Advisory

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If you have any questions about this Advisory, please contact:

REBECCA MATTHEWS
203.498.4502
rmatthews@wiggin.com

JODY ERDFARB
203.363.7608
jerdfarb@wiggin.com

HHS Issues Final Rule on Nondiscrimination in Health Programs and Activities

On May 18, 2016, the United States Department of Health and Human Services ("HHS") Office for Civil Rights ("OCR") issued a Final Rule implementing Section 1557 of the Affordable Care Act ("ACA"), which prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs and activities.[1] The purpose of the Final Rule is to help advance equity and reduce health disparities by protecting some of the populations that have been most vulnerable to discrimination in the health care context.

The Final Rule applies to "covered entities," which are: (1) health programs or activities that receive federal financial assistance from HHS; (2) health programs or activities administered by HHS; and (3) health programs or activities administered by a Title I entity, such as state-based and federally-facilitated marketplaces. Covered entities may include hospitals, health clinics, health insurance issuers, state Medicaid agencies, community health centers, physician's practices and home health care agencies. Consistent with OCR's enforcement of other civil rights authorities, the definition of "federal financial assistance" under the regulation does not include Medicare Part B, which means that physicians receiving only Medicare Part B payments are not covered. However, because almost all physicians receive payments from other HHS programs such as Medicaid or Medicare meaningful use payments, HHS believes that there are very few physicians excluded from the new regulations.[2]

Section 1557 of the ACA has been in effect since the ACA's enactment in 2010, however, the specific requirements in the new regulations become effective on July 18, 2016, with the exception of regulations that require changes to health insurance or plan benefit design, such as covered benefits, coinsurance, copayments, or deductibles, which become effective on the first day of the first plan year beginning on or after January 1, 2017. Except in the area of sex discrimination, the Final Rule applies pre-existing requirements in Federal civil rights laws to various entities. Because Section 1557 restates existing requirements, HHS does not anticipate that covered entities will undertake new actions or bear any additional costs in response to the issuance of the Final Rule.[3] There are, however, specific policies, actions and notices that are required of all covered entities to comply with the Final Rule. With the deadline of July 18, 2016 fast approaching, covered entities should review the Final Rule and its requirements and establish a work group to ensure implementation of the requirements.

SECTION 1557 OF THE ACA

Section 1557 of the ACA provides that an individual shall not be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health care program or activity, any part of which receives Federal financial assistance, or any program or activity that is administered by HHS, on the basis of race, color, national origin, sex, age, or disability.

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While such discrimination has already largely been prohibited in other laws, such as Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, the Age Discrimination Act of 1975, and Section 504 of the Rehabilitation Act of 1973, the ACA clarified its prohibition in health care settings.

DISCRIMINATION PROTECTIONS UNDER THE FINAL RULE

In 2013, OCR published a Request for Information to solicit information on discrimination in health care and, in 2015, OCR issued a Proposed Rule. The Final Rule finalizes many aspects of the Proposed Rule, but also makes several changes, as noted below.

The Final Rule generally refers to established statutes and case law to interpret the scope of the protections against discrimination in the health care context on the basis of race, color, national origin, sex, age or disability. In this context, the Final Rule clarifies that discrimination on the basis of sex includes discrimination based on an individual's sex; pregnancy; false pregnancy; termination of pregnancy; childbirth and related medical conditions; gender identity; and sex stereotyping. Covered entities must, therefore, provide individuals equal access to their health programs and activities without discrimination on the basis of sex and to treat individuals consistent with their gender identity.[4] In addition, covered entities may not deny or limit health services that are ordinarily or exclusively available to individuals of one sex to a transgender individual based on the fact that the individual's sex assigned at birth, gender identity, or gender otherwise recorded is different from the one to which such health services are ordinarily or exclusively available. Exceptions are permitted only where a covered entity can demonstrate an "exceedingly persuasive justification", that is, that the sex-specific health program or activity is substantially related to the achievement of an important health-related or scientific objective.[5]

While the Final Rule does not resolve whether discrimination on the basis of an individual's sexual orientation alone is a form of sex discrimination under Section 1557, HHS will evaluate complaints that allege sex discrimination related to an individual's sexual orientation, and HHS supports prohibiting sexual orientation discrimination as a matter of policy.[6]

In regard to health insurance, the Final Rule states that a covered entity may not take the following actions on the basis of race, color, national origin, sex, age, or disability:

- Deny, cancel, limit or refuse to issue or renew a health-related insurance plan or other health related coverage.
- Deny or limit a claim or impose additional cost-sharing or other limitations or restrictions on coverage.
- Engage in discriminatory marketing practices or adopt or implement discriminatory benefit designs in health-related insurance or other health-related coverage.
- Deny or limit coverage or a claim, or impose additional cost-sharing or other limitations or restrictions on coverage, for sex-specific health services provided to transgender individuals just because the individual seeking such services identifies as belonging to another gender.
- Categorically exclude coverage for all health services related to gender transition, and may not deny or limit coverage or impose additional cost-sharing or other limitations or restrictions on coverage for specific health services related to gender transition if those result in discrimination against a transgender individual.

Examples of discriminatory insurance design features include "placing most or all prescription medications that are used to treat a specific condition on the highest cost formulary tiers"; "applying age limits to services that have been found clinically effective at all ages"; and "requiring prior authorization and/or step therapy for most or all medications in drug classes such as anti-HIV protease inhibitors, and/or immune suppressants regardless of medical evidence". According to HHS, "The Final Rule does not require plans to cover any particular benefit or service or prohibit issuers from determining whether a particular health service is medically necessary, but a covered entity cannot have a coverage policy that operates in a discriminatory manner."[7]

EXCEPTIONS

The Final Rule includes two exceptions to the general prohibition on discrimination on the basis of race, color, national origin, sex, age, or disability. First, in regard to the prohibition on age discrimination, the Final Rule specifies that any exclusions that are applicable under the Age Discrimination Act of 1975, as set forth in 45 CFR § 91.3(b)(1), apply to claims of discrimination

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based on age under Section 1557 of the ACA. The exclusions consist of age distinctions mentioned in Federal, State, or local statutes or ordinances adopted by an elected, general purpose legislative body which: (i) provides any benefits or assistance to persons based on age; (ii) establishes criteria for participation in age-related terms; or (iii) describes intended beneficiaries or target groups in age-related terms.[8]

Second, the Final Rule explicitly states that the application of the regulations is not required to the extent that such application would violate applicable federal statutory protections for religious freedom and conscience. The Proposed Rule originally included a blanket religious exemption, but after receiving comments, HHS decided instead to adopt this more narrow exception.

In addition to these two exceptions, the regulations clarify that the Final Rule does not generally apply to discrimination by a covered entity against its own employees, such as hiring, firing, or promoting. HHS points out that such claims could continue to be brought under other laws, including Title VII, Title IX, Section 504, the ADA and the Age Discrimination in Employment Act, as appropriate. However, covered entities must ensure that their employee health benefit programs do not run afoul of Section 1557 and its implementing regulations. In addition, third party administrators may be held liable if their administration of a health plan is discriminatory.

MEANINGFUL ACCESS FOR INDIVIDUALS WITH LIMITED ENGLISH PROFICIENCY

Consistent with longstanding principles under civil rights laws, HHS makes clear that the prohibition on national origin discrimination requires covered entities to take reasonable steps to provide meaningful access to each individual with limited English proficiency who is eligible to be served or likely to be encountered within the entities' health programs and activities. An individual with limited English proficiency is a person whose primary language for communication is not English and who has a limited ability to read, write, speak, or understand English. In evaluating whether a covered entity has met this obligation, HHS will take into account relevant factors, including whether a covered entity has developed and implemented an effective written language access plan that is appropriate to its particular circumstances.

More specifically, the Final Rule requires that language assistance services be provided free of charge, be accurate and timely, and protect the privacy and independence of the individual with limited English proficiency. To that end, HHS requires covered entities to offer a qualified interpreter to an individual with limited English proficiency when oral interpretation is a reasonable step to provide meaningful access for that individual with limited English proficiency and to use a qualified translator when translating written content in paper or electronic form.

Covered entities are not permitted to:

a. Require an individual with limited English proficiency to provide his or her own interpreter;

b. Rely on an adult accompanying an individual with limited English proficiency to interpret or facilitate communication, except (i) in an emergency involving an imminent threat to the safety or welfare of an individual or the public where there is no qualified interpreter for the individual with limited English proficiency immediately available or (ii) where the individual with limited English proficiency specifically requests that the accompanying adult interpret or facilitate communication, the accompanying adult agrees to provide such assistance, and reliance on that adult for such assistance is appropriate under the circumstances;

c. Rely on a minor child to interpret or facilitate communication, except in an emergency involving an imminent threat to the safety or welfare of an individual or the public where there is no qualified interpreter for the individual with limited English proficiency immediately available; or

d. Rely on staff other than qualified bilingual/multilingual staff to communicate directly with individuals with limited English proficiency.

A covered entity is permitted to use video remote interpreting services so long as the services are provided in real-time and are full-motion video and audio over a dedicated high-speed, wide-bandwidth video connection or wireless connection that delivers high-quality video images that do not produce lags, choppy, blurry, or grainy images, or irregular pauses in communication. The video must provide a sharply delineated image that is large enough to display the interpreter's face and the participating individual's face regardless of the individual's body position and a clear,

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audible transmission of voices. In addition, the covered entity must provide adequate training to users of the technology and other involved individuals so that they may quickly and efficiently set up and operate the video remote interpreting.

INDIVIDUALS WITH DISABILITIES

Covered entities are required to take appropriate steps to ensure that communications with individuals with disabilities are as effective as communications with others in health programs and activities.[9] Appropriate auxiliary aids and services must be provided 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.

Examples of auxiliary aides include qualified interpreters on-site or through video remote interpreting; real-time computer-aided transcription services; telephone handset amplifiers; assistive listening devices; assistive listening systems; telephones compatible with hearing aids; closed caption decoders; voice, text, and video-based telecommunication products and systems, text telephones (TTYs), qualified readers; Braille materials and displays; screen reader software; magnification software; optical readers; secondary auditory programs; large print materials; accessible electronic and information technology; or other effective methods of making visually delivered materials available to individuals who are blind or have low vision.

Covered entities must also ensure that health programs or activities provided through electronic and information technology are accessible to individuals with disabilities, unless doing so would result in undue financial and administrative burdens or a fundamental alteration in the nature of the health programs or activities. When undue financial and administrative burdens or a fundamental alteration exist, the covered entity is required to provide information in a format other than an electronic format that would not result in such undue financial and administrative burdens or a fundamental alteration but would ensure, to the maximum extent possible, that individuals with disabilities receive the benefits or services of the health program or activity that are provided through electronic and information technology.

A covered entity is required to make reasonable modifications to policies, practices, or procedures when such modifications are necessary to avoid discrimination on the basis of disability, unless the covered entity can demonstrate that making the modifications would fundamentally alter the nature of the health program or activity.

Finally in regard to individuals with disabilities, Section 1557 incorporates the 2010 Americans with Disabilities Act Standards for Accessible Design as the standards for physical accessibility of new construction or alteration of buildings and facilities. There are some exceptions for facilities that were not covered by the 2010 Standards prior to July 18, 2016, the effective date on the Final Rule.

OTHER REQUIREMENTS

Other requirements set forth in the Final Rule include:

1. **Assurance Requirements:** Each entity applying for federal financial assistance will be required to submit an assurance that its health programs and activities will be operated in compliance with Section 1557 and with the new implementing regulations. HHS noted that the regulations implementing Title VI, Title IX, Section 504, and the Age Act all require similar assurances. This assurance requirement is also applicable to health insurance issuers seeking certification to participate in a Health Insurance Marketplace or states seeking approval to operate a state-based Marketplace.

2. **Adoption of Grievance Procedure:** Each covered entity that employs fifteen (15) or more individuals must adopt grievance procedures, incorporating appropriate due process standards, that provide for the prompt and equitable resolution of grievances alleging any prohibition of Section 1557 or its implementing regulations. HHS provides a sample grievance procedure at Appendix C of the Final Rule.

3. **Designation of Responsible Employee:** Each covered entity that employs fifteen (15) or more individuals must designate at least one employee to coordinate its efforts to comply with and carry out its responsibilities under Section 1557 and the implementing regulations, including the investigation of any grievances.

4. **Notification:** Each covered entity is required to "take appropriate initial and continuing steps" to notify beneficiaries, enrollees, applicants, and members of the public of the following:

    a. That the covered entity does not discriminate on the basis of race, color, national origin, sex, age, or disability in its health programs and activities;

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

c. That the covered entity provides language assistance services, including translated documents and oral interpretation, free of charge and in a timely manner, when such services are necessary to provide meaningful access to individuals with limited English proficiency;

d. How to obtain auxiliary aids and language assistance services;

e. Identification of, and contact information for, the employee responsible for the covered entity's coordination of efforts to comply with Section 1557 and its implementing regulations;

f. The availability of the grievance procedure and how to file a grievance; and

g. How to file a discrimination complaint with OCR.

Specifically, the regulations require that by October 16, 2016, each covered entity includes this notice in "conspicuously visible font size" in any significant publications and significant communications targeted to beneficiaries, enrollees, applicants, and members of the public and in any conspicuous physical locations where the entity interacts with the public.[10] In addition, each covered entity must post this notice in a conspicuous location on its website which is accessible from the home page.

The notices must include taglines, defined as short statements written in non-English languages that indicate the availability of language assistance services free of charge, in at least fifteen different languages spoken by individuals with limited English proficiency in the relevant state. In the Proposed Rule, HHS required that the posted taglines include the top fifteen languages spoken nationally, but in the Final Rule, HHS changed this requirement to the top fifteen languages in the relevant state, in order to make the posted information as accessible to even more individuals with limited English proficiency.

In the Final Rule, HHS added a modification to this notice requirement for significant publications and communications that are small sized, such as post-cards and tri-fold brochures. In those cases, the covered entity need only include a statement that the covered entity does not discriminate on the basis of race, color, national origin, sex, age, or disability in its health programs and activities and taglines in the top two languages spoken by individuals with limited English proficiency in the relevant state.

Note that in the Final Rule, HHS also states that covered entities may combine the content of these notices with the content of other notices required by civil rights laws. The Final Rule includes a sample notice at Appendix A and a sample tagline at Appendix B. In addition, HHS translated a sample notice and taglines into 64 languages. For translated materials, visit www.hhs.gov/civilrights/for-individuals/section-1557/translated-resources/index.html. HHS is allowing entities to exhaust their current stock of publications, rather than do a special printing of the publications to include the new notice. When covered entities restock their printed materials, they will be expected to include in those printed materials the newly required notice.

ENFORCEMENT

The existing enforcement mechanisms under Title VI, Title IX, Section 504 and the Age Act apply for redress of violations of Section 1557. These mechanisms include requiring covered entities to keep records and submit compliance reports to OCR, conducting compliance reviews and complaint investigations, and providing technical assistance and guidance. Where noncompliance or threatened noncompliance cannot be corrected by informal means, available enforcement mechanisms include suspension of, termination of, or refusal to grant or continue Federal financial assistance; referral to the Department of Justice with a recommendation to bring proceedings to enforce any rights of the United States; and any other means authorized by law.

According to the new 42 CFR §92.6, if OCR finds that Section 1557 and/or its implementing regulations have been violated, it shall "take remedial action as . . . may be required to overcome the effects of discrimination." OCR has a wide range of enforcement tools at its disposal and stated in the preamble that it would evaluate "each situation on a case-by-case basis." The Final Rule also recognizes that an individual may bring a civil action to challenge a Section 1557 violation and that compensatory damages re available in administrative and judicial actions.

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ACTION STEPS

1. **Policies and Procedures:** Covered entities must review and, as required, revise applicable policies and procedures to ensure that they comply with the anti-discrimination rules outlined in the Final Rule, particularly in respect to discrimination on the basis of sex. Policies and procedures must include a grievance procedure that explains where complaints and concerns regarding noncompliance can be investigated and resolved. Training content should be revised accordingly.

2. **Limited English Proficiency:** Reasonable steps must be taken to provide meaningful access to each individual with limited English proficiency. This includes designing and implementing a language access plan which provides accurate and timely language assistance services free of charge.

3. **Individuals with Disabilities:** Appropriate steps must be taken to ensure that communications with individuals with disabilities are as effective as communications with others, and that health programs or activities provided through electronic and information technology are accessible to individuals with disabilities. Auxiliary aids and services should be used as needed.

4. **Compliance Coordinator:** Any covered entity that employs fifteen (15) or more individuals must designate a compliance coordinator to comply with and carry out ACA Section 1557 and the implementing regulations, including the investigation of any grievances. Entities should publicize the identity of this individual so that people know who to contact if there is a problem.

5. **Notice:** Covered entities must include specific language and taglines to indicate the availability of language assistance free of charge. These notices must be included in significant publications and significant communications targeted to beneficiaries, enrollees, applicants, and members of the public; in any conspicuous physical locations where entities interact with the public; and in conspicuous locations on their websites.

[1] Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 96, 31376 (May 18, 2016) (to be codified at 45 C.F.R. pt. 92).
[2] Ibid., 31383.
[3] Ibid., 31446.
[4] Ibid., 31387.
[5] Ibid., 31377.
[6] Ibid., 31390.
[7] Ibid., 31434.
[8] 45 C.F.R. § 91.3 (2005).
[9] Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 96, 31471.
[10] Ibid., 31401.