

activity and can thus constitute unlawful discrimination under Section 1557 and this part. Under Title IX, harassing conduct creates a hostile environment if the conduct is sufficiently serious to interfere with or limit an individual's ability to participate in or benefit from a program. ^[127]For example, a provider's persistent and intentional refusal to use a transgender individual's preferred name and pronoun and insistence on using those corresponding to the individual's sex assigned at birth constitutes illegal sex discrimination if such conduct is sufficiently serious to create a hostile environment. Similarly, a provider using derogatory language because an individual is an unmarried sexually active or pregnant woman constitutes illegal sex-based harassment if such conduct is sufficiently serious to create a hostile environment. Consistent with the well-established interpretation of existing civil rights laws, OCR interprets the final rule to prohibit all forms of unlawful harassment based on a protected characteristic. Because it has been long-established that harassment is a form of prohibited discrimination under each of the laws cited in Section 1557 and this part, OCR does not believe a separate harassment provision is necessary and therefore declines to revise the proposed rule to include one.

Comment: Many commenters recommended that OCR add regulation text stating that the Tri-Agency Guidance ^[128]imposes legally enforceable obligations on entities covered by Section 1557 and that OCR has direct authority to enforce the Tri-Agency Guidance as well as the statutory and regulatory provisions therein articulated. ^[129]The Tri-Agency Guidance describes how States can structure their application and enrollment processes in compliance with Title VI and program authorities to ensure that State agencies do not administer federally assisted public benefit programs in a manner that delays or denies services to eligible individuals, including children, living in mixed-immigration status households.

Commenters asked for such regulatory language based on concerns that some covered entities administer their programs in a manner that discriminates based on national origin by delaying or denying access to public benefits based on practices such as: Erecting onerous documentation requirements; denying eligible applicants the opportunity to prove eligible income, identity, citizenship status, or immigration status; or making generalized assumptions about applicants' eligibility based on the actual or perceived immigration status or national origin of any family member. ^[130]Commenters also expressed concern that some covered entities fail to understand the eligibility differences between various immigrant visa statuses and length of residency requirements, fail to distinguish between applicants and non-applicants in requests for Social Security numbers (SSNs), or require the disclosure of SSNs or immigration status without first explaining the use or confidentiality of this information.

Response: OCR appreciates hearing from commenters on this important issue. However, we decline to explicitly reference, in regulation, the Tri-Agency Guidance and the authorities therein articulated for two main reasons. First, it is beyond the scope of this final rule to address program authorities over which OCR does not have enforcement authority.

Second, regulatory modifications to the proposed rule are unnecessary to allow OCR to address a covered entity's policy or practice, such as requiring the disclosure of SSNs or certain citizenship or immigration status information, that raises compliance concerns under Section 1557's prohibition of national origin discrimination. OCR addresses such issues under Title VI. ^[131]We similarly have authority to address such issues under Section 1557 and this part when, for example, an individual's complaint alleges that a covered entity has implemented a facially-neutral policy, such as requiring the disclosure of immigration status from applicants and non-applicants, that has a disparate impact on individuals of a particular national origin group.

Thus, to the extent that the Tri-Agency Guidance identifies situations that may raise Title VI compliance concerns and offers best practices for resolving those concerns, this information is equally applicable to health programs and activities covered under Section 1557 as it is to the health and human service programs addressed in the Tri-Agency Guidance. The Department continues to adhere to the principles set forth in the Tri-Agency Guidance in the implementation of the Department's programs ^[132]and through OCR's enforcement of Title VI. OCR intends to apply these principles in our enforcement of Section 1557 and this part and will continue to accept complaints alleging that covered entities' actions deter eligible individuals from applying for benefits offered by health programs and activities on the basis of their national origin. Section 1557 and this part, however, do not alter programmatic laws and regulations that restrict eligibility for particular health programs to persons of certain immigration or citizenship statuses, and thus allow covered entities to make requests for that information when required by such authorities. ^[133]

Comment: A few commenters recommended that HHS clarify its longstanding position that the regulations implementing Section 504 require health care entities with fewer than 15 employees to provide auxiliary aids and services to persons with impaired sensory, manual, or speaking skills, where necessary to afford such persons an equal opportunity to benefit from the service in question. These commenters pointed out that while 45 CFR 84.52(d)(1) requires the provision of auxiliary aids only by covered entities with 15 or more employees, 45 CFR 84.52(d)(2) provides that the Director may require recipients with fewer than 15 employees to provide auxiliary aids where the provision of aids would not significantly impair the ability of the recipient to provide its benefits or services. The commenters recognized that in 2000, HHS issued a notice in the Federal Register announcing that the Director had decided to require recipients with fewer than 15 employees to provide appropriate auxiliary aids pursuant to 42 CFR 84.52(d)(2). ^[134]However, the commenters also asserted that some judicial decisions have questioned whether the Director's notice constitutes a binding legislative rule or merely a policy statement by HHS. ^[135]Accordingly, these commenters were concerned that the proposed rule's incorporation of 45 CFR 84.52(d) might not be clear enough to also incorporate the Director's notice that health care entities with fewer than 15 employees must provide auxiliary aids and services on the same basis as health care entities with 15 or more employees.

Response: To ensure clarity as to our intent, we have revised the language in § 92.101(b)(2)(i) to delete the reference to 45 CFR 84.52(d) and have added new language to that section requiring covered entities—regardless of the number of people they employ—to provide appropriate auxiliary aids and services to persons with impaired sensory, manual, or speaking skills where necessary to afford such persons an equal opportunity to benefit from the service in question.

As explained in the Director's original notice adopting this policy, OCR believes that Section 504's auxiliary aids and services requirement should be applied to covered entities with fewer than 15 employees in the interest of uniformity and consistent administration of law. Under Title III of the ADA,

privately operated public accommodations are obligated to provide appropriate auxiliary aids and services, regardless of their size, where necessary to ensure effective communication with individuals with disabilities, unless they can demonstrate that taking such steps would fundamentally alter the nature of their program, services or activities, or would result in undue financial and administrative burdens.^[136] OCR's decision to require all entities, regardless of size, to provide auxiliary aids and services under Section 1557 and this part thus furthers consistency among disability discrimination laws; importantly, it also furthers the ACA's goal of improving access to health coverage and health care because requiring all entities to provide auxiliary aids and services will result in enhanced services for people with disabilities. Moreover, because this requirement has been OCR's policy for more than a decade, covered entities are familiar with the obligations it imposes.

Comment: A few commenters asked that OCR add language to the rule declaring that medical treatment for individuals with disabilities must be as effective as treatment for individuals without disabilities.

Response: At § 92.101(b)(2)(i), the final rule incorporates **45 CFR 84.4(b)(1)(iii)** of the Section 504 implementing regulation, which states that recipients may not provide qualified individuals with disabilities “with an aid, benefit, or service that is not as effective as that provided to others. . . .” Such benefits include medical treatment, though recipients cannot, and are not required under the rule to, ensure equally effective outcomes.

Comment: A number of commenters urged that OCR make clear that, consistent with the requirements of Title II of the ADA and Section 504,^[137] disability-based discrimination under Section 1557 encompasses the needless segregation of individuals with disabilities. They pointed, in particular, to the need to make clear that covered entities must make coverage and reimbursement decisions that support serving individuals with disabilities in integrated settings unless doing so would fundamentally alter the entities' service systems, citing to the HHS Guidance on Medicaid Managed Care.^[138]

Response: We agree that since Section 1557 explicitly incorporates Section 504's prohibitions against disability-based discrimination, it therefore encompasses a ban on the unnecessary segregation of individuals with disabilities. As such, and as required by Title II of the ADA and Section 504 and interpreted in *Olmstead v. L.C.*^[139] and its progeny, public entities (State and local governments) must administer services to individuals with disabilities in the most integrated setting appropriate to their needs unless doing so is a fundamental alteration of the public entity's service delivery system. The “most integrated setting” mandate applies to the full spectrum of the public entity's service delivery system, including coverage and reimbursement decisions, when the entity “(1) directly or indirectly operates facilities and or/programs that segregate individuals with disabilities; (2) finances the segregation of individuals with disabilities in private facilities; and/or (3) through its planning, service system design, funding choices, or service implementation practices, promotes or relies upon the segregation of individuals with disabilities in private facilities or programs.”^[140] OCR will continue its ongoing *Olmstead* enforcement efforts under Section 504 and Title II of the ADA, as well as Section 1557 and this part, where appropriate.

Comment: Several commenters recommended that OCR specify that age-related distinctions are prohibited, apart from exclusions in the Age Act for (1) age distinctions contained in a Federal, State or local statute or ordinance that provide benefits based on age, establish criteria for participation in age-related terms, or describe intended beneficiaries to target groups in age-related terms, and (2) actions that reasonably take into account age as a factor necessary to the normal operation or the achievement of any statutory objective of such program or activity. Under these comments, for example, a decision to limit coverage of a service to individuals in a particular age range, even though that service is also effective for individuals of other ages, would violate Section 1557 if the age limitation is not based on a statute or ordinance and is not necessary for the normal operation or achievement of the goals of the service.

Response: OCR declines to adopt the standard recommended by the commenters. As noted elsewhere, the rule permits actions based on age to overcome the effects of conditions that resulted in limited participation in the covered entity's health program or activity based on age.^[141] We also note that other provisions of the rule incorporate provisions in the regulation implementing the Age Act that permit age distinctions in HHS regulations and a recipient's provision of special benefits to the elderly or children.^[142]

Comment: A few commenters asked that OCR clarify that State mandates that have age limits are exempt and that States are allowed to create new State mandates that have age distinctions if that is clinically appropriate.

Response: As reflected in the provision of the final rule at § 92.2(b)(1), age distinctions contained in Federal, State, or local statutes or ordinances adopted by an elected, general purpose legislative body are not covered by the final rule. States may adopt new laws that contain age distinctions; those distinctions would not violate the final rule.^[143]

Comment: One commenter asked us to clarify the application of Section 1557 with respect to age rating in health insurance plans and related employer contributions.

Response: As we noted above, OCR is incorporating in the final rule 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.^[144] For instance, age rating in premium rates within a 3:1 ratio in MarketplaceSM plans would not violate Section 1557 because it is permitted under the ACA.^[145] Further, this rule would not prohibit a covered entity from establishing and applying, or offering a plan on a MarketplaceSM that establishes or applies, in a nondiscriminatory manner, neutral rules related to employer contribution amounts, such as contributing a fixed percentage or dollar amount of each employee's premium or placing a cap on the total amount of employer contributions, even though the dollar amount of the contribution or the employee's share of the premium may be smaller or greater for some employees than for others based on the permissible age rating of the employee's premium.

Comment: One commenter recommended that OCR clarify that in order to operate in a nondiscriminatory manner, issuers must ensure that their plans do not impose arbitrary age, visit, or coverage limits. This commenter pointed out that children often need more frequent preventive and supportive services than adults, including immunizations, developmental assessments and screenings, and nutritional counseling, to enable them to maintain or improve their health into adulthood. Furthermore, children with special health needs may need additional services, such as speech or physical therapy, on a more frequent basis than adults to enable them to develop specific skills or meet their developmental potential. Similarly, children will also require replacement of durable medical equipment or devices on a much more frequent schedule than is provided in an adult benefit package.

Response: OCR agrees that arbitrary age, visit, or coverage limitations could constitute discrimination, including discrimination based on age, in certain cases, for example where consideration of age is not necessary to the normal operation of a health program. In addition, as noted above, where differential treatment is justified by scientific or medical evidence, such treatment will not be considered discriminatory. The general prohibition of discrimination in the rule applies to these issues.

Comment: Commenters noted that due to the educational context for which they were created, Title IX regulations do not reach the full breadth of discriminatory actions on the basis of sex that are prohibited by Section 1557; these commenters recommended that the final regulation incorporate prohibitions from Title VI, Section 504, and the Age Act to more fully address discrimination on the basis of sex in health programs and activities. In addition, commenters stated that the final rule should make clear that in the absence of a finding of discrimination, a covered entity may take affirmative action to overcome the effects of conditions which resulted in limited participation by persons on the basis of sex.

Response: OCR appreciates the concern raised by the commenters that, due to the fact that Title IX applies only to educational programs, the full range of specific discriminatory actions prohibited under other laws is not explicitly included in Title IX's regulations. OCR has revised the final regulation to incorporate additional language in § 92.101(b)(3) to help clarify the full breadth of discriminatory actions that can constitute sex discrimination under Section 1557. Additionally, both the proposed and the final rule make clear in § 92.6 (Remedial Action and Voluntary Action) that covered entities are permitted, but not required, 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 any prohibited ground covered under the regulation.

Comment: Several commenters noted that although sex-specific programs may be clinically necessary in some instances, for example, in clinical trials that aim to determine whether sex differences exist in the manifestation or recommended treatment of certain diseases, the Department should clarify that sex-specific programs—*i.e.*, those in which participation is limited to members of one sex only—are permissible only when they are narrowly tailored and necessary to accomplish an essential health purpose.

Response: OCR agrees with commenters that sex-specific programs (programs limited exclusively to one sex) should be permitted only under limited circumstances. OCR believes that the constitutional standard established by the Supreme Court in *United States v. Virginia* ^[146] provides the most appropriate level of protection and thus has chosen to adapt this standard for application in evaluating the lawfulness of sex-specific health programs or activities under Section 1557 and this part. In *Virginia*, the Court stated that a governmental entity attempting to justify a sex-specific program must demonstrate an “exceedingly persuasive justification” for a sex-based classification in accordance with the U.S. Constitution's Equal Protection Clause. ^[147] As the Court explained, this means that the governmental entity must show “at least that the [challenged] classification serves important governmental objectives and that the discriminatory means employed are substantially related to the achievement of those objectives.” ^[148] In *Virginia*, which challenged Virginia Military Institute's male-only admissions policy, the Court found that the governmental entity had fallen “far short of establishing the exceedingly persuasive justification” necessary to sustain a sex-based classification. ^[149] The Court made clear that proffered justifications cannot rely on overbroad generalizations and cannot be hypothesized or invented post hoc in response to litigation. ^[150]

Under this demanding standard, as adapted in this rule, a sex-specific health program or activity classification is unlawful unless the covered entity can show an exceedingly persuasive justification for it, that is, that the sex-based classification is substantially related to the achievement of an important health-related or scientific objective. In evaluating a complaint of discrimination challenging a covered entity's sex-specific health program or activity, OCR may consider a variety of factors relevant to the particular program or activity. In all cases, however, OCR will expect a covered entity to supply objective evidence, and empirical data if available, to justify the need to restrict participation in the program to only one sex. In no case will OCR accept a justification that relies on overly broad generalizations about the sexes.

Under this standard, OCR anticipates that most health researchers will be able to justify sex-specific clinical trials, such as those that test treatments for sex-specific conditions or that evaluate differences in responses to treatment regimens among the sexes, based upon the scientific purposes of the study. Where there is no clinical or scientific rationale for making a program sex-specific, by contrast, a covered entity that offers such a program would need to demonstrate, through such means as research literature, empirical data, accepted professional standards, and/or facts specific to participants in the program, that maintaining the sex segregation of the program is necessary for the program to achieve its purpose. Overly broad generalizations would not be sufficient.

No commenters asked OCR to adopt the sex-specific standards authorized in Title IX or the Department of Education's Title IX regulations. OCR has chosen to apply an adapted constitutional standard under Section 1557 rather than the standard authorized in Title IX and the Department of Education's Title IX regulations because, as noted in the proposed rule, and by several commenters, the single-sex educational exceptions found in Title IX and the Department of Education's Title IX regulations—such as exceptions for some single-sex education programs (*e.g.*, contact sports in physical education classes; classes on human sexuality; and choruses) when certain requirements are met—do not readily apply in a context grounded in health care.

In addition, we note that OCR's adaptation of the constitutional standard as the standard to be applied to sex-specific health programs or activities under

Section 1557 is consistent with the constitutional standard that already applies to sex-specific public health programs and activities, which are covered entities under this rule if they receive Federal financial assistance. OCR has adapted the standard to use the term “important health-related or scientific objective,” in recognition of the fact that the rule's provision on sex-specific programs or activities applies to both private and public covered entities in the context of health programs and activities. The same Section 1557 nondiscrimination standards, including this adapted standard, apply to health programs or activities subject to this rule whether public or private covered entities operate them.

Finally, as we initially noted in the proposed rule, we do not intend to prohibit separate toilet, locker room, and shower facilities where comparable facilities are provided to individuals, regardless of sex. OCR recognizes that under some existing Federal, State and local laws, rules or regulations, certain types of sex-specific facilities such as restrooms may be permitted. The approach taken by OCR is consistent with the long standing approach taken to these types of facilities.

However as previously stated in the discussion of the definition of “on the basis of sex” in § 92.4, even where it is permissible to make sex-based distinctions, individuals may not be excluded from health programs and activities for which they are otherwise eligible based on their gender identity. ^[151]Courts have rejected claims that any legal right to privacy is violated and that one person suffers any cognizable harm simply by permitting another person access to a sex-specific program or facility which corresponds to their gender identity. ^[152]

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 § 92.101 with the following modifications:

We have re-designated § 92.101(b)(1) as § 92.101(b)(1)(i), and added a new section § 92.101(b)(1)(ii), which prohibits aiding or perpetuating discrimination against an individual by providing significant assistance to an entity or person that discriminates on the basis of race, color, or national origin against beneficiaries of the covered entity's health program or activity. Similarly, we have re-designated § 92.101(b)(4) as § 92.101(b)(4)(i), and added a new section § 92.101(b)(4)(ii), which prohibits aiding or perpetuating discrimination against an individual by providing significant assistance to an entity or person that discriminates on the basis of age against health program or activity beneficiaries. These provisions complement similar provisions incorporated in the final rule with respect to disability and sex discrimination and are included to ensure that we are providing the same protections from race, color, national origin, and age discrimination as are provided with respect to sex and disability discrimination.

In addition, we have changed the language in § 92.101(b)(2)(i) to exclude reference to 45 CFR 84.52(d). We are re-designating the existing regulation text at § 92.202 as § 92.202(a), and adding a new subsection, § 92.202(b) that requires covered entities—regardless of the number of people they employ—to provide appropriate auxiliary aids and services to persons with impaired sensory, manual, or speaking skills, where necessary to afford such persons an equal opportunity to benefit from the service in question.

We have re-designated the existing regulation text at § 92.101(b)(3) as § 92.101(b)(3)(i). We have added new subsections, § 92.101(b)(3)(ii) and § 92.101(b)(3)(iii) to clarify the full breadth of discriminatory actions prohibited by Section 1557 on the basis of sex. Last, we have added a new subsection, § 92.101(b)(3)(iv) to clarify when covered entities may provide a sex-specific health program or activity.

Subpart C—Specific Applications to Health Programs and Activities

Section 1557 is unique among Federal civil rights laws in that it specifically addresses discrimination in health programs and activities. To provide additional specificity regarding nondiscrimination requirements in this setting, Subpart C builds upon pre-existing civil rights regulations referenced in Subpart B.

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

Overview of § 92.201

In § 92.201, OCR proposed to effectuate Section 1557's prohibition on national origin discrimination as it affects individuals with limited English proficiency in health programs and activities of covered entities.

We explained that for individuals with limited English proficiency, lack of proficiency in English—and the use of non-English languages—is a direct outgrowth of, and is integrally tied to, their national origins. ^[153]It is well-established under Title VI and its implementing regulation that a prohibition on national origin discrimination requires covered entities to take reasonable steps to provide meaningful access to individuals with limited English proficiency. ^[154]The U.S. Supreme Court has held that the provision of language assistance services is essential to ensure the equality of opportunity promised by nondiscrimination laws. ^[155]As we stated in the Department's 2000 LEP Policy Guidance:

The key to providing meaningful access for LEP persons is to ensure that the recipient/covered entity and LEP person can communicate effectively. The steps taken by a covered entity must ensure that the LEP person is given adequate information, is able to understand the services and benefits available, and is able to receive those for which he or she is eligible. The covered entity must also ensure that the LEP person can effectively communicate the relevant circumstances of his or her situation to the service provider. ^[156]

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

In § 92.201(a), we proposed to adopt the well-established principle that covered entities must take reasonable steps to provide meaningful access to health programs and activities for all individuals with limited English proficiency whom the covered entities serve or encounter.^[157] We provided that, consistent with our longstanding enforcement of Title VI, we intended the general obligation in paragraph (a) to be a context-specific standard that the Director considers in light of the particular facts.^[158]

We stated that the proposed standard balances two core principles critical in effectuating Section 1557's prohibition of national origin discrimination. First, the Department must "ensure that [health programs and activities] aimed at the American public do not leave some behind simply because they face challenges communicating in English."^[159] We noted that provider-patient communication is essential to the concept of patient centeredness, which is a core component of quality health care and has been shown to improve patients' health and health care.^[160] Second, we stated that the level, type and manner of language assistance services required under paragraph (a) should be assessed based on the relevant facts, which may include the operations and capacity of the covered entity.

For these reasons, proposed paragraph (b) identified how the Director will evaluate whether a covered entity has met the requirement in paragraph (a).^[161] In paragraph (b)(1), we proposed to require the Director to consider, and give substantial weight to, the nature and importance of the health program or activity, including the particular communication at issue. In paragraph (b)(2), we proposed to require the Director to take other relevant factors into account and identified some of those that might be relevant.

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

In paragraph (b)(2)(iii), we provided that the prevalence of the primary language in which the individual with limited English proficiency communicates, among those eligible to be served or likely to be encountered by the health program or activity, might also be relevant.

In paragraphs (iv) and (v) of proposed § 92.201(b)(2)—the final illustrative factors listed—we noted that the resources available to the covered entity and the costs of language assistance services might also be relevant in a particular case.

In proposed paragraph (c), we clarified that language assistance services required under paragraph (a) must be provided free of charge, be accurate and timely, and protect the privacy and independence of the individual with limited English proficiency.^[162]

Specific Requirements for Interpreter Services and Restricted Use of Certain Persons to Interpret or Facilitate Communication § 92.201(d) and (e)

In paragraphs (d) and (e), OCR proposed to codify standards described in the Department's LEP Guidance regarding qualified interpreters for individuals with limited English proficiency and the use of family members or friends as interpreters or to facilitate communication.^[163] These proposed standards account for issues of competency, confidentiality, privacy, and conflict of interest that arise as a result of relying on informal (or ad hoc) interpreters. We noted that paragraphs (d) and (e) are consistent with oral interpretation standards that OCR has advanced through its resolution of Title VI cases and compliance reviews.^[164]

Specifically, in paragraph (d), OCR proposed to address standards applicable to oral interpretation. We provided that when a covered entity is required by paragraph (a) to provide oral interpretation as a reasonable step to provide meaningful access to an individual with limited English proficiency, the covered entity must offer that individual a qualified interpreter.

In paragraph (e), we proposed restrictions on the use of certain persons to interpret or facilitate communication for an individual with limited English proficiency. We proposed that paragraph (e) apply in addition to, and regardless of, the appropriate level, type or manner of language assistance services a covered entity is required to provide. In paragraph (e)(1), we proposed to prohibit a covered entity from requiring an individual with limited English proficiency to provide his or her own interpreter. However, in paragraphs (e)(2)(i) and (ii), we proposed to identify narrow and finite situations in which a covered entity may rely on an adult accompanying an individual with limited English proficiency to interpret. In paragraph (e)(3), we proposed to prohibit a covered entity from relying on a minor child to interpret or facilitate communication and identified an exception to this prohibition that is narrower in scope than the exception identified in (e)(2)(i) and (ii).

We explained that in lieu of the approach we proposed in paragraphs (d) and (e), we considered proposing that all covered entities have the capacity to provide, in their health programs or activities, qualified interpreters for individuals with limited English proficiency through telephonic oral interpretation services available in at least 150 non-English languages. OCR invited comment on what oral interpretation services, if any, we should require and how such approaches appropriately balance the provision of meaningful access to individuals with limited English proficiency and covered entities' flexibility to identify the means of providing such access.

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

In paragraph (f), we proposed that no individual with limited English proficiency should be required to accept language assistance services, consistent with an individual's right to self-determination. We provided that a covered entity cannot coerce an individual to decline language assistance services. We also provided that if an individual with limited English proficiency voluntarily declines an offer of language assistance services from the covered entity, a

covered entity could denote, in the individual's file or records, the language assistance services offered and the declination.^[165]

Alternative Approaches

In the proposed rule, we described alternate approaches we considered and requested comment on these approaches and any others to effectuate Section 1557's prohibition of national origin discrimination as it affects individuals with limited English proficiency. For instance, we noted that independent of the proposed requirements of § 92.201, covered entities, including Health Insurance Marketplaces, State agencies administering Medicaid and Children's Health Insurance Program (CHIP) programs, and qualified health plan issuers, must comply with any applicable language access requirements in other laws and regulations.^[166] We invited comment on whether the requirements under different authorities should be harmonized and if so, to what extent and how.

We also stated that we considered a regulatory scheme requiring covered entities to provide meaningful access to each individual with limited English proficiency by providing effective language assistance services, at no cost, unless such action would result in an undue burden or a fundamental alteration of the health program or activity.^[167]

We further noted that we considered a regulatory scheme requiring covered entities to provide a range of language assistance services in the non-English languages spoken by State-wide populations with limited English proficiency that meet defined thresholds. Such thresholds would provide a minimum number of non-English languages in which covered entities would be required to deliver oral interpretation services; to translate written vital documents and Web site content; and to include taglines on vital documents and on Web sites.^[168] We requested comment on whether OCR should require thresholds, and if so, what thresholds should be required, and to what geographic areas or service areas the thresholds should apply. We also sought comment on whether OCR should permit covered entities to implement their obligations with a phased-in approach.

We also noted that we considered a regulatory scheme that would impose enhanced obligations on a subset of covered entities. We sought comment on what characteristics should define covered entities that could have enhanced obligations, such as whether the covered entity is of a certain type or size, has frequent contact with individuals with limited English proficiency, or operates particularly important health programs or activities, among other potential factors. We listed potential categories of covered entities that could have enhanced obligations, such as State agencies administering Medicaid or CHIP; Health Insurance Marketplaces; the Department in its operation of its health programs or activities; or covered entities that have a minimum number of beds, employees, or locations, such as hospitals, nursing homes or skilled nursing facilities, home health agencies, and retail pharmacies (including mail-order pharmacies).^[169] We described that under this alternate approach, instead of evaluating each case on its particular facts, the Director would evaluate a covered entity's compliance based on whether the entity provided the range of language assistance services in the non-English languages specified.^[170] We invited comment on this proposal.

We further requested comment on whether covered entities should be required to systematically prepare to provide language assistance services in their health programs or activities, such as through the establishment of policies and procedures or through other advance planning mechanisms. We stated that in OCR's experience, covered entities are in a better position to meet their obligations to provide language assistance services in a timely manner to individuals with limited English proficiency when those entities identify, in advance, the types and levels of services that will be provided in each of the contexts in which the covered entity encounters individuals with limited English proficiency.

OCR noted that an advance planning requirement could require each covered entity to identify all resources for providing language assistance services; annually assess the frequently-encountered or highly prevalent languages in the service area of the health program or activity; establish written procedures to which frontline staff could refer when encountering individuals with limited English proficiency; and monitor and oversee the quality of language assistance services provided. We also noted that an advance planning requirement could require each covered entity to build its capacity to provide language assistance services to meet the needs of the national origin populations that the entity serves. We requested comment on the types of advance planning mechanisms, if any, that should be required and why.

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

The comments and our responses regarding § 92.201 are set forth below:

Overall, commenters supported the proposed rule's inclusion of specific provisions addressing meaningful access for individuals with limited English proficiency. We received numerous comments written in non-English languages submitted by individuals with limited English proficiency who expressed how essential it is to have language assistance services, at no cost, to understand forms, invoices, and medication instructions. Many comments from the health care provider and insurance industry, as well as from organizations representing individuals with limited English proficiency, agreed that it is essential that individuals, regardless of national origin, be able to access covered entities' health programs and activities. We received many comments, however, regarding the scope and parameters of covered entities' obligations under the final rule.

Comment: Many commenters recommended revising the categories of individuals to whom a covered entity has an obligation to take reasonable steps to provide meaningful access. Specifically, commenters recommended that a covered entity's obligation should apply to those "eligible to be served" or

“likely to be affected by” the covered entity's health programs and activities. Commenters suggested that proposed § 92.201(a), which stated that the obligation of a covered entity runs to those who the entity “serves or encounters in its health programs and activities,” unduly narrowed the scope of the covered entity's obligation.

Response: In response to commenters' recommendations, we have replaced the phrase “that it serves or encounters” with “eligible to be served or likely to be encountered.” We agree with commenters that a covered entity must be prepared to take reasonable steps to provide meaningful access to individuals beyond those who actually walk into, or contact, that entity. Where a covered entity is likely to encounter, but is unprepared to assist, individuals of particular national origin groups in the languages in which they communicate, those individuals are unlikely to seek services from, or participate in, the entity's health programs or activities, thereby perpetuating barriers to individuals' access to care.

We chose the phrase “eligible to be served or likely to be encountered” because it is one of the formulations in the HHS LEP Guidance of the population to which a covered entity has an obligation.^{~~1711~~} In addition, commenters' proposal that a covered entity's obligation applies to individuals “likely to be affected by” the covered entity's health programs and activities gave covered entities less concrete guidance about their obligations relative to the phrase “likely to be encountered.”

Comment: Numerous commenters recommended that OCR revise the general obligation in § 92.201(a) to require that covered entities “provide meaningful access” to each individual with limited English proficiency rather than “take reasonable steps to provide meaningful access.” Commenters explained that because “meaningful access” is already a subjective standard, requiring “reasonable steps to provide meaningful access” substantially dilutes covered entities' obligations to provide language assistance services.

These commenters suggested that language assistance should be provided in every situation and that oral interpretation, in particular, should be provided “on demand.” Commenters suggested that the final rule make this basic obligation clear because some covered entities turn away individuals with limited English proficiency, stating that the entity does not provide language assistance services. For instance, one commenter shared that it is common for individuals with limited English proficiency to use a hospital emergency department as a source of primary care because the individuals' physicians do not offer qualified interpreters for individuals with limited English proficiency. Commenters also suggested that the Director's weighing of the illustrative factors set out in § 92.201(b) should focus exclusively on whether the covered entity provided the appropriate type, form, and manner of language assistance.

Response: We decline to modify the general obligation in § 92.201(a) because it reflects familiar and longstanding requirements applicable under Title VI.^{~~1721~~} In addition, the regulatory scheme provides in 92.201(b)(1) that in assessing this standard, the Director will consider, and give substantial weight to, the nature and importance of the health program or activity and the particular communication at issue, which places covered entities on notice about the way in which we will evaluate the Title VI standard within the context of health programs and activities. OCR interprets the requirement that covered entities take “reasonable steps to provide meaningful access” to demand that each entity, as an initial step, assess the need to provide language assistance services to each individual with limited English proficiency and respond to that need by providing the appropriate language assistance services on a timely basis.

As we stated in the proposed rule, safe and quality health care requires an exchange of information between the health care provider and patient for the purposes of diagnoses, treatment options, the proper use of medications, obtaining informed consent, and insurance coverage of health-related services, among other purposes.^{~~1731~~} This exchange of information is jeopardized when the provider and the patient speak different languages and may result in adverse health consequences and even death.^{~~1741~~} Indeed, the provision of health care services, by its “very nature[,] requires the establishment of a close relationship with the client or patient that is based on sympathy, confidence and mutual trust,”^{~~1751~~} which cannot be established without effective communication.

Comment: Some commenters expressed concern about the potential financial and administrative burden to provide language assistance services. Many of these commenters expressed support for the proposed rule's inclusion of specific provisions addressing access for individuals with limited English proficiency but also urged that public and private health insurance issuers update medical codes and fee schedules to allow providers to receive reimbursement for the provision of language assistance services.

Some commenters offered proposals for minimizing the costs to covered entities for providing language assistance services—oral interpretation services in particular. These recommendations included that OCR facilitate access to telephonic oral interpretation, at no cost to covered entities, and that OCR ensure that covered entities have adequate funding to provide qualified interpreters for individuals with limited English proficiency.

Response: We appreciate hearing commenters' concerns and having the benefit of commenters' recommendations to lessen potential cost and administrative barriers that covered entities may face. It is beyond the scope of this rulemaking to adopt recommendations that OCR fund qualified interpreters or direct issuers to modify medical codes and fee schedules to reimburse health care providers for their provision of language assistance services.^{~~1761~~}

OCR encourages covered entities to work together to leverage their ability to provide language assistance services in the most cost-effective and efficient ways to meet their respective obligations under § 92.201(a) before using costs as a reason to limit language assistance services.^{~~1771~~} OCR also encourages professional associations and organizations to consider what role they can play in helping their members meet the requirements of § 92.201; we provided similar encouragement in the HIPAA Privacy Rule.^{~~1781~~}

We further remind State agencies receiving Federal financial assistance for Medicaid and the Children's Health Insurance Program that States may claim

Federal matching funds for the costs of written translation and oral interpretation as administrative expenses or as medical assistance-related expenses. ^[179]Further, increased funding may be available when States claim the cost of written translation and oral interpretation as administrative expenses if such language assistance services are provided for the “enrollment, retention, and use of services” for individuals with limited English proficiency eligible for CHIP and for Medicaid-eligible children and their families. ^[180]In addition, we remind qualified health plan issuers that the ACA requires, as a condition of an issuer's health plan receiving certification as a qualified health plan, that the issuer implement a quality improvement strategy for the qualified health plan that provides increased reimbursement or other incentives for the implementation of activities to reduce health and health care disparities, including through the use of language services. ^[181]We encourage health insurance issuers to structure their health plan payment structures to consider health care providers' expenses in providing language assistance services.

We decline to accept the recommendation that OCR facilitate access to telephonic oral interpretation services for all covered entities. Such facilitation is beyond the scope of the Federal government's role and is an impractical solution to address the needs of diverse Section 1557 covered entities. However, OCR does share best practices and useful resources, such as through the Federal government's Interagency Working Group on Limited English Proficiency, at www.LEP.gov.

Comment: We received numerous comments on whether the final rule should include an advance planning requirement for covered entities to be systematically prepared to provide language assistance services in their health programs and activities. The vast majority of these comments recommended that the final rule include such an advance planning requirement—specifically, the development and implementation of a language access plan that addresses the needs of the limited English proficient population in the service area of a covered entity's health program or activity. Commenters reasoned that a regulatory requirement is the most effective method of holding covered entities accountable for engaging in meaningful advance planning.

One commenter observed that many covered entities already evaluate the type of language assistance services they are obligated to provide, pursuant to the current HHS LEP Guidance, and thus that codifying this requirement would not impose a significant additional burden on covered entities. This commenter also asserted that an advance planning requirement is analogous to the approach of § 92.7, which requires certain covered entities to have a grievance procedure in place. Another commenter shared that in updating her employer's language access plan, the availability of online tools and resources greatly reduced the commenter's anticipated burden of what advance planning would require.

We received many comments recommending that the final rule identify specific required components of a language access plan, including the types of language access services the covered entity will provide and in what languages, based on the languages spoken by eligible individuals with limited English proficiency in the covered entity's service area. One commenter underscored that to increase efficiency and maximize cost savings, a language access plan should identify multiple types of language assistance services that a covered entity can use for different situations or even within one encounter. This commenter asserted that relying on just one kind of language assistance service may not be appropriate for all communications.

Another commenter recommended that the final rule mirror California's regulations on advance planning mechanisms for the provision of language assistance services. ^[182]This commenter stated that, consistent with California's regulations, OCR should require that language access plans identify all points of contact with individuals with limited English proficiency; provide a procedure for recording individuals' primary language; identify vital documents; provide a procedure for the translation of vital documents; provide a procedure to request translation of specific other documents; require training on language access services for all staff likely to have contact with individuals with limited English proficiency; require the assessment of the qualifications of bilingual/multilingual staff; and adopt written policies and procedures regarding the provision of language assistance services, including a procedure for contracting with language service vendors. Other commenters agreed that prior to using individuals to provide interpretation or translation services, covered entities should be required to evaluate or verify the individuals' knowledge, skills and abilities to confirm that they meet the definition of a qualified interpreter or a qualified translator for an individual with limited English proficiency.

We received a small number of comments opposing a requirement for advance planning. One commenter acknowledged that a language access plan is important in ensuring that covered entities are systematically prepared to provide language assistance services but recommended that OCR should merely encourage, not require, advance planning activities. The commenter observed that developing a language access plan may be too burdensome for small covered entities.

Response: Based on the comments received, we have added a factor—the only illustrative factor in § 92.201(b)(2)—that requires the Director to consider, if relevant, whether the entity has developed and implemented an effective written language access plan, appropriate to its particular circumstances. The language “appropriate to its particular circumstances” conveys our recognition that the nature and extent of the voluntary planning in which a covered entity may choose to engage will vary depending on the entity's particular health programs and activities, its size, its geographic location, and other factors. A language access plan need not be long, complex, or burdensome.

We note that a written language access plan has long been recognized as an essential tool to ensure adequate and timely provision of language assistance services, including compliance with the general obligation in § 92.201(a) and the quality standards in § 92.201(d)-(f). For instance, for over 15 years, **Executive Order 13166** has required each Federal agency to create and implement a language access plan responsive to the needs of the limited English proficient population it serves. ^[183]Moreover, the development and implementation of a written language access plan is consistent with OCR's longstanding enforcement processes ^[184]and resolution agreements regarding Title VI. ^[185]Although we are not requiring language access plans, we encourage entities to consider whether and how they can engage in advance planning to facilitate their ability to meet their obligations under § 92.201 to serve individuals with limited English proficiency on a timely basis.

We decline to outline the minimum expectations for a language access plan, if a covered entity chooses to develop and implement one, because that approach would be too prescriptive. Nonetheless, in our experience, effective language access plans often, among other components, address how the

entity will determine an individual's primary language, particularly if the language is an unfamiliar one; identify a telephonic oral interpretation service to be able to access qualified interpreters when the need arises; identify a translation service to be able to access qualified translators when the need arises; identify the types of language assistance services that may be required under particular circumstances; and identify any documents for which written translations should be routinely available. OCR remains available to covered entities as a resource for technical assistance in the development and implementation of language access plans in their health programs and activities. HHS offers helpful guidance on this subject,^[186] as does the U.S. Department of Justice.^[187] We encourage covered entities to refer to these materials to assist their advance planning activities.

Comment: Many commenters recommended modifications to, and additional clarification regarding, the list of factors that the Director will take into account, if relevant, among other relevant factors in evaluating a covered entity's compliance with its general obligation in § 92.201(a). These comments fall into four main categories. First, many commenters requested that we add additional factors to the list in § 92.201(b)(2)(i)-(v). Commenters were concerned that absent explicit references to these factors, the Director would not, or could not, consider them. Examples of factors that commenters requested that we add include:

- The frequency with which a covered entity encounters, or is likely to encounter, a particular non-English language;
- the impact to the consumer if language assistance services are not provided;
- the extent to which covered entities can lessen their own cost burdens through technology and reasonable business practices, if the Director considers the costs of language assistance services; and
- if and when a covered entity is permitted to choose a less costly language assistance service than the one an individual may request.

Second, many commenters recommended that we combine the “costs of language assistance services” in proposed § 92.201(b)(2)(v) with “[a]ll resources available to the covered entity” in proposed § 92.201(b)(2)(iv) into a single factor because the two are inherently intertwined.

Third, some commenters requested that OCR clarify in the final rule how the factors in proposed § 92.201(b)(2)(i)-(v) would be weighted relative to each other, if relevant and thus evaluated by the Director in a given case. Most commenters who requested clarification recommended that the costs of language assistance services and the resources available to the covered entity not be weighted more heavily than the other factors or become dispositive.

Fourth, a number of commenters requested clarification on the function that the length and complexity of the communication in proposed § 92.201(b)(2)(i) would have in the Director's evaluation of a particular case.

Response: After considering the comments received, we have revised the final rule to eliminate the illustrative factors and to articulate only one factor: Whether a covered entity has developed and implemented an effective written language access plan appropriate to its circumstances. We agree with some commenters' concerns that including multiple illustrative factors in the regulatory text may create the erroneous impression that the Director will not consider relevant factors absent from § 92.201(b)(2). Were OCR to modify § 92.201(b)(2) to include all factors suggested by commenters, however, the long list of factors might unintentionally create an unworkable regulatory scheme in the attempt to capture any possible factor that might be relevant in some circumstances.

Given these concerns, § 92.201(b)(1)-(2) of the final rule 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 requires the Director to take into account all other relevant factors, including whether the entity has developed and implemented an effective language access plan. We have identified this factor in particular to provide a concrete reminder to covered entities that they may wish to take action to prepare to provide language assistance services to the individuals with limited English proficiency that they will serve or encounter. We reiterate, however, that adoption of a language access plan is a voluntary measure that is not required by the rule; we will continue to evaluate, on a case-by-case basis, whether entities have taken reasonable steps to provide meaningful access and will evaluate all relevant factors in making that assessment.

We recognize that the absence of illustrative factors in regulation text may diminish clarity regarding the Director's evaluation of a covered entity's compliance with § 92.201(a). To provide guidance to covered entities on our intended interpretation of § 92.201(b)(2) and to be responsive to comments received on the illustrative factors proposed, the following preamble discussion sets forth a range of factors that may be relevant in any given case.^[188]

As an initial matter, we note that one of the factors commenters recommended we add, which is the impact to the individual of failing to provide language assistance services, is necessarily encompassed within § 92.201(b)(1) regarding an evaluation of the nature and importance of the health program or activity and the particular communication at issue.^[189]

Factors that may be relevant in a particular case for the Director to consider pursuant to § 92.201(b)(2) include but are not limited to: the length, complexity, and context of the communication; the prevalence of the language in which the individual communicates among those eligible to be served or likely to be encountered by the health program or activity; the frequency with which a covered entity encounters the language in which the individual communicates; whether a covered entity has explored the individual's preference, if any, for a type of language assistance service, as not all types of language assistance services may work as well as others in providing an individual meaningful access to the covered entity's health program or activity; the cost of language assistance services and whether a covered entity has availed itself of cost-saving opportunities; and all resources available to the covered entity, including the entity's capacity to leverage resources among its partners or to use its negotiating power to lower the costs at which language assistance services could be obtained.

We decline to adopt commenters' suggestions to create a regulatory scheme that assigns particular weight to any specific relevant factor because the Director will consider and weigh all relevant factors pursuant to § 92.201(b)(2) on a case-by-case basis.

Because we have eliminated the factors in proposed 92.201(b)(2)(i)-(v), it is moot whether OCR should combine the proposed factor on the costs of language assistance services with the proposed factor on resources available to the covered entity. Nevertheless, costs and resources are intertwined, which is a principle reflected in the HHS LEP Guidance with respect to Title VI ^[190] and a principle we reiterated with respect to Section 1557 in the proposed rule. ^[191]

With respect to commenters' requests for clarification on the relevance that the length and complexity of a particular communication has on the type of language assistance a covered entity should provide, we note that this factor is emblematic of the fact-based nature of the inquiry described in § 92.201(b)(1)-(2). Where a document is long and complex, it may in some cases be necessary for a covered entity to provide a written translation so that an individual with limited English proficiency can refer back to or study it at a later time. In other cases, however, a covered entity may meet the requirements of this section by summarizing the document orally for a qualified interpreter to then convey to the individual with limited English proficiency, if such approach is sufficient to provide the individual with limited English proficiency meaningful access to the information. ^[192]

Comment: Many commenters supported the requirement in proposed § 92.201(c) that a covered entity provide language assistance services to an individual with limited English proficiency in a timely manner. Some commenters further suggested that the final rule set out specific time frames for the provision of oral interpretation, written translation, and taglines. For instance, some commenters recommended that we revise § 92.201(c) to require oral interpretation immediately upon request, written translations within 30 days after the English version is finalized, and taglines simultaneously with English documents. These commenters asserted that oral telephonic interpretation services should be available, at a minimum, no more than 30 minutes after a covered entity encounters an individual with limited English proficiency.

Response: We decline to include prescriptive timeframes for the provision of language assistance services. There is no one definition of “timely” that applies to every type of interaction with every covered entity at all times. Consequently, consistent with the overarching framework of § 92.201, a determination of whether language assistance services are timely will depend on the specific circumstances of each case. We reiterate our statement from the proposed rule that language assistance is timely when it is provided at a place and time that ensures meaningful access to persons of all national origins and avoids the delay or denial of the right, service, or benefit at issue. ^[193]

Comment: Some commenters suggested that the final rule prohibit the use of computer-automated translation. These commenters suggested that reliance on automated translation is not accurate for the highly specialized vocabulary and terminology used in the health care and health insurance settings, especially for less common non-English languages.

Response: We decline to codify a prohibition on the use of automated translation as part of the final rule because such a requirement may unintentionally stifle innovation in this rapidly developing area. Furthermore, depending on the language at issue as well as the content of the translation, some translation technologies are advantageous to facilitate the translation of written content when used along with a qualified translator who independently verifies the accuracy and quality of the translation. ^[194] For instance, translation memory software stores segments of previously translated phrases and can improve a qualified translator's efficiency, especially when updating documents. ^[195]

We do, however, agree with commenters' concerns regarding the use of some automatic translation technologies, which “is particularly dangerous, and can lead to very serious misunderstandings and adverse consequences for medical documents.” ^[196] For example, machine translation programs translate text by performing simple substitution of words using statistical techniques, which may produce highly unreliable translations for certain languages and written content. ^[197] As a result, using automated translation as the only tool for translating written documents would fulfill a covered entity's obligation under § 92.201(a) only if a qualified translator reviewed the translation for accuracy and edited it as needed. ^[198] OCR encourages covered entities to understand the strengths and weaknesses of the technology and software programs that qualified translators use. ^[199]

Comment: Commenters identified that some covered entities lack policies or practices to confirm or evaluate a staff member's skills as a qualified translator or to serve as a qualified interpreter for an individual with limited English proficiency. For instance, commenters stated that they are aware of situations where individuals who are qualified to interpret—but not translate—are nonetheless translating complex documents such as informed consent forms and discharge instructions. Comments recommended that the final rule require covered entities to evaluate staff members' non-English language proficiency and other skills to ensure that they are qualified before permitting them to interpret, translate, or communicate with individuals with limited English proficiency in the individuals' primary languages.

Response: We share commenters' concerns and, in response, have modified the rule in two ways. First, the final rule requires a covered entity to use a qualified translator for translating written content with respect to its health programs and activities. As the Department stated in its LEP Guidance, “[t]he permanent nature of written translations [] . . . imposes additional responsibility on the recipient to take reasonable steps to determine that the quality and accuracy of the translations permit meaningful access by LEP persons.” ^[200] We broadened the title of § 92.201(d) to reflect that this paragraph now addresses specific requirements for written translation in addition to oral interpreter services. The text in proposed paragraph (d) addressing specific requirements for oral interpretation is now reflected as paragraph (d)(1); new paragraph (d)(2) addresses the use of qualified translators.

Second, we added a new paragraph (4) to § 92.201(e) to restrict covered entities from relying on staff who do not meet the definition of “qualified bilingual/multilingual staff” in § 92.4. In OCR's enforcement experience, covered entities too frequently rely on staff members who possess only a rudimentary familiarity speaking and understanding a non-English language (for example relying on their “high school” level of language proficiency) to communicate with individuals with limited English proficiency. This can result in miscommunication and the omission of relevant information, which can in turn result in a lower standard of care and raise questions about whether consent provided by an individual with limited English proficiency was truly informed. Similarly, we have found that qualified bilingual staff members sometimes serve as interpreters even though they do not possess the non-verbal

skills of interpreting nor adhere to generally accepted principles of interpreter ethics.

Comment: Some commenters recommended that the final rule not restrict covered entities from relying on friends or family of individuals with limited English proficiency to provide oral interpretation, even when the companion is a minor. These commenters noted that some individuals with limited English proficiency prefer to use their companions to interpret; they also observed that minor children are frequently involved in many aspects of their parents' health care; accordingly, commenters stated that awareness of their parents' health care needs may equip children of individuals with limited English proficiency to act as patient advocates for their parents.

In contrast, numerous commenters supported the proposed rule's standards for oral interpretation and the proposed restrictions on certain persons to interpret or facilitate communication. For instance, one health care provider shared that a high risk hospital was unprepared to provide oral interpretation to a woman in labor. The patient's child had to interpret what her mother was saying but the child did not know the proper terminology to understand the provider's medical questions about a fatal high risk condition.

In addition, many commenters who are limited English proficient shared that some covered entities have required individuals to bring their own interpreters, at a cost to the individual. Others shared that family members and children have served as interpreters for them, which has been insufficient because such family members and children do not have the requisite skills to interpret accurately.

Response: We decline to eliminate the specific requirements in § 92.201(d)-(e) of the proposed rule regarding oral interpretation or the restrictions on certain persons to facilitate communication or interpret. Commenters' recommendations run contrary to HHS's longstanding guidance under Title VI ~~[201]~~ and to OCR's experience and enforcement practices. ~~[202]~~ In many circumstances, family members, friends, and especially children, are not competent to provide quality, accurate oral interpretation. For communications of particularly sensitive information, oral interpretation by an individual's family or friend often also implicates issues of appropriateness, confidentiality, privacy, and conflict of interest. Thus, covered entities may not rely on family members, friends, or other informal interpreters to provide language access services unless the situation meets an applicable exception in § 92.201(e)(2)-(3) of the final rule. This exception sufficiently balances an individual's preferences with an interest in ensuring competent language assistance services by allowing individuals to use accompanying adults to interpret in some circumstances.

Comment: One commenter suggested that entities should be exempt from complying with the HIPAA Privacy Rule when providing a qualified interpreter for an individual with limited English proficiency when required under § 92.201(a) of this final rule. Specifically, the commenter was concerned that Section 1557 covered entities would be forced to use or disclose protected health information in violation of the Privacy Rule when engaging interpreter services.

Response: OCR is responsible for enforcing the HIPAA Privacy Rule in addition to the rule implementing Section 1557. We note that, in most instances, a qualified interpreter will be a business associate or a workforce member of the covered entity. If a qualified interpreter is a business associate, a covered entity may disclose protected health information to the qualified interpreter if it obtains satisfactory assurances that the interpreter will use the information only for the purposes for which the interpreter was engaged and will safeguard the information from misuse. Such satisfactory assurances must be in writing and in the form of a contract between the covered entity and the qualified interpreter. If a qualified interpreter is a workforce member of the covered entity, a covered entity may share information with that interpreter as an employee or another type of agent of the entity (*e.g.*, hired through a contract or on the covered entity's staff as a volunteer).

Determining the relationship between the interpreter and the covered entity is a covered entity's HIPAA obligation and is unchanged by Section 1557 or this part. We encourage covered entities to review OCR's HIPAA Frequently Asked Questions (FAQ) regarding business associates at http://www.hhs.gov/ocr/privacy/hipaa/faq/business_associates/760.html, and OCR's HIPAA FAQ regarding interpreters at <http://www.hhs.gov/hipaa/for-individuals/faq/528/can-my-health-care-provider-discuss-my-health-information-with-an-interpreter/>.

Comment: A few commenters suggested that the final rule urge covered entities to provide an in-person qualified interpreter for an individual with limited English proficiency as the default type of oral interpretation. These commenters explained that covered entities should rely on remote interpretation via telephone or video only in urgent situations or if an in-person interpreter is unavailable. These commenters reasoned that use of remote interpretation technologies may miss nuances of the communication and result in less accurate or less comprehensible communication. A few commenters recommended that a covered entity's use of remote interpretation services, via phone or video, be limited to administrative matters that can be addressed in 10 minutes or less. Moreover, in response to comments received in 2013 on OCR's Request for Information on Section 1557, some commenters identified concerns with the use of video remote interpretation services because the video connections used often were of a poor quality.

Response: We believe that commenters' recommendations regarding restrictions on remote oral interpretation are unnecessarily prescriptive and inconsistent with the fact-based, contextualized analysis under Title VI and this final rule. However, in situations where visual cues and other messages depend on physical as well as verbal communication, remote interpretation may not be adequate to provide meaningful access to an individual with limited English proficiency.

To address concerns that video remote interpreting technologies may result in less comprehensible communication, we are setting performance standards in § 92.201(f) of this final rule for video remote interpreting services ~~[203]~~ used for oral interpretation for an individual with limited English proficiency. These standards are designed to achieve parity with the regulation in the disability rights context regarding video remote interpreting technologies. Thus, the standards in § 92.201(f)(1)-(4) of the final rule closely parallel the standards on video remote interpreting services in § 92.202 regarding effective communication for individuals with disabilities, which in turn rely on the standards under Title II for the use of sign language interpreters. ~~[204]~~

Comment: We received a few comments expressing concern about proposed § 92.201(f), re-designated in the final as § 92.201(g), which provides that an

individual with limited English proficiency shall not be required to accept language assistance services offered by a covered entity. Some commenters recommended that proposed § 92.201(f) permit a covered entity to require the presence of a qualified interpreter, even if an individual with limited English proficiency has declined language assistance services.

Commenters suggested that when the individual who declines language assistance services is a patient, the health care provider's ability to accurately diagnose medical conditions is undermined. Commenters similarly stated that when the individual who declines language assistance services is a limited English proficient health care decision-maker for a child, that decision-maker would not be able to appropriately consent to, or participate in, a child's treatment plan. These commenters recommended requiring that a covered entity's insistence on a qualified interpreter be made in a non-coercive and culturally-appropriate manner.

Response: OCR interprets proposed § 92.201(f), which this final rule re-designates as § 92.201(g), to allow a covered entity to use a qualified interpreter when it is a reasonable step to provide an individual with limited English proficiency access to the covered entity's health program or activity. Although an individual with limited English proficiency can decline a qualified interpreter for herself, nothing in the rule is intended to bar a provider from using a qualified interpreter to assist the provider in communicating with, and assuring appropriate treatment to, the individual.^[205] As a result, OCR does not intend for § 92.201(g) of the final rule to restrict a covered entity from using a qualified interpreter in either of the situations commenters raised. We also remind covered entities that, as we stated in the proposed rule, they may not discourage individuals with limited English proficiency from accepting language assistance services.

Comment: Some commenters proposed that OCR regulate the data sources to which covered entities may refer to assess the prevalence of languages spoken by individuals with limited English proficiency in their respective service areas. Commenters also recommended that OCR provide covered entities with resources, such as data-driven maps of languages spoken by limited English proficient populations in their respective service areas, to facilitate covered entities' assessments.

Response: We decline to accept commenters' suggestions, but we support covered entities' efforts to assess the language needs of their respective service areas. An assessment is a foundational best practice for a language assistance services program.^[206] Data sources that may be useful include data from the United States Census Bureau, particularly the American Community Survey; utilization data from the covered entity's files for individuals with limited English proficiency; data from State and local governments; school system data; data from community agencies and organizations; and data from refugee or immigrant serving agencies.^[207] Covered entities, however, are in the best position to determine what local or regional data sources are best suited to their needs. When using any data source, covered entities should look at the reliability, stability, and currency of the data to understand its strengths and weaknesses.

Comment: Many commenters provided feedback on OCR's request for comments on whether the final rule should set thresholds for the non-English languages in which covered entities must provide a range of language assistance services. The majority of comments on this issue focused on thresholds for the translation of vital documents.

Commenters supporting thresholds for written translation suggested that this policy improves access for individuals with limited English proficiency; streamlines OCR's compliance determinations; eliminates ambiguity by providing clear, quantifiable standards for covered entities; is consistent with other Departmental regulations specifying thresholds for written translation; and mitigates the risk that covered entities forgo written translation entirely.

Commenters recommended a variety of thresholds, such as those requiring translation based on the number of languages, percentage of language speakers, or the number of language speakers in a covered entity's service area, or composite thresholds mixing and matching these approaches. Some commenters simply stated that vital documents should be translated into the most commonly encountered languages in a covered entity's service area. Others suggested that OCR codify the threshold for translation of vital documents that is articulated as a safe harbor in the HHS LEP Guidance: translation into languages spoken by at least 1,000 persons or at least 5% of those present in the service area.^[208] Other commenters asserted that numeric thresholds for translation are too rigid to be applied universally, and recommended that the final rule focus on translating materials for certain health programs, such as clinical research or health insurance programs.

Response: Although we have extensively considered whether to include thresholds for written translation and/or oral interpretation as either a safe harbor or as an across-the-board minimum requirement, we decline to set such thresholds in the final rule. First, although thresholds may improve access for some national origin populations, the approach does not comprehensively effectuate Section 1557's prohibition of national origin discrimination. Setting thresholds would be both under-inclusive and over-inclusive, given the diverse range, type, and sizes of entities covered by Section 1557 and the diverse national origin populations within the service areas of entities' respective health programs and activities.

For instance, a threshold requiring all covered entities, regardless of type or size, to provide language assistance services in languages spoken by 5% of a county's limited English proficient population could result in the provision of language assistance services in more languages than the entity would otherwise be required to provide under its obligation in § 92.201(a). This threshold would apply regardless of the number of individuals with limited English proficiency who are eligible to be served or likely to be encountered by the covered entity's health program or activity and regardless of the covered entity's operational capacity. Similarly, this threshold could leave behind significant numbers of individuals with limited English proficiency, served by a covered entity's health program or activity, who communicate in a language that constitutes less than 5% of the county's limited English proficient population.

Although some Departmental regulations set thresholds, those regulations address entities or health programs of similar sizes and types, such as qualified health plan issuers, Marketplaces, Medicare Advantage, and Medicare Part D. In comparison, Section 1557 and this part regulate more diverse types of

covered entities with potentially more diverse limited English proficient populations. We are concerned that significant limited English proficient populations might receive no or inadequate language assistance services under a threshold-based regulation. We are also concerned about the burden an across-the-board translation threshold might place on small covered entities.

Moreover, we value the flexibility inherent in the contextualized approach we have chosen to assess compliance with the requirement to take reasonable steps to provide meaningful access. We thus decline to impose the prescriptive standards recommended by the commenters as inconsistent with this customized regulatory approach.

Comment: We received many comments in response to whether the rule should require enhanced language access obligations for some types of covered entities and if so, what types of entities should be subject to enhanced obligations. Some commenters suggested that enhanced obligations would be appropriate for certain covered entities that offer particularly significant or large health programs or activities, such as the Department, State agencies administering Medicaid or CHIP, Marketplaces, and qualified health plan issuers. These commenters asserted that these covered entities possess both the resources and the means to meet enhanced obligations and that they can leverage economies of scale. The commenters also asserted that imposing enhanced obligations on these entities would benefit smaller entities by making translated documents more widely available.

Commenters also addressed the scope of enhanced language access obligations, suggesting that such obligations should include requiring oral interpretation in at least 150 languages and the translation of documents into languages spoken by individuals with limited English proficiency when such individuals constitute 5% of, or 500 people in, the State population or the covered entity's service area.

A few commenters opposed enhanced language access obligations for certain types of covered entities. Specifically, one commenter asserted that there was no principled reason for retail pharmacies, which the proposed rule listed as an example of a covered entity that could have enhanced obligations under § 92.201, ~~[209]~~ to be subject to enhanced language access obligations.

Response: We reiterate our view that the contextualized approach in § 92.201 best considers both the needs of individuals with limited English proficiency and the potential burden on covered entities. Creating uniform, across-the-board requirements for particular categories of covered entities is, like thresholds, both under-inclusive and over-inclusive. For example, some smaller entities may operate in areas with significant concentrations of individuals with limited English proficiency; these entities may need to provide a broader scope of language assistance services to meet the requirements of § 92.201 than do other entities of similar size in less diverse areas. Similarly, State agencies that administer Medicaid and CHIP programs will differ with respect to the size and diversity of the limited English proficient populations they serve and the resources available to them.

Comment: Some commenters asserted that HHS, other Federal Departments, and States already heavily regulate health insurance issuers covered by Section 1557, thus subjecting them to multiple language access regulations at the State and Federal level. These commenters recommended two policy approaches to streamline Federal and State language access requirements: (1) Harmonize nondiscrimination rules across all Federal and HHS programs to create a national standard; and/or (2) permit a deeming approach that allows compliance with Federal or State language access laws to suffice for compliance with Section 1557, and similarly allow compliance with Section 1557 to suffice for compliance with other Departmental regulations addressing language access. In contrast, numerous commenters supported our fact-specific, contextualized approach and urged consideration of additional factors (*see* discussion *supra*) that would require the more robust provision of language assistance services.

Response: The Department understands the potential for confusion and burden that can be imposed where entities are subject to multiple sets of overlapping requirements. For this reason, we have harmonized, to the extent possible, the tagline requirement in § 92.8(d)(1) with the tagline requirement applying to Marketplaces and qualified health plan issuers under 45 CFR 155.205(c)(2)(iii)(A). ~~[210]~~ We will continue to coordinate as appropriate within HHS and with other Federal departments to ensure that the application and enforcement of requirements under Section 1557 is consistent with other provisions of Federal law or regulations.

However, we decline to adopt an approach that otherwise automatically harmonizes nondiscrimination rules or deems compliance with other laws sufficient for compliance with Section 1557. As we noted above in the discussion of deeming in the General Comments, it is common for entities to be subject to multiple State and Federal regulations, even when some of those regulations have been adopted by a single Federal agency. Indeed, even under CMS regulations for instance, Health Insurance Marketplaces, ~~[211]~~ State agencies administering Medicaid and CHIP programs, ~~[212]~~ and qualified health plan issuers, ~~[213]~~ are subject to multiple differing requirements with regard to language assistance services.

With specific regard to language assistance services, there are likely numerous situations in which a qualified health plan issuer's compliance with the meaningful access provisions of 45 CFR 155.205(c) would suffice to meet the requirements of Section 1557; indeed, there are instances in which 45 CFR 155.205(c) (*e.g.*, requiring that Marketplaces and qualified health plan issuers provide telephonic oral interpretation in 150 languages ~~[214]~~) might require more than would be required in a particular case under the fact-based analysis we adopt for Section 1557. However, we are concerned that there may be cases in which using CMS regulations alone to define a covered health insurance issuer's obligations could leave significant numbers of individuals with limited English proficiency without any, or adequate, access to language services.

In addition, automatically harmonizing requirements imposed on particular entities regulated by both Section 1557 and other laws that the Department enforces would undermine an equally important form of consistency: consistency in enforcement of the standards of Section 1557 and this part across all of the diverse categories of entities covered under the law.

For these reasons and the reasons discussed in the General Comments *supra*, we decline to adopt an approach that automatically deems compliance with CMS or other Federal regulations to be sufficient to demonstrate compliance with Section 1557. However, in circumstances where qualified health plan issuers' compliance with § 92.201 requires steps in addition to those required for compliance with 45 CFR 147.136 or 155.205, OCR will work with

qualified health plan issuers to bring them into compliance with § 92.201. In addition, OCR will consider a qualified health plan issuer's compliance with other applicable regulations in determining the appropriate enforcement action.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the provisions in § 92.201 with several modifications.

In § 92.201(a), we replaced the phrase “that it serves or encounters” with “eligible to be served or likely to be encountered.”

In § 92.201(b), we implemented a technical revision in paragraph (b)(1) and we modified paragraph (b)(2). With respect to the technical revision in paragraph (b)(1), we modified this proposed phrase: “the nature and importance of the health program or activity, including the particular communication at issue, to the individual with limited English proficiency” by replacing “including” with the conjunction “and.” This technical revision clarifies OCR's intent that the particular communication at issue will routinely be a component of the Director's evaluation when the Director gives substantial weight to the nature and importance of the health program or activity. In addition, we modified § 92.201(b)(2) to state that the Director, in evaluating compliance, will take into account all relevant factors, which includes whether a covered entity has developed and implemented an effective written language access plan, appropriate to its circumstances. We eliminated paragraphs (i) through (v) of § 92.201(b)(2).

In § 92.201(d), we broadened the title to reflect that this paragraph now addresses specific requirements for written translation in addition to oral interpretation services. The text in proposed paragraph (d) addressing specific requirements for oral interpretation is now reflected under a new paragraph (d)(1). We added paragraph (d)(2) to require covered entities to use a qualified translator when translating written content in paper or electronic form for its health programs or activities.

In § 92.201(e)(2)(i) and (e)(3), we added “for the individual with limited English proficiency” after “qualified interpreter” to conform to the revision of this term as defined in § 92.4 of the final rule. In addition, we added a new paragraph (e)(4) to address restrictions on a covered entity's use of staff other than qualified bilingual/multilingual staff to communicate directly with individuals with limited English proficiency, in their primary languages.

We re-designated paragraph (f) of § 92.201 in the proposed rule as paragraph (g) of § 92.201 in this final rule, and we added a new paragraph (f). New paragraph (f) provides that when a covered entity uses video remote interpreting services as the means to provide an individual with limited English proficiency oral language assistance, the video remote interpreting technology must meet the standards listed in § 92.201(f)(1)-(4) of this final rule.

Effective Communication for Individuals With Disabilities (§ 92.202)

In § 92.202 of the proposed rule, we proposed to incorporate the provisions governing effective communication with individuals with disabilities found in the regulation implementing Title II of the ADA, which applies to State and local government entities and requires covered entities to ensure that communications with individuals with disabilities are as effective as they are with individuals without disabilities. We noted that OCR typically looks to the ADA for guidance in interpreting Section 504 as the two laws contain very similar standards.

In the proposed rule, OCR considered whether to incorporate the standards in the regulation implementing Title II of the ADA or in the regulation implementing Title III of the ADA, or the standards in both regulations. Standards regarding effective communication under both regulations are very similar. We noted that there are, however, limited differences between the Title II and Title III regulations, regarding limitations on the duty to provide a particular aid or service where doing so may impose undue financial and administrative burdens, and the obligation under the Title II regulation to give primary consideration to the choice of an aid or service requested by the individual with a disability.

OCR proposed to apply the Title II standards to all entities covered under the proposed rule. We noted that although OCR could apply Title II standards to States and local government entities and Title III standards to private entities, we believe it is appropriate to hold all recipients of Federal financial assistance from HHS to the higher Title II standards as a condition of their receipt of that assistance. We also noted that it is appropriate to hold HHS itself to the same standards to which the Department subjects the recipients of its financial assistance.

We also proposed that where the regulatory provisions referenced in § 92.202 use the term “public entity,” that term shall be replaced with “covered entity.”

The comments and our responses regarding § 92.202 are set forth below.

Comment: A few commenters suggested that HHS urge covered entities to consider the gender preferences of patients for interpreters. These commenters suggested that patients may not be comfortable with interpreters of the opposite gender, particularly in settings that involve nudity such as in an obstetrics and gynecology appointment.

Response: We recognize the commenters' privacy concern, but we decline to accept the commenters' suggestion. We believe that identification with a certain gender specified by the patient is not a characteristic necessary to interpret for an individual with a disability or an individual with limited English proficiency. The definitions of qualified interpreter for an individual with a disability and qualified interpreter for an individual with limited English proficiency set forth in § 92.4 require an interpreter who adheres to generally accepted interpreter ethics, which would include respecting a patient's privacy and comporting oneself with discretion and professionalism in sensitive situations such as the settings described by the commenters. We believe that an interpreter of any gender can display these qualities and thus adequately perform the interpretation duties required of him or her. In those cases

where an interpreter is unable to provide interpretation consistent with these standards, the interpreter would be unqualified for those reasons. In addition, acceding to the commenter's request could result in gender discrimination, which contravenes the purpose of other provisions of this rule.

Comment: A few commenters suggested that OCR apply cultural competency standards, such as the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care (CLAS), to entities serving people with disabilities.

Response: Although OCR does not codify the CLAS standards as part of this regulation, OCR agrees that the CLAS standards provide valuable guidance to covered entities regarding the provision of services that are responsive to diverse cultural beliefs and practices, preferred languages, health literacy and other communication needs, and that promote compliance with the final rule. OCR encourages adoption of the CLAS standards by covered entities for interactions with all their patients and not simply for those with disabilities.

Comment: Some commenters suggested that OCR strengthen effective communication regulations by including the proposed provision regarding the restricted use of certain persons to interpret or facilitate communication contained in § 92.201(e) for individuals with limited English proficiency in § 92.202 for individuals with disabilities.

Response: We appreciate the commenters' suggestion, and note that § 92.202 incorporates provisions of the ADA regarding the restricted use of certain persons to interpret or facilitate communication; it is comparable to the provision in the final rule regarding restrictions on the use of certain persons to interpret or facilitate communication with individuals with limited English proficiency.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, including comments regarding the auxiliary aids and services requirement in § 92.101(b)(2)(i) (discussed above), we are finalizing the provisions proposed in § 92.202 by re-designating the existing regulation text at § 92.202 as § 92.202(a), and adding a new subsection, § 92.202(b) requiring covered entities—regardless of the number of people they employ—to provide appropriate auxiliary aids and services to persons with impaired sensory, manual, or speaking skills, where necessary to afford such persons an equal opportunity to benefit from the service in question.

Accessibility Standards for Buildings and Facilities (§ 92.203)

The Section 504 regulatory provisions incorporated into Subpart B in this regulation contain program accessibility requirements that apply to existing facilities as well as new construction and alterations. In § 92.203 of the proposed rule, we proposed to establish specific accessibility standards for new construction and alterations. We noted that these standards are consistent with existing standards under the ADA.

Under paragraph (a), we proposed that each facility or part of a facility in which health programs or activities are conducted that is constructed or altered by or on behalf of, or for the use of, a recipient or State-based MarketplaceSM shall comply with the 2010 ADA Standards for Accessible Design (2010 Standards), as defined in the ADA Title II regulations, ~~42151~~ if construction or alteration was commenced on or after January 18, 2018. We proposed that all newly constructed or altered buildings or facilities subject to this section shall comply with the requirements for a “public building or facility” as defined in Section 106.5 of the 2010 Standards.

We also proposed that new construction and alterations of such facilities would also be subject to the new construction standards found in the Section 504 implementing regulation at [45 CFR 84.23](#)(a) and (b).

Under paragraph (b), we proposed that each facility or part of a facility in which health programs or activities are conducted that is constructed or altered by or on behalf of, or for the use of, a recipient or State-based MarketplaceSM before January 18, 2018 in conformance with UFAS, the 1991 ADA Standards for Accessible Design (1991 Standards), or the 2010 Standards be deemed to comply with the requirements of this section and with [45 CFR 84.23](#) (a) and (b), cross referenced in § 92.101(b)(2)(i) with respect to those facilities. Thus, we proposed that if the construction or alteration of facilities began prior to the effective date of paragraph (a) of this section, the facilities be deemed in compliance if they were constructed or altered in conformance with applicable standards at the time of their construction or alteration.

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

OCR considered adding specific language regarding accessibility standards for medical diagnostic equipment. However, we noted that the United States Access Board is currently developing standards for accessible medical diagnostic equipment and, therefore, we are deferring proposing specific accessibility standards for medical equipment. We further noted that a health program or activity's use of medical diagnostic equipment would be covered by Section 1557 under the general prohibition of discrimination on the basis of disability in § 92.101.

The comments and our responses regarding § 92.203 are set forth below.

Comment: Numerous comments supported requiring immediate compliance with the 2010 ADA Standards for new construction and alterations. Commenters urged that OCR not give covered entities an 18-month grace period for compliance because the 2010 Standards already apply to the vast majority of facilities covered by this proposed rule. They maintained that an approach which emphasizes the uniform application of the 2010 Standards

upon publication of the 1557 rule will enable greater consistency among implementing agencies, given the overlapping jurisdiction that OCR has with the Department of Justice.

Response: OCR agrees with the comments in part. Because the great majority of entities covered by the final rule are already subject to the 2010 Standards, the regulation has been revised to require covered entities that were covered by the 2010 Standards prior to the effective date of this final rule to comply with the 2010 Standards for new construction or alterations that commence on or after the effective date of the final rule. However, there may be some entities covered by the final rule that were not covered by the 2010 Standards prior to the effective date of the final rule. For those entities, application of the 2010 Standards would be new; thus, these entities are given 18 months to comply with the final rule with respect to new construction and alterations. We anticipate that these changes will have only a de minimis impact on cost as nearly all of the entities affected are already subject to the 2010 Standards.

Comment: Numerous commenters recommended that OCR not deem compliance with the UFAS as compliance with Section 1557 for facilities that were constructed or altered prior to 18 months after publication of the final rule. They stated that the UFAS is functionally deficient for people with disabilities; barriers are permitted under the old standard that negatively affect people with mobility and strength disabilities; and, as recognized in the preamble to the proposed rule, nearly all of the facilities covered under the proposed rule are already subject to the 2010 Standards.

Response: OCR appreciates the concern raised by the commenters and agrees with the reasoning underlying the recommendation. OCR has thus modified the language in § 92.203(b) to state that each facility or part of a facility in which health programs or activities are conducted that is constructed or altered by or on behalf of, or for the use of, a recipient or State-based MarketplaceSM in conformance with the 1991 Standards or the 2010 Standards is deemed to comply with the requirements of the final rule with respect to those facilities, if the construction or alteration was commenced before the effective date of the final rule. Conformance with the UFAS will constitute compliance with the requirements of the final rule only with respect to facilities where construction or alteration was commenced before the effective date of the final rule and only where the facility or part of the facility was not covered by the 1991 Standards or 2010 Standards.

Comment: One commenter recommended that OCR limit the facility accessibility requirements to areas of facilities that actually host consumers (patients of providers, in-person enrollees, etc.) and not apply them to covered entities' facilities more generally. The commenter observed that the ADA standards apply to places of public accommodation, and that if a facility is not public-facing, existing ADA requirements for employees already apply and do not need to be incorporated into this rule. The commenter believed that limiting these requirements to public-facing areas of entities would address consumer needs without creating undue financial and administrative burdens. As an example, the commenter stated that many issuers operate call centers that do not provide face-to-face services to their consumers; therefore, the commenter asserted, it is unclear why the call center would need to comply with physical facility accessibility standards.

Response: OCR notes that applying the building accessibility requirement to facilities or parts of facilities not used in any manner by customers or other program beneficiaries in most cases would be inconsistent with the limited application of the final rule to employment and employees. Thus, this provision is interpreted in light of the limitations on coverage of employment in § 92.101(a) (2); as such, the building accessibility requirement does not apply to facilities or parts of facilities that are visited only by employees of the covered entity except as provided in § 92.208. We believe that this approach is consistent with the ACA's goal of increasing consumer access to health care services and with Section 1557's focus on discrimination against patients, enrollees and other beneficiaries in health programs and activities.

However, we also note that the ADA applies to employment and, in addition, that nearly all of the entities subject to the facility access requirements in the final rule are also subject to facility access requirements under Section 504. Complaints of discrimination related to program accessibility can be brought by employees under the ADA and Section 504, and entities should ensure that they are in compliance with accessibility requirements, including the 2010 Standards, under the ADA.

Comment: Several commenters recommended that OCR require covered entities to make each of their existing facilities accessible to and usable by persons with disabilities. These commenters were concerned that if the accessibility requirement is not applied to each individual facility, then a large for-profit insurance carrier could decide that, among the great majority of its providers who operate in existing facilities, only a small percentage need to be physically accessible or have accessible equipment. Moreover, commenters expressed concern that those accessible providers could be clustered together in some central location, and whenever a member called member services and mentioned the need for accessibility, that member would be actively directed toward the more limited subset of accessible provider offices.

Response: The change urged by the commenter would constitute a new requirement that is inconsistent with existing standards under Title II of the ADA and Section 504, neither of which has been interpreted to require each existing facility to be accessible; rather, they require that the recipient operate each program or activity so that, when viewed in its entirety, it is readily accessible to individuals with disabilities.^[216] Thus, we decline to accept the recommendation. We do note that issuers covered by this rule are responsible for ensuring that their health programs provide equal access to individuals without discrimination on the basis of disability. OCR also notes that most providers are recipients of Federal financial assistance from HHS and are themselves independently subject to the nondiscrimination requirements, including program accessibility requirements, in the final rule as well as under Title III of the ADA.

Comment: Some commenters urged that the requirement to comply with accessibility standards be primarily placed on the owners of buildings and facilities, rather than on the providers who rent space. One commenter said that OCR should provide resources and training to small business renters so that they understand what terms in their leases are necessary to ensure that landlords take reasonable responsibility for ensuring their facilities comply with Section 1557.

Response: OCR declines to accept the recommendation to place primary responsibility for compliance with accessibility standards on building owners. Under longstanding legal interpretations of the ADA and Section 504, building owners and lessees each have obligations to refrain from discriminating with respect to program access. OCR also is declining to develop resources and training specifically for small business renters, but notes that the Department of Justice has materials on compliance with accessibility standards under the ADA that may be of use to these entities.^[217] In addition, the ADA National Network in HHS supports ten regional centers that provide information, guidance and training on the ADA through services tailored to meet the needs of business, government and individuals at local, regional and national levels.^[218] OCR also will develop and make available, before the effective date of the final rule, training materials that cover requirements related to accessibility for individuals with disabilities.

Comment: Some commenters urged OCR to exempt entities that are places of public accommodation under Title III of the ADA from the requirements for physical accessibility under Section 1557, stating that additional requirements are confusing and burdensome for small providers. Another commenter recommended that if a health program or activity would not, under Title III of the ADA, be required to be in compliance with a given standard under the 2010 Standards, then the health program or activity should also be exempt from that standard for the purposes of Section 1557 enforcement.

Response: While entities subject to Title III of the ADA include both entities that receive Federal financial assistance and those that do not, the final rule applies only to entities that receive Federal financial assistance, as well as the Department and entities established under Title I of the ACA. We believe it is reasonable to hold entities that receive Federal financial assistance to the accessibility requirements under the final rule, regardless of the standards to which they might be subject under Title III.

Comment: Some commenters said that OCR should require covered entities to make publicly available information on whether medical diagnostic equipment is accessible, so that individuals with disabilities can make informed decisions when choosing a health care provider. A number of commenters recommended that new accessibility standards should be applicable only when physicians upgrade or replace their existing equipment.

Response: As the preamble to the proposed rule noted, standards for accessible medical equipment are in development by the Access Board; thus, OCR is not requiring compliance with specific accessibility standards at this time. In the absence of such standards, covered entities are not in a position to advise or publicize whether their equipment complies with particular standards. Nonetheless, we noted and reiterate here that general accessibility standards that apply to health programs and activities apply to medical equipment, and health service providers must ensure that their health programs and activities offered through the use of medical equipment are accessible to individuals with disabilities.

Summary of Regulatory Changes

For the reasons set forth above and considering the comments received, we have revised § 92.203(a) to state that each covered facility must comply with the 2010 Standards, if the construction or alteration was commenced on or after the effective date of the final rule, except that if a covered facility was not covered by the 2010 Standards prior to the effective date of the final rule, it must comply with the 2010 Standards if the construction was commenced after 18 months after the effective date of the final rule.

For the reasons set forth above and considering the comments received, we have also modified the language in § 92.203(b) to state that each covered facility constructed or altered in conformance with the 1991 Standards or the 2010 Standards will be deemed to comply with the requirements of this section and with **45 CFR 84.23**(a) and (b), cross-referenced in § 92.101(b)(2)(i) with respect to those facilities, if the construction or alteration was commenced before the effective date of the final rule. Further, each covered facility that was constructed or altered in conformance with UFAS will be deemed to comply with the requirements of this section and with **45 CFR 84.23**(a) and (b), cross-referenced in § 92.101(b)(2)(i) with respect to those facilities, if the construction was commenced before the effective date of the final rule and the facility was not covered by the 1991 Standards or 2010 Standards.

Accessibility of Electronic and Information Technology (§ 92.204)

In § 92.204(a), we proposed to require covered entities to ensure that their health programs or activities provided through electronic and information technology are accessible to individuals with disabilities, unless doing so would impose undue financial and administrative burdens or would result in a fundamental alteration in the nature of an entity's health program or activity.^[219] For example, we stated that a Health Insurance MarketplaceSM creating a Web site for application for health insurance coverage must ensure that individuals with disabilities have an equal opportunity to benefit from the Web site's tool that allows comparison of health insurance coverage options, quick determination of eligibility, and facilitation of timely access to health insurance coverage by making its new Web site accessible to individuals who are blind or who have low vision.

We noted that this provision is consistent with existing standards applicable to covered entities. Specifically, Section 508 of the Rehabilitation Act requires that electronic and information technology developed, procured, maintained, or used by Federal agencies be accessible for individuals with disabilities. Section 508 applies to HHS administered health programs or activities, including the Federally-facilitated Marketplaces. Section 504, which applies to recipients of Federal financial assistance, including issuers that receive Federal financial assistance, and Titles II and III of the ADA, which apply to State and local government entities and places of public accommodation, respectively, similarly have been interpreted to require that covered entities' programs, services, and benefits provided through electronic and information technology be accessible to individuals with disabilities.^[220] In addition, some States have adopted Section 508 or Web Content Accessibility Guidelines (WCAG) standards for State agency Web sites or electronic and information technology more broadly.

In paragraph (b), we proposed to require State-based Marketplaces and recipients of Federal financial assistance to ensure that their health programs and activities provided through Web sites comply with the accessibility requirements of Title II of the ADA. We noted that our proposed regulatory text

cross-references the Title II regulations as a whole, therefore incorporating any future changes to the Title II regulations. We also noted that these requirements are informed by the Department's extensive experience with web-based technology through Federal grant-making programs, including programs that provide funds for State infrastructure changes to allow electronic applications for coverage through the Medicaid program and the Health Insurance Marketplaces, provider adoption of electronic health records, and the development of web-based curricula for health care professionals.

In the proposed rule, we explained that based on the Department's prior experience in this field, we believe that including an explicit, rather than implicit, requirement for electronic and information technology is necessary to clarify the obligations of covered entities to make this technology accessible. In addition, we noted that absent an explicit requirement for accessible electronic and information technology, people with disabilities might not have opportunities to participate in services, programs, and activities that are equal to and as effective as those provided to others, further exacerbating existing health disparities for persons with disabilities.

Given the existing requirements under Section 504, Section 508, and the ADA applicable to information provided through electronic and information technology as a whole, and given the importance of technologies, such as kiosks and applications, to access to health care, health-related insurance and other health-related coverage, we proposed to include an explicit accessibility requirement that applies to all of a covered entity's electronic and information technology, rather than to web access only. We sought comment on this proposal.

We also proposed a general accessibility performance standard for electronic and information technology, rather than a requirement for conformance to a specific set of accessibility standards. We provided that the application of this general accessibility performance standard would be informed by future rulemaking by the Access Board and the Department of Justice. We sought comment on whether the regulation should impose a general accessibility performance standard for electronic and information technology or require that electronic and information technology comply with standards developed pursuant to Section 508 by the Access Board,¹²²¹ or the Worldwide Web Consortium's Web Accessibility Initiative's WCAG 2.0 AA.

As noted above, we proposed that covered entities would have a defense to making their health programs and activities provided through electronic and information technology accessible if doing so would impose undue financial and administrative burdens or would result in a fundamental alteration in the nature of the health program or activity. In determining whether an action would impose such undue burdens, we proposed that a covered entity must consider all resources available for use in the funding or operation of the health program or activity.

We noted that when undue financial and administrative burdens or a fundamental alteration are determined to exist, the covered entity is still required to provide information in a format other than an accessible electronic format that would not result in such undue financial and administrative burdens or a fundamental alteration, but would ensure, to the maximum extent possible, that individuals with disabilities receive the benefits or services of the health program or activity that are provided through electronic and information technology.

The comments and our responses regarding § 92.204 are set forth below.

Comment: A few commenters objected to § 92.204's focus on individuals with disabilities. These commenters noted that Section 1557's nondiscrimination mandate guards against discrimination on the basis of race, color, national origin, sex, and age, as well as disability. Therefore, these commenters recommended that OCR state in § 92.204 that covered entities must ensure that their health programs or activities provided through electronic information and technology are accessible to individuals in all protected classes, not just individuals with disabilities.

Response: Section 92.204 addresses the unique accessibility issues for individuals with disabilities. However, § 92.204's focus on disability does not limit the application of general nondiscrimination principles to the accessibility of health programs and activities offered through electronic and information technology to other groups. Thus, the general prohibition of discrimination set forth in § 92.101(a) requires the accessibility of health programs and activities offered through electronic and information technology, without discrimination on the basis of race, color, national origin, sex, age, or disability.

Comment: One commenter expressed concern that many patients and clients lack internet connectivity in their homes and communities. This commenter stated that while providers should design web-based tools and resources that are user-friendly, appropriate, and effective for patients and clients with disabilities, the providers will need to use alternative creative means to meet the needs of those they serve who lack such connectivity in their homes or communities.

Response: OCR recognizes that many persons lack internet connectivity in their homes and communities and may therefore be unable to access web-based tools and resources provided by covered entities, and encourages entities to develop creative means to meet the needs of these individuals.

Comment: Several commenters asked that OCR clarify the scope of the electronic and information technology requirements. Specifically, these commenters asked OCR whether § 92.204's requirements are limited to the provision of health services.

Response: Section 92.204's requirements are coextensive with, and bounded by, the coverage of Section 1557. Thus, the rule requires covered entities to make all health programs and activities provided through electronic and information technology accessible. Accordingly, this requirement reaches activities such as an online appointment system, electronic billing, and comparison of health plans offered by a Health Insurance MarketplaceSM. OCR believes that the regulatory text encompasses this approach.

Comment: A few commenters asked OCR to clarify whether the general requirement under subsection (a) to make health programs and activities that are provided through electronic and information technology accessible applies only to health programs or activities provided through electronic and information technology that are accessed by consumers or also to a covered entity's internal facing electronic information technology. Other commenters urged OCR to limit the application of the general requirement under subsection (a) only to health programs or activities provided through electronic and

information technology that are directly related to the activity that made the organization a covered entity and that are accessed by consumers. Conversely, several other commenters recommended that OCR extend the application of subsection (a) to employees of covered entities.

Response: OCR addressed a similar issue in considering facility access requirements above. There, OCR noted that extending the facility accessibility requirement to facilities not used in any manner by customers or other program beneficiaries in most cases would be inconsistent with the limited application of the final rule to employment and employees. Thus, we noted that the facility accessibility requirement is interpreted in light of the limitations on coverage of employment in § 92.101(a)(2).

Similarly, in considering the application of the requirement in the final rule to accessibility of health programs and activities offered through electronic and information technology, we are mindful that the final rule has limited application to employment and employees. In consideration of this limitation, we clarify that the accessibility requirements in the final rule are limited to health programs and activities offered through electronic and information technology that is used by consumers or other program beneficiaries and do not apply to electronic and information technology that is used only by employees of a covered entity and that does not affect or impact customers or program beneficiaries, except as provided in § 92.208.

We also note that the ADA and Section 504 apply to employment, and virtually all of the entities subject to the requirement for accessibility of health programs and activities offered through electronic and information technology in the final rule are also subject to similar general accessibility requirements in the ADA and Section 504. Entities covered by the final rule should be mindful of their obligations under these other laws.

Comment: Some commenters recommended that OCR require different standards for accessibility of electronic and information technology for entities covered under Title II of the ADA, which applies to State and local government entities, and entities covered under Title III of the ADA, which applies to places of public accommodation and commercial facilities.

Response: OCR declines to apply different standards under the final rule. As noted above, State or local government entities that are covered under Section 1557 are already subject to the Title II standards. In addition, the other entities covered under Section 1557 are health programs and activities that either receive Federal financial assistance from HHS or are conducted directly by HHS. Although OCR could apply Title II standards to States and local entities and Title III standards to private entities, we believe it is appropriate to hold all recipients of Federal financial assistance from HHS to the higher Title II standards as a condition of their receipt of that assistance. As a result, OCR declines to impose different standards as recommended by the commenters. This approach is consistent with our approach to § 92.202, in which we are applying Title II standards to all entities covered under Section 1557 with respect to effective communication.

Comment: One commenter asked that OCR exempt places of public accommodation under the ADA from the requirements to make electronic and information technology accessible. Other commenters suggested that the electronic and information technology requirements in the proposed rule are too confusing and burdensome for small providers.

Response: Places of public accommodation covered under the ADA already are required to make health programs and activities offered through electronic and information technology accessible to individuals with disabilities. The ADA does not exempt small providers from this requirement. Thus, the requirements under this final rule should be familiar to entities covered under the ADA.

Comment: Many commenters recommended that OCR require compliance with the accessibility standards set forth in WCAG 2.0, with Level AA as the minimum benchmark. These commenters suggested that compliance with a specific standard would offer clarity to covered entities and consistency to consumers. These commenters also favored WCAG over Section 508 because WCAG is technology agnostic, meaning it is broken down by function rather than product-type, and can apply to future innovations as well as current uses of technology. These commenters also noted that the Access Board is modeling the refreshed Section 508 standards on WCAG 2.0 Level AA, ensuring that HHS's adoption of such a technical standard guarantees that there will be one, universal set of accessibility benchmarks.

Conversely, one commenter stated that OCR should not impose a specific accessibility standard for electronic and information technology, arguing that a specific standard may slow innovation and the establishment of potentially effective electronic information technology alternatives.

Response: OCR has decided not to adopt specific accessibility standards at this time. Nonetheless, we are still requiring covered entities to ensure that health programs and activities provided through electronic and information technology are accessible to individuals with disabilities, unless doing so would impose undue financial and administrative burdens or would result in a fundamental alteration in the nature of an entity's health program or activity. Thus, when a covered entity chooses to provide a health program or activity through electronic and information technology, the entity must ensure that the technology is accessible as necessary for individuals with disabilities to have equal access to the health program or activity. In our experience, where a covered entity chooses to provide health programs and activities through electronic and information technology, it is difficult to ensure compliance with accessibility requirements without adherence to standards such as the WCAG 2.0 AA standards or the Section 508 standards. Accordingly, OCR strongly encourages covered entities that offer health programs and activities through electronic and information technology to consider such standards as they take steps to ensure that those programs and activities comply with requirements of this regulation and other Federal civil rights laws. Due to the increasing importance of electronic and information technology in health care and health insurance coverage, OCR will continue to closely monitor this area, including developments in the standards developed by the Department of Justice and the Access Board.

Comment: A few commenters asked that OCR give covered entities at least 24 months to come into compliance with the requirements of § 92.204 because they believe there is a significant shortage of available expertise on electronic and information technology. Other commenters recommended that physicians should not be required to comply with new standards until they are ready to upgrade or purchase a new technology product. Still others asked that OCR delay enforcement pertaining to electronic and information technology until health programs and activities can easily select appropriate

accessible technology that has been certified by OCR to comply with established standards for accessible technology.

However, many other commenters urged OCR to reject any requests to delay or phase-in the requirements of § 92.204. These commenters pointed out that § 92.204 builds on and reinforces other longstanding accessibility requirements in Federal law; accordingly, it should not be overly burdensome for covered entities to adjust to the requirements of this rule.

Response: OCR is requiring compliance with the requirements of § 92.204 as of the effective date of this regulation. Section 92.204 largely reflects existing standards under the ADA and Section 504, and accordingly, most covered entities are already required to meet § 92.204's standards. Moreover, and with respect to those few covered entities that were not previously subject to the ADA and Section 504 standards, existing undue burden analysis provides adequate safeguards for covered entities that are unable to comply with the requirements of § 92.204 by the effective date.

Comment: One commenter suggested that the responsibility for redesigning health information and technology to improve accessibility should be placed on software vendors and developers rather than on issuers and providers.

Response: The final rule applies to, among other entities, entities that conduct health programs or activities and that receive Federal financial assistance from HHS. Those entities, consistent with longstanding requirements under the ADA and Section 504, must make health programs and activities offered through electronic and information technology accessible to individuals with disabilities. This obligation is not new. Covered entities are not obligated to redesign health information and technology; accessible technology exists and is available to entities covered by the final rule. Thus, HHS is declining to make the change proposed.

Comment: Several commenters suggested that OCR include a reference to specific ADA regulations requiring effective communication in § 92.204. ¹²²²¹ These commenters noted that some of these regulations are the legal origin of the final rule's statement that covered entities must make health programs and activities provided through electronic and information technology accessible. Although these commenters acknowledged that not all of the regulations concerning auxiliary aids and services will apply in the electronic and information technology context, they believe that the explicit incorporation of relevant aspects of these ADA regulations would inform covered entities of other obligations that they might otherwise overlook, such as the obligation to consult and work with individuals with disabilities as part of the entity's effective communication obligation.

Response: OCR believes that intent is clear in the regulation as written. Although OCR is declining to include a reference to **28 CFR 35.160** and succeeding sections in § 92.204, as proposed by the commenters, these sections are incorporated in § 92.202 of the final rule, addressing effective communication with individuals with disabilities. Covered entities are required to comply with both sections of the final rule.

Comment: A few commenters asked OCR to state that electronic information and technology must be functional so that a person with a disability can enjoy all of the same functionality in an equally effective manner and with substantially equivalent ease of use as a user without a disability.

Response: OCR is clarifying here that a covered entity's electronic and information technology must be functional as necessary to ensure that an individual with a disability has equal access to a covered entity's health program and activity. We believe that the regulatory text encompasses this approach.

Comment: Several commenters called attention to problems that persons with disabilities frequently encounter when attempting to access health care. For example, one commenter pointed out that health care service providers' Web sites often include content like videos with audio components. The commenter noted that these videos often lack closed captioning or American Sign Language (ASL) translations that would make the information provided in the video accessible to people with hearing-related disabilities. Accordingly, this commenter suggested that OCR modify § 92.204 to require covered entities to caption or provide ASL translations of audio-based content on their Web sites so that all audio based content is accessible for deaf and hard of hearing individuals.

Another commenter pointed out that, when blind patients seek treatment at a doctor's office, they are often expected to make appointments or fill out required documentation expected of new patients using an inaccessible online portal. In these situations, the blind patient is forced to rely on a third party for assistance and, regardless of their personal relationship, disclose confidential information to that person such as the patient's medical history, illnesses, medications, and history of disease or genetic patterns running in the patient's family. Accordingly, this commenter asked that OCR clarify that covered entities need to make online portals accessible so that blind individuals have the same level of privacy and confidentiality as other individuals.

Response: Under the final rule, covered entities must ensure that the health programs and activities they offer through electronic and information technology are accessible to individuals with disabilities. OCR is not prescribing specific standards for ensuring accessibility and so declines to adopt the commenters' recommendation. However, OCR notes that under § 92.202(a), which incorporates **28 CFR 35.160(b)(2)**, “[i]n order to be effective, auxiliary aids and services must be provided [to individuals with disabilities] . . . in such a way as to protect the privacy and independence of the individual with a disability.” We further remind covered entities to consider the range of accessibility issues that arise for individuals with disabilities and the technology-based solutions that are available to address these issues. The confidentiality of health information is a critical issue, and covered entities must ensure that the private health information of individuals with disabilities is appropriately protected.

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 § 92.204 without modification.

Requirement To Make Reasonable Modifications (§ 92.205)

In § 92.205, we proposed to require covered entities to make reasonable modifications in policies, practices, or procedures when necessary to avoid discrimination on the basis of disability, unless they can demonstrate that the modification would fundamentally alter the nature of the health program or activity.

We did not receive any significant comments regarding § 92.205. For the reasons set forth in the proposed rule, we are finalizing the provisions proposed in § 92.205 without modification.

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

In § 92.206, we proposed that covered entities be required to provide individuals equal access to their health programs or activities without discrimination on the basis of sex and to treat individuals consistent with their gender identity. We proposed that this provision applies to all covered health programs and activities, and prohibits, among other forms of adverse treatment, the discriminatory denial of access to facilities administered by a covered entity. We noted that this proposed approach is consistent with the principle that discrimination on the basis of sex includes discrimination on the basis of gender identity and that failure to treat individuals in accordance with their gender identity may constitute prohibited discrimination.

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

For clarity and consistency within the final rule, we have made some technical revisions to § 92.206. First, regarding a covered entity being prohibited from denying or limiting health services, we are adding the words “to a transgender individual” after “a covered entity shall treat individuals consistent with their gender identity, except that a covered entity may not deny or limit health services, that are ordinarily or exclusively available to individuals of one gender,” to clarify that the exception is limited to transgender individuals. We note that similar to the discussion in § 92.207(b)(3), we recognize that not every health service that is typically or exclusively provided to individuals of one sex will be a health service that is appropriately provided to a transgender individual. Nothing in the rule would, for example, require a covered entity to provide a traditional prostate exam to an individual who does not have a prostate, regardless of that individual's gender identity. But for health services that are appropriately provided to an individual, the covered entity must provide coverage for those health services on the same terms regardless of an individual's sex assigned at birth, gender identity, or recorded gender. Second, we are deleting the phrase “in a medical record” to address concerns that “medical records” could be understood as referring only to clinical notes of a health care provider.

The comments and our responses regarding § 92.206 are set forth below:

Comment: A majority of commenters strongly supported the requirement that covered entities provide equal access to health programs and activities without discrimination on the basis of sex and treat individuals consistent with their gender identity. Several commenters noted that discrimination in access to gender-specific facilities remains one of the most common and harmful forms of sex-based discrimination against transgender people, singling them out for humiliation and causing them to avoid the use of such facilities and the associated medical care. Numerous commenters strongly encouraged OCR to strengthen § 92.206 with explicit protections for individuals with non-binary gender identities who need access to gender-specific programs and facilities, and to affirm that individuals with non-binary gender identities should be permitted to determine which facilities are appropriate for them.

Response: OCR recognizes the difficulty that individuals with non-binary gender identities may face in accessing gender-specific programs and facilities. The rule makes clear that in order to meet their obligations under § 92.206, covered entities must treat all individuals consistent with their gender identity, including with regard to access to facilities. OCR has revised the definition of “gender identity” to clarify individuals with non-binary gender identities are protected under the rule from all forms of discrimination based on their gender identity. Thus, OCR does not believe that it is necessary to reiterate protections for non-binary individuals in this context.

Comment: Commenters noted that because pregnant women have experienced considerable discrimination in accessing certain health care services such as mental health care and drug treatment services, the final rule should state that equal access without discrimination on the basis of sex includes equal access without discrimination on the basis of pregnancy.

Response: OCR recognizes the difficulty many pregnant people experience in accessing certain health care services. In response to this concern, OCR is clarifying here that the equal program access provision under § 92.206 is simply a specific application of the more general prohibition of discrimination under § 92.101(a). Under both provisions, denial of program access on any of the prohibited bases, including pregnancy or related medical conditions, is prohibited.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the provision as proposed in § 92.206 with technical revisions to clarify our intent and ensure consistency with other parts of the final rule.

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

In § 92.207 of the proposed rule, we provided specific details regarding the prohibition of discrimination on the basis of race, color, national origin, sex, age, or disability in the provision and administration of health-related insurance or other health-related coverage. We proposed that this prohibition applies to all covered entities that provide or administer health-related insurance or other health-related coverage, including health insurance issuers and group health plans that are recipients of Federal financial assistance and the Department in the administration of its health-related coverage programs. We noted that this section is independent of, but complements, the nondiscrimination provisions that apply to the Health Insurance Marketplaces ^[223] and to issuers of qualified health plans ^[224] under other Departmental regulations, and that entities covered under those provisions and Section 1557 are obligated to comply with both sets of requirements.

Based on the longstanding civil rights principles discussed in connection with the definition of “health program or activity” in § 92.4, we proposed to apply this part to all of the coverage and services of issuers that receive Federal financial assistance, whether those issuers' coverage is offered through the Marketplace SM, outside the Marketplace SM, in the individual or group health insurance markets, or as an employee health benefit program through an employer-sponsored group health plan. ^[225] We provided an example illustrating that an issuer participating in the Marketplace SM, and thereby receiving Federal financial assistance, that also offers plans outside the Marketplace SM would be covered by the regulation for all of its health plans, as well as when it acts as a third party administrator for an employer-sponsored group health plan. ^[226]

Paragraph (a) proposed a general nondiscrimination requirement, and paragraph (b) provided specific examples of prohibited actions. Paragraphs (b)(1) and (2) proposed to address the prohibition on denying, cancelling, limiting, or refusing to issue or renew a health-related insurance plan or policy or other health-related coverage, denying or limiting coverage of a claim, or imposing additional cost sharing or other limitations or restrictions, on the basis of an enrollee's or prospective enrollee's race, color, national origin, sex, age, or disability, and the use of marketing practices or benefit designs that discriminate on these bases.

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

In paragraphs (b)(3) through (5) of the proposed rule, we proposed to address discrimination faced by transgender individuals in accessing coverage of health services. We proposed in paragraph (b)(3) that to deny or limit coverage, deny a claim, or impose additional cost sharing or other limitations or restrictions on coverage of any health service is impermissible discrimination when the denial or limitation is due to the fact that the individual's sex assigned at birth, gender identity, or gender otherwise recorded by the plan or issuer is different from the one to which such services are ordinarily or exclusively available. ^[227] Under the proposed rule, coverage for medically appropriate health services must be made available on the same terms and conditions under the plan or coverage for all individuals, regardless of sex assigned at birth, gender identity, or recorded gender.

In addition, we noted that many health-related insurance plans or other health-related coverage, including Medicaid programs, currently have explicit exclusions of coverage for all care related to gender dysphoria or associated with gender transition. Historically, covered entities have justified these blanket exclusions by categorizing all transition-related treatment as cosmetic or experimental. ^[228] However, such across-the-board categorization is now recognized as outdated and not based on current standards of care. ^[229]

OCR proposed to apply basic nondiscrimination principles in evaluating whether a covered entity's denial of a claim for coverage for transition-related care is the product of discrimination. We noted that based on these principles, an explicit, categorical (or automatic) exclusion or limitation of coverage for all health services related to gender transition is unlawful on its face under paragraph (b)(4); in singling out the entire category of gender transition services, such an exclusion or limitation systematically denies services and treatments for transgender individuals and is prohibited discrimination on the basis of sex.

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

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

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

Paragraph (c) of § 92.207 of the proposed rule provided that the enumeration of specific forms of discrimination in paragraph (b) does not limit the general applicability of the prohibition in paragraph (a) of this section. Paragraph (d) of the proposed rule provided that nothing in § 92.207 is intended

to determine, or restrict a covered entity from determining, whether a particular health care service is medically necessary or otherwise meets applicable coverage requirements in any individual case.

The comments and our responses regarding § 92.207 are set forth below.

Comment: Numerous commenters requested clarification regarding the rule's applicability to various health programs or activities that are regulated under other Federal requirements and recommended that OCR deem health programs and activities that comply with existing Federal regulations as in compliance with, or exempt from, Section 1557. For example, commenters requested that compliance with CMS regulations pertaining to qualified health plans or insurance benefit design, such as prescription drug formularies designed by a pharmacy and therapeutics committee, ~~[230]~~ be deemed compliance with the final rule. Numerous commenters also requested that OCR harmonize its language access requirements with existing CMS regulations. This is addressed in the discussion of § 92.201.

In addition, other commenters sought clarification as to the applicability of the rule to wellness programs ~~[231]~~ and value-based insurance designs ~~[232]~~ that are regulated by other Federal departments and agencies, and similarly requested that compliance with other Federal laws regarding these programs be deemed compliance with this final rule. Conversely, regarding employer wellness programs, one commenter wanted OCR to expressly prohibit covered entities from implementing outcomes-based employee wellness programs that base financial rewards or penalties on outcome standards that are coextensive with or directly related to a disability, such as an outcome standard related to high glucose levels, which are directly related to diabetes.

Response: For the same reasons discussed in connection with the General Comments above, ~~[233]~~ we reject the recommendation to deem health programs or activities that comply with other Federal regulations as automatically in compliance with, or exempt from, the final rule. As a general matter, OCR does not view a covered entity's compliance with other Federal regulations, adopted with different requirements and for different purposes, as determinative of a covered entity's compliance with Section 1557 or other Federal civil rights laws that we enforce. Moreover, deeming compliance in this context must be considered in light of the potential harmful consequences to consumers' health that may occur if covered entities do not adhere to civil rights obligations.

While we reject deeming, OCR will consider a covered entity's compliance with other applicable Federal laws in evaluating a covered entity's compliance with this final rule, and will continue to coordinate with other Federal agencies to promote consistency and avoid duplication in enforcement efforts.

Further, we clarify that evidence-based insurance designs and wellness programs offered through covered entities, such as a health insurance issuer or a group health plan that receives Federal financial assistance, are health programs or activities that are subject to the final rule. We decline to expressly prohibit a particular type of practice by wellness programs in the final rule, as complaints will be reviewed on a case-by-case basis. We note that CMS has made clear that covered entities are responsible for ensuring compliance with other applicable Federal and State laws, including nondiscrimination obligations under Federal laws. ~~[234]~~ We remind covered entities that employer-sponsored wellness programs are considered an employee health benefit program and that employers will be subject to liability for discrimination in such programs under the circumstances identified in § 92.208.

Comment: Several commenters expressed concern that covered entities would not be able to revise their health insurance coverage or other health coverage to comply with the regulation within 60 days after publication, and requested that the effective date of the final rule, in particular § 92.207, be delayed until January 1, 2017 or 2018. ~~[235]~~ These commenters explained that health insurance plans are filed for review with CMS and State insurance regulators during the year before the calendar year in which the plan is offered for sale. Thus, depending on the publication date of the final rule, the commenters suggested that delaying the effective date to plan years (in the individual market, policy years) beginning in 2017 or 2018 would be necessary for issuers to avoid the administrative challenges associated with applying the final rule's requirements in the middle of a plan year or policy year, including amending benefit designs, revising premium rates if applicable, and refiling the products for review with CMS and State insurance regulators. In addition, the commenters noted that issuers are not permitted to adjust rates mid-year for some insurance products.

By contrast, one commenter supported maintaining the proposed effective date, arguing that the benefits of more immediate implementation of the final rule outweigh any expenses or confusion associated with mid-year policy revisions.

Response: We appreciate the concerns expressed by the commenters but we are maintaining the effective date as 60 days after the date of publication of the final rule, except in the limited circumstances described below. Section 1557 has been in effect since its passage as part of the ACA in March 2010, and covered entities have been subject to its requirements since that time. To delay implementation of the final rule would delay the existing and ongoing protections that Section 1557 currently provides and has provided since enactment. ~~[236]~~

That said, 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.

Comment: Several commenters representing issuers and large employers recommended that the rule exempt from Section 1557 benefits that constitute excepted benefits under section 2791(c) of the Public Health Service Act (codified at 42 U.S.C. 300gg-91(c)), which generally are exempt from market

reforms under the ACA and HIPAA portability requirements. Excepted benefits include, but are not limited to: limited scope dental and vision plans; coverage only for a specified disease or illness; and Medicare supplemental health insurance (also known as Medigap).^[237] Commenters suggested that being excepted from the ACA market reforms and HIPAA portability requirements should result in exemption from Section 1557. Others stated that covering excepted benefits under the rule would serve as a disincentive to employers to provide these benefits due to increased litigation risk.

Response: We are not exempting benefits excepted from ACA market reforms and HIPAA portability requirements from the final rule. If an issuer providing these benefits receives Federal financial assistance and is principally engaged in providing health benefits, all of its operations will be covered by the rule; if it is not principally engaged, we will apply the rule to its federally funded health programs and activities. Many of the benefits excepted from the ACA market reforms and HIPAA portability rules will meet the definition of “health program and activity.”^[238]

Nothing in the text of Section 1557 limits its coverage only to health programs and activities created or regulated by other provisions of the ACA. Indeed, Section 1557’s incorporation of the four civil rights laws to which it refers, as those laws were amended by the CRRRA, conclusively suggests otherwise. Moreover, Title VI, Section 504, and the Age Act independently apply to these benefits,^[239] and other civil rights laws, such as Title VII, apply to these benefits when they are provided as a fringe benefit of employment by employers covered by that law.

There are several statutorily-defined categories of excepted benefits that are exempt from the ACA market reforms and HIPAA portability requirements if certain conditions are satisfied, such as when medical benefits are incidental or secondary to other insurance benefits, when the benefits are limited in scope or supplemental, or when the benefits are provided as independent, non-coordinated benefits.^[240] Excepted benefits do not provide comprehensive medical coverage and do not satisfy the individual or employer responsibility provisions under the ACA. But these characteristics do not justify an exemption from the requirements of Section 1557, which reflects the fundamental policy that entities that operate health programs and activities, any part of which receives Federal funds, cannot use those funds to discriminate—however broad or narrow the scope of those health programs and activities may be.

Comment: Some commenters requested that OCR address a number of issues that are not within the purview of OCR or Section 1557, including the scope of essential health benefit coverage and establishing minimum network adequacy requirements.

Response: OCR appreciates the commenters’ suggestions, but the commenters’ requests are beyond the scope of this regulation. CMS is statutorily responsible for establishing and regulating the scope of essential health benefits and network adequacy requirements for health insurance issuers. Absent any allegation that a covered entity has discriminated on a basis prohibited by Section 1557, OCR lacks authority to address the terms of these CMS regulations.

Comment: Several commenters asked that OCR exercise more stringent and consistent oversight over consumer access to a wide range of specialists and subspecialists. Commenters pointed out that many qualified health plans in the MarketplaceSM offer network-based plans, and enrollee cost-sharing can be substantially lower when care is delivered by an in-network provider. The commenters expressed concern that some issuers appear to systematically exclude from their provider networks high-cost providers or those in certain high-cost specialties. The commenters suggested that narrow networks could potentially be discriminatory if they deprive patients of reasonable access to a specialty provider or if they discourage enrollment by individuals with specific health needs.

Response: OCR agrees that provider networks with a wide range of specialists and subspecialists are beneficial for consumers and appreciates the concerns expressed about the effect of the exclusion of certain specialists from an issuer’s network. We clarify, however, that it is beyond the scope of this regulation to establish uniform or minimum network adequacy standards. Qualified health plan issuers are subject to network adequacy requirements under CMS regulations.^[241]

Comment: Some commenters asked OCR to clarify that issuers cannot discriminate against providers based on a provider’s protected status. That is, these commenters recommended that OCR make clear that Section 1557’s prohibition of discrimination is not limited in scope to the health care consumer and extends to other entities that may be engaged in health programs and activities.

Response: OCR clarifies that covered entities providing or administering health-related insurance or other health-related coverage may not discriminate against or exclude health care providers they contract with on the basis of the provider’s race, color, national origin, sex, age, or disability. OCR reminds covered entities that they may have obligations under other Federal laws prohibiting discrimination against providers^[242] or against employees.^[243]

Comment: A few commenters asked OCR to amend § 92.207(a) so that it more clearly describes the various activities that a covered entity may perform that are considered “administering” health-related insurance or other health-related coverage. Specifically, these commenters asked that OCR add language to § 92.207(a) explaining that administering health-related insurance or other health-related coverage may include claims processing, rental of a provider network, designing plan benefits or policies, drafting plan documents, processing or adjudicating appeals, administering disease management services, and pharmacy benefit management.

Response: We appreciate the commenters’ suggestion, but we believe the regulatory text is clear as written and does not require further clarification. The term “administering” is broad enough to encapsulate a variety of activities related to the administration of health-related insurance or other health-related coverage.

Comment: We received a number of comments related to the proper handling of claims alleging discrimination in employee health benefit plans that are covered by both this rule and other Federal laws and regulations. For example, several commenters recommended that the rule not apply to the services of third party administrators providing administrative services to self-insured group health plans. These commenters asserted that Congress did not intend

for third party administrators to be covered by Section 1557 and asserted that third party administrators do not design plans, are not responsible for determining the benefits covered under the plan, and are required by ERISA ~~[244]~~ to administer plans as they are written. Commenters also asserted that coverage of third party administrators would indirectly subject self-insured group health plans to Section 1557 and create an unlevel playing field between third party administrators operated by issuers that receive Federal financial assistance and those that do not, thereby creating a disincentive for self-insured group health plans to contract with third party administrators that participate as issuers in the MarketplaceSM and a resulting disincentive for issuers to offer qualified health plans on the MarketplaceSM. These commenters also emphasized that self-insured group health plans are already subject to extensive Federal regulation under ERISA.

Some commenters representing issuers and larger employers also objected to language in footnote 73 ~~[245]~~ in the preamble of the proposed rule stating that when an entity that acts as a third party administrator is legally separate from the issuer that receives Federal financial assistance, we will engage in a case-by-case analysis to determine whether the third party administrator is subject to the rule. These commenters stated that the rule should never extend beyond the legal entity that receives the Federal financial assistance.

Response: We are not excluding third party administrator services from the final rule; however, we are adopting specific procedures to govern the processing of complaints against third party administrators.

Third party administrator services are undeniably a health program or activity, as they involve the administration of health services. Under the final rule, if an entity that receives Federal financial assistance is principally engaged in providing or administering health services, health insurance coverage, or other health coverage, then, consistent with the approach taken under the civil rights laws referenced in Section 1557 and under the CRRRA, as discussed *supra*, ~~[246]~~ all of its operations are covered. Thus, if an issuer that receives Federal financial assistance is principally engaged in providing health insurance and also provides third party administrator services, there is no principled basis on which to exclude the law's application to the third party administrator services or to treat them differently from other entities and services covered by the rule.

Commenters' assertion that employers or group health plans may have an incentive to contract with third party administrators that are operated by entities that do not receive Federal financial assistance does not justify exempting third party administrator services from the rule. Commenters' rationale would undermine the application of all of the civil rights laws that attach obligations to the receipt of Federal financial assistance; if any competitive disparity exists here, it is no different than in other types of businesses in which some entities receive Federal financial assistance and others do not.

Moreover, the fact that third party administrators are governed by other Federal laws such as ERISA is not a reason to exempt them from Section 1557. ERISA itself explicitly preserves the independent operation of civil rights laws, by providing that nothing in ERISA "shall be construed to alter, amend, modify, invalidate, impair, or supersede any law of the United States . . . or any rule or regulation issued under any such law." ~~[247]~~ And in any event, the fact that entities are subject to regulation under other Federal statutory schemes adopted for other purposes does not justify insulating them from the obligation to comply with civil rights requirements. ~~[248]~~

Commenters expressed a number of concerns related to the relationship between third party administrators and the employers whose self-insured group health plans they administer. OCR clarifies here that, contrary to the understanding of some commenters, Section 1557's coverage of a third party administrator under the rule does *not* extend to the coverage of an employer providing a group health plan that is being administered by the third party administrator. The rule addresses employer liability separately from that of issuers that receive Federal financial assistance; ~~[249]~~ under Section 1557, an employer is liable for discrimination in its employee health benefit programs only if the employer is principally engaged in health services, health insurance coverage, or other health coverage, or otherwise satisfies one of the criteria set forth in § 92.208. Whether an employer's group health plan is administered by a third party administrator that is a covered entity is not relevant in this analysis.

In response to commenters' arguments on this point, however, OCR recognizes that third party administrators are generally not responsible for the benefit design of the self-insured plans they administer and that ERISA (and likely the contracts into which third party administrators enter with the plan sponsors) requires plans to be administered consistent with their terms. ~~[250]~~ Thus, if a plan has a discriminatory benefit design under Section 1557, a third party administrator could be held responsible for plan features over which it has no control.

Based on these comments, OCR is adjusting the way in which it will process claims that involve alleged discrimination in self-insured group health plans administered by third party administrators that are covered entities. Fundamentally, OCR will determine whether responsibility for the decision or other action alleged to be discriminatory rests with the employer or with the third party administrator. Thus, where the alleged discrimination is related to the administration of the plan by a third party administrator that is a covered entity, OCR will process the complaint against the third party administrator because it is that entity that is responsible for the decision or other action being challenged in the complaint. Where, for example, a third party administrator denies a claim because the individual's last name suggests that she is of a certain national origin or threatens to expose an employee's transgender or disability status to the employee's employer, OCR will proceed against the third party administrator as the decision-making entity. Where, by contrast, the alleged discrimination relates to the benefit design of a self-insured plan—for example, where a plan excludes coverage for all health services related to gender transition—and where OCR has jurisdiction over a claim against an employer under Section 1557 because the employer falls under one of the categories in § 92.208, OCR will typically address the complaint against that employer.

As part of its enforcement authority, OCR may refer matters to other Federal agencies with jurisdiction over the entity. Where, for example, OCR lacks jurisdiction over an employer responsible for benefit design, OCR typically will refer or transfer the matter to the EEOC and allow that agency to address the matter. The EEOC has informed OCR that, provided the filing meets the requirements for an EEOC charge, the date a complaint was filed with OCR will be deemed the date it was filed with the EEOC (although any subsequent denial of a renewed coverage request could be separately challenged by a timely complaint).

This approach is consistent with our efforts to ensure coordination with other Federal agencies that can also exercise jurisdiction over the subject of a particular complaint. Thus, we will also coordinate with the Office of Personnel Management (OPM) in the handling of claims alleging discrimination in the Federal Employees Health Benefits (FEHB) Program. OPM is charged by Federal statute ~~[251]~~ with offering FEHB plans as a fringe benefit of Federal employment and, in that role, approves benefit designs and premium rates, sets rules generally applicable to FEHB carriers, adjudicates and orders payment of disputed health claims, and adjusts policies as necessary to ensure compliance with nondiscrimination standards. As a result, OCR will refer to OPM complaints that allege discrimination in the FEHB Program where OPM is the entity with decision-making authority over the challenged action; OPM will treat these claims as complaints filed against OPM and will seek relief comparable to that available were these claims to be processed by OCR under Section 1557.

In response to the comments requesting additional clarification on footnote 73 in the proposed rule, we reiterate that we will engage in a case-by-case inquiry to evaluate whether a third party administrator is appropriately subject to Section 1557 as a recipient in situations in which the third party administrator is legally separate from an issuer that receives Federal financial assistance for its insurance plans. This analysis will rely on principles developed in longstanding civil rights case law, such as the degree of common ownership and control between the two entities, ~~[252]~~ and will also examine whether the purpose of the legal separation is a subterfuge for discrimination—that is, intended to allow the entity to continue to administer discriminatory health-related insurance or other health-related coverage. ~~[253]~~ But we note that a third party administrator is unlikely to be covered by this final rule where it is a legal entity that is truly independent of an issuer's other, federally funded, activities.

Comment: Commenters requested clarification on OCR's approach when evaluating whether a prohibited discriminatory action occurred under § 92.207(b).

Response: We clarify that OCR's approach in applying basic nondiscrimination principles, as discussed in the proposed rule under § 92.207(b)(5) ~~[254]~~ relating to coverage for specific health services related to gender transition, is the same general approach that OCR will take when evaluating denials or limitations of coverage for other types of health services. In other words, OCR will evaluate whether a covered entity utilized, in a nondiscriminatory manner, a neutral rule or principle when deciding to adopt the design feature or take the challenged action or whether the reason for its coverage decision is a pretext for discrimination. For example, if a plan limits or denies coverage for certain services or treatment for a specific condition, OCR will evaluate whether coverage for the same or a similar service or treatment is available to individuals outside of that protected class or those with different health conditions and will evaluate the reasons for any differences in coverage. Covered entities will be expected to provide a neutral, nondiscriminatory reason for the denial or limitation that is not a pretext for discrimination.

Comment: One commenter asked OCR to clarify that targeted marketing practices designed to reach certain populations to increase enrollment, such as specific segments of those who are uninsured or underserved, are not considered discriminatory. This commenter pointed out that some issuers sometimes launch targeted campaigns to reach a high number of uninsured in their service areas. In so doing, issuers may study the profile of uninsured populations, and based on the results of that study, may concentrate their marketing efforts on certain demographic groups that are disproportionately uninsured or underserved. The commenter cited a Gallup Poll that indicated that roughly one-third of Hispanics remain uninsured, which the commenter stated creates a particular need for issuers to help educate and expand coverage for this community. The commenter sought reassurance that OCR will not consider it discriminatory to target enrollment efforts where they will make the most difference.

Response: Congress intended the ACA to help uninsured and underserved populations gain access to care. Nothing in this regulation is intended to limit targeted outreach efforts to reach underserved racial or ethnic populations or other underserved populations. Indeed, it is OCR's intention that this regulation will increase access for uninsured and underserved populations, much as other Departmental regulations implementing the ACA have strived to do. ~~[255]~~

Comment: Several commenters recommended that we define “marketing practices” in the regulatory text of § 92.207(b)(2). These commenters suggested that the inclusion of a precise definition for “marketing practices” would serve to clarify the scope of § 92.207(b)(2).

Response: We decline to define “marketing practices” in the final rule because to do so would be overly prescriptive. We emphasize, however, that we intend to interpret the term “marketing practices” broadly; such practices would include, for example, any activity of a covered entity that is designed to encourage individuals to participate or enroll in the covered entity's programs or services or to discourage them from doing so, and activities that steer or attempt to steer individuals towards or away from a particular plan or certain types of plans. We remind covered entities that other Departmental regulations address marketing practices, ~~[256]~~ and covered entities are obligated to comply with all applicable Federal and State laws regarding such practices.

Comment: Many commenters recommended that we define “benefit design” in the regulatory text of the final rule. These commenters suggested that the inclusion of a precise definition of “benefit design” would serve to clarify the scope of § 92.207(b)(2). In addition, numerous commenters requested that we codify or provide examples of benefit designs that discriminate on the basis of race, color, national origin, sex, age, or disability. A number of commenters urged OCR to consider specific types of benefit designs as constituting per se discrimination under § 92.207(b)(2) of the final rule.

Response: We appreciate commenters' requests for guidance and clarification regarding potentially discriminatory benefit designs and suggestions for scenarios that constitute per se discrimination. However, we decline to define “benefit design” in the final rule because to do so would be overly prescriptive. ~~[257]~~ We also decline to codify examples of discriminatory benefit designs because determining whether a particular benefit design results in discrimination will be a fact-specific inquiry that OCR will conduct through its enforcement of Section 1557. For the same reason, we avoid characterizing specific benefit design practices as per se discriminatory in the final rule. ~~[258]~~

OCR will analyze whether a design feature is discriminatory on a case-by-case basis using the framework discussed above. We reiterate that our

determination of whether a practice constitutes discrimination will depend on our careful analysis of the facts and circumstances of a given scenario. OCR recognizes that covered entities have discretion in developing benefit designs and determining what specific health services will be covered in their health insurance coverage or other health coverage. The final rule does not prevent covered entities from utilizing reasonable medical management techniques; nor does it require covered entities to cover any particular procedure or treatment. It also does not preclude a covered entity from applying neutral, nondiscriminatory standards that govern the circumstances in which it will offer coverage to all its enrollees in a nondiscriminatory manner. The rule prohibits a covered entity from employing benefit design or program administration practices that operate in a discriminatory manner.

Comment: We received a number of comments requesting that OCR add language to § 92.207(b) clarifying that categorical exclusions of certain conditions, such as coverage related to developmental disabilities or maternity care, are prohibited.

Response: While categorical exclusions of all coverage related to certain conditions could raise significant compliance concerns under Section 1557, OCR believes that existing regulatory language is sufficient to address this scenario. For example, the law has long recognized that discrimination based on pregnancy is a form of sex discrimination,^[259] and OCR has interpreted Section 1557 in the same manner by defining the term “on the basis of sex” in this regulation to include “discrimination on the basis of pregnancy, false pregnancy, termination of pregnancy, or recovery therefrom, childbirth or related medical conditions.” As a result, it is unnecessary to add language in response to commenters' concerns.

We note that some products known as excepted benefits, which are subject to this final rule as discussed *supra*, provide limited scope benefits or coverage only for a specified disease or illness.^[260] It would not be discriminatory for such products to include exclusions of coverage for conditions that are outside the scope of the benefits provided in those products. Accordingly, the purpose and scope of the coverage provided under health-related insurance or health-related coverage are factors that OCR will consider in determining whether an exclusion of all coverage for a certain condition is discriminatory under this final rule.

Comment: In light of OCR's statement in the preamble to the proposed rule that “[t]he proposed rule does not require plans to cover any particular benefit or service, but a covered entity cannot have a coverage policy that operates in a discriminatory manner,”^[261] a few commenters asked OCR to clarify that the solution to a potentially discriminatory benefit design could be addition of coverage for a benefit or service.

Response: OCR agrees that the solution to a potentially discriminatory benefit design could be coverage, or added coverage, of a benefit or service.

Comment: The proposed rule invited comment as to whether the approach of § 92.207(b)(1)-(5) is over- or under-inclusive of the types of potentially discriminatory claim denials experienced by transgender individuals in their attempts to access coverage and care, as well as on how nondiscrimination principles apply in this context.^[262] Many commenters supported OCR's approach in prohibiting a range of practices that discriminate against transgender individuals by denying or limiting coverage for medically necessary and medically appropriate health services. Numerous commenters asserted that the protections at § 92.207(b)(3)-(5) are vital to ensuring that transgender individuals are able to access the health coverage and care they need and urged OCR to preserve these provisions in the final rule.

For instance, many commenters strongly supported the proposed rule's prohibition against categorical or automatic exclusions of coverage for all health services related to gender transition. These commenters further supported the proposed rule's prohibition against otherwise denying or limiting coverage, or denying a claim, for health services related to gender transition if such a denial or limitation results in discrimination against a transgender individual. These commenters expressed hope that these prohibitions will serve to eliminate the significant barriers that transgender individuals have faced in accessing coverage for transition-related care, such as counseling, hormone therapy, and surgical procedures that they said had previously been denied to them because they have been viewed as cosmetic or experimental. Many commenters also favored the prohibition against denying, limiting, or otherwise restricting coverage for health services that are ordinarily or exclusively available to individuals of one sex based on an individual's gender identity. Commenters indicated that the proposed rule's protections will help to resolve various health care disparities suffered by transgender individuals.

Several commenters, however, opposed the protections that the proposed rule affords to transgender individuals. Some commenters suggested that covered entities should be permitted to categorically exclude coverage for transition-related health services based on moral or religious convictions that an individual's biological sex, or sex assigned at birth, should not be altered. Other commenters suggested that OCR is exceeding its legal authority by addressing covered entities' provision of coverage to transgender individuals because discrimination based on gender identity should not be recognized as a form of sex discrimination.

Response: We agree with the commenters who expressed their general support of the protections for transgender individuals afforded by the provisions at § 92.207(b)(3)-(5), and therefore we are keeping the provisions as proposed. We believe that it is important to ensure that civil rights protections are extended to transgender individuals to afford them equal access to health coverage, including for health services related to gender transition. As we stated in the preamble to the proposed rule, the across-the-board categorization of all transition-related treatment, for example as experimental, is outdated and not based on current standards of care.^[263]

Further, we disagree with commenters who asserted that sex-based discrimination does not include discrimination based on gender identity. As discussed previously,^[264] OCR's definition of discrimination “on the basis of sex” is consistent with the well-accepted interpretations of other Federal agencies and courts. Further, as previously noted in this preamble,^[265] we decline to adopt a blanket religious exemption in the final rule as any religious concerns are appropriately addressed pursuant to pre-existing laws such as RFRA and provider conscience laws.

Comment: A significant number of commenters recommended that OCR revise the language in § 92.207(b)(4) that prohibits categorical exclusions or limitations of “all health services related to gender transition” to remove the word “all,” and proposed modifications to § 92.207(b)(3)-(5) relating to the