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CLIENT ALERT

Nondiscrimination Standards Under ACA Section 1557: Now Is the Time to Act

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Key Implementation Elements of the Final Rule

Who: A health program or activity, any part of which receives federal financial assistance, and any program or activity administered by an executive agency or an entity established under Title I of the Affordable Care Act

What: An individual may not be excluded from participation in, denied the benefits of, or otherwise subjected to discrimination on the basis of race, color, national origin, sex, age, or disability in, certain health programs and activities

When: Effective ***July 18, 2016***, unless 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) are required—in which case, provisions will apply on the first day of the first plan year (or policy year in the individual market) beginning ***on or after January 1, 2017***

Health insurers and group health plan sponsors must closely review the final rule titled "Nondiscrimination in Health Programs and Activities" ("Final Rule") implementing Section 1557 of the Affordable Care Act ("ACA") that was published by the U.S. Department of Health and Human Services ("HHS") on May 18, 2016.[1] Section 1557 prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs and activities. To address issues of discrimination in the health programs and activities of certain "Covered Entities" (defined below), the Final Rule clarifies and codifies existing nondiscrimination requirements and sets forth new standards to implement Section 1557, particularly with respect to the prohibition of discrimination on the basis of sex.

The Final Rule became effective on July 18, 2016; however, for those insurance issuers or group health plans that must alter their plan benefit designs based on the Final Rule, the effective date is the first day of the first plan or policy year on or after January 1, 2017. Regardless of the date and mechanism through which the Final Rule applies to you, now is the time to ensure that you understand the rule's requirements and implement needed policy or operational changes.

[1] 81 Fed. Reg. 31,375 (May 18, 2016), *available at* https://www.gpo.gov/fdsys/pkg/FR-2016-05-18/pdf/2016-11458.pdf.

Definitions

HHS, through such agencies as the Health Resources and Services Administration ("HRSA"), the Substance Abuse and Mental Health Services Administration ("SAMHSA"), the Centers for Disease Control and Prevention ("CDC"), and the Centers for Medicare & Medicaid Services ("CMS"), provides federal financial assistance via various mechanisms to health programs and activities of local governments, state governments, and the private sector.

"Federal financial assistance" includes grants, loans, subsidies, contracts of insurance, and other types of assistance. Such assistance also includes premium tax credits and advance payments of premium tax credits and cost-sharing reductions for health insurance coverage purchased through the Health Insurance Marketplaces.[2]

"Covered Entities" that are subject to the non-discrimination provisions in the Final Rule include:

- Entities receiving federal financial assistance through their participation in Medicare **(excluding Medicare Part B[3])** or Medicaid—for example:
    - short-term, rehabilitation, psychiatric, and long-term hospitals
    - facility-based and freestanding skilled nursing facilities/nursing facilities
    - home health agencies
    - physical therapy/speech pathology programs
    - end-stage renal disease dialysis centers
    - intermediate care facilities for individuals with intellectual disabilities
    - rural health clinics
    - independent practice physical therapy
    - comprehensive outpatient rehabilitation facilities
    - ambulatory surgical centers
    - hospices
    - organ procurement organizations
    - community mental health centers
    - Federally Qualified Health Centers
- Hospital-based, office-based, or freestanding laboratories that receive federal financial assistance through Medicaid payments for covered laboratory tests
- Community health centers receiving federal financial assistance through grant awards from HRSA

[2] An issuer participating in a Health Insurance Marketplace is receiving federal financial assistance, but a health care provider that contracts with such an issuer does not become a recipient of federal financial assistance by virtue of the contract. Similarly, physicians who contract to provide health services to hospitals or clinics that receive federal financial assistance do not become a recipient of federal financial assistance by virtue of the contract. However, many health care providers are expected to be subject to Section 1557 due to federal financial assistance that they receive in their own right.

[3] HHS does not consider Medicare Part B payments to physicians to be federal financial assistance.

- Health-related schools in the United States and other health education entities receiving federal financial assistance through grant awards to support health professional training programs that include oral health, behavioral health, medicine, geriatric, and physician's assistant programs

- State Medicaid agencies receiving federal financial assistance from CMS to operate the Medicaid Program, the Children's Health Insurance Program ("CHIP"), and the Basic Health Program

- State public health agencies receiving federal financial assistance from CDC, SAMHSA, and other HHS components

- Health Insurance Marketplaces established under Title I of the ACA (including 17 State-Based Marketplaces and 34 Federally Facilitated Marketplaces)

- Qualified health plan issuers receiving federal financial assistance through advance payments of premium tax credits and cost-sharing reductions (which include the health insurance issuers in the Federally Facilitated Marketplaces receiving federal financial assistance through advance payments of premium tax credits and cost-sharing reductions and issuers operating in the State-Based Marketplaces)

- Physicians receiving federal financial assistance through Medicaid payments, "meaningful use" payments,[4] and other sources

The term ''health program or activity'' means "the provision or administration of health-related services, health-related insurance coverage, or other health-related coverage, and the provision of assistance to individuals in obtaining health-related services or health-related insurance coverage."[5] For a Covered Entity that is principally engaged in providing or administering health-related services, health-related insurance coverage, or other health-related coverage, all of its operations are considered part of the health program or activity, including the provision of an employee health benefit program or wellness program to its employees.[6] Accordingly, if any part of a health care entity receives federal financial assistance, then all of its programs and activities are subject to the non-discrimination provisions in the Final Rule. However, the Final Rule does not apply to actions against a Covered Entity's own employees, including actions related to hiring, firing, promotion, or terms and conditions of employment.

Application of the Nondiscrimination Provisions

The core objective of Section 1557 is to prohibit discrimination in "any health program or activity" on the grounds prohibited under Title VI of the Civil Rights Act of 1964[7] (race,

[4] The Medicare Access and CHIP Reauthorization Act sunsets the "meaningful use" payment adjustments for Medicare physicians after 2018.
[5] 45 C.F.R. § 92.4 (effective July 18, 2016).
[6] *See* 45 C.F.R. § 92.208 (effective July 18, 2016).
[7] 42 U.S.C. 2000d *et seq*.

color, or national origin), Title IX of the Education Amendments of 1972[8] (sex), the Age Discrimination Act of 1975[9] (age), and Section 504 of the Rehabilitation Act of 1973[10] (disability). The Final Rule is not intended to apply a lesser standard for the protection of individuals from discrimination than the standards and regulations already applied under these laws. Further, nothing in the Final Rule is intended to be interpreted to invalidate or limit the existing rights, remedies, procedures, or legal standards available to individuals aggrieved under other federal civil rights laws or to supersede state or local laws that provide greater or equal protection against discrimination on the basis of race, color, national origin, sex, age, or disability. The HHS Office of Civil Rights ("OCR"), the agency responsible for enforcing Section 1557, concludes that the regulations promulgated in the Final Rule preempt state law only where the exercise of state authority directly conflicts with or prevents the application of the Final Rule.

HHS did not include a blanket religious exemption in the Final Rule; however, the Final Rule includes a provision noting that, insofar as the application of any requirement under the rule would violate applicable federal statutory protections for religious freedom and conscience, such application would not be required.[11] Further, HHS allows for sex-specific health programs or activities, but only where the Covered Entity can demonstrate an exceedingly persuasive justification (i.e., that the sex-specific program is substantially related to the achievement of an important health-related or scientific objective).[12]

HHS establishes numerous requirements for Covered Entities under the Final Rule. For example, a Covered Entity:

- must take reasonable steps to provide meaningful access to each individual with limited English proficiency;

- must take appropriate steps to ensure that communications with individuals with disabilities are as effective as communications with others in health programs and activities;

- if covered by the 2010 Americans with Disabilities Act ("ADA") Standards for Accessible Design prior to July 18, 2016, must comply with those standards for new construction or alterations by July 18, 2016, and compliance with the Uniform Federal Accessibility Standards will be deemed compliance with the Final Rule only if construction or alteration was commenced before July 18, 2016, and the facility or part of the facility was not covered by standards under the ADA;

- must ensure that its health programs or activities provided through electronic and information technology are accessible to individuals with disabilities, unless doing

[8] 20 U.S.C. 1681 *et seq*.
[9] 42 U.S.C. 6101 *et seq*.
[10] 29 U.S.C. 794.
[11] 45 C.F.R. § 92.2 (effective July 18, 2016).
[12] 45 C.F.R. § 92.101(b)(iv) (effective July 18, 2016).

so would result in undue financial and administrative burdens or a fundamental alteration in the nature of the health programs or activities;

- must provide individuals equal access to its health programs or activities without discrimination on the basis of sex and must treat individuals consistent with their gender identity;

- must not discriminate on the basis of race, color, national origin, sex, age, or disability when providing or administering health-related insurance or other health-related coverage;

- will be liable for violations of the Final Rule in any employee health benefit program that it provides to its employees and/or their dependents; and

- must not exclude from participation in, deny the benefits of, or otherwise discriminate against an individual or entity in, its health programs or activities on the basis of the race, color, national origin, sex, age, or disability of an individual with whom the individual or entity is known or believed to have a relationship or association.[13]

Actions That Covered Entities Must Take to Comply with the Final Rule

Each entity applying for federal financial assistance, each issuer seeking certification to participate in a Health Insurance Marketplace, and each state seeking approval to operate a State-Based Marketplace is required to submit an ***assurance*** that its health programs and activities will be operated in compliance with Section 1557.[14]

Each Covered Entity that employs 15 or more persons must designate at least one employee to ***coordinate compliance*** with the requirements of the Final Rule.[15] A Covered Entity that has already designated a responsible employee pursuant to the regulations implementing Section 504 or Title IX may use that individual to coordinate its efforts to comply with Section 1557.

Further, a Covered Entity that employs 15 or more persons must adopt a ***grievance procedure*** that incorporates appropriate due process standards and allows for the prompt and equitable resolution of complaints concerning actions prohibited by Section 1557.[16] HHS clarifies that an individual does not have to exhaust a Covered Entity's grievance procedure prior to filing a Section 1557 complaint. Additionally, HHS clarifies that a Covered Entity that already has a grievance procedure addressing claims of disability discrimination that meets the standards established under the Section 504 regulation may use that procedure to address disability claims under Section 1557. A Covered Entity may use that procedure to address all other Section 1557 claims, provided that the Covered Entity modifies the procedure to apply to race, color, national

[13] *See* 45 C.F.R. §§ 92.201-209 (effective July 18, 2016).
[14] 45 C.F.R. § 92.5 (effective July 18, 2016).
[15] 45 C.F.R. § 92.7(a) (effective July 18, 2016).
[16] 45 C.F.R. § 92.7(b) (effective July 18, 2016).

origin, sex, and age discrimination claims. HHS provides an example of how to structure a grievance procedure in Appendix C of the Final Rule.[17]

A Covered Entity must take appropriate initial and continuing steps to ***notify*** beneficiaries, enrollees, applicants, or members of the public of individuals' rights under Section 1557 and of Covered Entities' nondiscrimination obligations with respect to their health programs and activities.[18] Specifically, a Covered Entity's notice must include the following statements and information:

- The Covered Entity does not discriminate on the basis of race, color, national origin, sex, age, or disability
- The Covered Entity provides appropriate auxiliary aids and services, free of charge and in a timely manner, to individuals with disabilities
- The Covered Entity provides language assistance services, free of charge and in a timely manner, to individuals with limited English proficiency
- How an individual can access such aids and services referenced above
- The contact information for the responsible employee coordinating compliance with Section 1557 (when required)
- The availability of a grievance procedure (when required), and how to file a grievance
- How an individual can file a discrimination complaint with HHS

This notice must be posted in significant publications and communications, in conspicuous physical locations, and on the Covered Entity's website by ***October 16, 2016*** (90 days from the effective date of the Final Rule). HHS provides a sample notice and non-discrimination statement in Appendix A of the Final Rule.[19] Covered Entities may use the sample notice or they may develop their own. Covered Entities are encouraged, but not required, to post the notice in one or more of the most prevalent non-English languages frequently encountered in their geographic service areas. Further, Covered Entities may combine the required content of the notice with the content of other required notices, as long as the combined notice clearly informs individuals of their civil rights under Section 1557. However, a Covered Entity's compliance with the notification requirements in the Final Rule does not constitute compliance with the notice requirements of other federal civil rights laws, such as Title IX and Section 504.

[17] 81 Fed. Reg. at 31,473.
[18] 45 C.F.R. § 92.8(a) (effective July 18, 2016).
[19] 81 Fed. Reg. at 31,472.

Covered Entities must also post by ***October 16, 2016,*** taglines in at least the top 15 languages spoken by individuals with limited English proficiency in the state or states where the Covered Entity operates.[20] HHS provides a sample tagline in Appendix B of the Final Rule.[21] Covered Entities may develop their own taglines, and they may choose to include taglines in more than 15 languages. Further, for significant publications and significant communications that are small-sized, Covered Entities must include the non-discrimination statement (in lieu of the full notice) and taglines in at least the top two languages spoken by individuals with limited English proficiency in the relevant state or states. OCR has posted translated resources in 65 languages, including a notice of nondiscrimination, a statement of nondiscrimination, and taglines, on its website for Covered Entities to use.[22]

A recipient of federal financial assistance or State-Based Marketplace that has been found to have discriminated on any of the bases prohibited by Section 1557 will be required to take ***remedial action*** to overcome the effects of that discrimination.[23] Further, a Covered Entity may take ***voluntary action*** in the absence of a finding of discrimination to overcome the effects of conditions that result or resulted in limited participation by persons based on race, color, national origin, sex, age, or disability.[24]

Equal Program Access on the Basis of Sex

The Final Rule requires Covered Entities to provide "equal access to its health programs or activities without discrimination on the basis of sex."[25] The Final Rule uses the same definition for "on the basis of sex" as the proposed rule, which was released by HHS on September 8, 2015 ("Proposed Rule").[26] Specifically, this term "includes, but is not limited to, discrimination on the basis of pregnancy, false pregnancy, termination of pregnancy, or recovery therefrom, childbirth or related medical conditions, sex stereotyping, and gender identity."[27]

Sex Stereotyping

OCR continues to rely upon the U.S. Supreme Court's holding in *Price Waterhouse v. Hopkins*[28] to support its inclusion of sex stereotyping in the definition of "on the basis of sex." In the Final Rule, OCR clarified that sex stereotypes can be based on expectations about gender roles.

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[20] 45 C.F.R. § 92.8(d) (effective July 18, 2016).
[21] 81 Fed. Reg. at 31,473.
[22] OCR, Translated Resources for Covered Entities, *available at* http://www.hhs.gov/civil-rights/for-individuals/section-1557/translated-resources/index.html.
[23] 45 C.F.R. § 92.6(a) (effective July 18, 2016).
[24] 45 C.F.R. § 92.6(b) (effective July 18, 2016).
[25] 45 C.F.R. § 92.206 (effective July 18, 2016).
[26] *See* Epstein Becker Green Client Alert "HHS Releases Far-Reaching Proposed Rule to Prohibit Discrimination by 'Covered Entities' Pursuant to Section 1557 of the Affordable Care Act" (Oct. 14, 2015), *available at* http://www.ebglaw.com/news/hhs-releases-far-reaching-proposed-rule-to-prohibit-discrimination-by-%E2%80%9Ccovered-entities%E2%80%9D-pursuant-to-section-1557-of-the-affordable-care-act/.
[27] 45 C.F.R. § 92.40 (effective July 18, 2016).
[28] 490 U.S. 228 (1989).

Sexual Orientation

Under the Final Rule, OCR will evaluate complaints alleging sex discrimination related to an individual's sexual orientation to determine whether the complaints can be addressed under Section 1557. In explaining this decision, OCR noted that it received comments both requesting OCR to explicitly state that discrimination on the basis of sex includes discrimination based on sexual orientation and, conversely, asserting that OCR does not have such authority to include sexual orientation because no federal appellate court has interpreted Title IX or Title VII to protect a same-sex relationship.

While acknowledging that no federal appellate court has concluded that federal laws prohibiting sex discrimination include a prohibition on sexual orientation discrimination, OCR noted that some recent court decisions have found that discrimination relating to an individual's sexual orientation is prohibited because it constitutes discrimination on the basis of sex stereotyping.

As such, OCR concluded that "Section 1557's prohibition of discrimination on the basis of sex includes, at a minimum, sex discrimination related to an individual's sexual orientation where the evidence establishes that the discrimination is based on gender stereotypes."[29] However, OCR did not say that discrimination on the basis of an individual's sexual orientation alone is a form of discrimination under Section 1557. Covered Entities should pay close attention for legal developments as this area of unsettled law is ripe for litigation.

Gender Identity

Like the Proposed Rule, the Final Rule also requires Covered Entities to "treat individuals consistent with their gender identity."[30] OCR defines "gender identity" to mean an individual's internal sense of gender, which may be different than the sex assigned at birth. In response to comments about potential ambiguity regarding non-binary gender identities, OCR revised the Proposed Rule's definition of "gender identity" to include the clause "which may be male, female, neither, or a combination of male and female."

The Final Rule also clarifies that the term "gender identity" encompasses "gender expression" and "transgender status." OCR noted that this is consistent with the position taken by some courts and federal agencies; therefore, these types of discrimination are prohibited under the Final Rule.

Gender Discrimination in Health-Related Insurance and Other Health-Related Coverage

The Final Rule adopts Section 92.207 of the Proposed Rule—which prohibits a Covered Entity from discrimination on the basis of race, color, national origin, sex, age, or disability—without substantive modification. This section also lists specific prohibited practices, including implementing a categorical coverage exclusion or limitation for all

[29] 81 Fed. Reg. at 31,390.
[30] 45 C.F.R. § 92.206 (effective July 18, 2016).

health services related to gender transition and denying or limiting coverage for a transgender individuals for any health services that are ordinarily available to individuals of one sex because the person's sex assigned at birth is different from the one for which such health services are ordinarily available.

OCR refused to provide examples of discriminatory benefit designs. Instead, OCR will analyze "whether a design feature is discriminatory on a case-by-case basis" using the "facts and circumstances of a given scenario."[31] OCR did acknowledge that Covered Entities have discretion in developing benefit designs and that 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."[32] Specifically, OCR changed Section 92.101 to provide that sex-specific health programs or activities are allowable only where the Covered Entity can demonstrate an "exceedingly persuasive justification" that the sex-specific program is "substantially related to the achievement of an important health-related or scientific objective."[33]

Some commenters expressed concerns that Covered Entities would not be able to revise their health insurance coverages and other offerings by July 18, 2016. OCR refused to delay the implementation of the Final Rule, but to the extent the rule requires changes to health insurance benefit design, OCR did delay implementation until the first day of the first plan year beginning on or after January 1, 2017.

Individuals with Limited English Proficiency and Auxiliary Aids and Services

The Final Rule requires Covered Entities to provide meaningful access to individuals with limited English proficiency.[34] In evaluating compliance with this requirement, the Final Rule requires the Director of the OCR 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." The Final Rule further requires that the Director "take into account all other relevant factors, including whether the entity has developed and implemented an effective language access plan, appropriate to its particular circumstances." The specific list of illustrative factors for the Director to consider that was set out in the Proposed Rule is no longer included in the Final Rule.

Covered Entities may need to provide oral language assistance, written translation of documents and websites, and taglines. Language assistance services required must be provided free of charge to individuals with limited English proficiency. These services must also be accurate and timely and protect the individual's privacy and independence. OCR noted that the definition of "timely" would depend on the circumstances of each situation. Further, OCR would consider the costs of language assistance services and the resources available to the Covered Entity—including the Covered Entity's ability to

[31] 81 Fed. Reg. at 31,434.
[32] *Id*.
[33] 81 Fed. Reg. at 31,470.
[34] 45 C.F.R. § 92.201 (effective July 18, 2016).

leverage resources among its partners—in evaluating whether the requirements of the Final Rule are met.

Even though the Final Rule does not list specific, mandatory methods for providing language assistance, it does contain some important prohibitions. A Covered Entity cannot require an individual to provide his or her own interpreter. The Final Rule also prohibits a Covered Entity from relying on a family member or a minor child to provide translation services, except in an emergency, unless the individual requests that the adult interpret and such assistance is appropriate under the circumstances. Additionally, a Covered Entity cannot require an individual to accept language assistance services. The Final Rule also provides technical requirements for the use of remote video interpretation services.

The Final Rule requires that individuals with disabilities be provided with auxiliary aids and services, including alternative written formats, such as Braille, and sign-language interpreters.

While Section 92.8 of the Final Rule contains an extensive notice required for Covered Entities, OCR modified that section to now only require Covered Entities to post a shorter nondiscrimination statement, along with a limited number of taglines, in significant communications that are small-sized. OCR is translating a sample nondiscrimination statement that Covered Entities can use.

Enforcement

The Final Rule states that OCR will apply existing enforcement mechanisms available under Title VI, Title IX, Section 504, and the Age Discrimination Act of 1975 for purposes of Section 1557 enforcement. Further, compensatory damages for violations of Section 1557 will be available in appropriate administrative and judicial actions brought under the Final Rule.

For recipients of federal financial assistance and State-Based Marketplaces, if such an entity fails to provide OCR with requested information in a timely, complete, and accurate manner, OCR may find noncompliance with Section 1557 and initiate appropriate enforcement procedures, including beginning the process for fund suspension or termination and taking other action authorized by law. Further, an individual or entity may bring a civil action to challenge a violation of Section 1557 in a U.S. district court in which the recipient or State-Based Marketplace is found or transacts business.

For health programs or activities administered by HHS, including the Federally Facilitated Marketplaces, the procedural provisions applicable to Section 504 apply to complaints and compliance reviews concerning discrimination on the basis of race, color, national origin, sex, age, or disability for such health programs and activities. The Final Rule also allows OCR to obtain all of the relevant information needed to investigate a complaint or determine compliance in a particular health program or

activity administered by HHS. Further, HHS is prohibited from retaliating against any individual for the purpose of interfering with any right or privilege under Section 1557.[35]

Considerations for Implementation of the Final Rule

The intent of the Final Rule is to provide consumers and Covered Entities with a set of standards that will help them understand and comply with the requirements of Section 1557. The determination of whether a certain practice is discriminatory typically requires a nuanced analysis that is fact-dependent; therefore, it is not possible to identify all issues and circumstances that may raise compliance concerns. HHS advises that Covered Entities should keep in mind the purposes of the ACA and Section 1557—to expand access to care and coverage and eliminate barriers to access—when interpreting requirements of the Final Rule.

In general, Covered Entities have been subject to preexisting requirements in federal civil rights laws related to the prohibition of race, color, national origin, age, or disability discrimination for years. The prohibition of sex discrimination, however, is new for many Covered Entities and will likely require changes in action and behavior to comply with this new prohibition. Further, Covered Entities should consider whether they will provide training to the appropriate staff and incorporate the requirements of the Final Rule into their existing non-discrimination policies and procedures.

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[35] *See* 45 C.F.R. §§ 92.301-303 (effective July 18, 2016).

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