title VII has . . . been held to protect against adverse employment actions taken because of the employee's close association with black friends or coworkers"); (internal citations omitted); *Tetro v. Elliot Popham Pontiac, Oldsmobile, Buick & GMC Trucks Inc.*, 173 F.3d 988, 994–95 (6th Cir. 1999) (holding that white plaintiff with biracial child stated a claim under Title VII based on his own race "even though the root animus for the discrimination is a prejudice against the biracial child"); *Parr v. Woodmen of the World Life Ins.*, 791 F.2d 888, 892 (11th Cir. 1986) ("Where a plaintiff claims discrimination based upon an interracial marriage or association, he alleges by definition that he has been discriminated against because of his race."); *Arceneaux v. Vanderbilt University*, 25 Fed. Appx. 345 (6th Cir. 2001) (unpub'd) (treating sex discrimination as associational discrimination).

on associational discrimination is also consistent with the approach taken in the ADA, which includes a specific prohibition of discrimination based on association with an individual with a disability.⁹⁶

Associational discrimination prohibited by this rule can arise in multiple contexts. For example, a primary care physician could not refuse to accept a new patient because the physician disapproves of this individual's family relationships; *i.e.*, because of the race, color, national origin, age, sex, or disability-status of one or more of the patient's family members. This refusal is impermissible associational discrimination because it is on grounds prohibited by Section 1557. That is, if the patient's family member(s) was not of a particular race, color, national origin, age, sex, or disability-status, the individual would have been accepted as a new patient.

Similarly, a physician could not deny a medical appointment to a patient who is an individual without a disability on the basis that the patient will be accompanied by a family member who is deaf and who will require a sign language interpreter; § 92.202 of this proposed rule requires effective communication with individuals with disabilities, including companions with disabilities, and denying an appointment based on the patient's association with an individual with a disability who needs an interpreter thus would constitute associational discrimination based on disability.⁹⁷

Subpart D—Procedures

Enforcement Mechanisms (§ 92.301)

This proposed section restates the language of Section 1557 regarding enforcement, which provides that the enforcement mechanisms under Title VI, Title IX, the Age Act, or Section 504 apply for violations of Section 1557. These existing enforcement mechanisms include requiring covered entities to

⁹⁶ 42 U.S.C. 12182(b)(1)(E). See also *Loeffler v. Staten Island Univ. Hosp.*, 582 F.3d 268, 279 (2d Cir. 2009) (permitting associational discrimination claim under Section 504); *Falls v. Prince George's Hosp. Ctr.*, No. 97–1545, 1999 U.S. Dist. LEXIS 22551 (D. Md.1999) (holding that parent had an associational discrimination claim under Title III of the ADA because hospital directly discriminated against parent by requiring hearing parent to act as interpreter for child who was deaf). See generally http://www.eeoc.gov/facts/association_ada.html.

⁹⁷ Thus, pursuant to § 92.202, when a patient's companion, such as a family member or friend, is an appropriate person with whom the provider should communicate under the circumstances, the provider must provide auxiliary aids and services to a deaf or hard of hearing companion to ensure that communication with that individual is as effective as it would be with a companion who is not deaf or hard of hearing.

⁹³ Health insurance issuers whose products are offered by an employer through its employee health benefit plans would continue to be covered under the standards set forth in Section 92.207: where an issuer receives Federal financial assistance, its operation of all of its health plans, whether offered through the Marketplace, the individual or group health insurance markets, or employee benefit plans, will be covered under this part. This analysis is independent of the analysis in proposed Section 92.208 of the employer's liability for discrimination in the employee benefit plans that it sponsors.

keep records and submit compliance reports to OCR, conducting compliance reviews and complaint investigations, and providing technical assistance and guidance. Where noncompliance or threatened noncompliance cannot be corrected by informal means, the enforcement mechanisms provided for and available under the civil rights laws referenced in Section 1557 include suspension of, termination of, or refusal to grant or continue Federal financial assistance; referral to the Department of Justice with a recommendation to bring proceedings to enforce any rights of the United States; and any other means authorized by law.⁹⁸ In addition, based 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. A private right of action and damages are also available for violations of Section 1557 by Title I entities. We seek comment on these positions.

Procedures for Health Programs and Activities Conducted by Recipients and State-Based Marketplaces (§ 92.302)

Proposed § 92.302 specifies the regulatory procedures that will apply to claims under Section 1557 for health programs and activities conducted by recipients and State-based Marketplaces. The administrative procedures provided for and available under Title VI are found in the regulation implementing Title VI, at 45 CFR 80.6–80.11 and 45 CFR part 81. These administrative procedures are incorporated into the regulation implementing Title IX at 45 CFR 86.71 and the regulation implementing Section 504 with respect to recipients at 45 CFR 84.61. Section 92.302(a) incorporates these procedures into the proposed rule with respect to race, color, national origin, sex, and disability discrimination. The administrative procedures provided for and available under the Age Act are found in the regulation implementing the Age Act at 45 CFR 91.41 through 91.50. Section 92.302(b) incorporates these procedures into the proposed rule with respect to age discrimination.

Section 92.302(c) also provides that an individual may bring a civil action in a United States District Court in which a recipient or State-based Marketplace is located, as provided for and available under Section 1557.

Procedures for Health Programs and Activities Administered by the Department (§ 92.303)

As noted, Section 1557 expressly states that the enforcement mechanisms provided for and available under Title VI, Title IX, Section 504, or the Age Act shall apply for purposes of violations of Section 1557. The administrative procedures provided for and available under Section 504—which is the only one of these statutes that applies to Federally conducted, as well as Federally assisted, programs—for programs and activities administered by the Department are found in the regulation implementing Section 504 at 45 CFR 85.61 and 85.62. These procedures shall apply with respect to complaints and compliance reviews of health programs or activities administered by the Department, including the Federally-facilitated Marketplaces, concerning discrimination on the basis of race, color, national origin, sex, age, or disability.

The proposed rule adds two provisions that are not found in 45 CFR 85.61 and 85.62. The first provision relates to OCR's access to information. This provision, which is in accordance with OCR's practice under Section 504, is designed to ensure that OCR has the ability to obtain all of the relevant information needed to investigate a complaint or determine compliance in a particular health program or activity administered by the Department, and mirrors similar requirements for recipients under the Title VI regulation.

The second provision prohibits the Department, including the Federally-facilitated Marketplaces, from retaliating against any individual for the purpose of interfering with any right or privilege under Section 1557 or the proposed rule or because the individual has made a complaint, testified, assisted, or participated in any manner in an investigation, proceeding, or hearing under Section 1557 or this proposed rule. Section 504 of the Rehabilitation Act, to which the Department is already subject, provides that the procedures, rights, and remedies under Title VI are available to any individual aggrieved by an act or failure to act by any recipient of Federal financial assistance or Federal provider of such financial assistance under Section 504. Thus, the prohibition of retaliation under Title VI applies to the Department under Section 504. The retaliation provision in the proposed rule is simply an extension of this existing prohibition. This provision is also in accordance with a similar requirement for recipients under the

Title VI regulation at 45 CFR 80.7(e); the Department should hold itself to the same standards to which it holds recipients of Federal financial assistance.⁹⁹

Information Collection Requirements

This notice of proposed rulemaking would call for new collections of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). As defined in 5 CFR 1320.3(c), “collection of information” comprises reporting, recordkeeping, monitoring, posting, labeling and other similar actions. The title and description of those entities that must collect the information and an estimate of the total annual burden follow. The estimate covers the time for reviewing and posting the collections required.

Title: Notice on Nondiscrimination in Health Programs and Activities.

OMB Control Number: XXXX–XXXX.

Summary of the Collection of Information: Under the proposed rule, each entity applying for Federal financial assistance, each health insurance issuer seeking certification to participate in a Marketplace, and each entity seeking approval to operate a Title I entity would be required to submit an assurance that its health programs and activities will be operated in compliance with Section 1557 of the Affordable Care Act (ACA).

In addition, each covered entity subject to the proposed rule would be required to post a notice of certain important information, including that the covered entity provides auxiliary aids and services, free of charge, in a timely manner, to individuals with disabilities, when such aids and services are necessary to provide an individual with a disability an equal opportunity to benefit from the entity's health programs or activities; and language assistance services, free of charge, in a timely manner, to individuals with limited English proficiency, when those services are necessary to provide an individual with limited English proficiency meaningful access to a covered entity's health programs or activities. Furthermore, each covered entity would be required to post taglines in the top 15 languages spoken by individuals with limited English proficiency nationally,

⁹⁹ Further, as the U.S. Supreme Court observed in *Jackson v. Birmingham Bd. of Educ.*, 544 U.S. 167, 181 (2005), “providing individual citizens effective protection against discriminatory practices . . . would be difficult, if not impossible, to achieve if persons who complain about sex discrimination did not have effective protection against retaliation” (internal citations omitted). The same principle is true for discrimination under Section 1557.

⁹⁸ See 45 CFR 80.8(a).

informing individuals with limited English proficiency that language assistance services may be available.

Additionally, each covered entity that employs 15 or more persons would be required to adopt grievance procedures that incorporate appropriate due process standards and that provide for the prompt and equitable resolution of grievances alleging any action that would be prohibited by Section 1557. Each such entity would also be required to designate at least one individual to coordinate its efforts to comply with and carry out its responsibilities under Section 1557, including the investigation of any grievance communicated to it alleging noncompliance with Section 1557.

Need for Information: The requirement that every entity applying for Federal financial assistance, seeking certification to participate in a Health Insurance Marketplace, or seeking approval to operate a Title I entity, submit an assurance of compliance, is similar to the current regulatory requirements under 45 CFR 80.4(a), 84.5 and 91.33. These requirements protect individuals by assuring that covered entities will comply with all applicable nondiscrimination statutes and their implementing regulations.

The posting of a notice of certain important information and the posting of taglines in the top 15 languages spoken by individuals with limited English proficiency nationally are necessary to ensure that individuals are aware of their protections under the law, and are grounded in OCR's experience that failures of communication based on the absence of auxiliary aids and services and language assistance services raise particularly significant compliance concerns under Section 1557, as well as Section 504 and Title VI.

The requirements that every covered entity that employs 15 or more persons adopt a grievance procedure and designate at least one individual to coordinate its efforts to comply with and carry out its responsibilities under Section 1557 are similar to requirements included in the Title IX and Section 504 implementing regulations. Through its case investigation experience, OCR has observed that the presence of a coordinator and grievance procedure helps to bring concerns to prompt resolution within an entity, leading to lower compliance costs and more efficient outcomes.

Proposed Use of Information: OCR would use this information to ensure covered entities' adherence to the statutory requirements imposed under Section 1557 and this proposed rule.

OCR would enforce the requirements by verifying during investigations of covered entities that an entity has submitted an assurance of compliance, posted the notice of important information and taglines and, for each covered entity that employs 15 or more persons, that an individual has been designated to coordinate its compliance efforts and that appropriate grievance procedures have been adopted, as required.

Description of the Respondents: The respondents are each entity applying for Federal financial assistance, each issuer seeking certification to participate in a Marketplace, and each entity seeking approval to operate a Title I entity. These include such entities as hospitals, home health agencies, community mental health centers, skilled nursing facilities, and health insurance issuers.

Number of Respondents: The number of respondents is estimated to include the 278,565 covered entities affected by the proposed rule.

Burden of Response: Because the proposed rule would provide a model assurance of compliance, a model notice of important information, and model taglines in the top 15 languages, the burden on respondents is minimal. Additionally, because all recipients of Federal financial assistance with 15 or more employees are already expected to have in place a grievance procedure and a designated individual to coordinate their compliance responsibilities, the burden to comply with this requirement will be minimal for most respondents.

While the requirement to submit an assurance of compliance is subject to the Paperwork Reduction Act (PRA), OCR believes the burden associated with this requirement is exempt from the PRA in accordance with 5 CFR 1320.3(b)(2). OCR believes that the time, effort, and financial resources necessary to comply with this requirement should be considered a usual and customary business practice and would be incurred by covered entities during their ordinary course of business.

OCR estimates the burden for responding to the proposed notice requirement would be 17 minutes to download/print and post the notice of important information and that the burden to download/print and post taglines in the top 15 languages nationally would also be 17 minutes, for a burden total of 34 minutes. We estimate that administrative or clerical support personnel would perform these functions. Based on the wage rate for a Clerical Support Worker (\$22.94) we estimate the annual burden cost for these two requirements to be approximately \$4.8 million.

Regarding the requirement that every covered entity that employs 15 or more persons adopt grievance procedures and designate at least one individual to coordinate its efforts to comply with and carry out its responsibilities under Section 1557, based on OCR's compliant workload increase since the passage of Section 1557, we anticipate that within the first five years following the rule's enactment, complaints will increase approximately 1%, but eventually will drop off as covered entities modify their policies and practices in response to the proposed rule. We estimate that medical and health service managers would handle the grievances. Taking 1% of the annual wage rate for medical and health service managers (\$101,340) and increasing that amount by 100% to account for fringe benefits and overhead, we estimate the total annual burden cost for this requirement to be approximately \$118.7 million.

Thus, the total estimated annual burden cost for the proposed information collection requirements will be approximately \$123.5 million.

We ask for public comment on the proposed information collection to help us determine:

1. Whether the proposed collection of information is necessary for the proper performance of the functions of OCR, including whether the information will have practical utility;
2. The accuracy of the estimated burden associated with the proposed collection of information;
3. How the quality, utility, and clarity of the information to be collected may be enhanced; and
4. How the burden of complying with the proposed collection of information may be minimized, including through the application of automated collection techniques or other forms of information technology.

Comments regarding the collection of information proposed in this rule must refer to the proposed rule by name and docket number and must be submitted to both OMB and the Docket Management Facility where indicated under **ADDRESSES**, by the date specified under **DATES**.

Regulatory Impact Analysis

I. Introduction

A. Executive Orders 12866 and 13563

Executive Order 12866¹⁰⁰ directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential

¹⁰⁰ E.O. 12866, 58 FR 51735 (1993).

economic, environmental, public health and safety effects; distributive impacts; and equity). Executive Order 13563¹⁰¹ is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866. The Office of Management and Budget (OMB) has determined that this proposed rule is a “significant regulatory action” under Executive Order 12866. Accordingly, OMB reviewed this proposed rule.

B. The Need for a Regulation

Section 1557 of the ACA prohibits an individual from being excluded from participation in, denied the benefits of, or otherwise subjected to discrimination on the basis of race, color, national origin, sex, age or disability in certain health programs and activities. It applies the protections available under Title VI, Title IX, the Age Act, and Section 504 to any health program or activity, any part of which is receiving Federal financial assistance, and to any program or activity that is administered by an Executive Agency or any entity established under Title I of the ACA.¹⁰² Under this section, the Secretary of the Department is authorized to promulgate regulations to implement Section 1557. The purpose of this regulatory action is to implement Section 1557 of the ACA.

One of the central aims of the ACA is to expand access to health care and health coverage for all individuals. Equal access for all individuals without discrimination is essential to achieving this goal. Discrimination in the health care context can often lead to poor and inadequate health care or health insurance or other coverage for individuals and exacerbate existing health disparities in underserved communities. Individuals who have experienced discrimination in the health care context often postpone or do not seek needed health care; individuals who are subject to discrimination are denied opportunities to obtain health care services provided to others, with resulting adverse effects on their health status. Moreover, discrimination in health care can lead to poor and ineffective distribution of health care resources, as needed resources fail to reach many who need them. The result is a marketplace comprised of higher medical costs due to delayed treatment, lost wages, lost productivity, and the misuse of people’s talent and energy.¹⁰³

To help address these issues, this regulation seeks to clarify the application of the nondiscrimination provision in the ACA to any health program or activity receiving Federal financial assistance or administered by HHS or any entity established under Title I. Such clarity will promote understanding of and compliance with Section 1557 by covered entities and the ability of individuals to assert and protect their rights under the law.

In addition, Executive Order 13563 directs Federal agencies to improve regulations and regulatory review by promoting the simplification and harmonization of regulations and to ensure that regulations are accessible, consistent and easy to understand. Regulations implementing the civil rights laws referenced in Section 1557 contain certain inconsistencies across common areas and subject matters, reflecting, among other things, differences in time and experience when the regulations were issued. The approach taken in the proposed rule is to simplify and make uniform, consistent, and easy to understand the various nondiscrimination requirements and rights available under Section 1557, as appropriate.

C. Examples of Covered Entities and Health Programs or Activities Under the Proposed Regulation

This proposed rule would apply to any entity that has a health program or activity, any part of which receives Federal financial assistance from the Department, any health program or activity administered by the Department, or any health program or activity administered by an entity created under Title I of the ACA. The following are examples of covered entities as well as health programs or activities under the proposed rule.

Causes and Consequences of Racial and Health Disparities (2008), available at http://hospitals.unm.edu/dei/documents/eval_cause_conse_apha.pdf; Carol Rose DeLilly and Jacquelyn H. Flaskerud, Discrimination and Health Outcomes, 33(11), Issues Ment. Health Nurs., 801–804 (2012), available at <http://informahealthcare.com/doi/abs/10.3109/01612840.2012.671442>; Timothy Waldmann, Urban Institute, Estimating the Cost of Racial and Ethnic Health Disparities (2009), available at <http://www.urban.org/research/publication/estimating-cost-racial-and-ethnic-health-disparities>; LaVera M. Crawley, David K. Ahn, and Marilyn A. Winkleby, Perceived Medical Discrimination and Cancer Screening Behaviors of Racial and Ethnic Minority Adults, 17(8), Cancer Epidemiol Biomarkers Prev., 1937–1944 (2008), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2526181/>.

1. Examples of Covered Entities With a Health Program or Activity, Any Part of Which Receives Federal Financial Assistance From the Department

This Department, through agencies such as the Health Resources and Services Administration (HRSA), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Centers for Disease Control and Prevention (CDC), and the Centers for Medicare & Medicaid Services (CMS), provides Federal financial assistance through various mechanisms to health programs and activities of local governments, State governments, and the private sector. An entity may receive Federal financial assistance from more than one component in the Department. For instance, Federally qualified health centers receive Federal financial assistance from CMS by participating in the Medicare or Medicaid programs and also receive Federal financial assistance from HRSA through grant awards. Because more than one funding stream may provide Federal financial assistance to an entity, the examples we provide may not uniquely receive Federal financial assistance from only one HHS component.

(1) Entities receiving Federal financial assistance through their participation in Medicare or Medicaid (about 133,343 facilities).¹⁰⁴ Examples of these entities include:

- Hospitals (includes short-term, rehabilitation, psychiatric, and long-term)
- Skilled nursing facilities/nursing facilities—facility-based
- Skilled nursing facilities/nursing facilities—freestanding
- Home health agencies
- Physical therapy/speech pathology programs
- End stage renal disease dialysis centers
- Intermediate care facilities for individuals with intellectual disabilities
- Rural health clinics
- Physical therapy—independent practice
- Comprehensive outpatient rehabilitation facilities
- Ambulatory surgical centers
- Hospices
- Organ procurement organizations
- Community mental health centers
- Federally qualified health centers

(2) Laboratories that are hospital-based, office-based, or freestanding that receive Federal financial assistance through Medicare or Medicaid payments for covered laboratory tests (about 445,657 laboratories with Clinical Laboratory Improvement Act certification).

(3) Community health centers receiving Federal financial assistance

¹⁰⁴ CMS Provider of Service file for June 2014.

¹⁰¹ E.O. 13563, 76 FR 3821 (2011).

¹⁰² Patient Protection and Affordable Care Act, Pub. L. 111–148 (2010) (codified at 42 U.S.C. 18116).

¹⁰³ Kristen Suthers, American Public Health Association: Issue Brief: Evaluating the Economic

through grant awards from HRSA (1,200 community health centers).¹⁰⁵

(4) Health-related schools in the United States and other health education entities receiving Federal financial assistance through grant awards to support 40 health professional training programs that include oral health, behavioral health, medicine, geriatric, and physician's assistant programs (171 health-related schools and other health education entities).¹⁰⁶

(5) State Medicaid agencies receiving Federal financial assistance from CMS to operate Medicaid and CHIP programs (includes every State, the District of Columbia, Puerto Rico, Guam, the Northern Marianas, U.S. Virgin Islands, and American Samoa).

(6) State public health agencies receiving Federal financial assistance from CDC, SAMHSA, and other HHS components (includes each State, the District of Columbia, Puerto Rico, Guam, the Northern Marianas, U.S. Virgin Islands, and American Samoa).

(7) Qualified health plan issuers receiving Federal financial assistance through premium tax credits or cost-sharing reductions (which include at least the 169 health insurance issuers receiving Federal financial assistance through premium tax credits and cost sharing reductions and at least 11 issuers operating in the State Based Marketplaces that we were able to identify).¹⁰⁷ We seek comment on identifying additional issuers in the State-based Marketplaces.

(8) Physicians receiving Federal financial assistance through Medicaid payments, "meaningful use" payments, and other sources, but not Medicare Part B payments, as the Department does not consider Medicare Part B payments to physicians to be Federal financial assistance.

In regard to the eighth category of entities that may be covered by this proposed rule—physicians—we estimate that this proposed rule likely covers almost all licensed physicians because they accept Federal financial assistance from sources other than Medicare Part B. Most physicians participate in more than one Federal, State, and local health program that receives Federal financial assistance, and many practice in several different settings, e.g., they may practice in a

hospital but also practice privately and develop nursing home plans of care at the local nursing home. We have data, by program, for the number of physicians receiving payment from each program, but there is no single, unduplicated count of physicians across programs. We can compare the various counts of physicians with the number of all licensed and practicing physicians in the United States as enumerated in the Area Health Resource File maintained by HRSA, but even this benchmark file may contain duplicate counts of licensed physicians as explained later in the analysis.

In spite of the difficulty in obtaining an unduplicated physician count, we provide our best estimate of the number of physicians receiving Federal financial assistance by analyzing and comparing different data sources and drawing conclusions from this analysis. Based on 2010 Medicaid Statistical Information System data (the latest available), about 614,000 physicians accept Medicaid payments and are covered under Section 1557 as a result.¹⁰⁸ This figure represents about 69% of licensed physicians in the United States when compared to the 890,000 licensed physicians reported in the Area Health Resource File. In addition, physicians receiving Federal payments from non-Part B Medicare sources will also come under Section 1557. For example, as of January 2014, 296,500 Medicare-eligible professionals had applied for funds to support their "meaningful use" technology efforts.¹⁰⁹ Adding the 614,000 physicians who receive Medicaid payments to the 296,500 physicians who receive meaningful use payments yields over 900,000 physicians potentially reached by Section 1557 because they participate in Federal programs other than Part B of Medicare. Because physicians can receive both Medicaid and meaningful use payments, and these figures are not adjusted for duplication, the 900,000

result is probably best interpreted as an upper bound.

Earlier, we identified several grant programs from various Department agencies that fund a variety of health care programs in which physicians participate and thus come under Section 1557, such as the National Health Service Corps, HRSA-funded community health centers, programs receiving NIH research grants, and SAMHSA-funded programs. Furthermore, physicians participating in a CMS gain-sharing demonstration project who receive gain-sharing payments would be covered under Section 1557 even if they did not participate in Medicare and Medicaid or any other health program or activity that receives Federal financial assistance. Again, there will be duplication and overlap with physicians who accept Medicaid or Medicare meaningful use payments, or other payments apart from Medicare Part B payments. Nevertheless, at least some of these physicians add to the total number of physicians reached under Section 1557 because some of them are not duplicates and do not accept Medicaid or Medicare meaningful use payments. We do not have an exact number, but adding these physicians may bring the total participating in Federal programs other than Part B to over 900,000.

When we compare the upper bound estimated number of physicians participating in Federal programs other than Medicare Part B (over 900,000) to the number of licensed physicians counted in HRSA's Area Health Resource File (approximately 890,000), we conclude that almost all practicing physicians in the United States are reached by Section 1557 because they accept some form of Federal remuneration or reimbursement apart from Medicare Part B.¹¹⁰ We invite the public to submit information regarding physician participation in health programs and activities that receive Federal financial assistance.

2. Examples of Health Programs or Activities Conducted by the Department

This proposed rule applies to the Department's health programs and activities, such as those administered by CMS, HRSA, CDC, IHS, and SAMHSA. Examples include the Indian Health Service tribal hospitals and clinics operated by the Department (about 876 hospitals and clinics) and the National Health Service Corps.¹¹¹

¹¹⁰ The Area Health Resource File itself double counts physicians who are licensed in more than one state. See *infra* discussion below at II.C.1.a.

¹¹¹ *Id.* at 66.

¹⁰⁵ U.S. Department of Health and Human Services, HRSA: Justification of Estimates for Appropriation Committee, 42 (2014).

¹⁰⁶ *Id.* at 16.

¹⁰⁷ Qualified Health Plans Landscape Individual Market Medical (2015), available at <https://data.healthcare.gov/dataset/2015-QHP-Landscape-Individual-Market-Medical/mp8z-jtg7>.

¹⁰⁸ John Holahan and Irene Headen, Kaiser Commission on Medicaid and the Uninsured, *Medicaid Coverage and Spending in Health Reform: National and State-by-State Results for Adults at or Below 133% FPL* (2010), available at <http://kff.org/health-reform/report/report-and-briefing-on-medicare-coverage-and/>. Estimates are based on data from FY 2010 MSIS.

¹⁰⁹ Mynti Hossain and Marsha Gold, Mathematical Policy Research Inc.: Prepared for The Office of the National Coordinator for Health Information Technology, U.S. Department of Health and Human Services, *Monitoring National Implementation of HITECH: Status and Key Activity Quarterly Summary*, (January to March 2014), available at http://www.healthit.gov/sites/default/files/globalevaluationquarterlyreport_january-march2014.pdf.

3. Examples of Entities Established Under Title I of the ACA

This proposed rule applies to entities established under Title I of the ACA. According to the CMS Center for Consumer Information and Insurance Oversight (CCIIO), there are Health Insurance Marketplaces covering 51 jurisdictions: (14 State-based-Marketplaces and 37 Federally-facilitated Marketplaces).¹¹² The proposed rule covers these Health Insurance Marketplaces.

II. Costs

As discussed above, it is important to recognize that the NPRM—except in the area of sex discrimination—applies pre-existing requirements in Federal civil rights laws to various entities, nearly all of which have been covered by these requirements for many years. Because the NPRM restates existing requirements, we do not anticipate that covered entities will undertake new actions or bear any additional costs in response to the issuance of the regulation with respect to the prohibition of race, color, national origin, age, or disability discrimination.

However, the prohibition of sex discrimination is new for many of the covered entities, and we do anticipate that the enactment of the regulation will result in changes in action and behavior by covered entities to comply with this new prohibition. Some of these actions will impose costs and others will not.

In addition, as noted above, Section 1557 applies to the Health Insurance Marketplaces, as entities newly created under Title I of the ACA. However, these entities, along with the qualified health plans issuers participating in the Health Insurance Marketplaces, are already covered by regulations issued by CMS that prohibit discrimination on the basis of race, color, national origin, sex, including sex stereotyping and gender identity, sexual orientation, age, or disability, and the Federally-facilitated Marketplaces are already covered by Section 504, which prohibits disability discrimination. Thus the impact of Section 1557 on these entities is limited.

The following regulatory analysis examines the costs and benefits that are attributable to this regulation only. While we make assumptions about possible behavioral responses to the regulation, we acknowledge that more information may be available to inform

these assumptions and we welcome comment.

We first analyze the costs we expect the proposed rule to create for covered entities. Then we examine the potential benefits the rule is likely to produce. In the subsequent analyses of costs in this RIA and the Regulatory Flexibility Act (RFA), we use data sets from the Census Bureau and Bureau of Labor Statistics for estimating burdens.¹¹³

A. Assumptions

The following cost assessment rests on certain key assumptions that include: (1) Voluntary activity on the part of covered entities that is triggered by the enactment of this regulation—and that would not have occurred absent the enactment of the regulation—which generates both costs and corresponding benefits; (2) to the extent that actions are required under the proposed rule where the same actions are already required by prior existing civil rights regulations, we assume that the actions are already taking place and thus that they are not a burden imposed by the proposed rule; (3) although the regulation does not require training at any time, we anticipate that covered entities may voluntarily provide one-time training to some employees on the requirements of the regulation at the time that the regulation is published; and (4) employers are most likely to train employees who interact with the public. Based on this assumption, we also assume employers likely will train between 40 and 60% of their employees, as the percentage of employees that interact with patients and the public varies by covered entity. For purposes of the analysis, we assume that 50% of the covered entity's staff will receive one-time training on the requirements of the regulation. We use the 50% estimate as a proxy, given the lack of certain information as described below. For the purposes of the analysis, we do not distinguish between employees whom covered entities will train and those who obtain training independently of a covered entity.

¹¹³ The HHS data used in this section provides the best measure of the number and type of entities covered under the regulation. They do not, however, link to cost data needed to conduct a cost-benefit analysis. To obtain cost data linked with the covered entities, we must use Census and Bureau of Labor Statistics data sets. Because the data from these bureaus is organized along industrial and occupational categories, we lose some accuracy in the count of covered entities. We have done our best to minimize the loss of accuracy and have opted to overcount rather than undercount affected entities.

B. Training

We assume covered entities will provide some workers a one-time awareness or familiarization training regarding the requirements in the regulation at the time of its issuance. We are counting the cost of training on all aspects of the regulation, not only on the new responsibilities under the regulation, as we believe covered entities will want to offer comprehensive training to employees, recognizing that refresher training can provide value. We invite comment on whether we should count only the cost of training on new responsibilities under the regulation.

We know that many employees work “behind the scenes” at large entities, and may not have contact with patients or the general public or otherwise have duties impacted by the requirements we are proposing and therefore may have little need for training. However, we are uncertain which employees those are. Furthermore, we do not know whether an entity rotates employees into different positions that may have patient contact or relevant duties, or whether, over time, an employee will switch to a position that places him or her in such a position, which may create a need for training.

We also lack information on State and local regulations that may require employees to receive training on civil rights provisions and whether those provisions are more or less rigorous than the ones we propose. Thus, workers in covered entities in States and local jurisdictions with civil rights provisions more robust than the ones we propose may need only minimal training. In State and local jurisdictions where civil rights provisions are not more robust, workers may need more training. As stated above, because we lack data on covered entities' training practices we are assuming that covered entities will voluntarily provide training on the final rule for between 40% and 60% of their staffs.

We welcome public comment and information that will help us focus our analyses on the specific entities and workers who likely will receive training.

In the following section, we identify the pool of workers and staff that we anticipate may need knowledge of the proposed rule. Next, we identify the covered entities that may choose to train their staffs to provide this knowledge. Last, we estimate the costs of presenting the training materials and the worker time that will be spent in training.

¹¹² 45 CFR part 155 sets forth the Exchange Establishment Standards that a State-based Marketplace must satisfy. CCIIO's approval of a State-based Marketplace is based on the approval criteria established in 45 CFR 155.105. Using these criteria, CCIIO counts 14 State-based Marketplaces, including the District of Columbia.

1. Number of Individuals Who Will Receive Training

a. Health Care Staffs and Managers

The Bureau of Labor Statistics¹¹⁴ Occupation Tables for codes 29–0000 (Healthcare Practitioners (29–1000) and Technical Occupations (29–2000)) and 31–0000 (Healthcare Support Occupations) reports, for 2013, that “7.8 million health diagnosing and treating practitioners, 2.9 million technicians and 3.9 million technical assistants” were working in the health care sector in 2013.¹¹⁵

The first category of health care staff that may receive training is comprised of health diagnosing and treating practitioners. This category includes physicians, dentists, optometrists, physician assistants, occupational, physical, speech and other therapists, audiologists, pharmacists, registered nurses, and nurse practitioners. The Bureau of Labor Statistics occupational code for this grouping is 29–1000 and the 2013 reported count is 4,833,840. We note that the Bureau of Labor Statistics reports the number of physicians as 623,380 in contrast to the 888,947 physicians reported in the HRSA Area Health Resource File.¹¹⁶ Although the Area Health Resource File is the best national count of the number of licensed physicians, we need data that link to physician earnings in order to assess impact, which the Area Health Resource File lacks. Because we must use alternative sources for the physician earnings data, we also reconcile the differences between the two sources with regard to the number of physicians counted in the economic analysis.

Because the Area Health Resource File’s count is based on licensure, it

includes physicians who may hold licenses in more than one State. There are a number of metropolitan areas that cross State boundaries and physicians practicing in these areas may be licensed in the adjoining States and, thus, will be counted more than once in the Area Health Resource File. On the other hand, the Bureau of Labor Statistics data, which report physician employment and income, may be an inaccurate count of physicians because of sampling error. We note that the sampling error reported for one physician specialty category is 6.1% and five out of seven specialty categories reported have sampling errors of 3% or greater. To resolve the difference between the Bureau of Labor Statistics and Area Health Resource File sources, we propose to take the midpoint of the difference between the two files.

The difference in the number of physicians in the Bureau of Labor Statistics and Area Health Resource File tables equals 265,567. Taking the midpoint yields 132,784 and adding this to the Bureau of Labor Statistics physician count gives us 756,164. Thus, the total count for Occupational code 29–1000—Healthcare Diagnostic and Treating Practitioners, after adjusting for the number of physicians, is 4.8 million.

The second category of health care staff that we assume will receive training is comprised of degreed technical staff (Occupation code 29–2000) and accounts for 2.8 million workers. Technicians work in almost every area of health care: From x-ray to physical, speech, psychiatric, dietetic, laboratory, nursing, and records technicians, to name but a few areas.

The third category of health care staff that we assume will receive training is comprised of non-degreed medical assistants (Occupation code 31–0000), and includes psychiatric and home health aides, orderlies, dental assistants, and phlebotomists. Health care support staffs (technical assistants) operate in the same medical disciplines as technicians, but often lack professional degrees or certificates. We refer to this workforce as non-degreed compared to medical technicians who generally have degrees or certificates. There are 3.9 million individuals employed in these occupations.

The fourth category of health care staff that we assume will receive training is health care managers (approximately 300,000 based on Bureau of Labor Statistics data for occupation code 11–9111).

The fifth category of health care staff that we assume will receive training is office and administrative assistants—

Office and Administrative Support Occupation (Occupation code 43–0000). These workers are often the first staff patients encounter in a health facility and, because of this, covered entities might find it important that staff, such as receptionists and assistants, receive training on the proposed regulatory requirements. Approximately 2.7 million individuals were employed in these occupations in health facilities in 2013.¹¹⁷

Below is a summary table of individuals employed in the health care sector.

TABLE 1—HEALTH CARE EMPLOYEES THAT MAY NEED TRAINING

Health diagnosing and treating practitioners plus 132,784 physicians not in the Bureau of Labor Statistics data	4,833,840
Degreed technicians	2,849,330
Non-degreed technicians	3,924,390
Medical and health services managers	300,180
Office and administrative support staff	2,739,640
Total	14,647,380

b. Employees Working for the Federally-Facilitated Marketplaces and State-Based Marketplaces and Issuers in Those Marketplaces

We have data from CMS/CCIIO on the number of issuers offering qualified health plans in the Federally-facilitated Marketplaces. We assume that many issuers that operate in the Federally-facilitated Marketplaces also operate in the State-based Marketplaces. However, to the extent there are issuers who operate in a State-based Marketplace only, an estimate of their employees will not be included in our count of issuers (derived from the CCIIO tables of issuers participating only in the 37 jurisdictions with Federally-facilitated Marketplaces). We propose to determine the number of employees working for those issuers participating in the Federally-facilitated Marketplaces and we assume, as noted above, that some of the same issuers and employees serve the State-based Marketplaces. Determining the number of employees working for issuers participating in the Health Insurance Marketplaces is problematic because we have no data directly linking the number of

¹¹⁴ National Occupational Employment and Wage Estimates United States (May, 2013), available at http://www.bls.gov/oes/2013/may/oes_nat.htm.

¹¹⁵ In choosing data from the Bureau of Labor Statistics 800 occupation tables rather than Bureau of Labor Statistics 400 industry tables, we are including health care workers employed in entities that may not receive Federal financial assistance. Thus, the count of employees included in the following analysis may be overstated. Using the alternative Bureau of Labor Statistics industry data is also problematic. The North American Industrial Code System (NAICS 623300—Continuing Care Retirement Communities and Assisted Living Facilities for the Elderly and NAICS 623900—Other Residential Care Facilities) may include both non-covered and covered entities. Were we to include these categories in the training analysis, the results would be similar to the results achieved using the occupational data presented above. Were we to exclude these categories, we might be undercounting staff needing training. Because the industry tables offered no advantage over the 800 occupation tables and the occupations data were simpler and more direct, we chose to use them rather than the industry tables.

¹¹⁶ HRSA, Area Health Resource File National, State and County Health Resources Information Database, available at <http://ahrh.hrsa.gov>.

¹¹⁷ Data from Bureau of Labor Statistics 400 industries table for the health care sector: North American Industry Classification System code 62. This code includes health care and social assistance (including private, State and local government hospitals).

employees to our data on participating issuers in the Federally-facilitated Marketplaces. Consequently, we must impute the number of employees working for issuers participating in the Federally-facilitated Marketplaces and, by extension, employees working for issuers in State-based Marketplaces.

We perform this imputation by first identifying the number of issuers offering qualified health plans in the Federally-facilitated Marketplaces. To determine the number of issuers offering qualified health plans in the Federally-facilitated Marketplaces, we looked at the 2015 Qualified Health Plan Landscape Individual and Small Business Health Options Program Market Medical files.¹¹⁸ The Qualified Health Plan Landscape Individual Market Medical file contains over 100,000 line items, and the Small Business Health Options Program Market Medical file contains over 50,000 line items listing each Federally-facilitated Marketplace plan for each county by metal level (bronze, silver, gold, and platinum) and catastrophic plans provided by each issuer. To determine the number of issuers in the individual and Small Business Health Options Program Marketplaces, we removed all plan line items to reduce the count to an unduplicated count of the issuers in the Federally-facilitated Marketplaces. We identified 155 individual plan issuers and 14 issuers in the Small Business Health Options Program that only issued group plans to employees of employers participating in the Small Business Health Options Program. Our total count of 169 issuers differs from the CCIIO sources, which counted issuers in each State in which they operated. For example, a national issuer such as Aetna that offers coverage through Federally-facilitated Marketplaces operating in several States was counted separately by CCIIO for each State in which it was qualified, whereas we counted it only once.¹¹⁹

In addition to 169 issuers participating in Federally-facilitated Marketplace, we are aware of 11 issuers participating only in the State-based Marketplaces. Thus, we calculate that the total number of issuers included in the analysis of covered issuers equals 180.

We next analyzed the number of employees working in the health

insurance industry in the following way. Using Census Bureau 2011 payroll and employment data (the latest data available) for North American Industry Classification System 524114—Direct Health Insurance¹²⁰ we attempted to match the number of employees to the health insurance entities. The Census data permitted us to divide all health insurance issuers into “large” (500 or more employees) and “small” (fewer than 500 employees) issuers, and from that we were able to estimate the number of employees for large and small issuers.

The Census data shows 805 small issuers and 180 large issuers. The ratio of small to large issuers is about 4.5 small issuers for every large issuer. We assumed the ratio of small to large issuers in the Health Insurance Marketplaces would be approximately the same as the ratio in the Census table. We ask for public comment on this assumption.

Applying this ratio to the issuers in the Federally-facilitated Marketplaces, we get 131 small issuers and 38 large issuers. We assume that the 11 issuers (for which we have data and have thus identified) operating in the State-based Marketplaces are likely to be classified as small, based on Census workforce data. Therefore, we are adding them to the 131 small issuers identified above, bringing the total number of small issuers to 142. We ask for public comment on this assumption.

Based on the Census data, the average number of employees in a small issuer is 34 and the average number of employees in a large issuer is 2,300. Multiplying the number of small issuers by the number of employees equals 4,828 employees in the 142 small issuers and 87,400 employees in the 38 large issuers. The combined total number of employees for small and large issuers in the Federally-facilitated Marketplaces is estimated to be 92,228 employees.

With respect to the majority of issuers operating in a State-based Marketplace that we have not been able to identify but would also be subject to the regulation, we do not have any direct data. However, the workforce data we have from the Census tables covers employees regardless of their work site. If any of the 169 issuers identified above operating in the Federally-facilitated Marketplaces also operate in the State-based Marketplaces, then some portion of the nearly 92,000 employees imputed to be working for the issuers in the

Federally-facilitated Marketplaces may also be working for issuers operating in the State-based Marketplaces. Thus, in effect, we are including employees working for issuers that operate in both the State-based Marketplaces and the Federally-facilitated Marketplaces in our count of employees who likely will receive training on the regulation.

At the same time that we include employees who work for issuers operating in both the Federally-facilitated Marketplaces and State-based Marketplaces, we lack direct data on issuers participating only in State-based Marketplaces. We are not able to include employees that work for insurance issuers that operate only in State-based Marketplaces, such as New York or California, which would be subject to the proposed rule. We invite public comment on ways we can identify issuers that participate only in State-based Marketplaces and the number of employees they employ.

A third category of workers who may need to be trained are Navigators receiving Federal financial assistance to support the functions they perform in assisting applicants to enroll in qualified health plans. CCIIO has awarded grant funding to 92 Navigator entities, and CCIIO estimates that 2,797 Navigators work for these 92 entities.¹²¹

We invite public comment on our approach to estimating the number of employees per issuer based on the Census data and seek any public information on issuers who operate only in State-based Marketplaces.

c. Medicaid and State and Local Health Department Employees

The Census Bureau State government payroll and employment data for 2013 shows the number of full-time employees working in State hospitals and departments of health as 531,251.¹²² The *State Medicaid Operations Survey: Second Annual Survey of Medicaid Directors* reports that the majority of State Medicaid agencies employed 750 or fewer full-time employees with a median workforce level of 421 employees.¹²³ Multiplying the median level of workers by 53 Medicaid agencies adds 22,313 workers to the number of State health

¹¹⁸ Qualified Health Plans Landscape Individual Market Medical (2015), available at <https://data.healthcare.gov/dataset/2015-QHP-Landscape-Individual-Market-Medical/mp8z-jtg7>.

¹¹⁹ We count the issuer only once because we assume the same enterprise will minimize training costs by preparing the same training materials for all its employees nationally.

¹²⁰ United States Census Bureau, Statistics of U.S. Businesses (SUSB) (2011), available at <http://www.census.gov/econ/susb/>.

¹²¹ HHS.gov/Health Care, By the Numbers: Open Enrollment for Health Insurance Fact Sheet, available at <http://www.hhs.gov/healthcare/facts/factsheets/2015/02/open-enrollment-by-the-numbers.html> (last visited June 12, 2015).

¹²² United States Census Bureau, Government Employment and Payroll (2013), available at <http://www.census.gov/govs/apes/>.

¹²³ National Association of State Medicaid Directors, *State Medicaid Operations Survey: Second Annual Survey of Medicaid Directors* (February 2014).

and hospital workers in health departments, bringing the total to 553,564 employees. (Although a more appropriate method of calculating the total would be to use the mean as the multiplier, OCR used the median because the mean was unavailable.) However, this number double counts medical personnel that were previously counted as discussed in part C.1.a (regarding health care staffs and managers who will receive training) in this Regulatory Impact Analysis.

Using the Bureau of Labor Statistics industry data for North American Industry Classification System code 999201: State government, including schools and hospitals, we identified 446,210 medical personnel employed by State governments.¹²⁴ Subtracting this number from the 553,564 employees we identified those employed in State government health services and Medicaid programs, which results in 107,354 additional State employees who may obtain training on the provisions of the regulation.

The method for identifying and removing duplicate State medical personnel from the count of State employees in the health and Medicaid programs may remove too many covered State employees. We assume that most State medical personnel work in health departments and Medicaid agencies, but some medical personnel work in other units of State government such as environmental protection or schools that are not included in the State agencies subject to the rule. We invite public comment and data on this point.

d. Non-Health Care Personnel in Pharmacies

The 2013 Census data for all US industries identifies 18,852 pharmacy establishments. The number of employees presented in the Census data includes both pharmacists and non-pharmacist personnel. At this point, we must refer back to the Bureau of Labor Statistics data on the number of health care workers reported for 2013 because the Bureau of Labor Statistics data divides the pharmacy workforce by occupation. The number of employees that Bureau of Labor Statistics reports were employed in pharmacies for 2013 is 706,000. The number of health care workers discussed in subsection II.C.1.a. above includes 348,381 pharmacists and other health care staff in occupation codes 29-0000 and 31-0000 reported to be working in pharmacies.¹²⁵ Because

we already counted the costs of health care workers employed in pharmacies in the analysis of health care staff, to achieve a more accurate estimate of the number of non-health care pharmacy workers, we must subtract the 348,381 health care staff from the total workforce Bureau of Labor Statistics reports. Removing health care staff from the Bureau of Labor Statistics data yields a net of 357,620 non-health care pharmacy workers in pharmacies who may receive training on the proposed rule.

The following table shows the total number of employees who may receive training; that is, the table shows the 50% of total workers whom we expect will receive training. The table does not include HHS employees conducting HHS health programs or activities because there are roughly 65,000 HHS total employees and many of these employees do not work in health programs or activities administered by HHS. For those employees who do work in health programs or activities administered by HHS, many may not have direct beneficiary contact. Given these limitations, we estimate the number of employees added would be very small and have little impact on overall cost.

TABLE 2—WORKERS THAT MAY RECEIVE TRAINING ON THE REGULATION

Medical health staffs and managers	7,323,690
Employees working for 180 issuers in the Health Insurance Marketplaces	46,114
State health employees	53,677
Navigators	1,399
Pharmacy workers (excluding health care personnel)	178,810
Total	7,633,717

2. Number of Covered Entities That May Train Workers

Just as there are a number of data sources for counting workforce, there are various sources for counting the number of health care entities. Many covered entities are controlled or owned by a single corporate entity and one can count each individual entity separately or count only the single corporate enterprise. For example, a multi-campus facility or vertically integrated entity that owns a hospital, a nursing home, and a home health agency and also operates an accountable care organization could count each of these entities separately—as does Medicare—or count them only once, with each entity treated as part of the corporate

entity. At this point, we make two assumptions: (1) Albeit not required to do so by the regulation, each covered entity will provide some training to its staff on the requirements of the regulation; and (2) when entities are controlled or owned by a corporate entity, the corporate entity will supplement or make any desired modification to the OCR training materials and distribute the training materials. We believe this last point to be especially true because rather than have each entity prepare its own training materials, the corporate entity is more likely to prepare one set of training materials and distribute the materials to its individual entities. This is because the corporate entity saves money by preparing a limited set of training materials and assures uniform quality and consistency in its policies across all its entities. It is also possible that some local health centers in a State may be managed from a central location that handles logistics and training materials. Therefore, we propose using the 2012 Census table that presents the number of firms and establishments. In the Census data, a corporate entity is referred to as a “firm” and the corporation’s facilities are “establishments.” When a firm has one establishment, the establishment is the firm. The difficulty we face in using these data sources is that the Census data captures all entity types that fit the definition of a health care service entity, including entities such as private retirement communities that are unlikely to receive Federal financial assistance and thus would not be covered by Section 1557. In our use of the Census data, we attempted to exclude types of entities that are not likely to receive Federal financial assistance by excluding retirement communities and other similar type entities in the file but have included entities that may receive Federal financial assistance, for example, community health centers and residential centers for individuals with intellectual disabilities.

To test our success in producing a list of covered entities from the Census data, we compared the number of entities we selected from the Census data and the number of entities included in the CMS Provider of Service file. However, to make the lists comparable, we have to remove the count of Clinical Laboratory Improvement Act laboratories from the CMS Provider of Service data files. There are close to 450,000 Clinical Laboratory Improvement Act laboratories located in hospitals, clinics, outpatient centers, and doctors’ offices.

¹²⁴ Bureau of Labor Statistics (BLS) 400 Industries tables available at: <http://www.bls.gov/oes/current/999201.htm>.

¹²⁵ The Area Health Resource File reports 272,022 pharmacists licensed in 2014.

Only a few thousand of these laboratories serve the public. The majority of laboratories serve the facility in which they are housed—including them in our comparison would grossly distort this comparison.

If we add the entities in the Provider of Service file (excluding Clinical Laboratory Improvement Act laboratories) and the number of community health centers to our list of affected entities that are not included in the Provider of Service file, we get a

total of 134,543 entities. Using the Census data, minus the categories for medical laboratories, we obtain a total of 139,164 establishments. It is evident that these numbers are very similar. However, as discussed earlier, we propose using only the number of firms for the analysis of the number of entities possibly conducting training, that is, 70,384 firms. As, noted, we believe firms and not establishments will modify or supplement materials and train employees.

In addition to the firms we include from the Census file, we must add physicians' office firms and pharmacy firms because they may also need to train some workers. Physicians' office firms and pharmacy firms are generally referred to as physician group practices and pharmacy chains.

Below we present the types and number of firms that we estimate will take part in the training for the regulation.

TABLE 3—NUMBER OF HEALTH CARE ENTITY FIRMS EXPECTED TO TAKE PART IN TRAINING

NAIC	Entity type	Number of firms
62142	Outpatient mental health and substance abuse centers	4,987
621491	HMO medical centers	104
621492	Kidney dialysis centers	492
621493	Freestanding ambulatory surgical and emergency centers	4,121
621498	All Other Outpatient Care Centers	5,399
6215	Medical and Diagnostic Laboratories	7,958
6216	Home health care services	21,668
6219	All other ambulatory health care services	6,956
62321	Residential intellectual and developmental disability facilities	6,225
6221	General medical and surgical hospitals	3,067
621991	Psychiatric and substance abuse hospitals	411
6221	Specialty (except psychiatric and substance abuse) hospitals	373
6231	Nursing Care Facilities (Skilled Nursing Facilities)	8,623
44611	Pharmacies and drug stores	18,988
6211	Offices of physicians	188,921
524114	Insurance Issuers	180
	Navigator Grantees	92
	Total Entities	278,565

3. Training Costs

a. Cost of Training Materials and Presentations

There are two components to the cost of training the workers we identified in the previous section: (1) The cost of training materials that is based on the number of covered entities identified in the previous section; and (2) the cost of employee time spent in training.

OCR estimates, based on its experience of training employees on other regulations it enforces, that training employees on this regulation will take about one hour of an employee's time. Based on discussions with firms that develop training materials, we estimate that developing or presenting materials for a one-hour course would cost about \$500. However, OCR proposes to provide covered entities with training materials that will cover the key provisions of the regulation that can be used by entities in conjunction with their own training materials. We estimate that OCR preparing the training materials on the regulation will substantially reduce the material preparation burden to covered entities and reduce the cost by about

three quarters or about \$375 per entity. Therefore, the costs to entities will equal \$125 multiplied by the number of entities that will prepare and present training materials. Based on its experience in preparing training materials for Health Insurance Portability and Accountability Act regulations and other civil rights regulations, OCR expects to spend \$10,000 to develop training materials that will prepare health care workers and managers to effectively implement the Section 1557 regulation.

Training materials can be presented in a number of ways. A common method for offering training materials is through e-courses that are distributed over an entity's computer network. Another method is to offer lectures to selected employees/staff and then have attendees present the materials to their co-workers as part of train-the-trainer programs. For small entities, one lecture session may be given to all employees. Regardless of presentation mode, we estimate that preparing the materials or having a lecturer will cost about the same amount.

Applying the \$125 per course materials to the number of firms (125 ×

278,565)—including the 169 health insurance issuers—equals \$34.8 million for the cost of developing training materials.

b. Cost of Employee Time

The next step is to compute the cost of employee time for training. This involves taking the hourly wage rate times one hour, times the number of employees expected to take the training. The problem we face is only the Bureau of Labor Statistics data provides employee median wage rates.¹²⁶ Census data presents only aggregate annual payroll data and we must calculate the cost of employee time indirectly. We are uncertain about how many employees identified in the workforce above will actually seek and obtain training and how many firms in the health sector will offer training. However, for the purposes of this analysis we assume that all firms may offer some training to their staffs, but because the training is voluntary, and because only a portion of

¹²⁶ We chose to use the median rather than the mean wage because the wage variances are large, ranging from \$22,400 to \$246,320 for annual salaries with mean hourly wages of \$10.77 to \$118.42 for Occupation 29–1000.

employees who have direct patient contact or otherwise have duties impacted by the regulation may require or take training, we assume that 50% of employees may receive training.

The occupation code 29–1000 (health care practitioners) applies to the 4.8 million professional staff and degreed technical staffs we discussed above. The Bureau of Labor Statistics reports the median hourly wage for this code as \$35.76. We estimate one hour of a worker's time would be required for training. To this amount we must add 100% for fringe benefits and overhead, which yields an adjusted hourly wage per employee of \$71.52. Assuming that half of the 4.8 million health care practitioners identified earlier receive or obtain training (2.4 million workers), and multiplying this number by the hourly employee wage plus fringe benefits and overhead for one hour equals slightly more than \$170 million in one-time training costs for practitioners.

For the degreed health care work force in occupation 29–2000, the median hourly wage is \$19.65. Adding 100% for fringe benefits and overhead equals \$39.30. The total training cost for one hour of training for half of the 2.8 million degreed technical staff (1.42 million workers) is about \$56.0 million. In addition, we must add the cost of training non-degreed staff (reported in occupation 31–0000) who earn a median hourly wage of \$12.54. Adding 100% for fringe benefits and overhead to the \$12.54 median hourly wage rate yields an adjusted wage of \$25.08. Multiplying this amount by half of the 3.9 million workforce yields a one-time cost of \$49.2 million.

To these amounts we must add the cost of training the medical and health service managerial staff in occupation 11–9111: 300,180 individuals with a median hourly pay rate of \$43.72. Adding 100% for fringe benefits and overhead gives us an adjusted hourly wage of \$87.44, and assuming that half of the managers would seek or receive training results in a one-time cost of \$13.1 million.

The cost of training occupation code 43–0000, office and administrative support workers employed in covered health care entities, is the product of the median hourly rate of \$15.26 adjusted for fringe benefits and overhead multiplied by the 2.7 million workers reported for North American Industry Classification System code 62: Health Care and Social Assistance (including private, State, and local government hospitals). Adding 100% for fringe benefits and overhead to the \$15.26 equals \$30.52. Multiplying the pay rate

by half the number of support and administrative personnel equals \$41.8 million.

For the remaining entities for which we cannot use Bureau of Labor Statistics data, we must use the industry payroll and employment Census data. To arrive at an estimate of the cost of time for training employees of health insurance issuers and State health and Medicaid agencies, we must divide the total annual payroll reported for these entities by the total number of employees and divide that number by the annual hours paid (2,080 hours), adjusted for fringe benefits and overhead.

For workers employed by the issuers participating in the Health Insurance Marketplaces, we must determine the hourly wage rate for workers employed in small and large issuers as we have described them above. The total number of workers in small entities (fewer than 500 workers) is 27,269 and the annual payroll is \$1.68 billion. The average wage per employee is \$61,895. Using the 2,080 hours for the annual number of work hours, we obtain an hourly rate of \$29.76. Assuming that the payroll amounts reported in the Census data do not include fringe benefits and overhead, we add 100% to the hourly rate to yield \$59.51 per hour. Multiplying this amount by half of the 4,454 employees in small issuers equals \$132,540 in one-time training costs.

The total number of employees employed by large issuers (500 or more) is 415,017 and the annual payroll is \$30.8 billion. The average annual wage is \$74,219. Dividing this figure by 2,080 hours yields an hourly wage rate of \$35.68. Multiplying by 100% for fringe benefits and overhead yields \$71.36. Multiplying this amount by 50% of the 87,400 workers equals slightly more than \$3.12 million in one-time training costs.

For State government workers employed in welfare, health, and hospital services, we divided the total number of workers the 2013 Annual Census Bureau reported (755,993 employees) into the annual payroll reported for the period (\$3,275,595,529). On an annual basis, the average salary per employee equals \$52,123. The hourly rate equals \$25.06 and multiplied by 100% for fringe benefits and overhead yields \$50.12 per worker for training costs.

In the *State Medicaid Operations Survey: Second Annual Survey of Medicaid Directors* cited earlier, States reported the median number of full-time Medicaid employees is 421. Using this number multiplied by the 53 Medicaid agencies in the 50 States, the District of

Columbia, Puerto Rico, Guam, and the other territories, we added 22,313 workers to the total of health and hospital workers reported in the Census data, bringing the total number of workers in covered State government entities to 553,564. We then subtracted the 446,210 medical personnel we accounted for in the training costs for all health care personnel and therefore were considered to be duplicative of the medical personnel previously counted in our analysis of medical staff workforce (occupations 29–1000, 29–2000 and 31–0000). This left a net of 107,354 State employees receiving training. Taking half of this number and multiplying it by \$50.12 equals a one-time training cost of slightly more than \$2.69 million.

Although we removed the cost of training the 446,210 medical personnel from the State training cost analysis to avoid double counting training costs, the cost of training half the medical staff may still fall to the States where they are employed. We estimate the cost to train State medical personnel to be approximately \$10.5 million.¹²⁷

The 2013 Bureau of Labor Statistics data for North American Industry Classification System pharmacies and drugstores reports a total workforce of 706,000 workers. As with the analysis for State employees, we must remove health care workers that are already counted in our training costs analysis of the health care workforce. To avoid double counting training costs for these occupations, we removed them from the count of the pharmacy workforce. However, the entities that employ these workers will still bear the cost for training them. At a median weighted wage of \$47.22, if employers trained half of the medical staff they employ, they would be responsible for \$8.2 million in training costs for the employees we excluded from the analysis to avoid double counting.¹²⁸

For the 357,620 non-medical pharmacy personnel, the cost of training half the employees equals the median hourly rate for pharmacy employees (\$13.37), or \$26.74 after adding 100% for fringe benefits and overhead. Total

¹²⁷ We calculated the cost of training the medical personnel using the weighted median hourly rate, \$47.22, multiplied by the 446,210 medical staff identified as employed in State governments.

¹²⁸ Determining the cost to train employees other than pharmacists and medical staff who work in pharmacies requires use of the Bureau of Labor Statistics industry data for North American Industry Classification System code 446110. These data show that for 2013, 348,380 medical practitioners, technologists and medical support staff (occupation code 29–1000 and 29–2000 and 31–000) were employed in pharmacies and drug stores.

costs for employee training time equals \$7.78 million.

The following table summarizes the training costs we estimate for the proposed rule.

TABLE 4—TOTAL TRAINING COSTS

	Number of entities/ workers	Cost
Training preparation costs (\$125/entity)/entity	* 278,565	\$34,820,625
Health care staff and managers training	7,323,690	335,137,611
Small Issuers in the Health Insurance Marketplace training	2,414	143,669
Large issuers in the Health Insurance Marketplace training	43,700	3,118,618
Navigators	1,399	120,551
State health, hospital and Medicaid worker training	53,677	2,690,291
Pharmacy worker training	178,810	6,791,203
Total	7,633,717	382,822,568

* Not included in column total.

D. Notification and Other Procedural Requirements

1. Designation of Responsible Employee and Adoption of Grievance Procedures

Pursuant to the regulations implementing Section 504, recipients of Federal financial assistance with 15 or more employees are required to designate a responsible employee to coordinate compliance with respect to nondiscrimination requirements and to have a grievance procedure to address complaints of discrimination under this law. Of the 279,000 covered health care entities, approximately 15% employ more than 15 employees, resulting in approximately only slightly more than 58,500 covered health care entities being required to have a grievance procedure and designate a responsible official. Thus, all recipients of Federal financial assistance with 15 or more employees are already expected to have in place a grievance procedure and a designated employee to coordinate their compliance responsibilities. The proposed rule standardizes the requirement to designate a responsible employee and adopt grievance procedures across all bases of discrimination prohibited under Section 1557.

To implement the proposed rule, a recipient of Federal financial assistance could increase the responsibilities of an already-designated employee to handle compliance with the proposed rule's nondiscrimination requirements. In addition, a recipient of Federal financial assistance could increase the scope of existing grievance procedures to accommodate complaints of discrimination under all bases prohibited under Section 1557. The costs associated with these requirements are the costs of training the designated employee on his or her increased

responsibilities and the costs associated with modifying the existing grievance procedures to reflect the additional bases of race, color, national origin, sex, and age. Here we are referring to employee training to perform their specific enforcement responsibilities, not one-time training in the provisions of the rule described in the training section above. We also note that grievance officials will probably receive specific training on their new responsibilities and that covered entities will probably provide this additional training and absorb the costs, which are expected to be minimal. Many covered entities already may be using their existing grievance procedures to address the additional cases covered under Section 1557.

State-based Marketplaces are required to designate an employee to handle compliance responsibilities and to adopt a grievance procedure under the ADA. The duties of the employee and the grievance procedure could be modified to reflect all the bases covered under Section 1557. We have not estimated the additional costs of training grievance officials on their individual enforcement responsibilities, but believe such cost would be absorbed in general training costs of all employees on their job responsibilities. Costs associated with modifying existing grievance procedures are covered in the section of the analysis on enforcement.

2. Notice Requirement

The implementing regulations of Title VI, Section 504, Title IX, and the Age Act require recipients of Federal financial assistance and, in the case of Section 504, the Department, to notify individuals that recipients (and, under Section 504, the Department) do not discriminate. The content of the

nondiscrimination notices varies based on the applicable civil rights law.

The proposed rule harmonizes notification requirements under Title VI, Section 504, Title IX and the Age Act, and standardizes the minimum information for a notice. The proposed rule also requires initial and continuing notification of individuals. The proposed rule provides that OCR will draft a sample notice in English that meets the requirements and will translate that notice into 15 additional languages. Covered entities have discretion to use the OCR sample notice or their own notice, if preferred, and to post the notice in non-English languages.

As all Section 1557 covered entities will need to create or update an existing notice of nondiscrimination, all covered entities can discharge their responsibilities under § 92.8(a) by replacing their current notices with the sample notice OCR will make available to all covered entities pursuant to § 92.8(c). Using the sample OCR notice means that covered entities will not have to compose their own notices; we expect nearly all covered entities will use the sample OCR notice.

All covered entities will incur costs, however, to implement § 92.8(a) of the proposed rule, which requires "initial and continuing" notification. Such notification is expected to involve:

- Downloading the notice from the OCR Web site;
- Printing copies of the notice for posting;
- Posting hard copies of the notice in public spaces of the office or facility; and
- Posting the notice on the entity's Web site, if it has one.

Approximately 278,500 covered entities would spend one minute downloading the notice from the OCR

Web site and then spend five minutes posting one copy of the notice in an average of two areas each. (Smaller entities may post the notice only in a reception area; larger entities may post the notice in emergency and reception areas.) Based on the fully loaded cost of \$30.52 per hour for a clerical worker, the cost for the average covered entity is estimated to be:

- Downloading the OCR notice—1 minute at \$30.52 per hour equals \$0.51;
- Printing 2 hard copies of the notice—1 minute at \$30.52 per hour equals \$0.51;
- Posting the notice in an average of two areas—5 minutes, at \$30.52 per hour equals \$2.54; and
- Preparing the OCR notice for posting on the facility's Web site and posting the notice on the Web site—ten minutes of a clerical worker's time adjusted for fringe benefits and overhead equaling \$5.08.

For each entity, the cost of downloading the notice, posting it in a public place and posting it to the entity's Web site is \$8.64. The total cost for the 279,000 covered entities is \$2,411,000.

Covered entities that distribute general or major publications targeted to patients, consumers, or members of the public will need to update these publications to include the new notice. However, as noted above, we are allowing entities to exhaust their current publications, rather than do a special printing of the publications to include the new notice. When covered entities restock their printed materials, they will be expected to include in those printed materials the notice that OCR will provide with the final rule.

Because we are permitting covered entities to exhaust their existing stock of publications with the current notices before using the new notice, we conclude that the notice requirement imposes no resource costs related to including updated notices in the publications. We invite public comment on our analysis. Section 92.8 provides covered entities discretion to post the OCR sample notice of nondiscrimination in 15 non-English languages, which can include languages that differ from OCR's list. The 15 languages cover over 90 percent of non-English language speakers. In addition, covered entities can draft and translate their own notice in however many languages they choose, if they prefer.

We examined CMS contractual cost for translating a one page notice into 13 languages which was \$1,000. Based on this figure, if we were providing notices to approximately 300,000 entities and used the same contractor, the costs to the Federal government would be a maximum of approximately \$1.4 million

dollars. However, because the Federal government would be posting the notice onto its Web site, rather than printing it, covered entities would have to bear the cost of downloading and printing the notice from OCR's Web site and then posting it.

We expect total costs to the government to be limited to \$1,000 to translate the notice into 15 languages and place the translated notices on OCR's Web site.

Although not required, we expect that many covered entities would choose to post the OCR-provided notice in one or more non-English languages on their Web sites, in their physical office space, and in certain publications they may have. We do not know how many covered entities would take this action or how many non-English language versions of the notice they would choose to post, or where they would make the non-English versions of the notice available. We invite comment on these issues.

Section 92.8 requires covered entities to publish taglines indicating the availability of language assistance services in the top 15 languages nationally. OCR will make these taglines available electronically in the 15 languages; therefore, there will be no burden to the covered entity other than the cost of printing and posting these taglines, as described above with respect to the notice. We are uncertain of the exact volume of taglines that will be printed or posted, but we estimate that covered entities will print and post the same number of tag lines as notices and therefore the costs would be comparable to the cost for printing and disseminating the notice, or \$2,411,000. The costs to the federal government for translating the taglines will approximately be the same as for printing the notices or \$1,000. We estimate that the combined costs of printing and distributing notices and tag lines will be \$4,822,000 for entities and \$2,000 for the Federal government. We seek public comment on this estimate.

E. Meaningful Access for Individuals With Limited English Proficiency (LEP)

Proposed § 92.201, which effectuates Section 1557's prohibition of national origin discrimination as it affects individuals with limited English proficiency, does not pose any new burden on covered entities. With regard to recipients of Federal financial assistance, the proposed rule adopts recipients' existing obligations under Title VI to take reasonable steps to provide meaningful access to individuals with limited English proficiency and codifies standards

consistent with long-standing principles from the HHS LEP Guidance regarding the provision of oral interpretation and written translation services. Because the proposed rule does not impose duties beyond recipients' legal obligations under Title VI, the proposed rule imposes no new burden.

Although Title VI does not apply to the Department, Executive Order 13166 "Improving Access to Services for Persons with Limited English Proficiency," has applied to HHS for nearly 15 years.¹²⁹ This Executive Order requires Federal departments to develop and implement a plan, consistent with the HHS LEP Guidance, to ensure that persons with limited English proficiency can meaningfully access the Department's programs and activities. HHS adopted a Language Access Plan in 2000, and updated it in 2014, to provide individuals with limited English proficiency meaningful access to HHS-conducted programs and activities.¹³⁰ Because the proposed rule does not impose duties beyond the Department's existing obligation under the Executive Order, the proposed rule imposes no new burden on the Department.

Title VI applies to Title I entities that receive Federal financial assistance, including State-based Marketplaces. Executive Order 13166 applies to the Federally-facilitated Marketplaces as an HHS-conducted health program. Additionally, both Federally-facilitated Marketplaces and State-based Marketplaces must already comply with language access provisions of the Federal regulations governing Health Insurance Marketplaces.¹³¹ For instance, 45 CFR 155.205(c) requires Health

¹²⁹ E.O. 13166, 65 FR 50121 (2000).

¹³⁰ U.S. Department of Health and Human Services, Language Access Plan (LAP) (2013).

¹³¹ Under Federal regulations governing the Health Insurance Marketplaces, the term "Exchange" includes a Marketplace that is "established and operated by a State . . . or by HHS." 45 CFR 155.20. Health plans seeking certification as qualified health plans must provide information on certain claims payment and rating practices, cost-sharing, and enrollee and participant rights in information in plain language, which "means language that the intended audience, including individuals with limited English proficiency, can readily understand and use" 42 U.S.C. 18031(e)(3)(B). Marketplaces must also provide language assistance services for applicants and enrollees who are limited English proficient for the following Marketplace functions, documents, and information: consumer assistance functions (including the Navigator Program), education and outreach activities; all applications, forms, and notices; a Marketplace's toll-free call center; and a Marketplace's Internet Web site, which includes comprehensive information on the costs, benefits, and quality of qualified health plans. 45 CFR 155.205(a), (d), (e), 155.230(b). These regulatory provisions incorporate by reference the language assistance services requirement in 45 CFR 155.205(c)(2).

Insurance Marketplaces to provide information to applicants and enrollees in a manner accessible to persons with limited English proficiency, including through the use of language assistance services, such as oral interpretation and written translation. We view covered entities' obligations under the proposed rule to "take reasonable steps to provide meaningful access" as imposing no greater burden than § 155.205(c) already imposes.

F. Nondiscrimination on the Basis of Sex

Section 1557 prohibits discrimination on the basis of sex, including sex stereotyping and gender identity, in certain health programs and activities. When providing services, including access to facilities, covered entities must provide individuals with equal program access on the basis of sex, and are required to treat individuals in a manner consistent with their gender identity.

Prior to the enactment of Section 1557, Title IX applied to educational institutions. Therefore, medical schools, nursing programs, and other health education programs were already prohibited from discriminating on the basis of sex. Under Section 1557 and this proposed regulation, health insurance issuers receiving Federal financial assistance, hospitals, clinics and other health facilities, HHS health programs and activities, and Title I entities, along with the staff and practitioners working in these health programs, are now similarly prohibited from discriminating on the basis of sex.¹³² This section discusses the costs associated with the prohibition of discrimination on the basis of sex in the proposed rule, taking into account the existing environment, including legal authorities that address equal access on the basis of sex.

Covered entities that provide or administer health services or health insurance coverage are covered by the prohibition of discrimination on the basis of sex, including sex stereotyping and gender identity. The costs that we anticipate that covered entities would incur relate to: (1) Training; (2) enforcement; (3) the posting of the notice; (4) the revision of policies and

procedures; and (5) some costs associated with changes in discriminatory practices. The costs related to training, enforcement, and the posting of the notice have already been discussed in this analysis. This section discusses costs related to changes in policy and procedures and potential changes in discriminatory practices.

Costs for Entities Providing or Administering Health Services

The NPRM would not invalidate specialties that focus on men or women, e.g., gynecology, urology, etc. Nor would providers have to fundamentally change the nature of their operations to comply with the regulation. For example, the NPRM would not require a provider that operates a gynecological practice to add to or change the types of services offered in the practice.

Under the sex discrimination prohibition, however, providers of health services may no longer deny or limit services based on an individual's sex, without a legitimate nondiscriminatory reason. Although a large number of providers may already be subject to state laws or institutional policies that prohibit discrimination on the basis of sex in the provision of health services, the clarification of the prohibition of sex discrimination in this regulation, particularly as it relates to discrimination on the basis of sex stereotyping and gender identity, may be new. We anticipate that a large number of providers may need to develop or revise policies or procedures to incorporate this prohibition. For example, if a hospital or other provider has specific protocols in place for domestic violence victims, but only engages that protocol for women, the provider would have to revise its procedures to require that protocol for all individuals regardless of sex. A provider specializing in gynecological services that previously declined to provide a medically necessary hysterectomy for a transgender man would have to revise its policy to perform the procedure on transgender individuals in the same manner it provides the procedure for other individuals.

Developing or Revising Policies and Procedures

We assume that it will take, on average, 3–5 hours for a provider to develop or modify policies and procedures concerning sex discrimination. We are selecting four hours, or the midpoint of this range, for our analysis. We further assume that three of the hours will be spent by a mid-level manager equivalent to a front-

line supervisor (Occupation code 43–1011), at a salary, with fringe benefits and overhead of \$48.52 per hour, and one hour will be spent by executive staff equivalent to a general and operations manager (Occupation code 11–1021), at a salary, with fringe benefits and overhead of \$81.84 per hour. We further assume that 75% of covered health providers will need to develop or modify policies and procedures, given that some proportion of health care providers already prohibit sex discrimination based on State law or institutional policies prohibiting discrimination generally. The total cost for the estimated 208,700 providers to make their policies and procedures consistent with the regulatory prohibition on discrimination on the basis of sex is estimated to be a one-time cost of approximately \$47.5 million, which we assume is divided evenly between the first two years of compliance.

The above estimates of time and number of entities that would have to revise their policies under the regulation is an approximate estimate based on general BLS data. Due to the wide range of types and sizes of covered entities, from complex multi-divisional hospitals to small neighborhood clinics and physician offices, the above estimates of time and number of entities that would have to revise their policies under the regulation is difficult to calculate. We invite the public to submit data and comments on our estimate.

Stopping Discrimination

For providers that discriminate on the basis of sex in violation of the proposed rule, some changes in behavior or action would be necessary to come into compliance. We anticipate some change in the patient population for which a particular provider provides care or the extent of services provided. However, the infrastructure and protocols for providing services or treatment are already in place; providers would simply have to start providing those existing services in a nondiscriminatory manner to individuals regardless of sex. For example, a provider could not refuse to treat a patient for a cold or a broken arm based on the patient's gender identity. Similarly, if the provider is accepting new patients, it must accept a new patient request from a transgender individual and cannot decline to accept a transgender person in favor of a person who is not transgender.

However, the proposed rule does not impose a burden on covered entities with respect to the number of patients treated. The proposed rule does not

¹³² We note that consistent with OCR's enforcement of other civil rights authorities, the proposed definition of Federal financial assistance under the regulation does not include Medicare Part B, making physicians receiving only Medicare Part B payments, not covered under the regulation. However, because almost all physicians receive payments from other Department programs such as Medicaid or Medicare meaningful use payments, we believe that there would be very few physicians excluded from these provisions.

require a covered entity to change the total number of patients it sees or to treat more patients than it currently accepts. Providers may continue to treat the same number of patients that were accepted prior to the issuance of this proposed rule, but they must do so in a nondiscriminatory manner. Thus, for example, if a provider is not accepting new patients, the provider does not have to accept a new patient request from a transgender person. We anticipate that the costs associated with these types of changes would be minimal.

Moreover, costs associated with administering care or treating a new patient generally would be offset by the reimbursement received by the provider for providing the care, in the same way the provider gets paid for existing care or treatment of patients. Thus, for example, for the hospital or other provider that needs to revise its protocol for domestic violence to require that protocol for all individuals regardless of sex, rather than just women, there would be little to no net increase in costs for treating men because the hospital or provider would be paid for its services in the same way it would be paid to treat a woman for the same care. We welcome comments on this assumption and information about costs.

Costs for Entities Providing or Administering Health Insurance Coverage

The ACA, including Section 1557, changed the health care landscape for millions of people by instituting protections against sex discrimination in the provision of health care and health insurance coverage. Prior to the ACA, it was standard health insurance practice to treat women differently in premium pricing and coverage of benefits,¹³³ while transgender individuals frequently experienced discrimination when seeking treatment.¹³⁴

The ACA addresses inequitable treatment by health plans based on sex in multiple ways. CMS regulations implementing the ACA prohibit Title I

entities¹³⁵ and most health insurance issuers¹³⁶ from discriminating based on sex, including sex stereotyping and gender identity, in addition to other bases. These market-wide provisions are applicable to health insurance issuers both on and off the Health Insurance Marketplace, which includes qualified health plan issuers¹³⁷ and health insurance issuers providing non-grandfathered coverage in the individual and group markets outside of the Health Insurance Marketplace.¹³⁸

In addition, the Affordable Care Act prohibits many health insurance issuers from charging higher premiums based on sex;¹³⁹ failing to provide essential health benefits that greatly impact women, such as maternity care;¹⁴⁰ failing to cover preventive services that are necessary for women's health, such as mammograms;¹⁴¹ and denying benefits based on pre-existing conditions¹⁴² or health factors,¹⁴³ many of which affect women's health, such as a history of a Caesarian section or a history of domestic violence.¹⁴⁴ Thus, health insurance issuers and the Health Insurance Marketplaces have already had to expand access to women and lesbian, gay, bisexual and transgender (LGBT) individuals under these health insurance market reforms, independent of Section 1557. The existence of these

other provisions circumscribes cost burdens on Health Insurance Marketplaces and issuers that are recipients of Federal financial assistance that are imposed by the prohibition of sex discrimination in the proposed rule. However, the proposed rule nonetheless would impose some costs.

Section 92.207 (Nondiscrimination in health insurance and other health coverage) of the proposed rule prohibits discrimination on the basis of sex, including sex stereotyping and gender identity, by a covered entity providing or administering health insurance or other health coverage. As noted, many of the same covered entities subject to Section 1557, including Health Insurance Marketplaces and health insurance issuers that are recipients of Federal financial assistance, are also subject to existing nondiscrimination provisions in CMS regulations. While the CMS regulations complement and do not replace Section 1557, the existing nondiscrimination requirements applicable to health insurance issuers and Health Insurance Marketplaces mean that these entities are aware that they are not permitted to discriminate on the basis of sex, including sex stereotyping and gender identity, and thus they are familiar with their nondiscrimination obligations under the law. We assume that these covered entities have already taken steps to comply with CMS regulations and so instituted changes in their policies and actions. To the extent these existing obligations overlap with Section 1557 and covered entities have taken steps required under the CMS regulations, this proposed rule will impose little or no burden on health insurance issuers and Title I entities to comply with Section 1557's prohibition on sex discrimination because these covered entities should already be in compliance with regulations that prohibit discrimination on the basis of sex, including sex stereotyping and gender identity.

Developing or Revising Policies and Procedures

There may be some incremental burden on issuers and Title I entities in terms of the additional guidance that this proposed rule provides related to sex discrimination, since, in some circumstances, it provides more detail than CMS regulations or guidance. Therefore, covered entities may have an increased burden when incorporating this rule into their existing nondiscrimination policies and procedures. For example, this rule specifies that an explicit categorical exclusion of coverage for health care

¹³³ See Adelle Simmons, Katherine Warren, and Kellyann McClain, *ASPE Issue Brief, The Affordable Care Act: Advancing the Health of Women and Children*, (January 9, 2015), available at http://aspe.hhs.gov/health/reports/2015/MCH/ib_mch.pdf; HHS.gov/Health Care, *The Affordable Care Act and Women Fact Sheet*, <http://www.hhs.gov/healthcare/facts/factsheets/2012/03/women03202012a.html> (last visited June 12, 2015).

¹³⁴ See Lambda Legal, *When Health Care Isn't Caring*, *Lambda Legal's Survey on Discrimination Against LGBT People and People Living with HIV*, (2010), available at <http://www.lambdalegal.org/publications/when-health-care-isnt-caring>.

¹³⁵ 45 CFR 155.120(c)(1)(ii) prohibits a Health Insurance Marketplace from discriminating based on race, color, national origin, disability, age, sex, gender identity, or sexual orientation.

¹³⁶ 45 CFR 147.104(e) prohibits health insurance issuers in the non-grandfathered individual, small and large group markets from employing benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs in health insurance coverage or discriminate based on an individual's race, color, national origin, present or predicted disability, age, sex, gender identity, sexual orientation, expected length of life, degree of medical dependency, quality of life, or other health conditions. 45 CFR 156.200(e) prohibits a qualified health plan issuer from discriminating on the basis of race, color, national origin, disability, age, sex, gender identity, or sexual orientation. 45 CFR 156.125(a) prohibits issuers that provide essential health benefits from using benefit designs that discriminate based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions. 45 CFR 156.125(b) requires issuers that provide essential health benefits to comply with 45 CFR 156.200(e).

¹³⁷ 45 CFR 147.104(e), 156.200(e) and 156.125(a)–(b) are applicable to qualified health plan issuers.

¹³⁸ 45 CFR 147.104(e) is applicable to non-grandfathered coverage in the individual, small and large group markets. 45 CFR 147.150(a) incorporates essential health benefits requirements (and implementing regulations at 45 CFR 156.200(e) and 156.125(a)–(b)) for non-grandfathered coverage in the individual and small group markets.

¹³⁹ 45 CFR 147.102.

¹⁴⁰ 45 CFR 156.110.

¹⁴¹ 45 CFR 147.130.

¹⁴² 45 CFR 147.108.

¹⁴³ 45 CFR 147.110.

¹⁴⁴ *ASPE Issue Brief*, *supra* note 133.

services related to gender transition is discriminatory on its face. To the extent a covered entity did not interpret sex discrimination on the basis of gender identity in this way, the covered entity would have to revise its policies and procedures to provide coverage consistent with this rule's parameters, which might include revising policies to include gender transition-related care.

However, we note that the number of major U.S. employers providing transgender-inclusive health care coverage has been increasing dramatically, from 0 in 2002, to 49 in 2009, 278 in 2013, 336 in 2014, and finally 418 in 2015.¹⁴⁵ This indicates that plans that offer transgender-inclusive health care are becoming readily available as models for issuers that may not offer such care, limiting their costs in developing or revising compliant policies and procedures.

Similar to the estimate for providers of health services, we assume that it will take, on average, three to five hours for issuers of health insurance coverage to develop or modify policies and procedures concerning sex discrimination. We are selecting four hours, or the midpoint of this range, for our analysis. We further assume that three of the hours will be spent by a mid-level manager, at a salary, with fringe benefits and overhead of \$57.60 per hour,¹⁴⁶ and one hour will be spent by executive staff, at a salary, with fringe benefits and overhead of \$122.15 per hour. Based on our best estimate of industry compliance with CMS regulations, we further assume that one-third or 33% of health insurance issuers will need to develop or modify policies and procedures. Based on an unduplicated count of issuers, we previously identified 180 issuers in the Federally-facilitated Marketplaces. One third of this number equals 60 issuers that we estimate would need to revise policies to address the prohibition of sex discrimination in this regulation. The costs to issuers to revise policies and procedures to provide coverage consistent with this rule's parameters equal 60 issuers multiplied by \$295 for a one-time cost of \$17,700.

Stopping Discrimination

In addition to the cost some covered health insurance providers may have for revising policies and procedures to

comply with the proposed rule, such providers may also incur a minimal cost related to the cost of coverage. In this regard, we note that the April 2012 California Department of Insurance Economic Impact Assessment on Gender Nondiscrimination in Health Insurance found that covering transgender individuals under California's private and public health insurance plans would have an "insignificant and immaterial economic impact" on costs.¹⁴⁷

This conclusion was based on evidence of low utilization and the estimated number of transgender individuals in California. The transgender population of California was estimated to range between 0.0022% and 0.0173%.¹⁴⁸ The study revealed that contrary to common assumptions, not all transgender individuals seek surgical intervention, and that gender-confirming health care differs according to the needs and pre-existing conditions of each individual.¹⁴⁹ Additionally, issuers in California that established premium surcharges after enactment of California's Gender Nondiscrimination in Health Insurance Law subsequently eliminated them because they found they did not spend the extra funds generated.¹⁵⁰

Based on the California study, we believe that providing transgender individuals non-discriminatory insurance coverage and treatment will impact a very small segment of the population due to the fact that the number of transgender individuals (and particularly those who seek surgical procedures in connection with their gender transition) in the general population is small, and will have minimal impact on the overall cost of care and on health insurance premiums.¹⁵¹

G. Accessibility of Electronic and Information Technology

Although Section 1557 requires covered entities to ensure that the health programs, services, and activities provided through electronic and information technology are accessible to individuals with disabilities, all covered

entities affected by Section 1557 already have these obligations under Section 508, Section 504 or the ADA.

1. HHS Health Programs and Activities, Including the FFM

Section 508 requires that electronic and information technology developed, procured, maintained, or used by Federal agencies be accessible for individuals with disabilities (both members of the public and Federal employees). Section 504 also establishes general obligations for Federal agencies to make their programs that are provided through electronic and information technology accessible to individuals with disabilities. Both Section 504 and Section 508 were in place before the passage of the ACA. There is, therefore, no additional burden under Section 1557 for HHS health programs, including the Federally-facilitated Marketplaces, as the Section 1557 requirements are consistent with the obligations these programs already have under Section 504 and Section 508.

2. Recipients of Federal Financial Assistance From HHS and Title I Entities

Section 504 also establishes general obligations for entities receiving Federal financial assistance to make their programs, services, and activities provided through electronic and information technology accessible to individuals with disabilities. The ADA imposes similar accessibility requirements on covered entities. The proposed regulation thus imposes no additional burden on recipients of Federal financial assistance from HHS because Section 1557 is consistent with existing standards these entities are already obligated to meet under the ADA and Section 504. Title I entities have no Section 1557 burden with respect to this proposed requirement, as the Title I entities must already be compliant with the ADA, which is consistent with the Section 1557 accessibility standards.

H. Enforcing the Rule

After grievances are filed with covered entities or complaints are filed with OCR, there are associated costs to investigate and resolve those grievances and complaints. We believe the following costs result from enforcement of the Section 1557 regulation:

- Costs to covered entities for modifying and implementing existing grievance procedures to cover grievances filed under Section 1557.
- Costs to OCR for reviewing and investigating complaints, monitoring

¹⁴⁵ Human Rights Campaign, *Corporate Equality Index, Rating American Workplaces on Lesbian, Gay, Bisexual and Transgender Equality*, 30, (2015), available at <http://www.hrc.org/campaigns/corporate-equality-index>.

¹⁴⁶ Using BLS occupation code 43-1011 and occupation code 11-1021 for the health insurance industry NAICS code 524114.

¹⁴⁷ State of California, Department of Insurance, *Economic Impact Assessment Gender Nondiscrimination in Health Insurance*. (Apr. 13, 2012).

¹⁴⁸ *Id.*

¹⁴⁹ *Id.* at 8.

¹⁵⁰ *Id.* at 6-7.

¹⁵¹ *Id.* at 9. Insurers in California that established a premium surcharge to cover the City of San Francisco's expected claim costs eventually eliminated the additional premium because they found their cost assumptions were 15 times higher than actual claims generated.

corrective action plans or taking other enforcement actions against covered entities.

We now proceed to estimate the aggregate costs of these enforcement procedures. In the analysis below, we analyze the costs to covered entities separately from the costs to OCR.

1. Costs to Covered Entities

Federal civil rights laws that were in place before Section 1557 became effective apply to entities that receive Federal financial assistance. Entities subject to those laws are already required to have in place an established grievance procedure to address disability discrimination complaints and complaints of sex discrimination in education programs. It is anticipated that any additional costs that may be imposed by this regulation would potentially arise because of the expansion of the grievance process to cover all bases covered under Section 1557, including race, color, national origin, and age, as well as sex discrimination in health care. It is expected that this may lead to a slight increase in additional grievances being filed, and require increased time to investigate and resolve these additional grievances.

To compute the anticipated costs for covered entities to enforce the proposed regulation, we looked to OCR data. The current number of civil rights complaints filed annually with OCR is approximately 3,000. Since the passage of Section 1557, OCR's complaint workload has increased slightly; with somewhere in the range of 15–20 unique Section 1557 cases filed each year. Stemming from the sentinel effects from the enactment of the regulation, if we include another ten cases per year, we calculate an increase of 30 cases per year or 1% of the annual caseload of 3,000. We assume the incremental workload will be similar for affected entities and thus will be approximately 1%. We anticipate that within the first five years following the rule's enactment, complaints will increase, but eventually will drop off as covered entities modify their policies and practices in response to the proposed rule. Although we have data on OCR's caseload, we have no data on the caseload of affected covered entities. We ask for public comment on the assumption regarding increased caseload.

If we assume that as a result of promulgating the proposed regulation, a designated grievance official for the 58,550 covered entities with 15 or more employees had to devote an additional 1% of his or her time to investigating discrimination grievances, incremental costs (including fringe benefits and overhead) would be \$118.7 million.

To arrive at this number we used the annual mean wage of \$101,340 for medical and health service managers (occupation code 11–9111) and took 1%. We increased the amount by 100% to account for fringe benefits and overhead, and multiplied the value by the number of covered health entities that we estimate have 15 or more entities using 2012 US business census data.

It is important to consider the assumptions we made in estimating the costs to covered entities. We assumed that all entities would experience the same proportional increase in complaints filed. This may not be accurate. We expect most covered entities will comply with the regulation and not see an increase in complaints. However, because we lack data to enable us to pinpoint which entities will experience an increase, we are required to make a general assumption about all covered entities. As such, we anticipate the resultant cost estimate to be an overestimation of the new costs for addressing grievances filed against covered health entities. We ask for public comment on these costs and estimates.

The same incremental calculations apply to the workloads of State agencies and the officials working in these agencies. If we assume the same 1% increase in caseload and the average mid-level State official salary is \$94,580 (including fringe benefits and overhead), we must multiply \$94,580 by the number of State covered entities.¹⁵² To arrive at the number of State covered entities we make the following assumptions:

- We assume that there are 53 Medicaid State agencies;
- We assume that there are 53 State health departments;
- We assume that each State and the District of Columbia has two State-run hospitals; and
- We assume that each of 3,143 counties has a county health department that provides direct health services (*e.g.*, immunization clinics) and is

accountable to the State Health Department. We assume that each of the county health departments has a designated official for handling grievances.

The total number of State covered entities is 3,351. Multiplying \$94,580 by 3,351 equals \$316.9 million. One percent of this value equals \$3.17 million.

2. Costs to OCR

We considered the various OCR enforcement costs together, based on OCR average salary data presented in its annual budgets. According to the FY 2016 President's Budget, \$28,400,000 and 137 Full Time Equivalents (FTEs) were requested for Enforcement and Regional Operations, at a cost of approximately \$201,000 per FTE. Of the 137 FTEs, approximately 40 FTEs spend 100% of their investigative time enforcing the civil rights laws.¹⁵³ If we make the same assumption we did above and assume the same 1% increase in caseload from the issuance of Section 1557, the anticipated increase in number of staff necessary would be approximately 0.4 of an FTE (1% of 40) and would cost approximately \$80,400.

Summary of Cost and Phase-in

The table below summarizes the costs attributable to the proposed regulation that covered entities may incur following enactment of the final regulation. We assume that half of the training costs and changes to policies and procedures on the prohibition of discrimination on the basis of sex will be incurred in the first year and the second half will be expended in the second year. For covered entities that will be printing and distributing notices to their patients and policy holders, we assume that all of the estimated printing and distribution costs will be expended in the first year after the effective date of the rule. Due to the likelihood that applicable changes will need to be phased in, we assume one half of the annual projected costs for investigating discrimination complaints will be incurred during the first year and three quarters of the annual projected enforcement costs will be spent in the second year and the full amounts in the third through fifth years. Information collection requirements and paperwork burden costs would be incurred within the first year after the effective date of the final regulation.

¹⁵² Based on the annual salary of Executive Secretary and Executive Administrative Assistant (Occupation code 43–6011 for Sector 99).

¹⁵³ This is based on an informal staff estimate.

TABLE 5—COST SUMMARY OF THE PROPOSED REGULATION FOLLOWING ENACTMENT OF THE FINAL RULE
[discounted 3% and 7% in millions]

	Year 1	Year 2	Year 3	Year 4	Year 5	Total/ Annualized *
Training (undiscounted)	191.4	191.4	0	0	0	382.8
Training (3%)	185.8	180.4	0	0	0	80.0
Training (7%)	173.7	157.6	0	0	0	80.8
Investigation (undiscounted)	59.3	89.0	118.7	118.7	118.7	504.3
Investigation (3%)	57.6	83.9	108.6	105.4	102.4	100.0
Investigation (7%)	53.8	73.3	88.6	80.4	73.0	90.0
Notice Publication (undiscounted)	4.8	0	0	0	0	4.8
Notice Publication (3%)	4.7	0	0	0	0	4.7
Notice Publication (7%)	4.4	0	0	0	0	4.4
Sex discrimination Policy and Procedure Changes (undiscounted)	23.7	23.7	0	0	0	47.5
Sex discrimination Policy and Procedure Changes (3%)	23.0	22.4	0	0	0	9.9
Sex discrimination Policy and Procedure Changes (7%)	21.5	19.5	0	0	0	10.0
Total (undiscounted)	279.2	304.1	118.7	118.7	118.7	939.4
Total (3%)	271.1	286.7	108.6	105.4	102.4	190.9
Total (7%)	253.4	250.4	88.6	80.4	73.0	162.82

* Discounted and annualized values take into account the cost of borrowing and paying back funds at hypothetical interest rates to simulate opportunity costs.

With this summary, we have completed our analysis the costs of the rule. Next, we examine the benefits that can be expected to accrue as a result of the proposed rule.

III. Benefits & Transfers

In enacting Section 1557 of the ACA, Congress recognized the benefits of equal access to health services and health insurance that all individuals should have, regardless of their race, color, national origin, age, or disability. Section 1557 brought together the rights to equal access that had been guaranteed under Title VI, the Age Act and Section 504. At the same time, Congress extended these protections and rights to individuals seeking access to health services and health insurance without discrimination on the basis of sex.

This proposed rule would implement the provisions of Section 1557. In most respects, the proposed rule clarifies existing obligations under existing authorities and we have noted in the cost analysis that we do not expect that covered entities would incur costs related to the clarification of those existing obligations in the proposed rule. However, we also noted that we expected that the prohibition of sex discrimination in the proposed rule would generate certain actions and other changes in behavior by covered entities and that these actions and changes would impose costs. These actions and other changes in behavior would also result in benefits.

The provisions prohibiting sex discrimination in the ACA increase the affordability and accessibility of health

care for women and transgender individuals. However, despite the ACA improving access to health services and health insurance, many women and transgender individuals continue to experience discrimination in the health care context. This continued discrimination demonstrates the need for further clarification regarding the prohibition of discrimination on the basis of sex.

Prior to the enactment of the ACA, insurance companies were allowed to impose higher premiums on women or deny women coverage altogether. If issuers did cover women, they frequently did not cover many women's health services, including routine preventive and wellness services, such as pap smears or mammograms. Insurance premiums previously differed by sex, based on additional actuarial risk for females relative to males; with the ACA's requirement of equal premiums for both sexes, the payments associated with that risk are transferred from impacted females (who previously paid for that risk through higher premiums) to entities in society.

In the transgender community, a major barrier to receiving care is a concern over being refused medical treatment based on bias against them.¹⁵⁴ In a 2010 report, almost half of LGBT respondents reported suffering some form of discriminatory treatment by providers when receiving medical care, while 26.7% of transgender respondents reported that they were outright refused

needed health care.¹⁵⁵ A 2008 survey revealed that 28% of transgender individuals reported being subject to harassment in medical settings and 50% reported having to teach their medical providers about transgender care.¹⁵⁶

Covered entities' patient nondiscrimination policies often do not include gender identity. The 2014 Human Rights Campaign Healthcare Equality Index, which evaluates health care facilities' LGBT policies and practices, found that among the 640 hospitals it evaluated, 501 had patient nondiscrimination policies but of those only 257 had a patient nondiscrimination policy that included both the terms "sexual orientation" and "gender identity."¹⁵⁷

With respect to access to nondiscriminatory health insurance coverage, Durso, Baker and Cray cite interviews from their survey of the difficulties that LGBT individuals have experienced seeking insurance.¹⁵⁸ The *Out to Enroll Report: Key Lessons for LGBT Outreach and Enrollment under the Affordable Care Act* focuses on the

¹⁵⁵ *Id.* at 9–10.

¹⁵⁶ National Center for Transgender Equality and National Gay and Lesbian Task Force, *Injustice at Every Turn: A Report of the national Transgender Discrimination Survey* (2008), available at http://www.thetaskforce.org/static_html/downloads/reports/reports/ntds_full.pdf.

¹⁵⁷ *The Human Rights Campaign*, *supra* note 145, at 12.

¹⁵⁸ Laura E. Durso, Kellan Baker, and Andrew Cray, Center for American Progress Issue Brief: *LGBT Communities and the Affordable Care Act Findings from a National Survey*, (October 10, 2013), available at <http://www.preventionjustice.org/wp-content/uploads/2013/10/CAP-LGBT-Messaging-Research.pdf>.

¹⁵⁴ *Lambda Legal*, *supra* note 134 at 12–13.

lack of adequate training of Navigator staff when encountering LGBT individuals seeking access to the Health Insurance Marketplaces. A major complaint voiced was that Navigator staff were unaware of the multitude of discriminatory practices and policy restrictions in which issuers engage to deny or restrict coverage of transgender individuals, and that Navigator staff lacked basic knowledge of health issues that are unique to transgender individuals.¹⁵⁹ Almost 24% of LGBT individuals, including transgender individuals, have stated that a major motivator for seeking out new insurance options would be learning that plans cannot discriminate against them.¹⁶⁰

Discrimination in the health care context leads to denials of adequate health care for individuals and increases in existing health disparities in underserved communities.¹⁶¹ Individuals who have experienced discrimination in the health care context often postpone or do not seek much needed health care, which may lead to negative health consequences.¹⁶² For example, LGBT health disparities include higher rates of mental health issues, including depression and suicide attempts, higher risk of HIV/AIDS, higher use of tobacco and other drugs, and higher risk of certain cancers, such as breast cancer, with some portion of the differential potentially attributable to barriers to health care.¹⁶³

By prohibiting discrimination on the basis of sex, including sex stereotyping and gender identity, Section 1557 would result in more women and transgender individuals feeling secure in obtaining coverage and accessing health services. Since 2013, the uninsured rate for women has declined by 7.7 percentage points, resulting in

nearly 7.7 million women gaining health insurance as of 2015.¹⁶⁴ Similarly, uninsured rates for LGBT individuals have dropped 8% since 2013, to approximately 20%.¹⁶⁵ While these declines in the rates of the uninsured are attributable to many factors, among these factors may be provisions in the ACA prohibiting discriminatory practices in insurance. We expect that issuance of the Section 1557 regulation could contribute to a reduction in the number of individuals who are uninsured, though the reduction would be much more modest.

The State of California, in an economic impact assessment of State practices prohibiting gender discrimination in health care, cites the following benefits:¹⁶⁶

1. Reduced violence against affected individuals;
2. Improved worker safety and improved productivity at work for affected individuals;
3. Reduced depression and suicide attempts among the affected population; and
4. Overall declines in substance abuse, smoking and alcohol abuse rates, and improvements in mental health among treated individuals in LGBT populations who receive appropriate medical treatment.

Moreover, because discrimination contributes to health disparities, the prohibition of sex discrimination in health care under Section 1557 can help reduce health disparities. While it is not possible to quantify the benefits of the reduction in health disparities, the benefits would include more people receiving adequate health care, regardless of their sex, including gender identity.

The health and longevity benefits discussed above as potential effects of this rule can only occur if additional or higher-quality medical services are provided to affected individuals. These services would be associated with costs (which we lack data to estimate). As discussed in the earlier discussion of actuarial risk, to the extent that changes in insurance premiums do not alter how society uses its resources, then effects of the rule would be transfers between members of society, rather than social costs or benefits. In addition to women and transgender individuals, health

service providers and the Federal government could also be recipients of these transfers. For example, in 2013, hospitals provided over \$50 billion in uncompensated care to the uninsured, and the Federal government pays approximately 62% of uncompensated care.¹⁶⁷ HHS estimates that there was a \$7.4 billion reduction in hospital uncompensated care costs attributed to ACA coverage expansions in 2014. Based on estimated coverage gains in 2014, uncompensated care costs are expected to continue to fall substantially following continued major insurance coverage expansions, including coverage expansions through the Health Insurance Marketplace.¹⁶⁸ While issuance of the Section 1557 regulation is not a factor in this projection, we believe that issuance of the Section 1557 regulation will likewise contribute to a decrease in payments by the Federal government for uncompensated care by promoting an increase in the number of individuals who have insurance when they receive care.

Aside from the specific benefits and transfers that women, transgender individuals, and the health care community can be expected to gain from the enactment of the regulation, there are more general benefits that are intangible and unquantifiable. These benefits derive from having a society that provides equal access to health care for all.

IV. Alternatives Considered

In the course of developing this regulation, the Department considered various alternatives. Some of those alternatives still under consideration are discussed in the preamble, and the Department invites public comment on those options. A discussion of alternatives considered cannot cover all alternatives considered by the Department. The following alternatives are meant to be a representative sample to show how burden reduction was a major consideration in constructing the standards in this regulation.

OCR considered requiring covered entities to provide separate notices, covering separate content, e.g., separate notices on the requirements concerning providing meaningful access for individuals with limited English proficiency; requirements concerning effective communication for individuals with disabilities; and policies on

¹⁵⁹ Out2Enroll, Key Lessons for LGBT Outreach and Enrollment under the Affordable Care Act, 24, (July 24, 2014), available at <http://out2enroll.org/key-lessons-for-lgbt-outreach-enrollment/>.

¹⁶⁰ Center for American Progress, *supra* note 158.

¹⁶¹ See Bruce G. Link and Jo C. Phelan, Conceptualizing Stigma, 27 Ann. Rev. Sociology 363, 371, 378–380 (2001) (discussing the consequences of stigmatization, including health disparities); Alexandra Brandes, The Negative Impact of Stigma, Discrimination, and the Health Care System on the Health of Gender and Sexual Minorities, 23 Tul. J. L. & Sexuality 155, 156, 160–161 (2014) (discussing how discrimination leads to health disparities); Kellan E. Baker, Center for American Progress, Open Doors for All, 1–2 (2015) (discussing how discrimination exacerbates LGBT health disparities).

¹⁶² Alexandra Brandes, The Negative Impact of Stigma, Discrimination, and the Health Care System on the Health of Gender and Sexual Minorities, 23 Tul. J. L. & Sexuality 155, 160 (2014) (stating “Bias from health care professionals reduces the likelihood that LGBTQ individuals will seek and receive quality care.”).

¹⁶³ Center for American Progress, *supra* note 158 at 2.

¹⁶⁴ ASPE Issue Brief, *supra* note 133 at 1–4.

¹⁶⁵ Kellan Baker, Laura E. Durso, and Andrew Cray, Center for American Progress, Moving the Needle, The Impact of the Affordable Care Act on LGBT Communities, 3 (November 2014), available at <https://www.americanprogress.org/issues/lgbt/report/2014/11/17/101575/moving-the-needle/>.

¹⁶⁶ California Department of Insurance, *supra* note 147, at 11.

¹⁶⁷ ASPE Issue Brief, *supra* note 133.

¹⁶⁸ ASPE Issue Brief: Insurance Expansion, Hospital Uncompensated Care, and the Affordable Care Act (March 23, 2015), available at: http://aspe.hhs.gov/sites/default/files/pdf/83961/ib_UncompensatedCare.pdf.

nondiscrimination. To reduce the burden on covered entities, the Department rejected this option in favor of a comprehensive single notice requirement.

OCR decided to further reduce the burden imposed on covered entities by the notice requirement by providing that it would develop and provide covered entities with a sample notice. OCR allows covered entities flexibility in complying with the proposed notice requirement by giving covered entities the option of using the sample notice or developing their own notice. Although OCR considered requiring covered entities to post the notice in 15 languages (Spanish (or Spanish Creole), Chinese, Vietnamese, Korean, Tagalog, Russian, Arabic, French Creole, French (including Patois, Cajun), Portuguese (or Portuguese Creole), Polish, Japanese, Italian, German, and Persian (Farsi)), it rejected that option. Instead, it will translate the notice into 15 languages and provide covered entities the discretion to post one or more of the translated notices, should they so choose. We believe that making translated notices readily available to covered entities maximizes efficiency and economies of scale, provides flexibility while minimizing burden, and helps provide greater access for beneficiaries and consumers. Additionally, although OCR considered requiring covered entities to create their own taglines in the top 15 national languages spoken by individuals with LEP, it rejected that option. Instead, OCR will provide covered entities the 15 translated taglines. As the tagline requirement for the covered entities only requires the cost of printing and posting, this burden is expected to be minimal.

OCR considered not providing training materials to covered entities on the requirements of the regulation. However, in order to reduce costs and burden, OCR is providing these materials which will reduce covered entities' costs of developing training materials from \$500 per entity to \$125 per entity, saving an estimated \$106 million. Entities are assumed to bear one quarter of the total costs. These costs result from paying the presenters who will run the training sessions, providing classroom space, and supplementing the OCR provided training materials (should they choose to do so).

OCR considered remaining silent on covered entities' obligations to comply with Section 1557's prohibition of national origin discrimination as it affects individuals with LEP. We rejected this approach because we were

concerned that the Department's silence would create ambiguity about covered entities' obligations to individuals with LEP and could jeopardize the access of individuals with LEP to covered entities' health programs and activities. Options for addressing the prohibition of national origin discrimination as it affects individuals with LEP are discussed in the preamble to the proposed rule.

OCR considered a regulatory scheme requiring covered entities to provide meaningful access to each individual with LEP by providing effective language assistance services, at no cost, unless such action would result in an undue burden or fundamental alteration. OCR also considered requiring covered entities of a certain type or size to have enhanced obligations to provide language assistance services. Such enhanced obligations could include providing a predetermined range of language assistance services in certain non-English languages that met defined thresholds. A covered entity that was not of a certain type or size still would be required to provide meaningful access to each individual with LEP in its health programs and activities, but the covered entity would not have to provide a predetermined range of language assistance services in certain non-English languages. OCR also explored applying the threshold requirement to standardized vital documents on a national, State, or county level as well as specific to a covered entity's geographic service area.

The strengths of these alternate regulatory schemes include limited obligations for small businesses providing health programs or activities and defined standards for larger entities. The costs of these approaches include the complexity of the regulatory scheme and the potential burden on the covered entities of a certain type or size that would have enhanced applications. OCR determined these costs outweighed the benefits at this time. As stated in the preamble, the Department invites public comment on these options.

OCR considered drafting new provisions addressing effective communication (apart from communication through electronic and information technology) with individuals with disabilities, but instead is incorporating provisions of the regulation implementing Title II of the ADA to ensure consistency for covered entities and potentially reduce burden by limiting resources spent on training and modification of policies and procedures.

Options regarding communication through electronic and information technology are discussed in the preamble to the regulation. Regarding the accessibility requirements under the proposed regulation, OCR considered two alternatives: (1) Clarifying the scope of the requirements by defining whether the standards adopted apply only to access to covered entities' Web sites or other means of electronic and information technology; and (2) updating the NPRM's current standards for determining accessibility to include newer functional standards such as the Web Content Accessibility Guidelines adopted by the World Wide Web Consortium or standards under Section 508. While these alternatives could potentially increase the burden on recipients of Federal financial assistance and State-based Marketplaces, they also would offer clarity to covered entities and would help enhance access for individuals with disabilities.

In the area of compliance, OCR considered having one set of procedures for all compliance activities involving recipients of Federal financial assistance and State-based Marketplace entities. Instead, OCR decided to adopt the unique Age Act procedures¹⁶⁹ for age-related compliance activities under Section 1557 because Age Act compliance activities and Section 1557 compliance activities regarding age discrimination are likely to substantially overlap.

With regard to other areas of compliance, OCR considered developing a separate set of procedures for Section 1557 compliance activities involving HHS health programs and activities, but decided to largely adopt the existing procedures for disability compliance activities involving HHS health programs and activities (with some enhancement) to improve efficiencies for OCR and the HHS health programs and activities covered by Section 1557.

V. Unfunded Mandates Reform Act of 1995

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits before issuing any rule that includes a Federal mandate that could result in expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million in 1995 dollars, updated annually for inflation. In 2015, that

¹⁶⁹ The Age Act procedures, for example, require mediation of all age discrimination complaints, and exhaustion of administrative remedies prior to the filing of a civil lawsuit.

threshold level is approximately \$144 million.

The Unfunded Mandates Reform Act does not address the total cost of a final rule. Rather, it focuses on certain categories of cost, mainly those “Federal mandate” costs resulting from: (1) Imposing enforceable duties on State, local, or tribal governments, or on the private sector; or (2) increasing the stringency of conditions in, or decreasing the funding of, State, local, or tribal governments under entitlement programs.

Our impact analysis shows that burden associated with training staff working for covered entities will be spread widely across health care entities, State and local governmental entities and a substantial number of health insurance issuers. The analysis estimates the unfunded burden will be about \$383 million in one-time training costs. We project that for the first few years following enactment of the final rule, private sector costs for investigating discrimination complaints may amount to \$119 million per year. Within the first five years following the rule’s enactment, we anticipate complaints to increase, but eventually to drop off as covered entities modify their policies and practices in response to the proposed rule.

As we explain in the RIA, we believe there will be benefits gained from the enactment of this regulation in the form of reduction in discrimination based on race, color, national origin, sex, age, and disability, the improvement in the quality of care underserved communities will receive.

VI. Executive Order 13132: Federalism

As required by Executive Order 13132 on Federalism, the Department has examined the effects of provisions in the proposed regulation on the relationship between the Federal government and the States. The Department has concluded that the proposed regulation does have Federalism implications but preempts State law only where the exercise of State authority directly conflicts with the exercise of Federal authority under the Federal statute.

The proposed regulation attempts to balance State autonomy with the necessity to create a Federal benchmark that will provide a uniform level of nondiscrimination protection across the country. The proposed regulation restricts regulatory preemption of State law to the minimum level necessary to achieve the objectives of the underlying Federal statute, Section 1557 of the ACA.

It is recognized that the States generally have laws that relate to

nondiscrimination against individuals on a variety of bases. State laws continue to be enforceable, unless they prevent application of the proposed rule. The proposed rule explicitly provides that it is not to be construed to supersede State or local laws that provide additional protections against discrimination on any basis articulated under the regulation. Provisions of State law relating to nondiscrimination that are “more stringent” than the proposed Federal regulatory requirements or implementation specifications will continue to be enforceable.

Section 3(b) of Executive Order 13132 recognizes that national action limiting the policymaking discretion of States will be imposed only where there is constitutional and statutory authority for the action and the national activity is appropriate in light of the presence of a problem of national significance. Discrimination issues in relation to health care are of national concern by virtue of the scope of interstate health commerce. The ACA’s provisions reflect this position.

Section 3(d)(2) of the Executive Order 13132 requires that where possible, the Federal Government defer to the States to establish standards. Title I of the ACA authorized the Secretary to promulgate regulations to implement Section 1557, and we have done so accordingly.

Section 4(a) of Executive Order 13132 expressly contemplates preemption when there is a conflict between exercising State and Federal authority under a Federal statute. Section 4(b) of the Executive Order authorizes preemption of State law in the Federal rule making context when “the exercise of State authority directly conflicts with the exercise of Federal authority under the Federal statute.” The approach in this regulation is consistent with these standards in the Executive Order in superseding State authority only when such authority is inconsistent with standards established pursuant to the grant of Federal authority under the statute.

Section 6(b) of Executive Order 13132 includes some qualitative discussion of substantial direct compliance costs that State and local governments would incur as a result of a proposed regulation. We have determined that the costs of the proposed rule would not impose substantial direct compliance costs on State or local governments. We have considered the cost burden that this proposed rule would impose on State and local health care and benefit programs, and estimate State and local government costs will be in the order of \$18.5 million in the first two years of implementation. The \$18.5 million

represents the sum of the costs of training State workers and enforcement costs attributable to State agencies analyzed above.

VII. Regulatory Flexibility Act

The RFA requires agencies that issue a regulation to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. The RFA generally defines a “small entity” as:

(1) A proprietary firm meeting the size standards of the Small Business Administration (SBA);

(2) A nonprofit organization that is not dominant in its field; or

(3) A small government jurisdiction with a population of less than 50,000 (States and individuals are not included in the definition of “small entity”).

HHS uses as its measure of significant economic impact on a substantial number of small entities a change in revenues of more than 3% for 5% or more of affected small entities.

If we judge that a rule would have a significant impact on a substantial number of small entities, we will consider alternatives to reduce the burden. To accomplish our task, we must first identify all the small entities that may be impacted, and then evaluate whether the economic burden we determined in the RIA represents a significant economic impact.

A. Entities That Will Be Affected

HHS has traditionally classified most health care providers as small entities even though some nonprofit providers would not meet the definition of “small entity” were they proprietary firms. Nonprofit entities are small if they are independently owned and operated and are not dominant in their fields.

The CMS Provider of Service file has indicators for profit and nonprofit entities, but these have proven to be unreliable. The Census data identifies firms’ tax status by profit and non-profit status but only reports revenues and does not report them by the profit and non-profit status of the entity.

1. Physicians

One class of providers we do not automatically classify as small businesses is physician practices. Physician practices are businesses and therefore are “small” if they meet the SBA’s definition. The current size standard for physicians (excluding mental health specialists)—North American Industry Classification System code 62111—is annual receipts

of less than \$11 million.¹⁷⁰ Using the Census data showing the number of firms, employees and payroll, we selected physicians that reported fewer than 20 employees as the top end for small physician offices. This equaled 17,855 entities or 9.4% of all physician offices defined as “large.” This left 171,000 offices or 90% as “small.”¹⁷¹

2. Pharmacies

Pharmacies also are businesses, and the size standard for them is annual receipts of less than \$27.5 million. According to U.S. Census Statistics of U.S. Businesses, there are 18,852 pharmacy and drug store firms (North American Industry Classification System code 44611). Because of the lack of revenue or receipt data for pharmacies, we are unable to estimate the number of small pharmacies based on the SBA size standard. However, using the number of employees taken from the Statistics of U.S. Businesses as a proxy for revenues, the data is divided by number of employees per firm and shows the number of employers with fewer than 20 employees and those with more than 20 employees.¹⁷² The number of firms with fewer than 20 employees

is 16,520 and represents 88% of the total number of pharmacy firms. It seemed reasonable to assume that firms with fewer than 20 employees satisfy the SBA size standard and thus we accepted that the number of small pharmacy firms equaled 16,520. As with the number of small physician offices, our method can only identify the minimum number of “small” pharmacies that meet the SBA size standard. We cannot determine the actual number of “small” pharmacies.

3. Health Insurance Issuers

Another class of covered entities that are business enterprises is health insurance issuers. The SBA size standard for health insurance issuers is annual receipts of \$38.5 million. Although the Blue Cross/Blue Shield companies that operate in some markets are organized as nonprofit entities, they often are large enough so as to not meet the definition of “small entity.”

Unfortunately, we cannot use the Census revenue data for estimating the number of small health insurance issuers because the Census data combines life and health insurance. Substituting costs for revenues allows us to obtain a rough estimate of the

number of large insurance issuers, realizing that cost will probably be less than revenues, thus giving us a lower count of large issuers. Using the National Health Expenditure for 2013, net cost of health insurance equaled \$173.6 billion. However, the 2012 Census data report a total of 815 health insurance issuers. Dividing the \$174 billion in costs by the number of insurance issuers reported in the census tables yields average costs of over \$213 million, which means that average annual revenues per issuer exceeds \$213 million. We conclude, therefore, that there are almost no small insurance issuers. The above analysis comports with the conclusion CMS published in the Health Insurance Web Portal Requirements (75 FR 24481, May 5, 2010).

4. Local Government Entities

We also exclude local governmental entities from our count of small entities because we lack the data to classify them by populations of fewer than 50,000. The following table shows the number of small covered entities we estimate may be affected by the proposed rule.

TABLE 6—SMALL COVERED ENTITIES

NAIC	Entity type	Number of firms
62142	Outpatient mental health and substance abuse centers	4,987
62141	HMO medical centers	104
62142	Kidney dialysis centers	492
62143	Freestanding ambulatory surgical and emergency centers	4,121
621498	All Other Outpatient Care Centers	5,399
6215	Medical and Diagnostic Laboratories	7,958
6216	Home health care services	21,668
6219	All other ambulatory health care services	6,956
62321	Residential mental retardation facilities	6,225
62199	General medical and surgical hospitals	3,067
621991	Psychiatric and substance abuse hospitals	411
6221	Specialty (except psychiatric and substance abuse) hospitals	373
6231	Nursing Care Facilities (Skilled Nursing Facilities)	8,623
44611	Pharmacies and drug stores	16,520
6211	Offices of physicians	171,000
	Navigator grantees	92
	TOTAL Small entities	258,176

B. Whether the Proposed Rule Will Have a Significant Economic Impact on Covered Small Entities

To determine the economic impact of the proposed rule, we divide the costs that small entities will bear by the number of small affected entities. We examine the costs we identified for

training, enforcement, and complying with the notice requirement and adjust those costs to reflect only the costs that small entities will incur.

1. Training

To remove the costs for training for large entities, we must remove both the

large entities and their associated workforce. We removed 17,855 physician firms with associated training costs of \$60.8 million and 2,332 pharmacies with associated training costs of \$11.4 million. Also, we removed costs borne by the 180 health insurance issuers we identified as

¹⁷⁰ U.S. Small Business Administration (SBA), Table of Small Business Size Standards Matched to North American Industry Classification System Codes. Small Business Administration, (June, 2014),

available at https://www.sba.gov/sites/default/files/Size_Standards_Table.pdf.

¹⁷¹ Physician practices may earn more than \$11 million per year and that would reduce the number of “large” practices to be excluded from the

analysis. But as we will later show, large practices will have proportionally larger workforce staff that must be excluded from the analysis.

¹⁷² U.S. Census Bureau, Statistics of U.S. Businesses, *supra* note 120.

participating in the Federally-facilitated Marketplaces, with training costs of about \$3.26 million. Also, removing State training costs from our computations reduces the costs allocated to small entities by \$13.9 million.

The total cost burden of the “large” entities we can identify (including cost of preparing materials and employee time) amounts to \$89.4 million.¹⁷³ Thus the estimated burden we are proposing to place on small entities for training equals \$293 million. Dividing this amount by the number of small entities in Table 6 gives an average burden of \$1,135.

2. Enforcement

We also identified costs for investigating discrimination complaints that covered entities may incur following enactment of the final rule in the enforcement section in this analysis. The total amount ascribed to investigating discrimination complaints for covered health care entities with 15 or more employees is estimated to be \$118.7 million per year over five years following final rule enactment. As we noted in the enforcement analysis, for purposes of the analysis, we assumed a uniform distribution of complaints across all covered entities.

To determine costs for investigating discrimination complaints for small entities, we divided the cost attributed to health care covered entities. Dividing health care covered entity investigation costs of \$118.7 million by the approximately 58,500 health care covered entities with 15 or more employees who are required to have grievance procedures under the proposed rule, yielding a cost per entity of \$2,029.

¹⁷³ We have removed the training and preparation costs for large and small issuers, equaling \$3,251,158. The amount includes training of State medical staffs (\$13,872,314), large physician offices (\$38,860,424), and large pharmacy firms (\$9,541,260). The amount of State medical staff training costs is 100%. Large physician office training costs are 68.3% of medical staff training costs based on the ratio of employees employed in large and small offices. The costs of medical staff training in large pharmacy firms is 85.7% and is similarly based on the ratio of employees employed in large and small firms.

3. Notice

We also examined the cost for covered entities of printing, translating, and posting new notices as required under this proposed regulation. The estimated cost for printing and distributing notice and tag lines for health care providers is approximately \$4.8 million. Dividing this amount by the 278,565 total health care providers equals \$17 per entity.

4. Revising Policies and Procedures to Prohibit Discrimination on the Basis of Sex

In the analysis of the cost for providers to revise their policies and procedures to conform to the prohibition of discrimination on the basis of sex, we estimate that 75% of total health care entities, or 208,700, would incur a cost of approximately \$47.5 million. To arrive at the cost per entity, we divide the cost by the 208,700 health care entities, which equals \$227 per entity.

5. Overall Burden on Small Entities

To estimate the overall burden cost on small entities, we must add training costs (\$1,135), the cost to an entity to investigate a complaint of discrimination (\$2,029), the costs for printing and distributing notices and tag lines (\$17), and the cost for providers to revise their policy and procedures for prohibiting sex discrimination (\$227). The total estimated overall burden of the proposed rule on small entities is approximately \$3,409.

The definition of a small entity varies with its North American Industry Classification System code; for physicians, the SBA defines the threshold revenues as up to \$11 million, for pharmacies up to \$25 million, and for health issuers up to \$38.5 million. An average cost of \$3,409 represents a de minimis percentage of their revenues and clearly less than the 3% standard that is set up under the RFA standards for significant impact. Furthermore we believe that fewer than 5% of all small entities will experience a burden of greater than 3% of their revenues. Ambulatory health care services facilities (North American Industry Classification System 621), for example,

are small entities with an average of 13 employees and revenue of \$1.7 million based on 2012 reported data for employees of 6.4 million and total revenues of \$825.7 million for 485,235 firms.¹⁷⁴ In addition, the majority of the costs associated with this rule are proportional to the size of entities, meaning that even the smallest of the affected entities are unlikely to face a substantial impact. Thus, we would not consider this proposed regulation a significant burden on a substantial number of small entities, and, therefore, the Secretary proposes to certify that the proposed rule will not have a significant impact on a substantial number of small entities.

VIII. Conclusion

For the most part, because this regulation is consistent with existing standards applicable to the covered entities, the new burdens created by its issuance are minimal. The major impacts are in the areas of voluntary training and enforcement where increased caseloads pose incremental costs on covered entities. It is possible, if broader options that extend existing civil rights requirements beyond their current scope were adopted after public comment in a final rule, that the burdens estimated in this RIA would increase. However, the rule as currently written does not include such expansions and therefore minimizes the imposition of new burdens. Nevertheless, it is still a major rule with approximately \$383 million in training costs over a two-year period and another \$122 million in increased annual enforcement costs. We also account for printing notice and tagline costs of \$5 million, and costs to revise policies and procedures of \$48 million, for a total of \$558 million. This RIA was organized and designed to explain the origin of these cost impacts to allow for meaningful public comment.

¹⁷⁴ U.S. Census Bureau, Statistics of U.S. Businesses. All sectors: Geographic Area Series: Economy-Wide Key Statistics: 2012: available at: http://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ECN_2012_US_00A1&prodType=table.

TABLE 7—ACCOUNTING STATEMENT

Accounting Statement				
Category	Primary Estimate	Low Estimate	High Estimate	Source
BENEFITS				
Qualitative Benefits	• Potential health improvements and longevity extensions as a result of reduced barriers to medical care for transgender individuals.			RIA
COSTS (millions)				
Annualized monetized	Covered entities train 40% of their employees on the new regulations	Covered entities train 60% of their employees on the new regulations
3%	190.9	174.9	206.9	RIA
7%	162.8	148.4	177.3	RIA
Non-quantified costs	Costs of increased provision of health care services as a result of reduced barriers to access for transgender individuals.			RIA
Transfers	Health insurance premium reductions for affected women, with offsetting increases for other premium payers in affected plans.			RIA
Effects on State & Local Governments	\$18.5 million costs in the first 2 years (training + enforcement)			RIA
Effects on Small Entities	Average \$3,409/small entity			RFA

List of Subjects in 45 CFR Part 92

Administrative practice and procedure, Civil rights, Discrimination, Elderly, Health care, Health facilities, Health insurance, Health programs and activities, Individuals with disabilities, Nondiscrimination, Reporting and recordkeeping requirements, Sex discrimination.

For the reasons set forth in the preamble, the Department of Health and Human Services proposes to add 45 CFR part 92 as follows:

PART 92—NONDISCRIMINATION ON THE BASIS OF RACE, COLOR, NATIONAL ORIGIN, SEX, AGE, OR DISABILITY IN HEALTH PROGRAMS OR ACTIVITIES RECEIVING FEDERAL FINANCIAL ASSISTANCE AND HEALTH PROGRAMS OR ACTIVITIES ADMINISTERED BY THE DEPARTMENT OF HEALTH AND HUMAN SERVICES OR ENTITIES ESTABLISHED UNDER TITLE I OF THE PATIENT PROTECTION AND AFFORDABLE CARE ACT

Subpart A—General Provisions

Sec.

- 92.1 Purpose and effective date.
- 92.2 Application.
- 92.3 Relationship to other laws.
- 92.4 Definitions.
- 92.5 Assurances required.

- 92.6 Remedial action and voluntary action.
- 92.7 Designation of responsible employee and adoption of grievance procedures.
- 92.8 Notice requirement.

Subpart B—Nondiscrimination Provisions

- 92.101 Discrimination prohibited.

Subpart C—Specific Applications to Health Programs and Activities

- 92.201 Meaningful access for individuals with limited English proficiency.
- 92.202 Effective communication for individuals with disabilities.
- 92.203 Accessibility standards for buildings and facilities.
- 92.204 Accessibility of electronic and information technology.
- 92.205 Requirement to make reasonable modifications.
- 92.206 Equal program access on the basis of sex.
- 92.207 Nondiscrimination in health-related insurance and other health-related coverage.
- 92.208 Employer liability for discrimination in employee health benefit programs.
- 92.209 Nondiscrimination on the basis of association.

Subpart D—Enforcement

- 92.301 Enforcement mechanisms.
- 92.302 Procedures for health programs and activities conducted by recipients and State-based Marketplaces.

- 92.303 Procedures for health programs and activities administered by the Department.

Appendix A to Part 92—Sample Notice Informing Individuals about Nondiscrimination and Accessibility Requirements

Appendix B to Part 92—Sample Tagline Informing Individuals with Limited English Proficiency of Language Assistance Services

Authority: 42 U.S.C. 18116, 5 U.S.C. 301.

Subpart A—General Provisions**§ 92.1 Purpose and effective date.**

The purpose of this part is to implement Section 1557 of the Patient Protection and Affordable Care Act (42 U.S.C. 18116), which prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs and activities. Section 1557 provides that, except as provided in Title I of the Patient Protection and Affordable Care Act (ACA), an individual shall not, on the grounds prohibited under Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, the Age Discrimination Act of 1975, or Section 504 of the Rehabilitation Act of 1973, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any

health program or activity, any part of which is receiving Federal financial assistance or under any program or activity that is administered by an Executive Agency or any entity established under Title I of the ACA. This part applies to health programs or activities administered by recipients of Federal financial assistance from the Department, Title I entities that administer health programs or activities, and Department-administered health programs or activities. The effective date of this part shall be [60 DAYS AFTER DATE OF PUBLICATION OF THE FINAL RULE].

§ 92.2 Application.

(a) Except as provided otherwise in this part, this part applies to every health program or activity, any part of which receives Federal financial assistance administered by the Department; every health program or activity administered by the Department; and every health program or activity administered by a Title I entity.

(b) Limitations:

(1) Exclusions to the application of the Age Discrimination Act of 1975, as set forth at 45 CFR 91.3(b)(1), apply to claims of discrimination based on age under Section 1557 or this part.

(2) [Reserved]

§ 92.3 Relationship to other laws.

(a) *Rule of interpretation.* This part shall not be construed to apply a lesser standard for the protection of individuals from discrimination than the standards applied under Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, Section 504 of the Rehabilitation Act of 1973, the Age Discrimination Act of 1975, or the regulations issued pursuant to those laws.

(b) *Other laws.* Nothing in this part shall be construed to invalidate or limit the rights, remedies, procedures, or legal standards available to individuals under Title VI of the Civil Rights Act of 1964, Title VII of the Civil Rights Act of 1964, the Architectural Barriers Act of 1968, Title IX of the Education Amendments of 1972, Sections 504 or 508 of the Rehabilitation Act of 1973, the Age Discrimination Act of 1975, the Americans with Disabilities Act of 1990, as amended by the Americans with Disabilities Act Amendments Act of 2008, or other Federal laws or to supersede State or local laws that provide additional protections against discrimination on any basis described in § 92.1.

§ 92.4 Definitions.

As used in this part, the term—

1991 Standards means the 1991 ADA Standards for Accessible Design, published at Appendix A to 28 CFR part 36 on July 26, 1991, and republished as Appendix D to 28 CFR part 36 on September 15, 2010.

2010 Standards means the 2010 ADA Standards for Accessible Design, as defined at 28 CFR 35.104.

ACA means the Patient Protection and Affordable Care Act (Pub. L. 111–148, as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. 111–152; 42 U.S.C. 18001 *et seq.*).

ADA means the Americans with Disabilities Act of 1990 (Pub. L. 101–336; 42 U.S.C. 12101 *et seq.*), as amended.

Age means how old an individual is, or the number of elapsed years from the date of an individual's birth.

Age Act means the Age Discrimination Act of 1975 (Title III of Pub. L. 94–135; 42 U.S.C. 6101 *et seq.*), as amended.

Applicant means an individual who applies to participate in a health program or activity.

Auxiliary aids and services include:

(1) Qualified interpreters on-site or through video remote interpreting (VRI) services, as defined in 28 CFR 35.104, 36.303(b); note takers; real-time computer-aided transcription services; written materials; exchange of written notes; telephone handset amplifiers; assistive listening devices; assistive listening systems; telephones compatible with hearing aids; closed caption decoders; open and closed captioning, including real-time captioning; voice, text, and video-based telecommunication products and systems, text telephones (TTYs), videophones, and captioned telephones, or equally effective telecommunications devices; videotext displays; accessible electronic and information technology; or other effective methods of making aurally delivered information available to individuals who are deaf or hard of hearing;

(2) Qualified readers; taped texts; audio recordings; Braille materials and displays; screen reader software; magnification software; optical readers; secondary auditory programs; large print materials; accessible electronic and information technology; or other effective methods of making visually delivered materials available to individuals who are blind or have low vision;

(3) Acquisition or modification of equipment and devices; and

(4) Other similar services and actions.

Covered entity means:

(1) An entity that operates a health program or activity, any part of which receives Federal financial assistance;

(2) An entity established under Title I of the ACA that administers a health program or activity; and

(3) The Department.

Department means the U.S. Department of Health and Human Services.

Director means the Director of the Office for Civil Rights (OCR) of the Department.

Disability means, with respect to an individual, a physical or mental impairment that substantially limits one or more major life activities of such individual; a record of such an impairment; or being regarded as having such an impairment, as defined and construed in the Rehabilitation Act, at 29 U.S.C. 705(9)(B), which incorporates the definition of disability in the ADA Amendments Act of 2008 (P.L. 110–325; 42 U.S.C. 12102.), as amended. Where this part cross-references regulatory provisions that use the term “handicap,” “handicap” means “disability” as defined in this section.

Electronic and information technology includes information technology and any equipment or interconnected system or subsystem of equipment that is used in the creation, conversion, or duplication of data or information.

(1) The term electronic and information technology includes, but is not limited to, telecommunications products (such as telephones), information kiosks and transaction machines, internet sites, multimedia, and office equipment such as copiers and fax machines.

(2) The term does not include any equipment that contains embedded information technology that is used as an integral part of the product, but the principal function of which is not the acquisition, storage, manipulation, management, movement, control, display, switching, interchange, transmission, or reception of data or information. For example, HVAC (heating, ventilation, and air conditioning) equipment such as thermostats or temperature control devices, and medical equipment where information technology is integral to its operation, are not electronic and information technology as defined in this part.

Employee health benefit program means:

(1) Health benefits coverage or health insurance provided to employees and/or their dependents established, operated, sponsored or administered by, for, or on

behalf of one or more employers, whether provided or administered by entities including but not limited to an employer, group health plan (as defined in the Employee Retirement Income Security Act of 1974 (ERISA), at 29 U.S.C. 1191(a)), third party administrator, or health insurance issuer.

(2) An employer provided or sponsored wellness program;

(3) An employer-provided health clinic; or

(4) Long term care coverage or insurance provided or administered by an employer, group health plan, third party administrator, or health insurance issuer.

Federal financial assistance. (1) Federal financial assistance means any grant, loan, credit, subsidy, contract (other than a procurement contract but including a contract of insurance), or any other arrangement by which the Federal government provides or otherwise makes available assistance in the form of:

(i) Funds;

(ii) Services of Federal personnel; or

(iii) Real and personal property or any interest in or use of such property, including:

(A) Transfers or leases of such property for less than fair market value or for reduced consideration; and

(B) Proceeds from a subsequent transfer or lease of such property if the Federal share of its fair market value is not returned to the Federal government.

(2) Federal financial assistance provided or administered by the Department includes all tax credits under Title I of the ACA, as well as payments, subsidies, or other funds extended by the Department to any entity providing health insurance coverage for payment to or on behalf of an individual obtaining health insurance coverage from that entity or extended by the Department directly to such individual for payment to any entity providing health insurance coverage.

Federally-facilitated Marketplaces means the same as “Federally-facilitated Exchange” defined in 45 CFR 155.20.

Gender identity is an individual’s internal sense of gender, which may be different from that individual’s sex assigned at birth. The way an individual expresses gender identity is frequently called “gender expression,” and may or may not conform to social stereotypes associated with a particular gender. A transgender individual is an individual whose gender identity is different from the sex assigned to that person at birth; an individual with a transgender

identity is referred to in this part as a transgender individual.

Health Insurance Marketplace means the same as “Exchange” defined in 45 CFR 155.20.

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. For an entity principally engaged in providing or administering health services or health insurance coverage, all of its operations are considered part of the health program or activity, except as specifically set forth otherwise in this part. Such entities include a hospital, health clinic, group health plan, health insurance issuer, physician’s practice, community health center, nursing facility, residential or community-based treatment facility, or other similar entity. A health program or activity also includes all of the operations of a State Medicaid program.

HHS means the U.S. Department of Health and Human Services.

Individual with a disability means any individual who has a disability as defined, for the purpose of Section 504 of the Rehabilitation Act of 1973, at 29 U.S.C. 705(20)(B)–(F), as amended.

Where this part cross-references regulatory provisions applicable to a “handicapped individual,” “handicapped individual” means “individual with a disability” as defined in this section.

Individual with limited English proficiency means an individual whose primary language for communication is not English and who has a limited ability to read, write, speak, or understand English.

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

(1) Oral language assistance, including interpretation in non-English languages provided in-person or remotely by a qualified interpreter, and bilingual or multilingual staff competent to communicate, in non-English languages using any necessary specialized vocabulary, directly with individuals with limited English proficiency;

(2) Written translation of documents and Web sites into languages other than English; and

(3) Taglines.

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, or gender identity.

Qualified individual with a disability means, with respect to a health program or activity, an individual with a disability who, with or without reasonable modifications to policies, practices, or procedures, the removal of architectural, communication, or transportation barriers, or the provision of auxiliary aids and services, meets the essential eligibility requirements for the receipt of aids, benefits, or services offered or provided by the health program or activity.

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) Is able, for an individual with a disability, to interpret effectively, accurately, and impartially, both receptively and expressively, using any necessary specialized vocabulary, and/or;

(ii) 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.

(2) For an individual with a disability, qualified interpreters 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).

Recipient means any State or its political subdivision, or any instrumentality of a State or its political subdivision, any public or private agency, institution, or organization, or other entity, or any individual, to whom Federal financial assistance is extended directly or through another recipient and which operates a health program or activity, including any subunit, successor, assignee, or transferee of a recipient.

Section 504 means Section 504 of the Rehabilitation Act of 1973 (Pub. L. 93–112; 29 U.S.C. 794), as amended.

Section 1557 means Section 1557 of the ACA.

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 expectations that gender can only be constructed within two distinct opposite and disconnected forms (masculinity and femininity), and that gender cannot be constructed outside of this gender construct (individuals who identify as neither, both, or as a combination of male and female genders).

State-based Marketplace means a Health Insurance Marketplace identified in paragraphs (1) and/or (2) of this definition for which a State has received approval from the Department pursuant to the standards in 45 CFR 155.105:

(1) A Health Insurance Marketplace that facilitates the purchase of health insurance coverage through qualified health plans in the individual market and that provides for the establishment of a Small Business Health Options Program; or

(2) A Health Insurance Marketplace that provides only for the establishment of a Small Business Health Options Program.

Taglines means short statements written in non-English languages that indicate the availability of language assistance services free of charge.

Title I entity means any entity established under Title I of the ACA, including State-based Marketplaces and Federally-facilitated Marketplaces.

Title VI means Title VI of the Civil Rights Act of 1964 (Pub. L. 88–352; 42 U.S.C. 2000d *et seq.*), as amended.

Title IX means Title IX of the Education Amendments of 1972 (Pub. L. 92–318; 20 U.S.C. 1681 *et seq.*), as amended.

§ 92.5 Assurances required.

(a) *Assurances*. An entity applying for Federal financial assistance to which this part applies shall, as a condition of any application for Federal financial assistance, submit an assurance, on a form specified by the Director, that the entity's health programs and activities will be operated in compliance with Section 1557 and this part. An issuer seeking certification to participate in a Health Insurance Marketplace or a State seeking approval to operate a State-based Marketplace to which Section 1557 or this part applies shall, as a condition of certification or approval, submit an assurance, on a form specified by the Director, that the health program or activity will be operated in compliance with Section 1557 and this part. An applicant or entity may incorporate this assurance by reference in subsequent applications to the Department for Federal financial assistance or requests for certification to

participate in a Health Insurance Marketplace or approval to operate a State-based Marketplace.

(b) *Duration of obligation*. The duration of the assurances required by this subpart is the same as the duration of the assurances required in the Department's regulations implementing Section 504, at 45 CFR 84.5(b).

(c) *Covenants*. When Federal financial assistance is provided in the form of real property or interest, the same conditions apply as those contained in the Department's regulations implementing Section 504, at 45 CFR 84.5(c), except that the nondiscrimination obligation applies to discrimination on all bases covered under Section 1557 and this part.

§ 92.6 Remedial action and voluntary action.

(a) *Remedial action*. (1) If the Director finds that a recipient or State-based Marketplace has discriminated against an individual on the basis of race, color, national origin, sex, age, or disability, in violation of Section 1557 or this part, such recipient or State-based Marketplace shall take such remedial action as the Director may require to overcome the effects of the discrimination.

(2) Where a recipient is found to have discriminated against an individual on the basis of race, color, national origin, sex, age, or disability, in violation of Section 1557 or this part, and where another recipient exercises control over the recipient that has discriminated, the Director, where appropriate, may require either or both entities to take remedial action.

(3) The Director may, where necessary to overcome the effects of discrimination in violation of Section 1557 or this part, require a recipient or State-based Marketplace to take remedial action with respect to:

(i) Individuals who are no longer participants in the recipient's or State-based Marketplace's health program or activity but who were participants in the health program or activity when such discrimination occurred; or

(ii) Individuals who would have been participants in the health program or activity had the discrimination not occurred.

(b) *Voluntary action*. A covered entity may take steps, in addition to any action that is required by Section 1557 or this part, to overcome effects of conditions that result or resulted in limited participation in the covered entity's health programs or activities by individuals on the basis of race, color, national origin, sex, age, or disability.

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

(a) *Designation of responsible employee*. Each covered entity that employs 15 or more persons shall designate at least one employee to coordinate its efforts to comply with and carry out its responsibilities under Section 1557 and this part, including the investigation of any grievance communicated to it alleging noncompliance with Section 1557 or this part or alleging any action that would be prohibited by Section 1557 or this part. For the Department, including the Federally-facilitated Marketplaces, the Office for Civil Rights (OCR) will be deemed the responsible employee under this section.

(b) *Adoption of grievance procedures*. Each covered entity that employs 15 or more persons shall adopt grievance procedures that incorporate appropriate 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. For the Department, including the Federally-facilitated Marketplaces, the procedures for addressing complaints of discrimination on the grounds covered under Section 1557 or this part will be deemed grievance procedures under this section.

§ 92.8 Notice requirement.

(a) Each covered entity shall take appropriate initial and continuing steps to notify beneficiaries, enrollees, applicants, or members of the public of the following:

(1) The covered entity does not discriminate on the basis of race, color, national origin, sex, age, or disability;

(2) The covered entity provides appropriate auxiliary aids and services, including qualified interpreters and information in alternate formats, free of charge and in a timely manner, when such aids and services are necessary to ensure an equal opportunity to participate to individuals with disabilities;

(3) The covered entity provides language assistance services, free of charge and in a timely manner, when such services are necessary to provide meaningful access to individuals with limited English proficiency;

(4) How to obtain the aids and services in paragraphs (a)(2) and (3) of this section;

(5) An identification of and contact information for the responsible employee designated pursuant to § 92.7(a), if applicable;

(6) The availability of the grievance procedure and how to file a grievance, pursuant to § 92.7(b), if applicable; and

(7) How to file a discrimination complaint with OCR in the Department.

(b) 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 that conveys the information in paragraphs (a)(1) through (7) of this section.

(c) 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.

(d) 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.

(e) 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.

(f)(1) Each covered entity shall post the English-language notice required by paragraphs (a) and (b) of this section and the taglines required by paragraph (d) of this section in a conspicuously-visible font size:

(i) In significant publications and significant communications targeted to beneficiaries, enrollees, applicants, or members of the public;

(ii) In conspicuous physical locations where the entity interacts with the public; and

(iii) In a conspicuous location accessible from the home page of the covered entity's Web site.

(2) A covered entity may also post the notice and taglines in additional publications and communications.

(g) A covered entity that complies with paragraphs (a), (b), (d), and (f) of this section meets the requirements of the regulation implementing Title VI, at § 80.6(d) of this subchapter, the regulation implementing Section 504, at §§ 84.8(a) and 85.12 of this subchapter, the regulation implementing Title IX, at §§ 86.8(b) and 86.9(a)(1) of this subchapter, and the regulation implementing the Age Act, at § 91.32(b) of this subchapter, as applicable.

Subpart B—Nondiscrimination Provisions

§ 92.101 Discrimination prohibited.

(a) *General.* (1) 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 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.

(2) Except as provided in § 92.208, this part does not apply to discrimination by a covered entity against its own employees.

(b) *Specific discriminatory actions prohibited.* Under any health program or activity to which this part applies:

(1) Each covered entity must comply with the regulation implementing Title VI, at § 80.3(b)(1) through (6) of this subchapter.

(2)(i) Each recipient and State-based Marketplace must comply with the regulation implementing Section 504, at §§ 84.4(b), 84.21 through 84.23(b), 84.31, 84.34, 84.37, 84.38, and 84.41 through 84.55 of this subchapter. Where this paragraph cross-references regulatory provisions that use the term “recipient,” the term “recipient or State-based Marketplace” shall apply in its place.

(ii) The Department, including the Federally-facilitated Marketplaces, must comply with the regulation implementing Section 504, at §§ 85.21(b), 85.41 through 85.42, and 85.44 through 85.51 of this subchapter.

(3) Each covered entity must comply with the regulation implementing Title IX, at § 86.31(b)(1) through (8) of this subchapter. Where this paragraph cross-references regulatory provisions that use the term “student,” “employee,” or “applicant,” the terms “individual” shall apply in its place.

(4) Each covered entity must comply with the regulation implementing the Age Act, at § 91.11(b) of this subchapter.

(5) The enumeration of specific forms of discrimination in this paragraph does not limit the generality of the prohibition in paragraph (a) of this section.

(c) The exceptions applicable to Title VI apply to discrimination on the basis of race, color, or national origin under this part. The exceptions applicable to Section 504 apply to discrimination on the basis of disability under this part. The exceptions applicable to the Age Act apply to discrimination on the basis of age under this part. These provisions are found at §§ 80.3(d), 84.4(c), 85.21(c), 91.12 through 91.15, and 91.17 through 91.18 of this subchapter.

(d) Where the regulatory provisions referenced in paragraphs (b)(1), (b)(3), (b)(4), and (c) of this section use the term “recipient,” the term “covered entity” shall apply in its place. Where the regulatory provisions referenced in paragraphs (b)(1), (b)(3), (b)(4), and (c) of this section use the terms “program or activity” or “program” or “education program,” the term “health program or activity” shall apply in its place.

Subpart C—Specific Applications to Health Programs and Activities

§ 92.201 Meaningful access for individuals with limited English proficiency.

(a) *General requirement.* A covered entity shall take reasonable steps to provide meaningful access to each individual with limited English proficiency that it serves or encounters in its health programs and activities.

(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

(2) Take other relevant factors into account. Such factors may include:

(i) The length and complexity of the communication involved;

(ii) The context in which the communication is taking place;

(iii) The prevalence of the language in which the individual communicates among those eligible to be served or likely to be encountered by the health program or activity;

(iv) All resources available to the covered entity; and

(v) The cost of language assistance services.

(c) *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.

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

(e) *Restricted use of certain persons to interpret or facilitate communication.* A covered entity shall not:

(1) Require an individual with limited English proficiency to provide his or her own interpreter;

(2) Rely on an adult accompanying an individual with limited English proficiency 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 where there is no qualified interpreter immediately available; or

(ii) Where the individual with limited English proficiency 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.

(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.

§ 92.202 Effective communication for individuals with disabilities.

A covered entity shall take appropriate steps to ensure that communications with individuals with disabilities are as effective as communications with others in health programs and activities, in accordance with the standards found at 28 CFR 35.160 through 35.164. Where the regulatory provisions referenced in this section use the term “public entity,” the term “covered entity” shall apply in its place.

§ 92.203 Accessibility standards for buildings and facilities.

(a) Each 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 shall comply with the 2010 Standards as defined in § 92.4, if the construction or alteration was commenced on or after [18 MONTHS FROM DATE OF PUBLICATION OF FINAL RULE]. Departures from particular technical and scoping requirements by the use of other methods are permitted where substantially equivalent or greater access to and usability of the facility is provided. All newly constructed or altered buildings or facilities subject to this section shall comply with the

requirements for a “public building or facility” as defined in Section 106.5 of the 2010 Standards.

(b) Each 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 in conformance with the Uniform Federal Accessibility Standards, the 1991 Standards, or the 2010 Standards as defined in § 92.4 shall be deemed to comply with the requirements of this section and with 45 CFR 84.23(a) and (b), cross-referenced in § 92.101(b)(2)(i) with respect to those facilities, if the construction or alteration was commenced before [18 MONTHS FROM DATE OF PUBLICATION OF FINAL RULE].

(c) Each building or part of a building that is constructed or altered by or on behalf of, or for the use of, the Department must be designed, constructed, or altered so as to be readily accessible to and usable by individuals with disabilities. The definitions, requirements, and standards of the Architectural Barriers Act, as established in Appendices C and D to 36 CFR part 1191, apply to buildings and facilities covered by this section.

§ 92.204 Accessibility of electronic and information technology.

(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.

(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.

§ 92.205 Requirement to make reasonable modifications.

A covered entity shall make reasonable modifications to policies, practices, or procedures when such

modifications are necessary to avoid discrimination on the basis of disability, unless the covered entity can demonstrate that making the modifications would fundamentally alter the nature of the health program or activity. For the purposes of this section, the term “reasonable modifications” shall be interpreted in a manner consistent with the term as set forth in the ADA Title II regulation at 28 CFR 35.130(b)(7).

§ 92.206 Equal program access on the basis of sex.

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

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

(a) *General.* A covered entity shall not, in providing or administering health-related insurance or other health-related coverage, discriminate on the basis of race, color, national origin, sex, age, or disability.

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

(1) Deny, cancel, limit, or refuse to issue or renew a health insurance plan or policy, or other health coverage, or deny or limit coverage of a claim, or impose 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;

(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;

(3) Deny or limit coverage, deny a claim, or impose additional cost sharing or other limitations or restrictions, on any health services that are ordinarily or exclusively available to individuals of one sex, based on the fact that an individual's sex assigned at birth, gender identity, or gender otherwise recorded by the plan or issuer is

different from the one to which such health services are ordinarily or exclusively available;

(4) Categorically or automatically exclude from coverage, or limit coverage for, all health services related to gender transition; 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.

(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.

(d) Nothing in this section is intended to determine, or restrict a covered entity from determining, whether a particular health service is medically necessary or otherwise meets applicable coverage requirements in any individual case.

§ 92.208 Employer liability for discrimination in employee health benefit programs.

A covered entity that provides an employee health benefit program to its employees and/or their dependents shall be liable for violations of this part in that employee health benefit program only when:

(a) The entity is principally engaged in providing or administering health services or health insurance coverage;

(b) The entity receives Federal financial assistance a primary objective of which is to fund the entity's employee health benefit program; or

(c) The entity is not principally engaged in providing or administering health services or health insurance coverage but operates a health program or activity, which is not an employee health benefit program, that receives Federal financial assistance; except that the entity is liable under this part with regard to the provision or administration of employee health benefits only to the employees in that health program or activity.

§ 92.209 Nondiscrimination on the basis of association.

A covered entity shall not exclude from participation in, deny the benefits of, or otherwise discriminate against an individual or entity in its health programs or activities on the basis of the race, color, national origin, age, disability, or sex of an individual with whom the individual or entity is known or believed to have a relationship or association.

Subpart D—Enforcement

§ 92.301 Enforcement mechanisms.

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

§ 92.302 Procedures for health programs and activities conducted by recipients and State-based Marketplaces.

(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, and disability 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.

(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 is found or transacts business.

§ 92.303 Procedures for health programs and activities administered by the Department.

(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 the Department, including the Federally-facilitated Marketplaces.

(b) The procedural provisions applicable to Section 504 at §§ 85.61 through 85.62 of this subchapter shall apply with respect to enforcement actions against the Department concerning discrimination on the basis of race, color, national origin, sex, age, or disability under Section 1557 or this part. Where this section cross-references regulatory provisions that use the term "handicap," this term shall be replaced with "race, color, national origin, sex, age, or disability."

(c) *Access to sources of information.* The Department 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 required of the Department 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 Department 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.

(d) *Intimidatory or retaliatory acts prohibited.* The Department 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.

Appendix A to Part 92 — Sample Notice Informing Individuals About Nondiscrimination and Accessibility Requirements

Discrimination is Against the Law

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

[Name of covered entity]:

- Provides free aids and services to people with disabilities to communicate effectively with us, such as:

- Qualified sign language interpreters
- Written information in other formats

(large print, audio, accessible electronic formats, other formats)

- Provides free language services to people whose first language is not English when needed to communicate effectively with us, such as:

- Interpreters
- Information translated into other languages

If you need these services, contact _____

If you believe that [Name of covered entity] has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with: [Name of Civil Rights Coordinator], [Mailing Address], [Telephone number], [TTY number—if covered entity has one], [Fax], [Email]. You can file a grievance in person, by mail, fax, or email. If you need help filing a grievance, [Name of Civil Rights Coordinator] is available to help you. You can also file a civil

rights complaint with the U.S. Department of Health and Human Services Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail, phone, or fax at: [Add address, phone and fax of OCR Headquarters Office]. Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

**Appendix B to Part 92—Sample Tagline
Informing Individuals With Limited
English Proficiency of Language
Assistance Services**

ATTENTION: If you speak [insert language], language assistance services, free of charge, may be available to you. Contact 1-xxx-xxx-xxxx (TTY: 1-xxx-xxx-xxxx).

Dated: September 1, 2015.

Sylvia M. Burwell,
Secretary.

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