Summary of HHS’s Final Rule on Nondiscrimination in Health Programs and Activities

Elizabeth Cornachione, MaryBeth Musumeci, and Samantha Artiga

Executive Summary

On May 18, 2016, the Department of Health and Human Services (HHS) published a final rule to implement Section 1557 of the Affordable Care Act (ACA), which prohibits discrimination in health coverage and care based on race, color, national origin, age, disability, and sex. These provisions incorporate existing federal non-discrimination law and policy and also contain some new protections. Key provisions include:

- Extending protections against sex discrimination to health coverage and care for the first time and including gender identity discrimination within the definition of sex discrimination;
- Codifying long-standing guidance regarding meaningful access for individuals with Limited English Proficiency, including the provision of free, accurate, and timely language assistance services;
- Incorporating existing law that requires reasonable modifications, effective communication, and readily accessible buildings and information technology to avoid disability-based discrimination; and
- Prohibiting discriminatory health insurance benefit designs and including specific coverage protections for transgender individuals.

The final rule does not:

- Resolve whether Section 1557’s prohibition on sex discrimination extends to discrimination based on sexual orientation alone, although HHS notes that such discrimination is prohibited under Section 1557 when it is based on gender stereotypes; or
- Set specific accessibility standards for medical equipment for people with disabilities, pending action by the U.S. Access Board.

HHS emphasizes Section 1557’s importance in achieving the ACA’s goals of expanding access to health care and insurance, noting that discrimination within these areas can contribute to poor health outcomes or coverage, increase health disparities among underserved communities, and negatively impact the distribution of health care resources. The final rule is effective on July 18, 2016, except for provisions that require changes to health insurance plan benefit design, which will take effect in the first plan year beginning on or after January 1, 2017.
Introduction

On May 18, 2016, the Department of Health and Human Services (HHS) finalized regulations to implement Section 1557 of the Affordable Care Act (ACA). Section 1557 prohibits certain entities that administer health programs and activities from excluding an individual from participation, denying program benefits, or discriminating based on race, color, national origin, sex, age or disability. While Section 1557 has been in effect since the ACA’s enactment, these regulations mark the first time HHS has issued implementing guidance. In the preamble to the final rule, HHS emphasizes Section 1557’s importance in achieving the ACA’s overarching goal of expanding access to health care and insurance for all individuals, noting that discrimination within health programs can contribute to poor and inadequate health outcomes or coverage, exacerbate existing health disparities in underserved communities, and lead to insufficient and ineffective distribution of health care resources.

Section 1557 seeks to coordinate existing federal non-discrimination laws, regulations, and policy as they apply to health coverage and care and to extend sex discrimination protections to health programs and activities. Specifically, the final rule incorporates the existing anti-discrimination tenants of Title VI (race, color and national origin), the Age Discrimination Act, and Section 504 (disability) as they apply to health care. It also extends the sex discrimination protections of Title IX, which only apply to educational programs, to health care. As such, it is the first federal civil rights law to prohibit discrimination on the basis of sex in health care. Moreover, the final rule defines sex discrimination to include discrimination on the basis of gender identity. In addition, the final rule codifies long-standing HHS policy guidance about the provision of language assistance services. The final rule is effective on July 18, 2016, except for provisions that require changes to health insurance benefit design, which will take effect in the first plan year beginning on or after January 1, 2017.

This issue brief summarizes key provisions of the final rule.

Key Provisions of the Section 1557 Final Rule

Entities Subject to Section 1557’s Non-Discrimination Provisions

The final rule applies to health programs and activities that receive Federal financial assistance from HHS; health programs and activities administered by HHS, including the Federally-facilitated Marketplace; and State-based Marketplaces established under the ACA. Box 1 provides examples of the types of entities subject to Section 1557. While Section 1557 applies more broadly to all health programs and activities that receive federal funding through any agency, HHS limits its final rule to the programs that it has authority to enforce. HHS encourages other federal agencies to adopt the standards from its rule when applying Section 1557 to the health programs and activities that they administer.

The final rule defines health programs and activities to include all operations of an entity that is principally engaged in the provision or administration of health-related services or health-related insurance coverage. Health programs and activities also include providing assistance obtaining health-related services or health-related insurance coverage. HHS interprets health programs and activities to include health education and research programs and reiterates that federal law already prohibits discrimination in federally funded research as well as in research at universities. The final rule extends non-discrimination protections to any research conducted within HHS as well as non-educational institutions. In
the preamble, HHS recognizes that research projects are often limited in scope, and therefore, research protocol criteria that target or exclude certain groups are warranted when justified for subjects’ health or safety, the scientific study design, or the research purpose. The rule also applies to employee health benefit programs in limited circumstances.

Box 1: Examples of the Types of Entities Subject to Section 1557

- Health care providers, such as physicians’ practices, hospitals, community health centers, nursing facilities, home health agencies, clinical laboratories, residential or community-based treatment facilities, intermediate care facilities for people with intellectual/developmental disabilities, hospices, and organ procurement centers
- Health-related schools and education and research programs
- State agencies, such as Medicaid, CHIP, and public health
- Health insurance issuers and third party administrators
- Navigators
- HHS programs, such as CMS, HRSA, CDC, IHS, SAMHSA, the Federally-facilitated Marketplace, and the Basic Health Program
- State-based Marketplaces
- Employers offering employee health benefit programs (in certain circumstances)


The final rule clarifies that Federal financial assistance includes not only funding received directly by covered entities but also premium and cost-sharing subsidies provided to individuals for coverage through the Federally-facilitated or State-based Marketplaces. As such, the rule applies to insurance carriers that offer plans through these Marketplaces. Moreover, the preamble clarifies that Section 1557 applies to all plans offered by these carriers, not just those available through the Marketplaces.

PROTECTIONS AGAINST DISCRIMINATION BASED ON SEX

Section 1557 and HHS’s final regulations, for the first time, extend protections against discrimination based on sex to health coverage and care. Covered entities must provide individuals equal access to health programs and activities without discrimination based on sex, including pregnancy, false pregnancy, termination of pregnancy, recovery from childbirth or related medical conditions. Sex discrimination also includes sex stereotypes, including expectations about gender roles, which could be an important protection for lesbian, gay, bisexual, and transgender individuals, among others.

Moreover, the final rule extends the definition of sex discrimination to include discrimination based on gender identity for the first time in the health care context. HHS clarifies that its inclusion of gender identity as part of sex discrimination includes gender expression and “transgender status” and encompasses individuals with non-binary gender identities.
In the preamble to the final rule, HHS specifies that Section 1557’s prohibition on sex discrimination includes discrimination related to sexual orientation where the evidence establishes that the discrimination is based on gender stereotypes. The final rule does not resolve whether Section 1557’s prohibition on sex discrimination extends to discrimination based on an individual’s “sexual orientation status” alone. HHS notes that the law in this area is continuing to evolve and will consider issuing further guidance.

Sex-specific health programs and activities are prohibited unless a covered entity can show that the sex-based classification is substantially related to the achievement of an important health-related or scientific objective. HHS expects that this standard will enable most health researchers 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. However, the rule does not offer a blanket allowance for all sex-specific research. If there is no scientific or clinical reason for a study to be restricted to one sex researchers would need to justify the reasons for this limitation.

The final rule does not include a blanket religious exemption related to Section 1557’s general prohibition against sex discrimination. Existing laws protecting religious freedom and belief, including provider conscience laws, the Religious Freedom Restoration Act, the ACA’s provisions regarding abortion services, and the ACA’s preventive health services regulations, continue to apply. The final rule clarifies that compliance with Section 1557 is not required if it would violate these laws.

Prohibition Against Discrimination Based on National Origin

Section 1557 prohibits discrimination based on an individual’s place of origin, his or her ancestor’s place of origin, and his or her manifestation of the physical, cultural, or linguistic characteristics of a national origin group. The rule adopts the Equal Employment Opportunity Commission’s definition of national origin. While Section 1557 does not explicitly ban discrimination based on citizenship or immigration status, as opposed to national origin, HHS notes that Section 1557 does prohibit policies or practices related to citizenship or immigration status that disproportionately affect individuals of a particular national origin group even if those policies or practices are not explicitly discriminatory.

Meaningful Access for Individuals with Limited English Proficiency (LEP)

Covered entities must take reasonable steps to provide meaningful access to each individual with LEP who is eligible to be served or likely to be encountered in their health programs and activities. The final rule incorporates existing Title VI regulations and HHS’s LEP policy guidance and outlines specific requirements related to provision of language assistance services. When assessing an entity’s compliance with this provision, the HHHS Office of Civil Rights (OCR) will take into account and give substantial weight to the nature and importance of the health program or activity and the communication at issue to the person with LEP. OCR also will consider other relevant factors, including whether the entity has developed and implemented an effective written language access plan. HHS did not establish a minimum threshold for non-English languages in which entities must provide language assistance, and it did not require entities to have a language access plan in the final rule. However, as indicated, the creation of a written language access plan is one factor OCR will consider in evaluating compliance.
Covered entities must provide free, accurate, and timely language assistance services and protect the privacy and independence of an individual with LEP. Covered entities must offer a qualified interpreter when reasonable for oral communication and use a qualified translator for written content. Moreover, the entity can only rely on qualified bilingual/multilingual staff to communicate directly with individuals with LEP. The rule defines the knowledge, skills, and abilities of a qualified interpreter and a qualified translator who may provide these services as well as for qualified bilingual and multilingual staff. The rule also adds performance standards for video remote interpreting services. The rule specifies that individuals with LEP are not required to accept language assistance services, although the preamble clarifies that a provider may use a qualified interpreter to assist the provider in communicating with an individual with LEP who has refused language assistance services.

An entity may not require an individual with LEP to provide his or her own interpreter. Moreover, the entity cannot rely on an adult accompanying the individual with LEP to interpret, except in emergency situations or when the individual specifically requests the adult to provide those services, the adult agrees to provide the assistance, and reliance on the adult is appropriate for the circumstances. Similarly, the entity may not rely on a minor child to interpret except in an emergency when no qualified interpreter is immediately available.

PROTECTIONS AGAINST DISCRIMINATION BASED ON DISABILITY

Covered entities must make reasonable modifications in policies, practices, and procedures to avoid disability-based discrimination, unless doing so would fundamentally alter the nature of the health program or activity. The final rule incorporates existing federal protections against disability-based discrimination from Section 504 of the Rehabilitation Act and the Americans with Disabilities Act (ADA). Covered entities must take appropriate steps to ensure effective communication with people with disabilities. To the extent that the ADA effective communication rules differ between Title II (which applies to state and local government) and Title III (which applies to places of public accommodation), HHS adopted the Title II rules for all entities subject to Section 1557. This requires Section 1557 covered entities to give “primary consideration” to the person with a disability’s choice of auxiliary aid or service. Auxiliary aids and services can include, as appropriate, qualified interpreters, a variety of assistive technology devices, and the provision of materials in alternative formats. The final rule clarifies that all covered entities, regardless of the number of employees, must provide appropriate auxiliary aids and services to people with impaired sensory, manual, or speaking skills, where necessary to afford those individuals an equal opportunity to benefit from the health program or activity.

Buildings and facilities where health programs and activities are conducted must be constructed and altered in a way that is readily accessible to and useable by people with disabilities. Specifically, HHS generally adopts the 2010 ADA Standards for Accessible Design for new construction or alternations of facilities of covered entities that receive Federal funding and State-based Marketplaces.
While Section 1557’s prohibition against disability-based discrimination in health programs and activities extends to medical equipment, HHS does not set specific accessibility standards in this area. The U.S. Access Board is still developing its standards for accessible medical equipment. In the meantime, HHS notes that providers must ensure that health programs and activities that involve the use of medical equipment are accessible to people with disabilities.  

Covered entities must make electronic and information technology in health programs and activities accessible to people with disabilities, unless doing so would create an undue financial or administrative burden or fundamentally alter the nature of the health program or activity. When providing an accessible electronic format creates an undue burden or fundamental alteration, covered entities still must provide information in another format that does not create an undue burden or fundamental alteration but that does ensure, to the maximum extent possible, that people with disabilities receive the benefits or services of the health program or activity provided through electronic or information technology.

**Prohibitions Against Discrimination in Health Coverage**

The final rule outlines several protections against discrimination in health insurance coverage determinations and administration. Under Section 1557, covered entities 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 insurance policy;
- Deny or limit coverage of a health insurance claim;
- Impose additional cost sharing or other limitations or restrictions on coverage; or
- Use discriminatory marketing practices or insurance benefit designs.

The final rule maintains that while health insurers cannot have coverage policies that operate in a discriminatory manner, they still may apply medical necessity rules when determining covered benefits. HHS also notes in the preamble that Section 1557 does not require insurers to cover any particular services. Provisions of the final rule that require changes in plan benefit design take effect in the first plan year on or after January 1, 2017. Such changes include covered benefits, benefits limitations or restrictions, and cost-sharing mechanisms such as coinsurance, copayments, and deductibles.

While the final rule states that covered entities may not employ discriminatory benefit designs, it is silent on whether certain practices are discriminatory. For example, placing all drugs to treat a single medical condition on the plan’s highest cost-sharing tier has been challenged in an administrative complaint filed with the OCR (Box 2). In separate guidance, HHS has identified this practice as an example of potential discrimination, along with applying age limits to services that have been found clinically effective at all ages, and requiring prior authorization and/or step therapy for all or most medications in drug classes such as anti-HIV protease inhibitors and/or immune suppressants regardless of medical evidence.
The final rule includes specific coverage protections for transgender individuals. While the rule generally requires that covered entities treat individuals consistent with their gender identity, as described above, it specifies a limited exception. The exception prohibits entities from denying or limiting health services (or imposing additional cost-sharing on services) that are ordinarily or exclusively available to individuals of one sex or gender based on the fact that the individual’s sex assigned at birth, gender identity, or gender in a medical or health insurance plan record differs from the one to which such health services are ordinarily or exclusively available. For example, a covered entity may not deny an individual treatment for ovarian cancer where the individual could benefit medically from the treatment, based on the individual’s identification as a transgender male.

The final rule also specifies requirements related to access to gender transition services. Specifically, an insurance plan may not categorically or automatically exclude or limit coverage for all health services related to gender transition or otherwise deny or limit coverage or deny a claim for specific health services related to gender transition, if such a policy results in discrimination against the individual seeking services. HHS notes that blanket exclusions of all gender transition services, which historically have been used by some Medicaid programs and health insurers, are now recognized as outdated and not based on current standards of care. However, the final rule does not affirmatively require covered entities to cover any particular procedure or treatment for transition-related care.

Compliance with and Enforcement of Section 1557’s Non-Discrimination Provisions

Each entity applying for federal financial assistance must assure its compliance with Section 1557. Assurances also are required by Marketplace issuers and states seeking approval to operate a State-based Marketplace.

Covered entities must post a notice regarding their non-discrimination policies by October 16, 2016. These notices must inform individuals about the bases of discrimination prohibited under Section 1557, the availability of free and timely auxiliary aids and services and language assistance services, how to access those services, contact information for the entity’s employee responsible for Section 1557 compliance, the entity’s Section 1557 grievance procedures, and OCR complaint procedures. Notices must be available to beneficiaries, enrollees, applicants, and members of the public. They must be printed in a conspicuously visible font and included in significant communications (such as handbooks and outreach publications), in
conspicuous physical locations where the entity interacts with the public, and in a conspicuous location on the covered entity’s website accessible from the homepage.69 Significant publications that are small-sized, such as postcards and tri-fold brochures, may include a shorter non-discrimination statement in lieu of the full notice.70 The final rule contains a sample notice and nondiscrimination statement.71

Covered entities must provide the notice in English and include taglines in the top 15 languages spoken by individuals with LEP within the state.72 Entities also may choose to post the notice in other non-English languages. Small-sized significant publications may include taglines in the top two non-English languages instead of 15.73 HHS will translate its sample notice and taglines into 64 languages.74

Covered entities that employ at least 15 people must adopt a grievance procedure that incorporates appropriate due process standards and provides prompt and equitable resolution of grievances under Section 1557.75 HHS and covered entities with more than 15 employees also must designate at least one employee to coordinate the entity’s efforts to carry out Section 1557 responsibilities, including the investigation of grievances.76 The final rule includes a sample grievance procedure.77 To ensure compliance with Section 1557, HHS will provide covered entities with a training curriculum on key provisions of the rule.78

Covered entities must take remedial action as required by the HHS OCR Director if they are found to have discriminated on any basis prohibited by Section 1557.79 If discrimination is not found, covered entities may also take voluntary actions to improve operations.80 OCR can enforce Section 1557 through informal mediation, reducing or eliminating a covered entity’s Federal financial assistance, or referring matters to the Department of Justice for litigation.81 The final rule also provides that private individuals and entities can sue in federal court to challenge alleged violations of Section 1557 by entities receiving Federal financial assistance and State-based Marketplaces.82 The final rule clarifies that compensatory damages are available for Section 1557 violations.83 Other existing federal, state, and local anti-discrimination laws also continue to apply.84

Looking Ahead
HHS’s final rule implementing the ACA’s Section 1557 nondiscrimination protections coordinates existing federal non-discrimination laws, regulations, and policy regarding race, color, national origin, age, and disability as they apply to health coverage and care. Section 1557 also extends sex discrimination protections to health care programs and activities and includes gender identity as a prohibited basis of discrimination. While the rule does not resolve whether sexual orientation should be a stand-alone basis for prohibited discrimination, HHS will recognize Section 1557 sex discrimination claims involving sexual orientation that are based on gender stereotypes. The rule codifies HHS’s long-standing policy guidance on language assistance services for individuals with LEP. It also incorporates existing provisions of Section 504 and the ADA to prohibit disability-based discrimination in health programs and activities, although it defers setting specific standards for accessible medical equipment pending forthcoming standards from the Access Board. The rule also prohibits insurers from using discriminatory benefit designs, although it does not identify specific actions that constitute discrimination such as the placement of all drugs to treat a single medical condition on the highest cost-sharing tier, which is the subject of a recent administrative complaint that is pending with OCR.
The final rule takes effect on July 18, 2016, except that provisions that require changes to plan benefit design are effective in the first plan year beginning on or after January 1, 2017. HHS’s final rule is an additional tool to prevent and remediate discrimination in the health context, and HHS encourages other federal agencies that fund health programs and activities to adopt its standards to fully implement Section 1557.
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2 42 U.S.C. § 18116; 45 C.F.R. § 92.101. In addition to prohibiting discrimination based on an individual’s own race, color, national origin, age, disability, or sex, Section 1557 also prohibits discrimination against an individual known or believed to have a relationship or association with someone else based on that other person’s race, color, national origin, age, disability, or sex. 45 C.F.R. § 92.209. For example, a primary care physician could not refuse to accept a new patient based on the disability status of one of the patient’s family members. 80 Fed. Reg. 54191.


4 45 C.F.R. § 92.1.

5 45 C.F.R. §§ 92.2, 92.4. Consistent with the HHS Office for Civil Rights’ enforcement of other civil rights authorities, the definition of Federal financial assistance does not include Medicare Part B payments. 81 Fed. Reg. 31383.

6 45 C.F.R. §§ 92.1, 92.2(a).


8 45 C.F.R. § 92.4.

9 Id.


11 Unless the primary purpose of the Federal financial assistance is to fund employee health benefits, Section 1557 does not apply to an employer’s provision of employee health benefits where the provision of those benefits is the only health program or activity operated by the employer. 45 C.F.R. § 92.208; 81 Fed.Reg. 31437.

12 45 C.F.R. § 92.4.


14 45 C.F.R. §§ 92.4 92.206.

15 45 C.F.R. § 92.206.


17 45 C.F.R. § 92.4.


19 Id.

20 Id.


23 45 C.F.R. § 92.2(b)(2).

24 Id.

25 45 C.F.R. § 92.4.


27 45 C.F.R. §92.201(a).

28 45 C.F.R. § 92.201(b)(1).

29 45 C.F.R. § 92.201(b)(2). HHS does not outline minimum requirements for a language access plan but notes that effective plans often address how the entity will determine an individual’s primary language; identify a telephonic interpretation service; identify a translation service; identify the types of language assistance services that may be required; and identify any documents for which written translations should be routinely available. 81 Fed. Reg. 31415.

30 45 C.F.R. § 92.201(c) and (d).

31 45 C.F.R § 92.201(e)(4).
HHS notes that whether Section 1557 applies to people with chronic conditions depends on whether an individual meets the final rule’s definition of disability, which is based on the ADA/504. 81 Fed. Reg. 31382.
Covered entities may exhaust their existing supply of hard copy publications before complying with this provision. 81 Fed. Reg. 31396.

Covered entities that serve individuals in more than one state may aggregate the number of individuals with LEP in those states to determine the top non-English languages spoken. 81 Fed. Reg. 31400.

The preamble indicates that covered entities may use the same grievance procedures and individuals as used to comply with Section 504 and Title IX if their scope is broadened to include all bases of discrimination prohibited by Section 1557. 81 Fed. Reg. 31394.

OCR will serve as the responsible employee for Section 1557 compliance in HHS programs and activities and the Federally-facilitated Marketplace. Id.

Id. at 31441.