

HHS FINAL RULE ON NONDISCRIMINATION IN HEALTH PROGRAMS AND ACTIVITIES - PART I: SEX DISCRIMINATION

On May 13, 2016, the Office of Civil Rights (“OCR”) of the Department of Health and Human Services (“HHS”) issued a final rule (“Final Rule”) implementing Section 1557 of the Patient Protection and Affordable Care Act (“ACA”). A copy of the Final Rule is available [here](#). The rule is scheduled to become effective on July 18, 2016.

The Final Rule will affect approximately 900,000 physicians and 133,000 facilities, including hospitals, home health agencies and nursing homes, in addition to hundreds of thousands of laboratories, insurers, health professional training programs and public health programs (“Covered Providers”). Failure to comply can result in loss of funding, and those who believe they experienced prohibited discrimination have the right to sue either individually or as part of a class action.

Because the Final Rule imposes numerous requirements on Covered Providers, we will be issuing a series of articles on the Final Rule. This first article focuses on provisions that aim to advance equality in the provision of health care by eliminating discrimination based on sex, gender identity and sex stereotyping. Notably, the new regulations add unprecedented federal protection under the ACA for transgender patients.

BACKGROUND

Section 1557 of the ACA provides that an individual shall not, on the basis of race, color, national origin, sex, age or disability be excluded from participation in, denied the benefits of or subjected to discrimination under any health program or activity that receives federal financial assistance. The Final Rule implements Section 1557 and applies to the following entities:

- All health programs and activities that receive federal financial assistance through HHS, including Medicaid, Medicare and the Children’s Health Insurance Program (“CHIP”);
- All programs receiving meaningful use payments, advance premium tax credits and federal funding for clinical research;
- Health programs and activities administered by HHS, including the federally facilitated marketplace;
- Health programs and activities administered by entities established under Title I of the ACA, such as state-based marketplaces; and
- Indian Health Service programs¹.

The Final Rule also directly applies to physicians who accept Medicare and Medicaid reimbursement or meaningful use information technology funding. However, the Final Rule does not apply to physicians who only receive reimbursement under Medicare Part B.

SEX DISCRIMINATION

In the past, discrimination regulations enforced by OCR barred discrimination based on race, color, national origin, disability or age. In the Final Rule, HHS extended discrimination protection to sex discrimination. The prohibition of sex discrimination protects individuals from discrimination based on the following factors:

- An individual’s sex;
- Pregnancy, childbirth and related medical conditions;
- Gender identity; and
- Sex stereotyping, including the stereotype that an individual must identify as either male or female.

Under the prohibition of sex discrimination:

- Individuals cannot be denied health care or health coverage based on their sex, including their gender identity and stereotyping;

- Women must be treated equally with men in the health care they receive and the insurance they obtain;
- Categorical coverage exclusions or limitations for all health care services related to gender transition are discriminatory;
- Individuals must be treated consistent with their gender identity, including in access to facilities;
- Providers may not deny or limit treatment for any health services that are ordinarily or exclusively available to individuals of one gender based on the fact that a person seeking such services identifies as belonging to another gender, provided that the service is necessary or appropriate; and
- Sex-specific health programs or activities are permissible only if the 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.

Additionally, it should be noted that while the Final Rule offers protection for transgender individuals, HHS declined to resolve whether sexual orientation discrimination is prohibited under Section 1557 as a form of sex discrimination. The Final Rule states that OCR will evaluate complaints alleging discrimination based on sexual orientation to determine whether they involve “discriminatory stereotyping of sexual attraction or behavior” as protected under Section 1557. However, the preamble to the Final Rule states that HHS supports prohibiting sexual orientation discrimination as a policy matter and will continue to monitor legal developments.

The Final Rule also prohibits certain indirect forms of discrimination and disparate impact, such as aiding or perpetuating discrimination through significant assistance to anyone violating the ACA. Further, a Covered Provider may not directly, or through contracts or arrangements, administer a program or use criteria that “have the effect of subjecting individuals to discrimination on the basis of sex, or have the effect of defeating or substantially impairing accomplishment of the objectives of the program with respect to individuals on the basis of sex.” Likewise, choice of facility and program locations cannot have the effect of sex discrimination or substantially impairing the objectives of the protections. Further, these nondiscrimination rights extend to individuals believed to have a relationship or association with someone protected under the regulations.

ENFORCEMENT

The ACA empowers HHS to notify an offender and suspend, terminate or refuse to continue federal funding to any organization that does not address noncompliance.

In addition to other enforcement procedures, Covered Providers should be aware that individuals may bring individual or class action violation claims directly against them in federal court. HHS has concluded that Section 1557 provides a new anti-discrimination cause of action for damages arising from alleged violations including disparate impact claims. Damages for these lawsuits could include compensatory damages and an award of the plaintiffs’ attorneys’ fees and costs.

COMPLIANCE AND REQUIRED NOTICES

The Final Rule goes into effect July 18, 2016, and the first round of notice requirements must be compliant within 90 days. Covered Providers are required to file an Assurance of Compliance with OCR. Covered Providers must provide notice to beneficiaries and the public stating that the Covered Provider does not discriminate under Section 1557 and how to file a discrimination complaint with OCR². Some notices must be displayed in a conspicuous physical location, be posted on the Covered Provider’s website and be included in all significant publications and communications targeted at enrollees, applicants and members of the public.

Additionally, Covered Providers with more than 15 employees must designate an employee responsible for compliance and adopt a grievance procedure.

IMPACT ON RELIGIOUS INSTITUTIONS

Following the publication of the Proposed Rule in September of 2015, several religiously affiliated organizations submitted comments to HHS requesting that the agency offer a blanket religious exemption to protect religious institutions, both as providers and employers, from having to perform, provide health insurance coverage for, pay for or facilitate in any way procedures that are contrary to their religious beliefs, such as transition services for transgender individuals.

Despite the request, HHS did not provide a blanket religious exemption. According to the agency, such an exemption could result in a

“denial or delay in the provision of health care to individuals and could discourage individuals from seeking necessary care, with serious, and in some cases, life-threatening results.” HHS also noted in its response that recent mergers of religious institutions with non-religious entities may leave individuals in rural communities with fewer health care options offering the full range of gender transition and women’s health services.

As an alternative to a blanket religious exemption, HHS reiterated that the Religious Freedom Restoration Act (“RFRA”), federal conscience clauses and other protections afforded under the ACA may serve to protect Covered Providers from having to provide services contrary to their religious beliefs. However, commenters in favor of the blanket exemption expressed concern that absent specific and clear conscience clause protections in the Final Rule for religious-affiliated entities, religious-affiliated providers may face ongoing legal challenges under RFRA for refusing to perform, refer for, pay for or cover procedures under the expanded definition of discrimination on the basis of sex.

PRACTICAL TAKEAWAYS

Any health care entity or individual provider potentially impacted by this rule should first evaluate whether it is covered by these new requirements.

Covered Providers should then review current policies, procedures and publications to identify necessary modifications prior to the applicable deadlines.

If you have questions about this topic or would like assistance with compliance with the new requirements under Section 1557, please contact:

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Please visit the Hall Render Blog at <http://blogs.hallrender.com/> or click [here](#) to sign up to receive Hall Render alerts on topics related to health care law.

¹ In response to comments by tribal organizations, including requests for exclusion from coverage, HHS clarified the definition of IHS programs and pointed to exceptions and defenses that may be raised by tribes.

² HHS has provided a model notice with the Final Rule.