The Federal Register

The Daily Journal of the United States Government

Rule

Nondiscrimination in Health Programs and Activities

A Rule by the **Health and Human Services Department** on **05/18/2016**

Action

Final Rule.

Summary

This final rule implements 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. The final rule clarifies and codifies existing nondiscrimination requirements and 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 of Health and Human Services (HHS or the Department) and entities established under Title I of the ACA. In addition, the Secretary is authorized to prescribe 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.

Unified Agenda

Nondiscrimination Under the Patient Protection and Affordable Care Act

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DATES:

Effective Date: This rule is effective July 18, 2016.

Applicability Dates: The provisions of this rule are generally applicable on the date the rule is effective, except to the extent that provisions of this rule require changes to health insurance or group health plan benefit design (including covered benefits, benefits limitations or restrictions, and cost-sharing mechanisms, such as coinsurance, copayments, and deductibles), such provisions, as they apply to health insurance or group health plan benefit design, have an applicability date of the first day of the first plan year (in the individual market, policy year) beginning on or after January 1, 2017.

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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. 2000**d *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.

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 how HHS applies the standards of Section 1557 to HHS-administered health programs and activities.[1]

A. Regulatory History

On August 1, 2013, the Office for Civil Rights of the Department (OCR) published a Request for Information (RFI) in the Federal Register to solicit information on issues arising under Section 1557. OCR received 402 comments; one-quarter (99) were from organizational commenters, with the

remainder from individuals.

On September 8, 2015, OCR issued a proposed rule, "Nondiscrimination in Health Programs and Activities," in the Federal Register, and invited comment on the proposed rule by all interested parties.[2] The comment period ended on November 9, 2015. In total, we received approximately 24,875 comments on the proposed rule. Comments came from a wide variety of stakeholders, including, but not limited to: Civil rights/advocacy groups, including language access organizations, disability rights organizations, women's organizations, and organizations serving lesbian, gay, bisexual, or transgender (LGBT) individuals; health care providers; consumer groups; religious organizations; academic and research institutions; reproductive health organizations; health plan organizations; health insurance issuers; State and local agencies; and tribal organizations. Of the total comments, 23,344 comments were from individuals. The great majority of those comments were letters from individuals that were part of mass mail campaigns organized by civil rights/advocacy groups.

B. Overview of the Final Rule

This final rule adopts the same structure and framework as the proposed rule: Subpart A sets forth the rule's general provisions; Subpart B contains the rule's nondiscrimination provisions; Subpart C describes specific applications of the prohibition on discrimination to health programs and activities; and Subpart D describes the procedures that apply to enforcement of the rule.

OCR has made some changes to the proposed rule's provisions, based on the comments we received. Among the significant changes are the following.

Section 92.4 now provides a definition of the term "national origin."

OCR decided against including a blanket religious exemption in the final rule; however, the final rule includes a provision noting that insofar as application of any requirement under the rule would violate applicable Federal statutory protections for religious freedom and conscience, such application would not be required.

OCR has modified the notice requirement in § 92.8 to exclude publications and significant communications that are small in size from the requirement to post all of the content specified in § 92.8; instead, covered entities will be required to post only a shorter nondiscrimination statement in such communications and publications, along with a limited number of taglines. OCR also is translating a sample nondiscrimination statement that covered entities may use in fulfilling this obligation. It will be available by the effective date of this rule.

In addition, with respect to the obligation in § 92.8 to post taglines in at least the top 15 languages spoken nationally by persons with limited English proficiency, OCR has replaced the national threshold with a threshold requiring taglines in at least the top 15 languages spoken by limited English proficient populations statewide.

OCR has changed § 92.101 to provide that sex-specific health programs or activities are allowable only where the covered entity can demonstrate an exceedingly persuasive justification, *i.e.,* that the sex-specific program is substantially related to the achievement of an important health-related or scientific objective.

OCR has changed § 92.201, addressing the obligation to take reasonable steps to provide meaningful access. That section now requires the Director to evaluate, and give substantial weight to, the nature and importance of the health program or activity and the particular communication at issue to the individual with limited English proficiency, and to take into account all other relevant factors, including whether the entity has developed and implemented an effective language access plan, appropriate to its particular circumstances. The final rule deletes the specific list of illustrative factors set out in the proposed rule.

Also, OCR has changed § 92.203, addressing accessibility of buildings and facilities for individuals with disabilities, to require covered entities that were covered by the 2010 Americans with Disabilities Act (ADA) Standards for Accessible Design prior to the effective date of this final rule to comply with those standards for new construction or alterations by the effective date of the final rule. The final rule also narrows § 92.203's safe harbor for building and facility accessibility so that compliance with the Uniform Federal Accessibility Standards (UFAS) will be deemed compliance with this part only if construction or alteration was commenced before the effective date of the final rule and the facility or part of the facility was not covered by standards under the ADA. As nearly all covered entities under the final rule are already covered by the ADA standards, these changes impose a de minimis cost.

Section 92.301 has been changed to clarify that compensatory damages for violations of Section 1557 are available in administrative and judicial actions to the extent they are available under the authorities referenced in Section 1557. Finally, we have added a severability clause to § 92.2, to indicate our intention that the rule be construed to give the maximum effect permitted by law to each provision.

In responding to the comments it received on the proposed rule, OCR has provided a thorough explanation of each of these changes in the preamble. OCR has also clarified some of the nondiscrimination requirements of Section 1557 and made some technical changes to the rule's provisions. In addition, we have added some definitions to proposed § 92.4, as summarized in the preamble to this final rule.

II. Provisions of the Proposed Rule and Analysis and Responses to Public Comments

A. General Comments

OCR received a large number of comments asking that we categorically declare in the final rule that certain actions are or are not discriminatory. For

example, some commenters asked that OCR state that a modification to add medically necessary care, or a prohibition on exclusions of medically necessary services, is never a fundamental alteration to a health plan. Similarly, other commenters asked that OCR include a statement in the final rule that an issuer's refusal to cover core services commonly needed by individuals with intellectual disabilities is discrimination on the basis of disability. Still other commenters asked that OCR state that limiting health care and gender transition services to transgender individuals over the age of 18 is discriminatory. Other commenters asked that OCR state that it is discriminatory to require individuals with psychiatric disabilities to see a mental health professional in order to continue receiving treatment for other conditions.

Many of these same commenters asked that OCR supplement the final rule with in-depth explanations and analyses of examples of discrimination. For example, several commenters asked that OCR add an example of discrimination in research trials. Similarly, many other commenters asked that OCR add an example of what they considered to be disability discrimination in health insurance practices, such as higher reimbursement rates for care in segregated settings.

OCR appreciates the commenters' desire for further information on the application of the rule to specific circumstances. OCR's intent in promulgating this rule is to provide consumers and covered entities with a set of standards that will help them understand and comply with the requirements of Section 1557. Covered entities should bear in mind the purposes of the ACA and Section 1557—to expand access to care and coverage and eliminate barriers to access—in interpreting requirements of the final rule. But we neither address every scenario that might arise in the application of these standards nor state that certain practices as a matter of law are "always" or "never" permissible. The determination of whether a certain practice is discriminatory typically requires a nuanced analysis that is fact-dependent. Nonetheless, OCR has included in the preamble a number of examples of issues and circumstances that may raise compliance concerns under the final rule.

OCR also received several comments, primarily from representatives of the insurance industry, recommending that where specific Centers for Medicare & Medicaid Services (CMS) or State requirements apply to covered entities, OCR should either (1) harmonize all standards with existing CMS rules, or (2) allow issuers to be deemed compliant with Section 1557 if they are compliant with existing Federal or State law. For example, some commenters requested that compliance with CMS regulations that pertain to qualified health plans or insurance benefit design, such as prescription drug formularies designed by a pharmacy and therapeutics committee, be deemed compliance with the final rule on Section 1557. These commenters were concerned that CMS or a State might approve a plan that OCR might later find discriminatory. The commenters sought clarification on how OCR will handle cases involving health plans regulated by multiple authorities, and suggested that a "deeming" approach would reduce confusion and avoid duplication of costs and administrative effort. Other commenters asked that compliance with language access standards promulgated by CMS or the States be deemed compliance with the final rule; those comments are discussed in more detail in the preamble at § 92.201.

OCR recognizes the efficiencies inherent in harmonizing regulations to which covered entities are subject under various laws. Indeed, entities covered under Section 1557 are likely also subject to a host of other laws and regulations, including CMS regulations, the Genetic Information Nondiscrimination Act of 2008,[3] the Family and Medical Leave Act, the ADA, Title VII of the Civil Rights Act of 1964, and State laws. OCR will coordinate as appropriate with other Federal agencies to avoid inconsistency and duplication in enforcement efforts.

That said, OCR declines to adopt a deeming approach whereby compliance with another set of laws or regulations automatically constitutes compliance with Section 1557. As to State laws, it is inappropriate to define requirements under Federal law based on what could be the varying, and potentially changing, requirements of different States' approaches. As to other Federal laws, OCR will give consideration to an entity's compliance with the requirements of other Federal laws where those requirements overlap with Section 1557. In such cases, OCR will work closely with covered entities where compliance with this final rule requires additional steps. But in the final analysis, OCR must, in its capacity as the lead enforcement agency for Section 1557, maintain the discretion to evaluate an entity's compliance with the standards set by the final rule. This is consistent with the approach taken by other agencies to civil rights obligations, in which compliance with one set of requirements, adopted under different laws or for different purposes, is not considered automatic compliance with civil rights obligations.

Subpart A—General Provisions

Purpose and Effective Date (§ 92.1)

In § 92.1, we proposed 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.

We also proposed 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.

The comments and our responses regarding the proposed effective date are set forth below.

Comment: Some commenters asserted that 60 days after publication of the final rule did not allow sufficient time for entities to come into compliance with Section 1557 and requested that the effective date be one year after publication of the final rule. Similarly, one commenter stated that State agencies covered by Section 1557 need at least 150 days to come into compliance with Section 1557. The commenter stated that State agencies need additional time to assess the impacts, align nondiscrimination requirements from multiple Federal agencies, and make the required policy, operational, and system changes.

Response: OCR does not believe that extending the effective date beyond 60 days is warranted, except with regard to specific provisions for which there is

a later applicability date, as set forth below. Most of the requirements of Section 1557 are not new to covered entities, and 60 days should be sufficient to come into compliance with any new requirements.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the provisions as proposed in § 92.1 with one modification. We recognize that some covered entities will have to make changes to their health insurance coverage or other health coverage to bring that coverage into compliance with this final rule. We are sensitive to the difficulties that making changes in the middle of a plan year could pose for some covered entities and are committed to working with covered entities to ensure that they can comply with the final rule without causing excessive disruption for the current plan year. Consequently, to the extent that provisions of this rule require changes to health insurance or group health plan benefit design (including covered benefits, benefits limitations or restrictions, and cost-sharing mechanisms, such as coinsurance, copayments, and deductibles), such provisions, as they apply to health insurance or group health plan benefit design, have an applicability date of the first day of the first plan year (in the individual market, policy year) beginning on or after January 1, 2017.

Application (§ 92.2)

Section 92.2 of the proposed rule stated that Section 1557 applies to all health programs and activities, any part of which receives Federal financial assistance from any Federal agency. It also stated that 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.

In paragraph (a), we proposed to apply the proposed rule, except as otherwise provided in § 92.2, to: (1) All health programs and activities, any part of which receives Federal financial assistance administered by HHS; (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.

In paragraph (b), we proposed limitations to the application of the final rule. We proposed the adoption of the existing limitations and exceptions that already, under the statutes referenced in Section 1557, govern the health programs and activities subject to Section 1557. We noted that 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.

In paragraph (b)(1), we proposed to incorporate the exclusions found in the Age Act, such that the provisions of the proposed rule would 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.[4] We requested comment on whether the exemptions found in Title IX and its implementing regulation should be incorporated into the final rule. We noted that unlike the Age Act, Section 504, and Title VI, which apply to all programs and activities that receive Federal financial assistance (including health programs and activities), Title IX applies only in the context of education programs and not to the majority of the health programs and activities subject to the proposed rule. In addition, we noted that many of Title IX's limitations and exceptions do not readily apply in a context that is grounded in health care, rather than education.

We invited comment on whether the regulation should include any specific exemptions for health service providers, health plans, or other covered entities with respect to requirements of the proposed rule related to sex discrimination. We stated that we wanted to ensure that the proposed rule had the proper scope and appropriately protected sincerely held religious beliefs to the extent that those beliefs may conflict with provisions of the proposed regulation. We noted that certain protections already exist with respect to religious beliefs, particularly with respect to the provision of certain health-related services; for example, we noted that the proposed rule would not displace the protections afforded by provider conscience laws,[5] the Religious Freedom Restoration Act (RFRA),[6] provisions in the ACA related to abortion services,[7] or regulations issued under the ACA related to preventive health services.[8] We invited comment on the extent to which these existing protections provide sufficient safeguards for any religious concerns in applying Section 1557.

We noted that a fundamental purpose of the ACA is to ensure that health services are available broadly on a nondiscriminatory basis to individuals throughout the country. Thus, we requested comment on any health care consequences that would ensue were the regulation to provide additional exemptions.

We also requested 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**.

The comments and our responses regarding § 92.2 are set forth below.

Comment: Some commenters recommended that the final rule apply not only to health programs and activities receiving Federal financial assistance from the Department, but to health programs and activities receiving Federal financial assistance from other Departments. The commenters noted that in enacting Section 1557, Congress delegated rulemaking authority to the Department; they therefore maintained that the Department has the authority to promulgate rules that apply to other Departments. Commenters further noted that the Department has greater expertise in the application of civil rights laws to health programs and activities than do other Departments, and further urged that HHS regulations applicable to health programs and activities receiving Federal financial assistance from other Departments would be afforded deference under *Chevron U.S.A.* v. *NRDC, Inc.* [9]

In the alternative, commenters recommended that we collaborate with other Departments to effectuate the provisions of the final rule and ensure that other Departments enter into delegation agreements or Memoranda of Understanding that grant HHS interpretation and enforcement authority over health programs funded and administered by other Departments or that commit other Departments to move quickly to engage in their own rulemaking on Section 1557.

Response: While the rule recognizes that Section 1557 itself applies to health programs and activities receiving Federal financial assistance from other Departments, we decline to extend the scope of the rule to health programs and activities receiving Federal financial assistance from other Departments. Drafting a rule applicable to health programs and activities assisted by other Departments would pose numerous challenges, one of which is that the Department lacks the information and expertise necessary to apply the rule to those programs without further engagement and collaboration with those Departments. We agree that expeditious implementation of Section 1557 by other Departments is desirable, and hope that the Department's final rule will inform enforcement of Section 1557 by other Departments with respect to their federally assisted health programs and activities. To this end, the OCR Director sent a memorandum encouraging coordination of enforcement responsibilities under Section 1557 to all Federal agencies in November 2015.

Comment: Commenters recommended that the final rule apply not just to programs administered by HHS, but also to programs administered by other Departments.

Response: We decline to make the rule applicable to programs administered by other Departments. We will, however, continue to work with other Departments that administer health programs and activities to help those Departments ensure that their programs are nondiscriminatory.

Comment: Many commenters responded to the proposed rule's request for comment on whether the rule should include a religious exemption for health care providers, health plans, or other covered entities with respect to the requirements of the rule related to sex discrimination, or whether existing protections, including RFRA, ACA regulations for preventive health services, and Federal provider conscience laws provide sufficient safeguards for religious concerns.

Most of the organizations that commented on this issue, including professional medical associations and civil rights organizations, and the overwhelming majority of individual commenters, many of whom identified themselves as religious, opposed any religious exemption on the basis that it would potentially allow for discrimination on the bases prohibited by Section 1557 or for the denial of health services to women. Several religious organizations also opposed a religious exemption, asserting that RFRA, the Federal provider conscience statutes, and State RFRA statutes, which many States have enacted, provide sufficiently strong protections for religious providers and institutions. Many commenters said that mergers of religiously-affiliated hospitals with other hospitals have deepened concerns that would be raised by providing a religious exemption, as the mergers may leave individuals in many communities with fewer health care options offering the full range of women's health services. Many commenters also pointed to the language in the majority opinion in the Supreme Court's decision in *Hobby Lobby* v. *Burwell* that RFRA is not a shield that permits discrimination "cloaked as religious practice to escape legal sanction." [10]

Some religious organizations that submitted comments strongly supported a religious exemption, arguing that faith-based health care providers and employers would be substantially burdened if required to provide or refer for, or purchase insurance covering, particular services such as gender transition services. Supporters of an exemption recommended that Section 1557 incorporate the religious exemption in Title IX, which exempts educational institutions controlled by religious organizations from the prohibition of sex discrimination if the application would be inconsistent with the religious tenets of the organization. [11] None of the commenters supporting a religious exemption asserted that there would be a religious basis for generally refusing to treat LGBT individuals for a medical condition, for example, refusing to treat a broken bone or cancer; rather, commenters asserted that the rule should exempt faith-based providers from providing particular services, such as services related to gender transition, that are inconsistent with their religious beliefs.

Response: As noted in the preamble to the proposed rule, certain protections already exist in Federal law with respect to religious beliefs, particularly with regard to the provision of certain health-related services. For example, we noted that the proposed rule would not displace the protections afforded by provider conscience laws, [12] RFRA, [13] provisions in the ACA related to abortion services, [14] or regulations issued under the ACA related to preventive health services. [15] Nothing in this final rule displaces those protections.

Although some commenters urged us also to incorporate Title IX's blanket religious exemption into this final rule, we believe that applying the protections in the laws identified above offers the best and most appropriate approach for resolving any conflicts between religious beliefs and Section 1557 requirements. With regard to abortion, for example, specific ACA provisions concerning abortion will continue to control, including, but not limited to, provisions that bar qualified health plans offered through a Marketplace[SM] [16] from discriminating against an individual health care provider or health care facility because of its unwillingness to provide, pay for, provide coverage of, or refer for abortions, [17] and provisions that state that nothing in the ACA shall be construed to require a qualified health plan to provide coverage of abortion as an essential health benefit. [18]

In other cases, application of RFRA is the proper means to evaluate any religious concerns about the application of Section 1557 requirements. The RFRA analysis evaluates whether a legal requirement substantially burdens the exercise of religion; if so, the question becomes whether the legal requirement furthers a compelling interest and is the least restrictive means to further that interest.

We believe that the government has a compelling interest in ensuring that individuals have nondiscriminatory access to health care and health coverage and, under RFRA, would assess whether a particular application of Section 1557 substantially burdened a covered entity's exercise of religion and, if so, whether there were less restrictive alternatives available. Claims under RFRA are individualized and fact specific and we would make these determinations

on a case-by-case basis, based on a thorough analysis and relying on the extensive case law interpreting RFRA standards.

We decline to adopt commenters' suggestion that we import Title IX's blanket religious exemption [19] into Section 1557. Section 1557 itself contains no religious exemption. In addition, Title IX and its exemption are limited in scope to educational institutions, and there are significant differences between the educational and health care contexts that warrant different approaches.

First, students or parents selecting religious educational institutions typically do so as a matter of choice; a student can attend public school (if K-12) or choose a different college. In the health care context, by contrast, individuals may have limited or no choice of providers, particularly in rural areas or where hospitals have merged with or are run by religious institutions. Moreover, the choice of providers may be even further circumscribed in emergency circumstances.

Second, a blanket religious exemption could result in a denial or delay in the provision of health care to individuals and in discouraging individuals from seeking necessary care, with serious and, in some cases, life threatening results. Thus, it is appropriate to adopt a more nuanced approach in the health care context, rather than the blanket religious exemption applied for educational institutions under Title IX.

Based on the foregoing, we have included a provision in this final regulation making clear that where application of this regulation would violate applicable Federal statutory protections for religious freedom and conscience, that application will not be required. The Department also retains the discretion to provide other accommodations or exemptions where permitted by Federal law and supported by sound public policy.

Comment: One commenter suggested that we clarify that the regulation applies only to a covered entity's health operations "in the United States."

Response: This regulation applies only to individuals who are subjected to discrimination, at least in part, in the United States and to the provision or administration of health-related services or health-related insurance coverage in the United States, consistent with the four statutes referenced in Section 1557. [20]

Consistent with the Department's Title VI regulation, [21] OCR interprets "United States" to include the U.S. territories. The definition of "recipient" of Federal financial assistance in the civil rights laws referenced in Section 1557 does not contain geographic limitations, and includes, in addition to States and political subdivisions, other "public or private agenc[ies], institution[s], or organization[s]." [22] Thus, health programs and activities of the U.S. Territories, and those provided or administered in the U.S. Territories, are covered by the final rule. [23]

Comment: One commenter requested that we clarify that expatriate health plans, plan sponsors of self-funded expatriate health plans, and issuers of fully-insured expatriate health plans are exempt from Section 1557 pursuant to the Expatriate Health Coverage Clarification Act of 2014 (EHCCA), [24] which provides generally that provisions of the ACA do not apply to expatriate health plans, employer plan sponsors of expatriate health plans, or expatriate health insurance issuers. The commenter noted that the EHCCA does not include any exceptions or special rules pertaining to Section 1557; thus, the commenter asserted, applying Section 1557 to expatriate health plans would be contrary to Congressional intent and would competitively disadvantage American health issuers in the global marketplace, resulting in consumers choosing offshore options and American issuers moving their plans offshore to compete.

Response: Section 3(a) [25] of the EHCCA specifies that the provisions of (including any amendment made by) the ACA and Title I and subtitle B of Title II of the Health Care and Education Reconciliation Act of 2010 shall not apply with respect to expatriate health plans; employers with respect to such plans, solely in their capacity as plan sponsors for such plans; or expatriate health insurance issuers with respect to coverage offered by such issuers under such plans, subject to the exceptions and special rules enumerated in Sections 3(B) and 3(C) of the EHCCA. Section 1557 is contained in Title I of the ACA; thus, pursuant to the EHCCA, Section 1557 does not apply with respect to expatriate health plans, expatriate health insurance issuers, or employer plan sponsors of expatriate plans, as defined in the EHCCA.

Comment: Tribes and tribal organizations submitted comments recommending that we make a number of changes throughout the rule and preamble to address the application of the rule to tribes and tribal health programs. Commenters objected to the characterization of **45 CFR 80.3**(d), the exception in the Title VI regulation for Indian health programs and other programs limited by Federal law to individuals of a particular race, color, or national origin, that has been incorporated into the Section 1557 rule, and recommended that we refer to **45 CFR 80.3**(d) throughout and describe it rather than simply cite to it. Commenters asked us to exempt tribes and tribal health programs from § 92.207 and § 92.208 and make clear that tribal governments and health programs can limit insurance to their members. Commenters asserted that Purchased/Referred Care [26] programs should be permitted to limit coverage and be held harmless for discrimination on the basis of disability, age, or sex. One commenter recommended several additional changes to the rule to address its application to tribes, including excluding tribes and tribal health programs from the definitions of "covered entity" and "health program or activity," and excluding assistance to tribes and tribal health programs from the definition of "Federal financial assistance," along with other changes intended to achieve this purpose. Commenters stated that the changes proposed were necessary to reflect the full scope of protections in Federal law for tribal classifications and tribal sovereignty.

Response: **45 CFR 80.3**(d) is not an exemption from coverage; it provides an exception to application of the prohibitions on race, color, and national origin discrimination when programs are authorized by Federal law to be restricted to a particular race, color, or national origin. The final rule incorporates that exception, and OCR will fully apply it, as well as other exemptions or defenses that may exist under Federal law. OCR intends to address any restrictions on application of the law to tribes in the context of individual complaints.

Comment: One tribal organization commented that tribal consultation on development of the rule was insufficient.

Response: We engaged in tribal consultation on the rule and, during that consultation, encouraged tribes and tribal organizations to submit comments on the proposed rule. Many did so. We believe that tribal consultation was sufficient.

Comment: One tribal organization stated that the reference to Indian Health Services (IHS) programs in the preamble was misleading, as some IHS programs are administered directly by tribes.

Response: We agree that the reference to IHS programs as an example of a federally administered program may be confusing, given that some IHS programs are administered directly by tribes. We have therefore changed the reference to "IHS programs" to "IHS programs administered by IHS."

Finally, we have added a severability clause to § 92.2, to indicate our intention that the rule be construed to give the maximum effect permitted by law to each provision. The rule provides that if a provision is held to be unenforceable in one set of circumstances, it should be construed to give maximum effect to the provision as applied to other persons or circumstances. Similarly, if a provision is held to be invalid or unenforceable, that provision should be severable from, and have no impact on the application of, the remainder of the rule. This provision is consistent with our interpretation of the Department's regulations implementing Title VI, Title IX, Section 504, and the Age Act.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the provisions as proposed in § 92.2, with two modifications. We are adding § 92.2(b)(2), which clarifies that if an application of Section 1557 requirements or this part would violate applicable Federal statutory protections for religious freedom and conscience, application of Section 1557 is not required. In addition, we have added § 92.2(c), containing a severability clause.

Relationship to Other Laws (§ 92.3)

In § 92.3 of the proposed rule, we proposed an explanation of the relationship of the rule to existing laws. Paragraph (a) proposed 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) proposed 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. OCR explained that this intent is derived from Section 1557(b) of the ACA. In addition to the statutes that are cited directly in Section 1557(b), the proposed rule cited the Architectural Barriers Act of 1968,[27] the Americans with Disabilities Act of 1990 (ADA),[28] and Section 508 of the Rehabilitation Act of 1973 (Section 508).[29] We noted that 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.

Summary of Regulatory Changes

OCR did not receive any comments on this provision. Therefore, for the reasons set forth in the proposed rule, we are finalizing the provisions as proposed in § 92.3 without modification.

Definitions (§ 92.4)

In § 92.4 of the proposed rule, we set out proposed definitions of various terms. The comments and our responses regarding § 92.4 are set forth below.

Disability. We proposed that the definition of "disability" be the same as the definition of this term in the Rehabilitation Act,[30] which incorporates the definition of disability in the ADA, as construed by the ADA Amendments Act of 2008.[31] In addition, we proposed to use the term "disability" in place of the term "handicap," which is used in some previous civil rights statutes and regulations. We provided that when we cross-reference other regulatory provisions, regulatory language that uses the term "handicap" shall mean "disability." We noted that this change in terminology does not reflect a change in the substance of the definition.

Comment: OCR received many comments related to the definition of disability. Several commenters asked OCR to provide additional guidance regarding the meaning of terms used within the definition of disability, including "physical or mental impairment," "major life activities," and "substantially limits." Other commenters asked OCR to include the term "chronic conditions" in the definition of disability or to add regulatory language to the definition of disability that creates a rebuttable presumption of disability for serious and chronic conditions. Still other commenters urged that OCR clarify that the definitions of disability and qualified individual with a disability are broad.

Response: As noted in the proposed rule, the definition of "disability" is the same as the definition of this term in the Rehabilitation Act, which incorporates the definition of disability in the ADA, as construed by the ADA Amendments Act of 2008. Thus, the proposed rule incorporates the definition of "major life activities" and the construction of all of the terms and standards in the definition of "disability" set forth in the ADA Amendments Act. We believe this definition is appropriate and that OCR's intent, consistent with the ADA Amendments Act, to broadly interpret the term "disability" is clear. Whether a chronic condition is a disability will depend on whether it falls within the definition of disability in the final rule.

Comment: A few commenters asked for a definition of the term "reasonable modification." Other commenters asked for a definition of "accessibility,"

especially as that term pertains to electronic and information technology. Both sets of commenters suggested that adding definitions to the final rule would provide greater clarity to covered entities.

Response: OCR believes that defining the terms "reasonable modification" and "accessibility" in this rule is unnecessary, given the meaning that these terms have acquired in the long history of enforcement of Section 504 and the ADA in the courts and administratively. We intend to interpret both terms consistent with the way that we have interpreted these terms in our enforcement of Section 504 and the ADA and so decline to add these definitions to the final rule.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the definition of "disability" as proposed without modification.

Electronic and information technology. We proposed to define "electronic and information technology" to be consistent with **36 CFR 1194.4**, the regulation implementing Section 508.

Comment: A few commenters recommended that OCR amend the definition of "electronic and information technology" to state that "electronic and information technology includes hardware, software, integrated technologies or related licenses, intellectual property, upgrades, or packaged solutions sold as services that are designed for or support the use by health care entities or patients for the electronic creation, maintenance, access, or exchange of health information." These commenters asserted that this definition, which is based on the definition of "health information technology" in the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009,[32] is preferable to the definition OCR proposed, which is based on the regulations implementing Section 508 that were promulgated in 2000. According to these commenters, the Section 508 definition is outdated and unduly narrow.

Response: As OCR stated in the Notice of Proposed Rulemaking, the definition of "electronic and information technology" is based on **36 CFR 1194.4**, the regulation implementing Section 508. OCR believes that a definition of "electronic and information technology" that is consistent with the regulations implementing Section 508 will reduce the possibility of confusing or conflicting standards for covered entities. Moreover, the definition used in the HITECH Act was created for use in another context and is narrower in some respects than would be appropriate for Section 1557. However, OCR also shares the commenters' concern that the current definition found at **36 CFR 1194.4** is outdated and unduly narrow. Accordingly, OCR notes the recent Access Board proposal to replace the term "electronic and information technology" with an updated term and definition.

Specifically, on February 27, 2015, the Access Board proposed to revise and update its standards for electronic and information technology developed, procured, maintained, or used by Federal agencies covered by Section 508.[33] As part of these proposed revisions and updates, the Access Board announced that it intends to replace the term "electronic and information technology" in **36 CFR 1194.4** with the term "information and communication technology" and revise the definition significantly to make it broader and more compatible with modern technology.[34] OCR believes that the changes proposed by the Access Board will address the commenters' concerns. Therefore, and in order to maintain consistency with Section 508 while also addressing commenters' concerns that the definition proposed by OCR is outdated and unduly narrow, OCR has decided to change the definition of "electronic and information technology" in this rule so that it means the same as "electronic and information technology" as defined at **36 CFR 1194.4** or any term that replaces "electronic and information technology" at **36 CFR 1194.4**. By citing to the regulation, OCR's definition will update with the Access Board's finalized rule.

Summary of Regulatory Changes

For the reasons set forth above and considering the comments received, we have changed the definition of "electronic and information technology" as proposed in § 92.4 to state that it means the same as "electronic and information technology," or any term that replaces it at **36 CFR 1194.4**.

Employee health benefit program. We proposed that 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**b(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 for a covered entity's employees.

Comment: One commenter requested that OCR clarify that wellness programs that are separate from the employee health benefit plan are still an "employee health benefit program."

Response: We agree that wellness programs separate from an employee health benefit plan fall within the definition of an employee health benefit program. For example, an employer providing a gift card to each employee who receives a flu shot would be a wellness program within the meaning of the regulation, regardless of whether the wellness program is part of the employer's group health plan. We believe that the definition of "employee health benefit program" in the regulation makes this clear and thus are not adopting any revisions.

Comment: Some commenters requested that the definition of "employee health benefit program" specifically include excepted benefits, as defined for purposes of section 2791(c) of the Public Health Service Act (codified at **42 U.S.C. 300**gg-91(c)), such as limited scope vision and dental insurance,

disease-specific insurance and fixed-indemnity plans.

Response: We do not believe it is necessary to include an exhaustive list of types of benefits that would be included as an "employee health benefit program." The definition is broad enough to encompass any health benefit coverage or health insurance provided by an employer to its employees. Excepted benefits are further discussed infra under § 92.207.[35]

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing this definition as proposed in § 92.4 with minor technical revisions for clarity and for consistency with other parts of the final rule. We are making minor technical corrections to correct the ERISA citation to read "**29 U.S.C. 1191**b(a)(1)"; to clarify that the term "sponsored wellness program" is an "employer-sponsored" wellness program; to add "coverage" to the term "health insurance"; and to clarify that long term care coverage or insurance is provided or administered "for the benefit of an employer's employees."

Federal financial assistance. We proposed that the term "Federal financial assistance" includes grants, loans, and other types of assistance in accordance with the definition of "Federal financial assistance" in the regulations implementing Section 504 [36] and the Age Act,[37] and also specifically includes subsidies and contracts of insurance, in accordance with the statutory language of Section 1557. We also proposed that, 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 was added to the proposed regulatory provision, modeled on the definition of "Federal financial assistance" in the regulation implementing Title IX, which clarifies that in the educational context, 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.[38] In the proposed rule, we noted that 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. Thus, we noted that an issuer participating in any Health Insurance Marketplace[SM] is receiving Federal financial assistance when advance payments of premium tax credits and/or cost sharing reductions are provided to or on behalf of any of the issuer's enrollees. We noted that a health care 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.

Comment: Many commenters objected to the statement in the preamble to the proposed rule that, consistent with OCR's enforcement of other civil rights authorities, the definition of Federal financial assistance does not include Medicare Part B. These commenters urged us to reverse this position, asserting that the historical rationale for the Department's position that Medicare Part B payments are not Federal financial assistance is inapplicable to Section 1557, which explicitly covers "contracts of insurance," and inconsistent with the current Medicare Part B payment scheme, in which providers are paid directly by the Medicare program instead of receiving payment from consumers who are then reimbursed by the Medicare program.

Response: OCR notes commenters' concerns, but does not believe that this rule is the appropriate vehicle to modify the Department's position.

Comment: We received many comments proposing that OCR revise the statement that a health care provider that contracts with an issuer does not become a recipient of Federal financial assistance by virtue of the contract. Commenters proposed that such a provider should become a recipient, and thus be covered by Section 1557, by virtue of the contract. The commenters expressed concern that under OCR's interpretation, such contractors would not be covered by the nondiscrimination requirements of Section 1557, thereby weakening the rule's effect.

Response: We do not believe the law supports the commenters' proposed across-the-board revision. Under the regulations implementing the statutes cited in Section 1557 and incorporated into this final rule, a recipient of Federal financial assistance is an entity to which Federal financial assistance is extended directly or through another recipient, including any successor, assignee, or transferee of a recipient. To determine whether an entity is a recipient of such assistance, courts look to the entity that Congress intended to assist or subsidize with those funds.[39] In this context, the contractor that is providing health services is not the intended recipient of a premium tax credit or cost-sharing reduction that an issuer receives and is therefore not covered under Section 1557 by virtue of the contract.

That said, there are numerous ways in which health services providers are recipients in their own right, whether the Federal financial assistance they receive comes through certain Medicare payments, Medicaid payments, or other funds from the Department. Therefore, instead of falling outside of Section 1557's purview, many health care providers will be subject to Section 1557 irrespective of their relationship to issuers receiving Federal financial assistance.

Moreover, nothing in the rule authorizes qualified health plan issuers or other issuers that are covered entities to contract away their own nondiscrimination obligations. Issuers must ensure that enrollees have equal access to health services provided by their coverage without discrimination on the basis of a prohibited criterion. Thus, even if individual providers do not independently receive Federal financial assistance, an issuer maintains a duty to ensure compliance with civil rights laws with respect to the treatment of its enrollees who use its networks.

Comment: One comment inquired whether the rule applies to programs in which the Department is an employer or when the Department offers benefits to Department employees.

Response: The Department is not covered as a federally assisted program, although the Department is covered by the rule as an administrator of health programs and activities. As to programs for Department employees, HHS is covered by employment discrimination laws, including Section 504 and Title

VII, protecting Federal employees.

Comment: One commenter raised concerns over the applicability of the rule to doctors in solo medical practice, to doctors who practice in many settings, and to medical students receiving student loans. The commenter suggested that the health program or activity—not the solo practitioner as an individual—be required to comply with the rule, and requested that we clarify how a doctor can determine whether she is covered by the rule as she moves between practice settings. The commenter also expressed concern that a disproportionate number of younger doctors would be required to comply with the rule as recipients of Federal financial assistance in the form of student loans.

Response: We have not modified the final rule in response to these comments; however, we offer the following for clarification.

Section 1557 applies to a recipient of Federal financial assistance, whether a hospital, clinic, medical practice, or individual physician. Where, for example, a doctor is an employee of a hospital and the hospital receives Federal financial assistance, the hospital's program is the relevant health program or activity and it is the hospital that will be held accountable for discrimination under Section 1557. Where, similarly, a doctor contracts as an individual to provide health services at a free neighborhood clinic that receives Federal financial assistance, the clinic is the recipient of Federal financial assistance and liable for discrimination; the doctor is simply a contractor who is assisting the clinic in performing clinic services.

When a doctor has a private medical practice that receives Federal financial assistance, and the doctor, through her practice, works as an attending physician at a hospital, it is the medical practice that is providing the services at the hospital, and thus the practice that is liable for the discrimination.[40] Moreover, a solo medical practice (whether incorporated or not) that receives Federal financial assistance is a covered health program or activity.[41]

This approach is consistent with longstanding interpretations of civil rights law and the definition of a "recipient" of Federal financial assistance in the regulations implementing Section 504, Title VI, Title IX and the Age Act.

Finally, regarding receipt of student loan payments as Federal financial assistance, we clarify that the educational institution—not the student—is the recipient of the Federal financial assistance in that circumstance. Although the money is paid directly to the student, the university or other educational institution is the intended recipient. This is consistent with longstanding regulations implementing civil rights laws.

We made two clarifying changes to the definition of Federal financial assistance. In the proposed rule, we defined Federal financial assistance in subsection (1) as any type of arrangement in which the Federal government "provides or makes available" assistance. In subsection (2), we explained that Federal financial assistance "provided or administered by the Department" includes tax credits and other subsidies under Title I of the ACA and other funds providing health insurance coverage. Because our intention was to explain further the meaning of (1) as it applies to the Department in (2), we have changed (2) to use the same terms used in (1). Thus, (2) now refers to Federal financial assistance "provided or made available" by the Department.

In addition, in the proposed rule, subsection (2) provided that "Federal financial assistance provided or administered by the Department includes all tax credits under Title I of the ACA," as well as other funds extended by the Department for providing health coverage. Because the Department plays a role in administering tax credits under Title I of ACA but does not have primary responsibility for administering that credit, and to ensure that tax credits under Title I of the ACA are understood to be included within the definition, we have modified this subsection to state that Federal financial assistance the Department provides or makes available includes Federal financial assistance that the Department plays a role in providing or administering.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing this definition as proposed in § 92.4 with two modifications. The language of Subsection (2) of the definition has been modified to state that Federal financial assistance the Department provides or makes available includes Federal financial assistance that the Department plays a role in providing or administering.

Gender identity. We proposed that the term "gender identity" means an individual's internal sense of gender, which may be different from an individual's sex assigned at birth. We noted that the way an individual expresses gender identity is frequently called "gender expression," and may or may not conform to stereotypes associated with a particular gender. We also noted in the proposed rule that gender may be expressed through, for example, dress, grooming, mannerisms, speech patterns, and social interactions. For purposes of this part, we proposed that 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. In the proposed rule, we noted that the approach taken in the proposed definition is consistent with the approach taken by the Federal government in similar matters.[42]

Comment: Several commenters suggested that we revise the definition of "gender identity" to reference non-binary identities in order to avoid ambiguity regarding application of the rule to individuals with non-binary gender identities. Some commenters noted that explicitly referencing non-binary identities in this definition would be important to avoid any doubt or misinterpretation given that gender has often been assumed to be binary, thus ignoring or marginalizing individuals with non-binary gender identities.

Response: OCR has made a slight change to the definition of "gender identity" to insert the clause "which may be male, female, neither, or a combination of male and female." The insertion of this clause helps clarify that those individuals with non-binary gender identities are protected under the rule.

Comment: Some commenters suggested that, consistent with previous court and Federal agencies' interpretations, OCR add "gender expression" to the definition of "gender identity" in order to make explicit our intention to protect individuals on this basis.

Response: In the proposed and final rules' definition of gender identity, we explain that the way an individual expresses gender identity is frequently called "gender expression." OCR is clarifying that throughout this final rule, we interpret references to the term "gender identity" as encompassing "gender expression" and "transgender status." This position is consistent with the position taken by courts and Federal agencies.[43] These bases of discrimination are protected under the rule.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the definition as proposed in § 92.4 with three modifications. The first sentence of the definition of gender identity has been revised to reference the application of the rule to individuals with non-binary gender identities. OCR also made a technical edit to the last sentence to delete reference to the term "transgender identity." Finally, for clarity and consistency within the final rule, OCR has made a technical revision to the definition of gender identity to clarify that a transgender individual is an individual whose gender identity is different from the sex assigned to that person at birth.

Health program or activity. We proposed that the term "health program or activity" means 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. We also proposed that, similar to the approach of the Civil Rights Restoration Act of 1987 (CRRA) [44] and except as specifically set forth otherwise in this part, [45] 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. We proposed that OCR interpret "principally engaged" in a manner consistent with civil rights laws that use this term.

In the proposed rule, OCR stated that we intended the plural "health programs or activities" used in this part to have the same meaning as the term "health program or activity" in the singular. Similarly, we noted that the 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."

We proposed to interpret "health programs and activities" to include programs such as health education and health research programs. 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, we determined that the application of Section 1557 to health research should impose limited additional burden on covered entities.

However, OCR recognized that health research is conducted to answer scientific questions and improve health through the advancement of knowledge; it is not designed to result in direct health benefits to participants. We also recognized 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, we noted that 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.[46] OCR noted that we do 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 did OCR propose to systematically review health research protocols.

We invited comment on programs and activities that should be considered health programs or activities.

Comment: We received comments requesting that we enumerate additional examples of a health program or activity, including but not limited to the Children's Health Insurance Program, all of the operations of Medicare, and student health plans.

Response: We agree that the Children's Health Insurance Program and other health programs operated by State and local governments are covered by the rule. We also agree that student health plans are a health program or activity covered by the rule, and note that all student health plans are covered by Title IX, as well as the other civil rights laws cited in Section 1557, if the institution receives Federal financial assistance.

Although the definition does not and could not specifically identify all health programs and activities covered by the rule (for example, we do not specifically mention programs that provide physical and/or behavioral health services, although they are health programs), we are adding the Children's Health Insurance Program and the Basic Health Program as additional examples, given their significance.

We decline to include "all the operations of Medicare" in the definition of health program or activity. While we agree that all parts of the Medicare program are a health program or activity, not all operations in the Medicare program constitute Federal financial assistance; as discussed above, Medicare Part B is excluded from the definition of Federal financial assistance under this rule and other HHS civil rights authorities.[47] Thus, we believe the proposed language could create confusion in determining the scope of the final rule.

Comment: Some commenters noted that OCR did not propose to define the term "health" in "health program and activity," and recommended that OCR use the definition of "health" adopted by the World Health Organization, which includes an individual's or population's physical, mental, or social well-being.[48]

Response: OCR declines to add a definition of "health," but interprets "health" to include physical and mental well-being.

Comment: Several commenters recommended that the rule apply only to the specific health program for which the entity receives Federal financial assistance, such as health insurance coverage sold through the Marketplace^{SM}, and not to other products and services provided outside the

Marketplace[SM] by issuers participating in the Marketplace[SM]. These commenters stated that applying the rule to operations or products that are not the direct recipients of Federal financial assistance conflicts with the plain meaning of Section 1557.

Response: Section 1557 prohibits discrimination under "any health program or activity, any part of which is receiving Federal financial assistance. . . ." By applying the prohibition if "any part" of the health program or activity receives Federal financial assistance, the law provides that the term "health program or activity" must be interpreted in a manner that uniformly covers all of the operations of any entity that receives Federal financial assistance and that is principally engaged in health services, health insurance coverage, or other health coverage, even if only part of the health program or activity receives such assistance. This interpretation serves the central purposes of the ACA, and effectuates Congressional intent, by ensuring that entities principally engaged in health services, health insurance coverage, or other health coverage do not discriminate in any of their programs and activities, thereby enhancing access to services and coverage.

This approach is consistent with the approach Congress adopted in the CRRA, which amended the four civil rights laws referenced in Section 1557 and defines "program or activity" to mean "all of the operations of . . . an entire corporation, partnership, or other private organization, or an entire sole proprietorship . . . which is principally engaged in the business of providing," among other things, a range of social and health services. The CRRA establishes that the entire program or activity is required to comply with the prohibitions on discrimination if any part of the program or activity receives Federal financial assistance. The CRRA has been consistently applied since its enactment in 1988, and we believe that Congress adopted a similar approach with respect to the scope of health programs and activities covered by Section 1557. If any part of a health care entity receives Federal financial assistance, then all of its programs and activities are subject to the discrimination prohibition.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are modifying the definition as proposed in § 92.4 to include the Children's Health Insurance Program and the Basic Health Program as additional examples of a health program or activity.

Individual with limited English proficiency. We proposed that the term "individual with limited English proficiency" codify the Department's longstanding 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 Persons [49] (HHS LEP Guidance). Under the proposed definition, an individual whose primary language for communication is not English is considered an individual with limited English proficiency if the individual has a limited ability to read, write, speak or understand English. Accordingly, we proposed that an individual whose primary language for communication is not English, even if he or she has some ability to speak English, is an individual with limited English proficiency if the individual has a limited ability to read, write, speak or understand English.

Commenters addressing this definition overwhelmingly supported its codification from the HHS LEP Guidance to regulatory text. We did not receive suggested revisions to the wording of this definition.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing this definition as proposed in § 92.4, without modification.

Language assistance services. OCR proposed that the term "language assistance services" identify types of well-established methods or services used to communicate with individuals with limited English proficiency, including (1) oral language assistance; (2) written translation of documents and Web sites; and (3) taglines. We noted that a covered entity has flexibility to provide language assistance services in-house or through commercially available options. We declined to offer an exhaustive list of available methods. However, we proposed that paragraph (1) identify the following as available methods to communicate orally with individuals with limited English proficiency: Oral interpretation (in-person or remotely) [50] and direct communication through the use of bilingual or multilingual staff competent to communicate directly, in non-English languages using any necessary specialized vocabulary, with individuals with limited English proficiency.

We did not receive suggested revisions to the wording of this definition. Comments we received on the specific types of language assistance services mentioned in the definition are addressed in the relevant portions of the preamble to § 92.4 for those respective terms.

For clarity and consistency within the final rule, we are replacing several phrases in this definition with other terms to conform to changes made in other provisions of the final rule. First, in paragraph (1) regarding oral language assistance, we are adding the words "for an individual with limited English proficiency" after "qualified interpreter" because § 92.4 now defines "qualified interpreter for an individual with limited English proficiency" separately from a "qualified interpreter for an individual with a disability." Also, because § 92.4 defines "qualified bilingual/multilingual staff," we are replacing "bilingual or multilingual staff competent to communicate, in non-English languages using any necessary specialized vocabulary" with "the use of qualified bilingual/multilingual staff to communicate." In paragraph (2) regarding written translation, we are replacing the reference to written translation of "documents and Web sites" to "written content in paper or electronic form." Finally, because § 92.4 defines "qualified translator," we are adding "performed by a qualified translator" after "written translation."

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the definition as proposed in § 92.4 with

technical revisions, as described in the preceding paragraph, to ensure consistency with other provisions of the final rule.

National origin. The proposed rule did not define the term "national origin."

Comment: A few commenters recommended defining "race, color, or national origin" to include "language" and "immigration status." Commenters asserted that "language" should be included to capture the application of national origin discrimination to individuals with limited English proficiency. As to immigration status, some commenters requested clarification that immigrants, and particularly non-U.S. citizens, are protected from discrimination on the basis of race, color, national origin, sex, age, or disability under Section 1557 and this part.

Response: In response to comments, we are providing further clarification on the scope of "national origin"; we determine it unnecessary to define "race" or "color." Thus, this final rule defines "national origin" consistent with the well-established definition of the term that the Equal Employment Opportunity Commission (EEOC) uses in its interpretation of Title VII of the Civil Rights Act of 1964.[51] This definition clarifies that national origin includes not only an individual's place of origin, but also his or her ancestor's place of origin, which reflects our intent that individuals born in the United States but who have an ancestry outside the United States are protected. This definition also clarifies that national origin includes an individual's manifestation of the physical, cultural, or linguistic characteristics of a national origin group.[52]

By contrast, we decline to include the term "immigration status" in the definition of "national origin." An individual's national origin is not the same as her citizenship or immigration status, and neither Title VI nor Section 1557 explicitly protects individuals against discrimination on the basis of citizenship or immigration status. However, as under Title VI, Section 1557 and this part protect individuals present in the United States, whether lawfully or not, who are subject to discrimination based on race, color, national origin, sex, age, or disability. Moreover, OCR considers an immigrant or noncitizen to state a cognizable national origin discrimination claim under Title VI,[53] Section 1557, and this part when the claim alleges that a covered entity's use of a facially neutral policy or practice related to citizenship or immigration status has a disparate impact on individuals of a particular national origin group.

Summary of Regulatory Changes

For the reasons set forth above and considering the comments received, we are defining the term "national origin" in § 92.4 to include an individual's manifestation of the physical, cultural, or linguistic characteristics of a national origin group as well as an individual's or her ancestor's place of origin.

On the basis of sex. We proposed that the term "on the basis of sex" includes, 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, and gender identity.

We noted that Section 1557 extends the grounds for discrimination found in the nondiscrimination laws cited in the statute (*i.e.,* race, color, national origin, sex, age, or disability) to certain health programs and activities. We noted that the HHS Title IX regulation explicitly includes discrimination on the basis of pregnancy as a form of discrimination on the basis of sex, and we proposed that the definition in this section mirror that regulation.[54]

We noted that the proposed inclusion of sex stereotyping reflects the Supreme Court's holding in *Price Waterhouse* v. *Hopkins,* [55] and that discrimination based on stereotypical notions of appropriate behavior, appearance or mannerisms for each gender constitutes sex discrimination.

We proposed that discrimination on the basis of sex further includes discrimination on the basis of gender identity. We noted that like other Federal agencies,[56] HHS has previously interpreted sex discrimination to include discrimination on the basis of gender identity.[57] We also noted that courts, including in the context of Section 1557, have recognized that sex discrimination includes discrimination based on gender identity.[58] Thus, we proposed to adopt formally this well- accepted interpretation of discrimination "on the basis of sex."

OCR stated that as a matter of policy, we also support banning discrimination in health programs and activities on the basis of sexual orientation. We noted that current law is mixed on whether existing Federal nondiscrimination laws prohibit discrimination on the basis of sexual orientation as a part of their prohibitions on sex discrimination. However, we further noted that a recent U.S. EEOC decision, *Baldwin* v. *Department of Transportation,* [59] concluded that Title VII's prohibition of discrimination "on the basis of sex" includes sexual orientation discrimination because discrimination on the basis of sexual orientation necessarily involves sex-based considerations.

We proposed that the final rule reflect the current state of nondiscrimination law, and we sought 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.

Comment: Several commenters commended OCR's inclusion of discrimination not only on the basis of pregnancy, but also on the basis of pregnancy-related procedures or conditions in the definition of "on the basis of sex" and noted that such a position is consistent with existing civil rights statutes. Other commenters noted concern that the inclusion of the phrase "termination of pregnancy" in the definition of "on the basis of sex" will be interpreted as requiring the provision or coverage of, or referral for, pregnancy termination, and urged OCR to state explicitly that neither Section 1557 nor the regulation imposes such a requirement.

Response: The definition of "on the basis of sex" established by this rule is based upon existing regulation and previous Federal agencies' and courts' interpretations that discrimination on the basis of sex includes discrimination on the basis of pregnancy, childbirth, false pregnancy, termination of pregnancy or recovery therefrom.

Additionally, the final rule balances an individual's right to access health programs and activities free from discrimination with protections for religious

beliefs and practices. As we explained in the preamble to the proposed rule and have reiterated here, this rule does not displace existing protections afforded by, for example, Federal provider conscience laws and RFRA. Again, with respect to concerns about potential conflicts between provisions of the final rule and individuals' or organizations' sincerely held religious beliefs, we refer to the discussion at § 92.2 in this preamble. With respect to abortion, moreover, nothing in Section 1557 displaces the ACA provisions regarding abortion, including but not limited to the provision that no qualified health plan offered through a Marketplace may discriminate against an individual health care provider or health care facility because of its unwillingness to provide, pay for, provide coverage of, or refer for abortions; [60] provisions that state that nothing in the ACA shall be construed to require a qualified health plan to provide coverage of abortion as an essential health benefit; [61] and the provision permitting States to prohibit abortion coverage in qualified health plans and restricting the use of Federal funding for abortion services. [62]

Comment: A significant number of commenters commended our inclusion of gender identity and sex stereotyping in the definition of "on the basis of sex" and noted that the inclusion is consistent with a growing body of legal precedent. Some commenters suggested OCR add transgender status and gender expression in the definition of "on the basis of sex" in order to make explicit our intention to protect individuals on these bases, consistent with previous court and Federal agency interpretations.

Conversely, a few commenters opined that the inclusion of gender identity discrimination as a form of discrimination on the basis of sex was based on erroneous interpretations of Title IX legislative history because Congressional intent to ban sex discrimination was based only on the biological classifications of males and females, not gender identity. A few commenters thought that OCR's reliance on previously adopted Federal agencies' interpretations was weak and unpersuasive and that the reliance on cases arising under Federal civil rights laws other than Title IX was misplaced, further pointing to a few recent court decisions under Title IX that rejected claims that discrimination on the basis of sex includes discrimination on the basis of gender identity.

A few commenters also suggested that the inclusion of "gender identity" as a prohibited basis of discrimination on the basis of sex may infringe upon individual patients' constitutional right to privacy by requiring those patients to participate in sex-specific programs or activities with a "non-biological" male or female and additionally contravenes employees' and faith-based organizations' religious beliefs by forcing them to participate in services affirming gender identity in violation of their religious convictions.

Response: The definition of "on the basis of sex" established by this rule is based upon existing regulation and previous Federal agencies' and courts' interpretations that discrimination on the basis of sex includes discrimination on the basis of gender identity and sex stereotyping. While OCR appreciates the commenters' request that we add transgender status and gender expression to the definition of "on the basis of sex," we do not believe that it is necessary to add these terms to the definition. As previously stated, we encompass these bases in the definition of "gender identity"; thus, references to "gender identity" include "gender expression" and "transgender status." Because the definition of "on the basis of sex" includes gender identity, further reference to transgender status or gender expression here is superfluous.

OCR also believes that its inclusion of gender identity is well grounded in the law and disagrees with those commenters who argued to the contrary. As the Supreme Court made clear in *Price Waterhouse* v. *Hopkins,* in prohibiting sex discrimination, Congress intended to strike at the entire spectrum of discrimination against men and women resulting from sex stereotypes. [63] Courts after *Price Waterhouse* interpret Title VII's protections against discrimination on the basis of sex as encompassing not only "sex," or biological differences between the sexes, but also "gender" and its manifestations. [64] In essence, *Price Waterhouse* thus rejects the reasoning, and vitiates the precedential value, of earlier Federal appellate court decisions that limited Title VII's coverage of "sex" to the anatomical and biological characteristics of sex. Moreover, courts frequently look to case law interpreting other civil rights provisions, including Title VII, for guidance in interpreting Title IX. [65]

OCR's approach accords with well-accepted legal interpretations adopted by other Federal agencies and courts. For example, Title IX Guidance issued by the U.S. Department of Education generally requires recipients of federal financial assistance to treat transgender students consistent with their gender identity. [66] The Fourth Circuit reversed a lower court decision dismissing the Title IX sex discrimination claim of a transgender student prohibited from using the school bathroom consistent with his gender identity, holding that the Department of Education's interpretation of its regulation was not plainly erroneous, and thus was entitled to controlling weight. [67]

The fact that there may be circumstances in which it is permissible to make sex-based distinctions is not a license to exclude individuals from health programs and activities for which they are otherwise eligible simply because their gender identity does not align with other aspects of their sex, or with the sex assigned to them at birth. The Department has a responsibility to ensure that health programs and activities of covered entities are carried out free from such discrimination.

To the extent that privacy considerations may be relevant in an anti-discrimination analysis, OCR will consider these interests in the context of individual complaints. We note, however, that at least one court has rejected a claim that an individual's legal right to privacy is violated simply by permitting another person access to a sex-specific program or facility that corresponds to their gender identity. [68] With respect to concerns about potential conflicts between provisions of the final rule and individuals' or organizations' sincerely held religious beliefs, we refer to the discussion at § 92.2 in this preamble.

Comment: A few commenters recommended that OCR clarify that the prohibition on sex discrimination extends to discrimination on the basis of the presence of atypical sex characteristics and intersex traits (*i.e.,* people born with variations in sex characteristics, including in chromosomal, reproductive, or anatomical sex characteristics that do not fit the typical characteristics of binary females or males). At least one commenter noted that this clarification is necessary because intersex people may face discrimination when medical providers or insurance companies follow policies which deem certain medical procedures available to only one sex, thereby excluding intersex people who may be registered under another sex.

Response: We agree with the commenters that the prohibition on sex discrimination extends to discrimination on the basis of intersex traits or atypical sex characteristics. OCR intends to apply its definition of "on the basis of sex" to discrimination on these bases.

Comment: Many commenters requested that OCR explicitly state in the rule that Section 1557's prohibition of discrimination on the basis of sex includes discrimination on the basis of sexual orientation. Other commenters asserted that Section 1557 did not intend to protect against sexual orientation discrimination and that OCR does not have authority to include this basis because no Federal appellate court has interpreted Title IX's or Title VII's ban on sex discrimination to protect same-sex relationships or conduct.

Response: As we noted in the preamble to the proposed rule, we support a prohibition on discrimination based on sexual orientation as a matter of policy. We believe that it is critical to meeting the goals of Section 1557 and, more broadly, the ACA, to ensure equal access to health care and health coverage. Indeed, these policy goals are reflected in the increasing number of actions taken by Federal agencies to ensure that lesbian, gay, and bisexual individuals are protected from discrimination. For example, CMS regulations bar discrimination on the basis of sexual orientation by Health Insurance Marketplaces and issuers offering qualified health plans;[69] Medicare regulations prohibit the restriction of visitation rights in hospitals based on sexual orientation (or gender identity);[70] and the Social Security Administration is now processing Medicare enrollments for same-sex spouses.[71] Court decisions have, moreover, repeatedly made clear that individuals and couples deserve equal rights regardless of their sexual orientation.[72]

The preamble to the proposed rule stated our policy position and noted that "[t]he final rule should reflect the current state of nondiscrimination law, including with respect to prohibited bases of discrimination" while seeking comment on the issue. While the preamble observed that no Federal appellate court has concluded to date "that Title IX's prohibition of discrimination `on the basis of sex'—or Federal laws prohibiting sex discrimination more generally—prohibits sexual orientation discrimination," it also noted recent court decisions that have prohibited discrimination in cases involving allegations of discrimination relating to an individual's sexual orientation on the grounds that such discrimination is discrimination on the basis of sex stereotyping.

Price Waterhouse v. *Hopkins* [73] is the foundational decision that underlies these legal developments. Though *Price Waterhouse* did not involve an allegation of discrimination based on an individual's sexual orientation, the Supreme Court recognized in that case that unlawful sex discrimination occurs where an individual is treated differently based on his or her failure to conform to gender-based stereotypes about how men or women should present themselves or behave. The Department of Justice has therefore taken the position that a well-pled complaint alleging discrimination against a gay employee because of his failure to conform to sex stereotypes states a viable sex discrimination claim under Title VII.[74] When a covered entity discriminates against an individual based on his or her sexual orientation, the entity may well rely on stereotypical notions or expectations of how members of a certain sex should act or behave. These stereotypes are precisely the type of gender-based assumptions prohibited by *Price Waterhouse.* [75]

Based on this understanding, some courts have recognized in the wake of *Price Waterhouse* that discrimination "because of sex" includes discrimination based on sex stereotypes about sexual attraction and sexual behavior[76] or about deviations from "heterosexually defined gender norms."[77] For example, a recent district court decision in the Ninth Circuit held that the distinction between discrimination based on gender stereotyping and discrimination based on sexual orientation is artificial, and claims based on sexual orientation are covered by Title VII and Title IX, not as an independent category of claims separate from sex and gender stereotyping, but as sex or gender discrimination.[78]

In addition, in *Baldwin* v. *Department of Transportation* the EEOC concluded that Title VII's prohibition of discrimination "because of sex" includes sexual orientation discrimination because discrimination on the basis of sexual orientation necessarily involves sex-based considerations.[79] The EEOC relied on several theories to reach this conclusion: A plain reading 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.*

For all of these reasons, OCR concludes that Section 1557's prohibition of discrimination on the basis of sex includes, at a minimum, sex discrimination related to an individual's sexual orientation where the evidence establishes that the discrimination is based on gender stereotypes. Accordingly, OCR will evaluate complaints alleging sex discrimination related to an individual's sexual orientation to determine whether they can be addressed under Section 1557.

OCR has decided not to resolve in this rule whether discrimination on the basis of an individual's sexual orientation status alone is a form of sex discrimination under Section 1557. We anticipate that the law will continue to evolve on this issue, and we will continue to monitor legal developments in this area. We will enforce Section 1557 in light of those developments and will consider issuing further guidance on this subject as appropriate.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing this definition as proposed in § 92.4 without modification.

Qualified bilingual/multilingual staff. In the proposed rule, we proposed to define "language assistance services" to include, as a type of oral language assistance, the use of staff members who are "competent to communicate, in non-English languages using any necessary specialized vocabulary, directly with individuals with limited English proficiency."[80] The proposed rule did not define the term "qualified bilingual/multilingual staff."

Comment: Some commenters observed that as an alternative to providing oral interpretation, many covered entities rely on staff members to serve individuals with limited English proficiency in their respective primary languages. According to these commenters, covered entities mistakenly assume that staff members who possess a rudimentary familiarity with at least one non-English language are competent to provide oral language assistance for the

covered entity's health program or activity. Commenters asked us to require covered entities to assess the proficiency of staff members who communicate directly with individuals with limited English proficiency in their respective primary languages.

Response: In response to commenters' observations, we have defined the term "qualified bilingual/multilingual staff" in § 92.4 to clarify the knowledge, skills, and abilities that a staff member must demonstrate for a covered entity to designate that staff member to provide effective oral language assistance. [81] Specifically, qualified bilingual/multilingual staff must demonstrate to the covered entity that they are proficient in English and at least one other spoken language, including any necessary specialized vocabulary, terminology and phraseology, and are able to effectively, accurately, and impartially communicate directly with individuals with limited English proficiency in their primary language. An individual who meets the definition of "qualified bilingual/multilingual staff" does not necessarily qualify to interpret or translate for individuals with limited English proficiency within the meaning of this rule.

Summary of Regulatory Changes

For the reasons set forth above and considering the comments received, we are defining the term "qualified bilingual/multilingual staff" in § 92.4 to clarify that such an individual must be proficient in speaking and understanding both spoken English and at least one other spoken language, including any necessary specialized vocabulary, terminology and phraseology, and must be able to effectively, accurately, and impartially communicate directly with individuals with limited English proficiency in their primary languages.

Qualified interpreter. We proposed that 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. In the proposed rule, the language in paragraph (1), applicable for interpreting for an individual with a disability, is the same as language in the regulations implementing Titles II and III of the ADA, at **28 CFR 35.104** and 36.104, respectively. The language in paragraph (2) of the proposed rule, 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. [82] We noted that 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.

We proposed that the definition of "qualified interpreter" includes criteria regarding interpreter ethics, including maintaining client confidentiality. As we stated in the proposed rule, bilingual or multilingual staff members may not possess competence in the skill of interpreting nor have knowledge of generally accepted principles of interpreter ethics. A qualified bilingual/multilingual nurse who is competent to communicate in Spanish directly with Spanish-speaking individuals may not be a qualified interpreter for an individual with limited English proficiency if serving as an interpreter would pose a conflict of interest with the nurse's treatment of the patient.

Comment: A few commenters suggested that OCR amend the definition of qualified interpreter to require interpreters to be licensed by State law in the State where the entity is providing services. Other commenters suggested that OCR require interpreters to be certified by a national nonprofit certification organization.

Response: We recognize the commenters' concerns regarding licensure and certification, but we decline to accept these recommendations. Although OCR considers licensure and certification as evidence that an interpreter is qualified, licensure and certification are neither necessary nor sufficient evidence of qualification for the following reasons. [83] First, OCR does not wish to unduly narrow the pool of qualified interpreters available to a covered entity by requiring certification or licensure; many interpreters who are currently unlicensed and uncertified are competent to translate at a level that would meet the requirements of Section 1557 and this part.

Second, there are several organizations, both for-profit and non-profit, that offer certification programs for interpreters. Even if the credentialing standards developed by those organizations currently satisfy Section 1557 requirements, the organizations' standards are subject to change and there is no assurance that such standards would consistently meet the standards of Section 1557. In addition, other national credentialing organizations could be established whose standards failed to meet the requirements of the law. Similar issues with respect to new and changing standards could also arise in the State licensing context.

Third, there are factors unrelated to credentials that could cause OCR to determine that an interpreter is unqualified. For example, if an interpreter has not practiced in a long time or is late to appointments, the interpreter might be unqualified regardless of the interpreter's State or non-profit credentials. For all of these reasons, we decline to amend the definition of qualified interpreter in the ways these commenters proposed.

Comment: We received many comments in support of the proposed rule's inclusion of a definition of "qualified interpreter." Some commenters, however, requested that we define a qualified interpreter who interprets for individuals with limited English proficiency separately from a qualified interpreter who interprets for individuals with disabilities, noting that there are significant differences between the provision of oral interpretation services in these two contexts. Other commenters suggested broadening the lexicon an interpreter must possess to be a qualified interpreter for a particular covered entity's health program. Specifically, commenters suggested that an interpreter's required knowledge and abilities to be "qualified" should include not only knowledge of any necessary specialized vocabulary but also knowledge of terminology and phraseology.

Response: We have modified § 92.4 to provide separate definitions of "qualified interpreter for an individual with limited English proficiency" [84] and "qualified interpreter for an individual with a disability." We agree that it is important to account for the qualifications necessary for interpreting for each set of individuals. In addition, we added the words "terminology" and "phraseology" in both definitions to align the final rule's description of the

requisite knowledge, skills, and abilities an interpreter must possess with those recognized within the field.

Summary of Regulatory Changes

For the reasons set forth above and considering the comments received, we no longer define "qualified interpreter" as one term. We are using the content from proposed paragraphs (1), (1)(i), and (2) to create a separate definition for "qualified interpreter for an individual with a disability" and similarly use the content from proposed paragraphs (1) and (1)(ii) to create a separate definition for "qualified interpreter for an individual with limited English proficiency." For both definitions, we added "terminology and phraseology" to the lexicon a qualified interpreter in both contexts must possess.

Qualified translator. The proposed rule did not use or define the term "qualified translator."

Comment: We received a significant number of comments recommending that the proposed rule define "qualified translator." Commenters explained that bilingual individuals do not necessarily possess the skill of translating or the knowledge of specialized terminology to be able to translate written documents from English to another language. Similarly, a qualified interpreter for an individual with limited English proficiency may not possess the knowledge, skills, and abilities to translate, as the skill of interpreting is different from the skill of translating.[85]

Response: In response to commenters' recommendations, we are adding the term "qualified translator" to the final rule. The final rule defines qualified translator as someone who translates effectively, accurately, and impartially; adheres to generally accepted translator ethics principles; and is proficient in both written English and at least one other written non-English language, including any necessary specialized vocabulary, terminology and phraseology. We agree with commenters that even if an individual meets the definition of "qualified bilingual/multilingual staff" or "qualified interpreter for an individual with limited English proficiency" under this rule, that individual does not necessarily possess the knowledge, skills, or abilities to translate written content in paper or electronic form used in a covered entity's health programs or activities.

Summary of Regulatory Changes

For the reasons set forth above and considering the comments received, we are defining the term "qualified translator" in § 92.4 to set out the competencies an individual must have to translate written content in paper or electronic form in the covered entity's health programs or activities.

Sex stereotypes. We proposed that 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. We noted that 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.

Comment: Commenters suggested that OCR revise the definition of "sex stereotypes" because, while accurate in describing the types of assumptions that may motivate discrimination against non-binary individuals, the definition is cumbersome and may not be readily understood by persons not familiar with the issue. Several commenters expressed concern that the proposed language might be interpreted as limiting sex discrimination based on sex stereotyping to only include discrimination based on gender identity. Commenters suggested affirming in the final rule that any form of sex discrimination on the basis of sex stereotypes constitutes sex discrimination, whether or not it also constitutes discrimination on the basis of gender identity. Some commenters requested that OCR provide examples illustrating discrimination based on sex stereotypes that can form the basis of prohibited sex discrimination.

Several commenters suggested that OCR clarify the definition of "sex stereotypes" to address the relationship between sex stereotypes and sexual orientation. In this regard, commenters suggested that OCR revise the definition of "sex stereotypes" to add that "sex-stereotypes also include gendered expectations related to the appropriate roles of men and women, such as the expectation that women are primary caregivers, and aspects of an individual's sexual orientation, such as the sex of an individual's sexual or romantic partners."

Response: We have added a reference in the regulatory text to make clear that sex stereotypes include gendered expectations related to the appropriate roles of a certain sex.[86] With regard to sexual orientation, we refer commenters to the discussion in the preamble addressing the definition of "on the basis of sex."[87]

Comment: Some commenters stated that the proposed definition of sex stereotypes is unprecedented in its breadth with no legal authority to support the proposition that individuals who claim to identify with non-binary genders constitute a protected class under Title IX or any other Federal law. Commenters suggested that it is impossible for an individual to have a non-binary gender identity.

Response: OCR has adopted the approach taken by the Federal government and numerous courts in similar matters—that sex stereotypes encompass not only stereotypes concerning the biological differences between the sexes, but also include stereotypes concerning gender norms.[88] As stated in the preamble to the proposed rule and clarified in the final rule, OCR recognizes that sex stereotypes can include the expectation that individuals consistently identify with only one of two genders (male or female), and that they act in conformity with the gender-related expressions stereotypically associated with that gender. Sex stereotypes can also include a belief that gender can only be binary and thus that individuals cannot have a gender identity other than male or female. OCR recognizes that an individual's gender identity involves the interrelationship between an individual's biology, gender, internal sense of self and gender expression related to that perception; thus, the gender identity spectrum includes an array of possible gender identities beyond male and female.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the definition as proposed in § 92.4 with the following modifications: We have clarified that sex stereotypes can be based on expectations about gender roles.

Taglines. In the proposed rule, we defined taglines as short statements written in non-English languages to alert individuals with limited English proficiency to the availability of language assistance services, free of charge, and how the services can be obtained.[89] We did not receive comments with suggested revisions to the wording of this definition.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing this definition as proposed in § 92.4 without modification.

Assurances Required (§ 92.5)

In § 92.5, we proposed that each entity applying for Federal financial assistance, each issuer seeking certification to participate in a Health Insurance Marketplace SM, and each state seeking approval to operate a State-based Marketplace SM be required to submit an assurance that its health programs and activities will be operated in compliance with Section 1557. We noted that 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.[90] We also proposed to revise the Assurance of Compliance HHS-690 Form to include all civil rights laws, including Section 1557, with which covered entities must comply.

The comments and our responses regarding § 92.5 are set forth below.

Comment: Several commenters recommended that OCR require covered entities to collect data on race, ethnicity, language, sex, gender, gender identity, sexual orientation, disability, and age. These commenters suggested that covered entities should be required to assess the populations they serve so that the covered entities can better plan how to meet the needs of those populations. The commenters also urged that OCR require annual submission of the data to OCR and develop standards to address training on data collection, privacy protections, safeguarding, voluntary reporting by patients, and supporting analyses based on multiple variables.

Response: OCR agrees that data collection is an important tool that can help covered entities to better serve their communities, and encourages covered entities to regularly evaluate the impact of the services they provide on different populations. However, OCR declines to require data collection as part of the assurances required under Section 1557. The Department collects data pursuant to Section 4302 of the ACA, and OCR has access to these data. In addition, OCR has the authority to require covered entities to collect data and to provide OCR access to information under §§ 92.302 and 92.303 of this part,[91] and will exercise this authority as needed and appropriate under particular circumstances in the future. With respect to recipients and State-based Marketplaces, §§ 92.302(a) and 92.302(b) incorporate the procedural provisions in the Title VI and the Age Act implementing regulations regarding enforcement actions under this part. Pursuant to these procedural provisions, when a recipient or State-based Marketplace SM fails to provide OCR with requested information in a timely, complete, and accurate manner, OCR may find noncompliance with Section 1557 and initiate appropriate enforcement procedures, including beginning the process for fund suspension or termination and taking other action authorized by law. OCR has inserted a new subsection (c) to § 92.302 to clarify that it has that it has this authority, and the text that was previously found at § 92.302(c) has been moved to the new § 92.302(d).

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 92.5 without modification.

Remedial Action and Voluntary Action (§ 92.6)

In § 92.6, we proposed provisions addressing remedial action and voluntary action by covered entities. In paragraph (a), we proposed that a recipient or State-based Marketplace SM 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. We proposed that similar to recipients and State-based Marketplaces, the Department, including the Federally-facilitated Marketplaces, is also obligated to address discrimination, but is subject to a different remedial process than recipients and State-based Marketplaces. In paragraph (b), we proposed to permit but 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 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.

The comments and our responses regarding § 92.6 are set forth below.

Comment: One commenter requested that OCR specifically list the remedial actions available to OCR as well as the circumstances under which such

remedial actions will be taken.

Response: In the discussion of enforcement mechanisms and procedures in the preamble to the proposed rule, OCR identified the range of enforcement tools available to OCR. However, it would not be feasible to specify the circumstances in which specific remedial actions would be taken. OCR evaluates each situation on a case-by-case basis and may use different remedial actions in different cases. In all cases, OCR attempts to achieve compliance and, in our experience, this approach has been successful.

Comment: One commenter requested clarification of the word "control" in the part of the regulation that states that where a recipient exercises "control" over a recipient that has discriminated, the Director may require both entities to take remedial action. Another commenter suggested that OCR only pursue remedial action against the entity actually found to have discriminated against an individual and not against the controlling entity.

Response: OCR declines to further define the word "control" as used in the regulation. This term has appeared in civil rights regulations enforced by OCR for many years, and its meaning has been established over time. OCR also declines to limit its authority to pursue remedial action with respect to an entity that exercises control over an entity that has discriminated. This too is longstanding authority under OCR's other authorities, and in OCR's experience, controlling entities that are recipients often play an important role in securing appropriate action to remedy discrimination.

Comment: One commenter suggested that there be limitations on the uses of remedial action. Specifically, the commenter stated that OCR should require remedial action only on behalf of individuals who either (1) applied to participate but were unable to participate due to alleged discrimination; or (2) had been participants and were subject to alleged discrimination. The commenter asserted that without such limitations, covered entities could be unfairly exposed to claims by individuals who would not have been participants notwithstanding any alleged discrimination.

Response: OCR does not believe that limiting the availability of remedial action as suggested is appropriate. It would not be consistent with Section 1557's and OCR's commitment to eliminating discrimination in all parts of a program or activity and remedying discrimination, where necessary, with respect to harmed individuals.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the provisions as proposed in § 92.6 without modification.

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

In § 92.7, we proposed requirements for each covered entity that employs 15 or more persons to designate a responsible employee to coordinate the entity's compliance with the rule and adopt a grievance procedure. Many entities covered by Section 1557 and this part are already required to designate a compliance coordinator and have a written process in place for handling grievances with respect to disability discrimination in all programs and activities or sex discrimination in education programs or activities.[92]

In paragraph (a), we proposed that a covered entity that employs 15 or more persons be required to designate at least one employee to coordinate compliance with the requirements of the rule. We noted that 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.

In paragraph (b), we proposed that a covered entity that employs 15 or more persons be required to adopt a grievance procedure that incorporates appropriate due process standards and allows for the prompt and equitable resolution of complaints concerning actions prohibited by Section 1557 and this part. We noted that a covered entity that already has a grievance procedure addressing claims of disability discrimination that meets the standards established under the Section 504 regulation may use that procedure to address disability claims under Section 1557. In addition, we noted that covered entities may use that procedure to address all other Section 1557 claims, provided that the entity modifies the procedure to apply to race, color, national origin, sex, and age discrimination claims.

We proposed that for the Department, including Federally-facilitated Marketplaces, OCR will be deemed the responsible employee. In addition, we proposed that OCR's procedures for addressing complaints of discrimination on the grounds protected under Section 1557 will be deemed grievance procedures for the Department, including for the Federally-facilitated Marketplaces.

In the proposed rule, OCR invited comment on whether all covered entities, not only those that employ 15 or more persons, should be required to designate responsible employees and establish grievance procedures.

The comments and our responses regarding § 92.7 are set forth below.

Comment: Some commenters opposed inclusion of proposed § 92.7, arguing that it is unnecessary and costly and has few benefits because discrimination in health programs and activities does not exist. Other commenters urged that Federal regulation in this area constrains covered entities' flexibility to decide how to address individuals' complaints of discrimination. Specifically, these commenters encouraged OCR to allow covered entities to retain existing internal grievance processes, leverage grievance processes within State agencies or within other entities, or develop new grievance procedures.

Response: We recognize commenters' concerns, but we disagree with commenters regarding the necessity of proposed § 92.7. To promote the effective and efficient implementation of Section 1557 and this part, it is necessary for covered entities with 15 or more employees to identify at least one individual

accountable for coordinating the covered entity's compliance and to have a written process in place for handling grievances. We recognize that not all covered entities are organized and operate in the same way. Thus, we do not prescribe who in the covered entity must serve as the responsible employee —nor do we prohibit combining this function with other duties so long as there is no conflict of interest.

In addition, we disagree with commenters that proposed § 92.7 is costly, limits covered entities' flexibility, or conflicts with existing internal or State-mandated grievance procedures. As we stated in the proposed rule, recipients of Federal financial assistance with 15 or more employees, as well as the State-based Marketplaces, could increase the responsibilities of an already-designated coordinator to include the coordination of compliance with Section 1557 and this part.[93] These entities could also increase the scope of the existing grievance procedures required under Section 504 and the ADA to accommodate complaints of discrimination addressing all bases prohibited under Section 1557. Moreover, nothing in the rule bars a covered entity from combining the grievance procedure required under Section 1557 with procedures it uses to address other grievances, including those unrelated to individuals' civil rights. As described in the Regulatory Impact Analysis of the proposed rule[94] and reiterated in the Regulatory Impact Analysis to this final rule, the costs associated with these requirements are estimated to be minimal.

Comment: Some commenters stated that the final rule should specify minimum regulatory requirements for the grievance procedure required in § 92.7(b). Such minimum requirements would include, for instance: Timeframes for filing, resolving, and issuing written decisions regarding complaints; an appeal process; notice regarding retaliation protections; and clarification that no person needs to exhaust a covered entity's grievance procedure prior to filing a Section 1557 complaint with OCR. These commenters urged OCR to adopt regulatory requirements, instead of a model grievance procedure only, stating that a model policy alone is insufficient to ensure that an entity's grievance procedure provides meaningful rights and protections.

Response: We understand the commenters' concerns, but we decline to promulgate minimum standards for the content of the grievance procedure required in § 92.7(b); such an approach would be too prescriptive. Because Section 1557 and this part cover a variety of types of entities, we want to preserve flexibility for entities to adapt the rule's requirements to their own health programs and operational capacity, so long as the rules result in the prompt and equitable resolution of complaints. However, to provide covered entities an example of how to structure a grievance procedure that affords individuals appropriate procedural safeguards and provides for the prompt and equitable resolution of complaints, we have included a sample procedure as Appendix C. We disagree with commenters that a sample grievance procedure is insufficient; rather, a sample grievance procedure provides guidance to covered entities while also preserving their flexibility. In response to commenters' suggestion that we note that an individual need not exhaust a covered entity's grievance procedure prior to filing a Section 1557 complaint, we clarify that no such exhaustion requirement exists, as reflected in the sample grievance procedure included as Appendix C to the final rule.

Comment: Many commenters supported the alternate approach that would require covered entities with fewer than 15 employees to comply with § 92.7. These commenters reasoned that requiring all covered entities to designate a coordinator and establish a grievance procedure would give each entity the internal mechanisms to resolve compliance issues earlier and informally, allowing them to potentially avoid a formal investigation by OCR. Accordingly, these commenters asserted that the importance of extending required compliance with § 92.7 to covered entities with fewer than 15 employees justified the anticipated additional expense of compliance.

Some commenters observed that the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule already requires many entities covered by Section 1557 and this part to implement grievance policies and identify compliance coordinators, regardless of the number of employees of the entity.[95] The commenters suggested that the implementation of these requirements under the HIPAA Privacy Rule has given entities with fewer than 15 employees covered by both the HIPAA Privacy Rule and Section 1557 and this part the experience necessary to implement the similar requirements of § 92.7. Because many of the covered entities with fewer than 15 employees, such as most health care providers receiving Federal financial assistance, are subject to the HIPAA Privacy Rule, commenters asserted that extending the requirements of § 92.7 to covered entities with fewer than 15 employees would impose a limited burden.

Conversely, some commenters suggested that compliance with § 92.7 would be too time consuming and costly for covered entities with fewer than 15 employees. These commenters explained that due to the small number of employees, small covered entities may have difficulty identifying an unbiased third-party employee to investigate and respond to grievances. For instance, commenters noted that it is not uncommon for the chief physician or other professional to serve as the compliance coordinator for a small covered entity, but that such a role would be inappropriate if that individual was the subject of a grievance. These commenters also observed that requiring a covered entity to handle internal grievances under Section 1557 might expose the entity to the risk of civil liability, because Section 1557 allows for private enforcement. These commenters recommended that OCR allow small covered entities flexibility in determining when to defer to outside counsel or other independent, unbiased third parties to address grievances and thus mitigate their liability risk.

Response: We decline to extend the requirements of § 92.7 to covered entities with fewer than 15 employees. Although we recognize the benefits that extension of the requirements of § 92.7 would generate, we conclude that the costs, which would be borne by small entities, likely outweigh the benefits. Although many covered entities with fewer than 15 employees may have already identified a compliance coordinator and implemented a grievance policy to comply with the HIPAA Privacy Rule, extending the requirements of § 92.7 to such entities would create additional costs, as entities would need to revise their existing policies and retrain compliance coordinators.

Although we decline to extend the requirement of § 92.7 to covered entities with fewer than 15 employees, nothing in the final rule bars a covered entity with fewer than 15 employees from designating an employee to coordinate compliance with Section 1557 and this part or from adopting and implementing a grievance procedure. As we stated in the proposed rule, in OCR's experience, the presence of a coordinator and grievance procedure enhances the covered entity's accountability and helps bring concerns to prompt resolution, oftentimes prior to an individual bringing a private right of action.

Summary of Regulatory Changes

For the reasons described in the proposed rule and considering the comments received, we are finalizing the provisions as proposed in § 92.7 with one technical modification in § 92.7(a): We replaced the reference to the "Office for Civil Rights" with "Director," as § 92.4 defines "Director" to mean the Director of the Department's OCR. We have also added a sample grievance procedure as Appendix C to the final rule to provide covered entities an example of a grievance procedure that meets the requirements of § 92.7(b).

Notice Requirement (§ 92.8)

In § 92.8, OCR proposed that each covered entity take initial and continuing steps to notify beneficiaries, enrollees, applicants, or members of the public of individuals' rights under Section 1557 and this part and of covered entities' nondiscrimination obligations with respect to their health programs and activities. 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.[96]

Paragraphs (a)(1)-(7) of proposed § 92.8 identify the components of the notice. Specifically, paragraph (a)(1) proposed that the notice include that the covered entity does not discriminate on the basis of race, color, national origin, sex, age, or disability.

Paragraph (a)(2) proposed 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. Paragraph (a)(3) proposed that the notice state that the covered entity provides 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.

Paragraph (a)(4) proposed 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) proposed that the notice provide contact information for the responsible employee coordinating compliance with Section 1557 and this part, where such a responsible employee is required by § 92.7(a).

Paragraph (a)(6) proposed that the notice state that the covered entity has a grievance procedure where such a grievance procedure is required by § 92.7(b), and information on how to file a grievance.

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

Proposed paragraph (b) stated that within 90 days of the effective date of this part, each covered entity shall post the notice required in § 92.8(a) in English, consistent with paragraph (f) of this section.

Paragraph (c) proposed that the Director shall make available a sample notice. We provided that covered entities may use this sample notice or may develop their own notices that convey the information in paragraphs (a)(1) through (7).

OCR invited comment on whether the proposed rule should permit covered entities to combine the content of the notice with the content of other notices that covered entities may be required to disseminate or post under Federal laws. OCR further invited comment on what steps covered entities may or should take to ensure that notices that combine the content required in § 92.8(a)(1)-(7) with other required notices do so without compromising the intent of § 92.8 to inform individuals of their civil rights under Section 1557 and this part. OCR also invited comment on whether the final rule should allow the notice to be modified for publications and other communication vehicles that may not have sufficient space to accommodate the full notice.

Paragraph (c) also proposed that the Director shall translate the sample notice into the top 15 languages 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. We encouraged covered entities to post one or more of the translated notices that the Director provides and to make the notice available in non-English languages other than those provided by the Director. OCR sought comments on 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.

With regard to the proposal that the Director provide translations of the sample notice, we described that we selected the top 15 languages spoken by individuals with limited English proficiency nationally as a data driven policy.[97] We noted that we plan to review U.S. Census Bureau data as newer data become 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 in additional non-English languages.

Paragraph (d) proposed 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 at least the top 15 languages spoken nationally by individuals with limited English proficiency. We requested comment on a sample tagline in Appendix B to the proposed rule.

Paragraph (e) proposed 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. OCR proposed this approach to maximize efficiency and economies of scale by enabling covered entities to

receive the benefits of having multi-language taglines available without incurring the associated translation costs.

In paragraph (f), we proposed that covered entities must post the English-language notice required in § 92.8(a) and taglines required in § 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. We sought comment on the scope of significant publications and significant communications.

We noted that covered entities that distribute significant publications or significant communications will need to update these publications to include the notice required in § 92.8(a) and taglines required in § 92.8(d). However, we proposed 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.

We stated that covered entities may satisfy the requirement to post the notice on the covered entity's home page 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 elsewhere on the Web site. Similarly, we stated with regard to the requirement to post taglines that covered entities can comply by posting "in language" Web links, which are links written in each of the 15 non-English languages posted conspicuously on the home page that direct the individual to the full text of the tagline indicating how the individual may obtain language assistance services. For instance, 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."

In the proposed rule, we invited comment on a State-based methodology for identifying the languages in which covered entities would be required to post taglines and for which the OCR Director would be required to translate the notice. We explained that the top 15 languages spoken by individuals with limited English proficiency nationally can differ from the languages spoken most frequently by individuals within the areas served by covered entities' health programs and activities. Thus, we invited comment on a requirement for entities to make taglines available in the top 15 languages spoken State-wide, rather than nationwide, by individuals with limited English proficiency. This threshold aligns with Federal regulations governing the Health Insurance Marketplaces and qualified health plan issuers.[98]

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

The comments and our responses regarding § 92.8 are set forth below.

Comment: Some commenters suggested that we revise the information required in § 92.8(a)(1)-(7) regarding the notice of individuals' rights. For instance, some commenters suggested that we specify that Section 1557 prohibits discrimination on the basis of "national origin, including primary language and immigration status" and "sex, including pregnancy, gender identity, sex stereotypes, or sexual orientation. . . ." These commenters asserted that the addition of these terms would more completely reflect the scope of protected classes under Section 1557. A few commenters recommended that the notice inform individuals of any religious accommodations or exemptions that the covered entity has received from compliance with civil rights laws and explain the services that the covered entity will and will not provide as a result of any religious exemptions or accommodations. Finally, a few commenters recommended revising §§ 92.8(a)(2) and (a)(3) to more closely parallel each other. For example, these commenters recommended that we list examples of language assistance services in paragraph (a)(3) and add a reference to providing meaningful access for persons with disabilities in paragraph (a)(2) of § 92.8.

Response: We decline to incorporate the suggestions made with regard to § 92.8(a)(1). The final rule defines the terms "on the basis of sex" and "national origin" in § 92.4, which is sufficient to define the scope of these protected classes as used in § 92.8(a)(1) and in Appendix A.[99] We are concerned that replicating the regulatory definitions of "on the basis of sex" and "national origin" in § 92.8(a)(1) and across-the-board in the final rule would dilute the concise, targeted message of the nondiscrimination statement and reduce the value of identifying the core bases on which discrimination is prohibited. Further, replicating the definitional text of these bases in § 92.8(a)(1) but not throughout the final rule may cause unnecessary confusion regarding the scope of discrimination prohibited by Section 1557 and this part. Accordingly, we decline to make the suggested revisions and are removing the terms "including sex stereotypes and gender identity" from the sample notice in Appendix A. OCR intended the nondiscrimination statement in § 92.8(a)(1) to convey covered entities' overarching nondiscrimination obligations in a simple and streamlined manner, as the notice requirements do in regulations implementing Title VI, Title IX, Section 504, and the Age Act.[100] The notice requirement of the Title IX implementing regulations does not require recipients of Federal financial assistance to identify exclusions from Title IX's application or exceptions to discrimination prohibited under Title IX.[101] Moreover, under the final rule, the availability of a religious exemption will depend on an analysis of the particular situation; thus, it would be difficult for an entity to state that it was exempt for all purposes. Accordingly, this final rule preserves the simplicity of the nondiscrimination statement consistent with other Federal civil rights laws.

We have revised § 92.8(a)(3) to list examples of language assistance services to parallel § 92.8(a)(2), which lists examples of auxiliary aids and services. We decline to modify the standards in paragraphs (a)(2) and (a)(3) because "meaningful access" is not the proper standard used in Section 504 for ensuring effective communication for individuals with disabilities.

Finally, as we stated in the proposed rule, Appendix A to part 92 is a sample notice. Covered entities are free to draft their own notices that convey the content in § 92.8(a)(1)-(7).

Comment: We received many comments addressing practical concerns about the size and length of required notices and taglines. Some commenters supported giving covered entities the flexibility to combine the content of the notice in § 92.8(a)(1)-(7) with other notices required under other Federal

laws. For instance, a few comments stated that the State-based Marketplaces should be allowed to combine the content of the notice in § 92.8(a) with disclosures required by Federal regulations governing the Health Insurance Marketplaces at **45 CFR 155.230**. Conversely, some commenters strongly opposed the idea of combining the content of the notice required in § 92.8(a) with other notices, reasoning that the combination, and likely modification, of the notice's content would diminish the clear message of the notice.

Some commenters expressed concern that posting the notice and the taglines in a "conspicuously-visible font size" as proposed in § 92.8(f)(1) and a "conspicuous physical location" as proposed in § 92.8(f)(1)(ii) would occupy prohibitive amounts of space for covered entities operating in small physical spaces, such as pharmacies. These commenters suggested that OCR permit covered entities operating in smaller physical spaces to post taglines in fewer than 15 non-English languages. Other commenters requested clarification from OCR on what constitutes a "conspicuous physical location" in § 92.8(f)(ii) and "conspicuously visible font size" in § 92.8(f)(1).

A number of commenters recommended that the final rule require covered entities to post the notice of individuals' rights—and not just taglines—in non-English languages.

Response: We intend to provide covered entities some flexibility to implement the requirements of § 92.8 in the manner that they determine meets the standards of this section while also reducing burden.

For instance, we will permit covered entities to combine the content of the notice in § 92.8(a)(1)-(7) with the content of other notices, such as notices required under other Federal civil rights laws. The content of the combined notice still must clearly convey the information required in § 92.8 (a)(1)-(7) and must separately meet any applicable notice requirements under relevant legal authorities. For instance, the regulations implementing Title IX and Section 504 require that a recipient provide a notice of individuals' rights to employees and applicants for employment.[102] Because this final rule is limited in its application to employment, it may not be sufficient for an entity covered by Title IX, Section 504, and Section 1557 and this part to rely on a notice conveying the content required in § 92.8(a)(1)-(7) as meeting its notice obligations under the regulations implementing Section 504 and Title IX. Accordingly, proposed paragraph (g), which is now re-designated as paragraph (h) of this final rule, no longer treats an entity's compliance with particular paragraphs of § 92.8 as constituting compliance with the notice provisions of other Federal civil rights authorities.

Specifically, § 92.8(h) now clarifies that covered entities may combine the content of the notice in § 92.8(a)(1)-(7) with the content of other notices as long as the combined notice clearly informs individuals of their civil rights under Section 1557 and this part. In addition to having flexibility with respect to combining notices, covered entities also have flexibility in determining the exact size and location of notices and taglines within their facilities as long as they do not compromise the intent of § 92.8 to clearly inform individuals of their civil rights under Section 1557 and this part.

The touchstone by which we will assess whether a covered entity's provision of notice and taglines is effective is whether the content is sufficiently conspicuous and visible that individuals seeking services from, or participating in, the health program or activity could reasonably be expected to see and be able to read the information.

Although we encourage covered entities to post the notice of individuals' rights in one or more of the most prevalent non-English languages frequently encountered by covered entities in their geographic service areas, we decline to require such posting in the final rule because of the resource burdens and opportunity costs to covered entities. Posted taglines sufficiently alert individuals to the language assistance services available and appropriately balance the educational value of the notices with the burdens to covered entities.

Given that we are not requiring covered entities to post notices in non-English languages, having taglines available in multiple languages is even more important to provide notice to individuals with limited English proficiency of the availability of language assistance services. Thus, we decline to reduce the number of languages in which taglines are required to appear, even for covered entities operating in smaller physical spaces. Covered entities have flexibility in determining the exact size and location of notices and taglines as long as they meet the requirements of this section.

Comment: We received many comments recommending alternative approaches to the proposed rule's requirement for taglines. A few commenters opposed the requirement in proposed § 92.8(d) as unnecessary because oral interpretation is generally available through the customer service telephone line listed on many consumers' health insurance cards. Some commenters suggested that the final rule should permit covered entities to include taglines on the inside of an envelope that a covered entity's health program or activity uses to mail a significant publication or a significant communication. A few commenters suggested replacing tagline text with an icon that would symbolize the availability of oral interpretation services. These commenters suggested that the icon would likely reach more language groups than taglines, and would also occupy substantially less space on significant publications and significant communications.

Response: We decline to eliminate the tagline requirement because such an approach would not provide adequate notice of language assistance services. We appreciate that many health insurance issuers provide telephonic oral interpretation services through their customer service lines/call centers—a number that usually appears on an insured individual's health insurance identification card. We do not, however, regard the mere availability of this information as adequate notice to individuals with limited English proficiency of the availability of language assistance services, much less as notice of each of the components of paragraphs (a)(1)-(7) of § 92.8. Moreover, this approach is not appropriate in all instances because not all covered entities rely on the use of an individual identification card.

In addition, we decline to authorize placement of taglines on the inside of an envelope. Such a placement would diminish the visibility of the taglines, downgrade their importance, and fail to adequately notify individuals because envelopes are generally torn open and then discarded.

With respect to use of an icon, we appreciate the commenters' suggestion and believe that it may hold promise in the future. However, we also decline

to require the use of an icon in the final rule. At this point in time, use of an icon alone would not provide consumers with sufficient notice of the availability of language assistance services, which is the intent of § 92.8(d).

Comment: A small number of commenters provided feedback on the application of the requirement to post the notice and taglines in significant publications and significant communications that are small in size, such as brochures, postcards, targeted fliers, small posters, and those that are communicated through social media platforms. Some commenters recommended that the final rule exempt such communications and publications from the posting requirement in § 92.8(f)(1)(i); others recommended that the final rule provide covered entities latitude to substantially shorten the notice and taglines for these publications and communications. Commenters advocating for either of these two positions stated that the limited amount of space in such publications and communications makes them an impractical medium for disclosures of civil rights.

Other commenters opposed any exceptions for significant publications and significant communications that are small-sized, given the importance of notifying individuals about their rights under Section 1557, such as how to obtain auxiliary aids and services for individuals with disabilities and how to obtain language assistance services for individuals with limited English proficiency.

Response: We agree that the notice and tagline requirements for small-sized significant publications and communications should be distinguished from the requirements for significant publications and significant communications that are not small-sized. We also agree with commenters who suggested that small-sized significant publications and significant communications are not well-suited to extensive civil rights disclosures and that they function to drive consumers to other sources of information, such as a covered entity's Web site, where the full civil rights notice and taglines are required by § 92.8(f)(iii). Furthermore, posting the full notice and all 15 taglines to small-sized publications and communications may obscure the content and message of the document, thus undermining the value of such publication or communication. As a result, we are modifying § 92.8(f)(1)(i) to exclude small-sized significant publications and communications from requirements to have a notice and at least 15 taglines.

We disagree, however, with fully exempting significant publications and significant communications that are small-sized from the notice and tagline requirements because these documents, such as tri-fold brochures, pamphlets, and postcards, often serve as a gateway for an individual to apply for, or participate in, a particular health program or activity. To this end, the final rule establishes a separate requirement for small-sized significant publications and significant communications: A covered entity must include a nondiscrimination statement in lieu of the full notice, and taglines in two non-English languages in lieu of all 15 taglines, on small-size significant publications and significant communications.

Specifically, we moved most of the text from proposed paragraph (b) into a new paragraph (b)(1) and added paragraph (b)(2), which addresses the obligation to post a nondiscrimination statement that conveys the information in § 92.8(a)(1) on small-sized significant publications and significant communications. Similarly, we moved most of the text from proposed paragraph (d) into a new paragraph (d)(1) and added paragraph (d)(2), which addresses the obligation to post taglines in at least the top two languages spoken by individuals with limited English proficiency in the relevant State or States on small-size significant publications and significant communications. Finally, we re-designated proposed paragraph (g) as paragraph (h) and we added new paragraphs (g)(1)-(2) to address the posting standards applicable to small-sized significant publications and significant communications.

In choosing a lower threshold than at least the top 15 languages spoken by individuals with limited English proficiency, we chose a concrete number of languages, rather than a threshold formulated as a percentage, because on average about two-thirds of the limited English proficient population in each State [103] is reached by the top two languages spoken by individuals with limited English proficiency in that State. Moreover, requiring a specific number of taglines makes the impact of the requirement predictable for all covered entities in planning how these two taglines, along with the nondiscrimination statement, will fit on their significant communications and significant publications that are small-sized. In almost all States, the top two languages spoken by individuals with limited English proficiency captures Spanish and the other most prevalent non-English language. This approach in paragraphs (b)(2), (d)(2), and (g)(1)-(2) of § 92.8 is more streamlined than requiring the full notice and all 15 taglines but still will inform the majority of individuals with limited English proficiency of their rights to be protected from discrimination under Section 1557 and this part.

In addition, we have added a sample nondiscrimination statement in Appendix A that conveys the information in § 92.8(a)(1), for which the Director will also provide translations. Accordingly, we have modified paragraph (c) of § 92.8 to state that the Director will provide translations of the sample nondiscrimination statement. The translations of the sample notice and sample nondiscrimination statement are for covered entities' discretionary use only—the final rule does not require the posting of the notice or nondiscrimination statement in non-English languages.

Comment: A substantial majority of commenters on § 92.8 provided feedback on the methodology for determining the number of languages in which covered entities will be required to post taglines. Some commenters supported the proposed rule's national methodology because of its simplicity, particularly for covered entities that operate in multiple States. Conversely, other commenters expressed concern that the national standard fails to account for concentrations of particular limited English proficient communities within areas served by covered entities' health programs and activities, including Native American languages spoken by those served in Tribal health programs. One commenter recommended that if the final rule includes a national standard, OCR should require taglines in the top 25 languages spoken nationally by individuals with limited English proficiency. This commenter further recommended that when calculating the top 25 languages, OCR should rely on a data set that "unbundles" bundled language groups, such as "other Asian languages," because some languages represented in bundled categories may be highly prevalent in the service area of a particular covered entity's health program or activity. [104]

Most commenters disfavoring a national methodology recommended that the languages in which covered entities must post taglines should be the top 15 languages spoken State-wide by individuals with limited English proficiency. Commenters explained that the State-wide threshold would be more attuned to the diversity of languages spoken by individuals with limited English proficiency in each State and would align with Federal regulations governing the Marketplaces and qualified health plan issuers. [105] Some of these commenters also recommended that the final rule should require covered entities that

serve individuals in multiple States to post more than 15 taglines if the composite list of each State's list aggregates to a total of more than 15 languages. These commenters reasoned that such an interpretation is necessary to further the purpose of addressing the diversity of languages spoken by individuals with limited English proficiency served by a particular covered entity.

Other commenters recommended other approaches, such as requiring taglines in languages in which at least 10% of individuals with limited English proficiency county-wide are exclusively literate,[106] or, in languages spoken by at least 5% of individuals with limited English proficiency or 500 individuals with limited English proficiency in the covered entity's service area, whichever yielded the greater number of languages. Still other commenters recommended that the rule allow covered entities to choose between a State-wide and a national methodology in determining the languages in which to post taglines, depending on the geographic scope of the intended audience for the "significant publication or significant communication" to which the taglines are posted. These commenters explained that a covered entity that operates nationally may choose to post on the covered entity's Web site taglines in languages based on a nationwide threshold but may choose to include on a significant communication to an individual taglines in languages based on a State-wide threshold for the State in which the individual resides.

Response: In response to commenters' recommendations, § 92.8(d)(1) of the final rule requires covered entities to post taglines in at least the top 15 languages spoken by individuals with limited English proficiency of the relevant State or States. Accordingly, paragraphs (d)(1)-(2) of § 92.8 refer to this State-based methodology rather than a national methodology. This threshold captures, on average, 90% of each State's LEP population.

We adopt a State-based approach for three main reasons. First, a State-based methodology is more attuned to the diversity of languages spoken by individuals with limited English proficiency and thus provides notice to more individuals with limited English proficiency.

Second, this State-wide approach better harmonizes with the number of languages in which taglines must be provided by Marketplaces and qualified health plan issuers under 45 CFR 155.205(c)(2)(iii)(A).[107] Section 92.8 of this final rule applies to all entities covered by Section 1557, but for Marketplaces and qualified health plan issuers that are subject to the tagline requirements at **45 CFR 155.205**(c)(2)(iii)(A) and § 92.8 of this final rule, our State-wide methodology lessens the burden to which Marketplaces and qualified health plan issuers might otherwise be subject.

Third, a county-level approach is impractical because detailed language data are not available for counties with populations of less than 100,000. For counties with populations of at least 100,000 for which detailed language data are available, there are limited data for individuals who speak English less than "very well" and speak a non-English language other than Spanish.[108] For county-level data that are available, moreover, we are concerned that sampling error would render many estimates of small language populations unreliable when assessed within the small geographic area of a county.

With regard to the data used to identify the languages under the State-based methodology in which the Director will translate the sample notice, sample nondiscrimination statement, and taglines, as required by § 92.8(c) and (e) of the final rule, we rely on the most recent bundled and unbundled five-year [109] data available from the U.S. Census Bureau. We rely on the data set that estimates the prevalence of foreign-language speakers who speak English less than "very well," [110] and we made technical adjustments, such as to remove any spoken languages that do not have a written equivalent in which the Director could translate a tagline.

We intend the threshold's application in § 92.8(d)(1)-(2), which applies to the "relevant State or States," to permit covered entities that serve individuals in more than one State [111] to aggregate the number of individuals with limited English proficiency in those States to determine the top 15 languages required by § 92.8(d)(1), or the top 2 languages required by § 92.8(d)(2) where each respective provision applies.[112] The languages produced from this aggregation are static with respect to the posting requirement in § 92.8(f). Using one of the three posting methods as an example—the posting of the taglines in a covered entity's physical locations required by § 92.8(f)(1)(ii)—a covered entity that operates multiple health programs serving individuals within various States, or that operates a health program with a multi-State service area, complies with § 92.8(f)(1)(ii) when it posts, in its physical locations across the States it serves, taglines in at least the top 15 languages spoken by the aggregate limited English proficient populations of those States, rather than of each individual State. We do not intend to require a covered entity that operates health programs in multiple States (or in States nationwide), or that administers a health program with a multi-State service area (or even a nationwide service area), to tailor the taglines for the specific State in which the entity is physically located or in which an individual with limited English proficiency, with whom the entity communicates, lives. This interpretation best balances the burden on covered entities with the notification of language assistance services to individuals required by § 92.8(d).[113]

We reiterate, however, that the requirements of § 92.8(d)(1)-(2) establish a floor; covered entities are free to include taglines in additional languages beyond 15 languages. For instance, a covered entity that has chosen to aggregate languages may choose to post taglines in all languages on the aggregated list rather than posting just the top 15 languages. Moreover, a covered entity that that operates health programs in multiple States or that administers a health program with a multi-State service area may decide not to aggregate. Instead, the entity may choose to tailor the taglines posted in its physical locations for the specific State in which the physical location exists; similarly, the entity may choose to tailor the taglines on a certain significant communication based on the State in which an individual with limited English proficiency, with whom the entity communicates, lives.

In addition, we note that complying with § 92.8(d)(1)-(2) is not a substitute for complying with the prohibition of national origin discrimination as it affects individuals with limited English proficiency under Section 1557 or this part, including the general nondiscrimination provisions in § 92.101 and the meaningful access provisions in § 92.201 of this final rule. Thus, although this section identifies the languages in which covered entities must post taglines, it does not relieve those entities of the separate obligation to take reasonable steps to provide meaningful access to individuals with limited English proficiency who communicate in other languages.

Comment: One commenter recommended including American Sign Language as a language for which a posted tagline be required in § 92.8(d). This commenter stated that taglines denoting the availability of American Sign Language Interpretation could communicate this message by displaying still

images, rather than a written language.

Response: We decline to include American Sign Language as a language for which a tagline is required in § 92.8(d)(1)-(2) because the notice of individuals' rights in § 92.8(a)(2), which must be posted in a conspicuously-visible font size and location just like taglines, addresses this issue. Specifically, paragraph (a)(2) requires that the notice of individuals' rights state that the covered entity provides auxiliary aids and services, which include sign language interpreters, to individuals with disabilities when necessary to provide such individuals an equal opportunity to benefit from the entity's health programs or activities.

Comment: A few commenters recommended that the final rule prescribe the location of taglines at or near the beginning of significant publications and significant communications. These commenters provided anecdotal evidence that individuals with limited English proficiency who received multi-page English notices requiring time-sensitive responses failed to see taglines appearing on the last page. Commenters explained that to the individuals' detriment, they discarded the notices without responding, resulting in termination of health insurance coverage and other negative outcomes. A number of commenters recommended that covered entities be required to include the text of all required taglines, not just the in-language link, conspicuously on the homepage of their Web sites.

Response: Although we encourage covered entities to include notices and taglines at the beginning of significant publications and significant communications to ensure that they are meaningfully accessible to the consumer, we decline to require this prescriptive approach as part of the final rule. In some circumstances, such as lengthy publications, it may be necessary to include the notice and taglines at the beginning of a document to meet the requirements of § 92.8(f)(1)(i) and (g)(1)-(2); in others, posting elsewhere, including on a separate insert [114] accompanying the English-language significant publication or significant communication, may be adequate. Furthermore, in today's increasingly electronic and digital age where covered entities may make their first impressions through Web content (often on small mobile devices), we are sensitive to covered entities' need for autonomy in designing and managing the appearance of their public internet home pages.

Although the law requires that individuals receive sufficient notice of language assistance services available to assist individuals with limited English proficiency in understanding the content of a covered entity's Web site, we believe that the use of in-language links permitted under this provision of the proposed rule is the approach that best balances notice to individuals against burden to covered entities.

Comment: Some commenters described the proposed requirement to post the notice in "significant publications and significant communications" as onerous. One commenter recommended that health plans provide the notice to individuals on an annual basis, along with individuals' annual enrollment package, instead of on each "significant publication and significant communication." Some commenters requested that OCR include, in regulation text, the examples of "significant publications and significant communications" we provided in the preamble to the proposed rule, specifically outreach publications and patient handbooks. A few commenters requested that OCR consult with other Federal agencies on the scope of "significant publications and significant communications" to establish a common understanding of this term so that covered entities whose publications and communications are regulated by more than one Federal agency are not subject to conflicting standards.

Other commenters were concerned about OCR's statement in the preamble of the proposed rule that OCR intended the scope of "significant publications and significant communications" to include not only documents meant for the public but also individual letters or notices to an individual, such as a letter to a consumer notifying the individual of a change in benefits. These commenters observed that, pursuant to existing Federal and State law, many letters already include disclosures and other legally mandated information; consequently, the requirement to post both the notice and taglines required in proposed § 92.8(a) and (d), respectively, might dilute the primary message of the letter and confuse or frustrate consumers. Some commenters requested clarification on how "vital documents" as used in the Department's LEP Guidance relates to "significant publications and significant communications" in § 92.8(f)(1)(i) of the proposed rule.

Response: We disagree with commenters' characterization of § 92.8(f)(1)(iii) as "onerous." We acknowledge that compliance with this subsection may impose some limited burdens on covered entities. However, these burdens are outweighed by the benefits that § 92.8(f)(1)(iii) will generate for individuals with limited English proficiency by making them aware, in their own languages, of the availability of language assistance services. Notifying individuals of their rights under Section 1557 and this part, including the availability of language assistance services for individuals with limited English proficiency and the availability of auxiliary aids and services for persons with disabilities, is critical to providing an equal opportunity to access health care and health coverage. For these reasons, OCR intends to interpret "significant communications and significant publications" broadly, which is consistent with the notice provisions of other Federal civil rights authorities, such as Section 504 [115] and Title IX. [116]

We decline to limit the posting requirement in § 92.8(f)(iii) to an annual frequency. The notice requirements in other Federal civil rights laws on which we modeled § 92.8 do not contain a similar limitation. Moreover we also note that not every covered entity sends annual notices.

We also decline to enshrine a list of examples of "significant publications and significant communications" in regulation for two main reasons. First, the final rule applies to such a diverse range of covered entities that codifying examples likely would not provide meaningful guidance to the full spectrum of covered entities regulated. Second, we intend to maximize covered entities' flexibility, and each covered entity is in the best position to determine which of its communications and publications with respect to its health programs and activities are significant.

In response to commenters who requested that "significant publications and significant communications" be limited to documents intended for the public, rather than those intended for specific individuals, we decline to limit the intended scope of such documents to those aimed only at the public at-large. We intend the scope of significant publications and significant communications to include not only documents intended for the public, such as outreach, education, and marketing materials, but also written notices requiring a response from an individual and written notices to an individual, such as those pertaining to rights or benefits. We have no reasoned basis to distinguish and exempt significant publications and significant communications

intended for specific individuals from significant publications and significant communications intended for the public at-large. Indeed, in some situations, a written notice with information tailored to a specific individual's benefits or participation may be even more important to that individual than a significant publication or significant communication conveying information to the public. Accordingly, an individual's awareness of his or her rights under Section 1557, such as the availability of auxiliary aids and services for persons with disabilities (required in § 92.8(a)(2) to be in the nondiscrimination notice) is just as important as information communicated to the public at-large. [117]

The HHS LEP Guidance uses the term "vital documents" to refer to the documents for which covered entities should prioritize written translations for individuals with limited English proficiency. [118] The HHS LEP Guidance does not define vital documents. Rather, the Guidance states that "[w]hether or not a document (or the information it solicits) is `vital' may depend upon the importance of the program, information, encounter, or service involved, and the consequence to the LEP person if the information in question is not provided accurately or in a timely manner." [119] The HHS LEP Guidance also provides examples of documents likely to be "vital," such as "consent and complaint forms, . . . [ ] written notices of eligibility criteria, rights, denial, loss, or decreases in benefits or services . . . [ ] [and] [a]pplications to participate in a recipient's program or activity or to receive recipient benefits or services." [120]

OCR intends for "vital documents" to represent a subset of "significant communications and significant publications"" in which covered entities must post the notice (or nondiscrimination statement in § 92.8(b), where applicable) and taglines required by § 92.8(d) and (f), among other electronic and physical locations. In clarifying this point, we emphasize that the HHS LEP Guidance uses the term "vital documents" to address how a covered entity should meet its Title VI obligations to translate entire documents. By contrast, we refer to "significant communications and significant publications" in this rule to identify the documents in which covered entities are required to post the notice of individuals' rights (or nondiscrimination statement, where applicable) and taglines. We are not adopting an across-the-board requirement for covered entities to translate certain written documents into a threshold number of languages.

Comment: Some commenters recommended that OCR provide funding and other resources to non-profit organizations for the purpose of creating a national social media campaign to publicize the requirements of Section 1557.

Response: It is beyond scope of the final rule for OCR to fund organizations' education and outreach efforts. OCR continues, however, to conduct outreach and provide technical assistance to inform covered entities of their obligations and individuals of their rights under Federal civil rights laws, including Section 1557 and this part. OCR will continue to disseminate, via web and social media platforms, fact sheets and other useful materials to covered entities and individuals.

Comment: OCR received a number of comments suggesting revisions to the sample notice in Appendix A and the sample tagline in Appendix B to the proposed rule, such as revisions to improve adherence to plain language writing principles. For example, with respect to the sample notice, a few commenters recommended revisions with respect to the provision of language assistance services: Adding the word "qualified" prior to the word "interpreters," which is listed as a type of language assistance service; replacing "first language" with "primary language"; replacing "translated into other languages" with "written in other languages"; and deleting "when needed to communicate effectively with us."

One commenter objected to the conditional tense of the sample tagline in Appendix B, which stated that "[i]f you speak [insert language], language assistance services may be available to you . . . ," expressing concern that it might deter an individual from asking for or about language assistance services. In addition, commenters suggested that the conditional phrasing of "may be available" is inconsistent with covered entities' obligations under § 92.201 to take reasonable steps to provide meaningful access to each individual with limited English proficiency.

A few commenters recommended that the sample tagline in Appendix B be shortened but offered no specific recommendations on shorter language. Some commenters suggested that OCR consumer test the sample notice in Appendix A of the proposed rule before providing it as a sample in the final rule.

Response: We share commenters' views that the sample notice should clearly convey civil rights information, which can often be complex. We agree with the specific revisions from commenters to improve the sample notice's statement about a covered entity's provision of language assistance services. We have modified Appendix A to the final rule to reflect these revisions, and have made technical revisions to include OCR's contact information for filing a complaint. In our view, the sample notice, with these modifications, adequately apprises individuals of their civil rights under Section 1557 and this part without providing irrelevant or confusing information. We remind covered entities that nothing in the final rule prohibits covered entities from drafting their own notices to meet the requirements of § 92.8(a)(1)-(7), which covered entities are free to consumer test.

In addition, we have added a nondiscrimination statement to Appendix A that covered entities can post on significant publications and significant communications that are small-sized.

We appreciate commenters' attention to the details of the sample tagline's phrasing. We have modified Appendix B to the final rule to address commenters' concerns that the tagline's conditional wording might deter an individual from asking for or about language assistance services. With technological advancements in language assistance services, we are confident that covered entities have the ability, at a minimum, to obtain qualified oral interpretation services in the languages in which covered entities will provide taglines, consistent with § 92.8(d)(1)-(2); thus, the sample tagline as modified states that language services "are" available. In addition, we replaced the word "contact" with "call" to simplify the vocabulary used for average literacy levels. The modifications we have made amplify taglines' function as a critical gateway to language assistance services. Taglines derive value not only from informing individuals with limited English proficiency of language assistance services but also from prompting individuals to contact the covered entity to obtain language assistance. We decline to shorten the sample tagline because we are concerned that doing so would compromise the tagline's

message and intent. We remind covered entities that Appendix B is a sample; covered entities are free to develop their own taglines as long as they provide taglines consistent with § 92.8(d)(1)-(2) of this part.

Summary of Regulatory Changes

For the reasons described in the proposed rule and considering the comments received, we have modified § 92.8 and Appendices A and B to part 92 as follows:

In § 92.8(a), we made technical modifications to paragraph (a) and paragraphs (a)(1)-(3). In paragraph (a) we replaced the conjunction "or" with "and." In paragraph (a)(1), we clarified that the nondiscrimination statement of the notice applies to the health programs and activities of a covered entity. In paragraph (a)(2), we inserted the phrase "for individuals with disabilities" after "qualified interpreters" because the final rule now defines qualified interpreters for individuals with disabilities separately from qualified interpreters for individuals with limited English proficiency. In paragraph (a)(3), we added examples of language assistance services to promote alignment with paragraph (a)(2), which provides examples of auxiliary aids and services.

Most of the text in proposed § 92.8(b) is now reflected in new paragraph (b)(1). We added paragraph (b)(2) that requires a covered entity to post a nondiscrimination statement consistent with newly-designated paragraph (g)(1), which applies to significant publications and significant communications that are small-sized. In newly-designated paragraph (b)(1) and (f)(1), we eliminated "English-language" before "notice" to avoid the incongruous result that a significant publication or significant communication written in a non-English language must include a notice written in English.

In § 92.8(c), we added language to convey OCR's plans to translate the sample nondiscrimination statement for covered entities to use at their discretion.

In paragraph (d) of § 92.8, we added paragraph designations (1) and (2) to distinguish the final rule's tagline requirements for significant publications and significant communications that are not small-sized from those that are small-sized. Most of the text in proposed paragraph (d) is now reflected in paragraph (d)(1). In newly-designated (d)(1), we replaced the national threshold with a threshold requiring taglines in at least the top 15 languages spoken by the limited English proficient population of the relevant State or States. In addition, we added a reference to the posting requirement in paragraph (f)(1) of § 92.8 for clarity. Paragraph (d)(2) identifies the tagline requirement for significant publications and significant communications that are small-sized. In paragraphs (c) and (e) of § 92.8, we replaced the national threshold with a reference to the languages triggered by the State-wide methodology described in paragraph (d)(1).

In § 92.8(f), we revised paragraph (f)(1) and paragraphs (f)(1)(i) and (iii). Specifically, in paragraph (f)(1), we made a technical revision to remove an errant reference to paragraph (b) and we replaced the reference to paragraph (d) with (d)(1) to conform to the new paragraph designations of the final rule. In § 92.8(f)(1)(i), we replaced the conjunction "or" with "and" as a technical revision to align the text with the same technical revision in § 92.8(a). In addition, we excluded publications and significant communications that are small-sized from the requirement to post the notice conveying all content in § 92.8(a)(1)-(7) and from the requirement to post all 15 taglines. In paragraph (f)(1)(iii), we clarified the location of the tagline when posted to the covered entity's Web site.

We re-designated paragraph (g) in the proposed rule as paragraph (h) in this final rule. In the final rule, paragraph (g) addresses covered entities' requirements to post a nondiscrimination statement and taglines in significant publications and significant communications that are small-sized. Specifically, paragraph (g)(1) addresses the requirement to post a nondiscrimination statement and paragraph (g)(2) addresses the requirement to post taglines.

Newly re-designated paragraph (h) no longer treats an entity's compliance with particular paragraphs of § 92.8 as constituting compliance with the notice provisions of other Federal civil rights authorities. We revised the paragraph to address a covered entity's permissive authority to combine the content of the notice in paragraphs (a)(1)-(7) of this section with the content of other notices.

In Appendix A to the final rule, we made the following changes to improve the plain language reading of the sample notice and to streamline the sample notice's messaging:

- Deleted "sex stereotypes and gender identity" from the end of the first sentence;
- Replaced "worse" with "differently," and deleted the pronoun "their" prior to listing the bases on which the covered entity does not discriminate;
- Replaced "first language" with "primary language";
- Deleted "when needed to communicate effectively with us";
- Added "qualified" to modify "interpreters" with respect to serving individuals with limited English proficiency;
- Replaced "translated into other languages" with "written in other languages";
- Added placeholders for a covered entity to provide not only the name of its civil rights coordinator but also the individual's title; and
- Added contact information for filing a complaint with OCR.

In addition, we added a sample nondiscrimination statement in Appendix A for covered entities to post in significant publications and significant communications that are small-sized and accordingly broadened the title of Appendix A to reflect its revised scope.

In Appendix B to the final rule, we modified the language by replacing "may be available" with "are available" and by adding language to improve the plain language reading of the sample tagline, by replacing "[c]ontact" with "call."

Subpart B—Nondiscrimination Provisions

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

Discrimination Prohibited (§ 92.101)

We proposed that § 92.101 of subpart B prohibit 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. We proposed that paragraphs (a) and (b) 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). In paragraph (c), we proposed to address exceptions to discrimination prohibited under the Title VI, Section 504, and Age Act regulations. We proposed that paragraph (d) effectuate technical changes in terminology to apply the provisions incorporated from other regulations to the covered entities obligated to comply with this proposed rule.

In paragraph (a)(1) of § 92.101 of the proposed rule, we restated 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 proposed to limit the ways in which the proposed rule applies to employment. We noted that except as provided in § 92.208, which addresses employee health benefit programs, the proposed rule does not generally apply to discrimination by a covered entity against its own employees. Thus, the proposed rule would not extend to hiring, firing, promotions, or terms and conditions of employment outside of those identified in § 92.208; such claims could continue to be brought under other laws, including Title VII, Title IX, Section 504, the ADA and the Age Discrimination in Employment Act,[121] as appropriate. We invited comment on our proposal to exclude these forms of employment discrimination from the scope of the proposed rule.

We proposed that paragraph (b) incorporate into the 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. We noted that 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. We therefore proposed that paragraphs (b)(1)-(4) incorporate the specific discriminatory actions prohibited under each civil rights law on which Section 1557 is grounded. We sought comment on this proposed approach.

We proposed that paragraph (b)(1) adopt the specific discriminatory actions prohibited by the Title VI implementing regulation, which appear at **45 CFR 80.3**(b)(1)-(6).

In paragraph (b)(2)(i), we proposed to address the specific prohibition of discrimination on the basis of disability with which recipients and State-based Marketplaces must comply. In paragraph (b)(2)(i), we proposed to adopt relevant provisions in the Section 504 implementing regulation for federally assisted programs and activities at **45 CFR part 84**. We provided that 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 proposed that paragraph (b)(2)(ii) address the specific prohibitions of discrimination on the basis of disability with which the Department, including the Federally-facilitated Marketplaces, must comply. We proposed that this paragraph adopt relevant provisions in the Section 504 implementing regulation for federally administered programs and activities at **45 CFR part 85**. We provided that 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.

We proposed that paragraph (b)(3) adopt the specific discriminatory actions prohibited by the Title IX implementing regulation, which appear at **45 CFR 86.3**(b)(1) through (8).

We also proposed that paragraph (b)(4) adopt the specific discriminatory actions prohibited by the Age Act implementing regulation, which appear at **45 CFR 91.11**(b).

In paragraph (b)(5), we proposed 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). We noted that 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).

In paragraph (c), we proposed to incorporate 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. We noted that, 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 limits to a protected class. We did not address the sex-based distinctions authorized in Title IX and its implementing regulation in the context of education programs or activities. We noted that these distinctions do not necessarily apply in the health care context. However, we also noted that Title IX and the Department of Education's Title IX regulations allow some single-sex education programs when certain requirements are met.[122] We did not propose to prohibit separate toilet, locker room, and shower facilities where comparable facilities are provided to individuals, regardless of sex, but sought 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.

Finally, we proposed that paragraph (d) effectuate technical changes to apply the provisions incorporated in § 92.101(b) and (c) to covered entities obligated to comply with the proposed rule by, among other things, replacing references to "recipient" in the incorporated provisions with "covered entity."

The comments and our responses regarding § 92.101 of subpart B are set forth below.

Comment: A few commenters recommended that OCR add the words "or deterred" to the general prohibition of discrimination, so that it would read as follows: "Except as provided in Title I of the ACA, an individual shall not, on the basis of race, color, national origin, sex, age, or disability, be excluded or deterred from participation in, be denied the benefits of, or otherwise be subjected to discrimination under any health program or activity to which this part applies."

Response: We believe the regulatory text, as it is currently written, conveys the intent to prohibit discriminatory deterrence from participation in a health program or activity. As OCR noted in the preamble to the proposed rule, paragraph (a)(1) of § 92.101 prohibits discrimination on the grounds prohibited under Title VI, Title IX, the Age Act, and Section 504 in any health program or activity to which this part applies. It is well established under these and other civil rights law that deterrence on the basis of a prohibited criterion is a form of discrimination. Similarly, discrimination on the basis of perceived race, color, national origin, sex, age, or disability is prohibited discrimination under the final rule, as it is under the authorities referenced in Section 1557.

Comment: One commenter asked for clarification that, when scientific evidence supports differential treatment to ensure safe, high-quality care, such treatment would not be considered discriminatory. This commenter pointed out that the risks and benefits of treatments may differ due to characteristics such as age, gender, physical stature, and genetics. For example, based on the best available science, experts have judged that, for men and younger women, absent a known family history, the risks associated with radiation exposure from routine mammograms outweigh the benefits. Thus, practice guidelines suggest not administering screening mammograms to women under a certain age or to men.

Response: Scientific or medical reasons can justify distinctions based on the grounds enumerated in Section 1557. We affirm this understanding of the final rule and believe that the regulatory text encompasses that approach.

Comment: A few commenters asked that OCR prohibit discrimination in health programs or activities on the basis of "health status, claims experience, medical history, or genetic information" in addition to race, color, national origin, sex, age, and disability.

Response: This rule implements Section 1557 of the ACA, which prohibits discrimination on the bases of race, color, national origin, sex, age, and disability. Accordingly, the commenters' request is beyond the scope of this rule. However, OCR recognizes that discrimination based on health status, claims experience, medical history, or genetic information can, depending on the facts, have a disparate impact that results in discrimination on a basis prohibited by Section 1557 and will process complaints alleging such discrimination accordingly. In addition, such discrimination also may violate other laws, such as other provisions of the ACA or the Genetic Information Nondiscrimination Act of 2008.[123]

Comment: Many commenters disagreed with the approach taken in the proposed rule to exclude discrimination in employment in areas other than employee health benefits. Commenters stated that the text of Section 1557 does not exclude employment discrimination; that Section 1557 protects "individuals," similar to Title IX's protection of "person[s];" and that Title IX has been interpreted to protect not just students but employees of educational institutions. They also noted that Section 504 covers employment without exception and that Title VI covers employment discrimination when it affects beneficiaries of the covered program.[124]

Response: For the reasons stated in the preamble to the proposed rule, OCR declines to interpret Section 1557 to grant itself jurisdiction (outside the context of employee health benefit plans under circumstances set out in § 92.208) over claims of employment discrimination brought by employees against their employers that are covered entities. In holding that both Title IX and Section 504 broadly prohibit discrimination in employment, the Supreme Court relied heavily on the legislative history and underlying purpose of these statutes.[125] By contrast, there is no indication that broadly prohibiting employment discrimination was a chief purpose of Section 1557, which is focused on discrimination against participants in health programs and activities. To the extent that employees who are subject to discrimination are employed by entities that are covered under other employment discrimination laws, their complaints can be brought under those other laws. And as to employees of small employers, we do not believe that Congress in Section 1557 intended to alter, across the board, the longstanding exclusion of small employers from most employment discrimination laws. That said, nothing in this rule is intended to alter the established principles underlying the unlimited coverage of employment discrimination under both Title IX and Section 504, and OCR will process such claims brought under these statutes under its longstanding procedures.[126]

Comment: Some commenters asked that OCR clarify that Section 1557's prohibition of discrimination on the basis of race, color, national origin, sex, age, or disability includes intersectional discrimination that might affect persons who are part of multiple protected classes. For example, discrimination against an African-American woman could be discrimination on the basis of both race and sex.

Response: OCR is clarifying here that Section 1557's prohibition of discrimination reaches intersectional discrimination. We believe that the regulatory text encompasses this approach.

Comment: Commenters noted that various forms of harassment in health care can discourage individuals from seeking care and suggested that OCR include a separate provision that explicitly prohibits all forms of harassment based on protected characteristics, including sexual harassment and other forms of sex-based harassment.

Response: OCR recognizes that various forms of harassment can impede an individual's ability to participate in or benefit from a health program or