HHS Proposes New Section 1557 Health Care Nondiscrimination Rules

August 2022

The Department of Health and Human Services (HHS) released a proposed rule on July 25, 2022, (the 2022 Proposed Rule) that would reinstate and broaden the protections under the Affordable Care Act's (ACA's) Section 1557 prohibition against discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs and activities. While similar to the original rules issued in 2016, the 2022 Proposed Rule is not identical. If finalized in its current form, the regulations aim to enhance health care protections for the LGBTQ community, women who need access to reproductive health care, and expand access to health care for individuals with limited English proficiency and disabilities.

Employer Impact

The 2022 Proposed Rule is not a final rule yet, but the 2022 Proposed Rule indicates that the Biden Administration intends to reinstate some of the Section 1557 requirements that were implemented under the Obama Administration and revoked under the Trump Administration.

If the 2022 Proposed Rules are finalized, insurers and third-party administrators (TPAs) that accept federal financial assistance in any of their operations would need to examine their documents and operations for potential Section 1557 discrimination issues, adjust their administration of benefits, reissue language access notices, and implement nondiscrimination policies and procedures. While the Obama-era rule categorically included group health plans, the 2022 Proposed Rule scales back this approach. Instead, only group health plans that directly receive federal financial assistance from HHS (e.g., a Medicare Part D employer-group waiver plan (EGWP)) would be a covered entity and subject to all of the additional Section 1557 requirements. In contrast, a group health plan that does not receive federal funds would not be subject to the additional requirements even if the employer who sponsors the plan receives federal funds. While most plans may not be responsible for Section 1557 requirements such as language access notices and maintaining nondiscrimination policies and procedures, many group health plans' designs could be implicated by an insurer or TPA who is a covered entity and administers the plan.

Even if Section 1557 does not directly apply to an employer's employment practices or group health plan, other nondiscrimination rules, including under Title VII of the Civil Rights Act of 1964 and the Americans with Disabilities Act (ADA), will continue to apply.

Background

In 2016, the Obama Administration issued final Section 1557 nondiscrimination regulations (the 2016 Rule) that ultimately required covered entities, including group health plans that received federal funds from HHS, to implement a number of protections including:

- Nondiscrimination with respect to gender transition benefits and gender identity;
- Limited English Proficiency (LEP) protections, including notices and language access taglines; and
- A grievance procedure for addressing complaints under Section 1557.

In 2020, the Trump administration scaled back the 2016 Rule with a new regulation (the 2020 Rule) that excludes protections for gender identity, sex stereotyping, and termination of pregnancy, and removes the LEP notice and tagline provisions.

In 2021, after the Supreme Court found in *Bostock v. Clayton County* that federal employment nondiscrimination law under Title VII of the Civil Rights Act includes prohibiting discrimination on the basis of sexual orientation and gender identity, HHS applied the reasoning in *Bostock* to the Section 1557 prohibition against discrimination on the basis of sex but did not otherwise modify the 2020 Rule.

Overview of the 2022 Proposed Rule

Applicability

Under the 2022 Proposed Rule, a "covered entity" must comply with Section 1557 nondiscrimination requirements, but the requirements only apply to:

- Every health program or activity, any part of which receives federal financial assistance, directly or indirectly, from HHS (e.g., hospitals, pharmacies, health insurance issuers, nursing home facilities, and state or local health agencies);
- Every health program or activity administered by HHS (e.g., Medicare); and
- ACA state Exchanges and federally facilitated Exchanges.

The 2022 Proposed Rule defines "covered entity" to include any recipient of federal financial assistance from HHS, HHS itself, and the ACA state Exchanges and federally facilitated Exchanges. As a result, Section 1557 applies to insurers and TPAs and arguably not to the group health plan, except in the very limited case of a self-insured plan that accepts federal funds.

Examples of federal financial assistance listed in the preamble of the 2022 Proposed Rule include Medicaid and the Children's Health Insurance Program, Medicare Part A, Medicare Part C (Medicare Advantage), Medicare Part D (drug coverage), and HHS grant programs. The 2022 Proposed Rule also includes Medicare Part B in its definition of federal financial assistance, a change from previous rules.

The 2022 Proposed Rule's nondiscrimination requirements explicitly do not apply to any employer with regard to its employment practices, including the provision of employee health benefits. Other federal nondiscrimination protections, including Title VII of the Civil Rights Act and the ADA, apply in that context.

Application to employer-sponsored group health plans

The 2022 Proposed Rule does not directly apply to an employer-sponsored group health plan unless the group health plan itself receives federal financial assistance, such as from an EGWP. Unlike under

the 2016 Rule, an employer that receives federal funds from HHS can be a covered entity, but this does not automatically implicate its group health plan under the 2022 Proposed Rule. HHS highlighted that the application of these rules to group health plans would be evaluated on a case-by-case basis and is requesting comment. Even if not subject to Section 1557, an employer and its group health plan continue to be subject to other nondiscrimination laws.

Application to insurers of fully insured group health plans

The 2022 Proposed Rule applies Section 1557 to insurers who receive federal financial assistance, including advance payments of premium tax credits and cost-sharing reductions through the Exchanges. The insurer, and not the employer-sponsored group health plan or the employer, is the covered entity and therefore is subject to Section 1557 nondiscrimination requirements. If the insurer does not receive federal financial assistance of any kind, Section 1557 does not apply to it because it is not a covered entity.

Application to TPAs of self-insured group health plans

The 2022 Proposed Rule applies to TPAs that receive federal financial assistance, either in their operations as a TPA or their operations as an insurer. The TPA, and not the employer-sponsored group health plan, is the covered entity under the 2022 Proposed Rule.

A TPA that is a covered entity would not be held liable for violating Section 1557 to the extent that the TPA is not responsible for the benefit design of a self-insured group health plan. However, where a TPA that is a covered entity is responsible for the development of plan administrative features, the group health plan document, or other policy documents that are adopted by the self-insured plan, the TPA (but not the employer or group health plan) could be liable for the discriminatory design feature of an employer's group health plan under Section 1557. If alleged discrimination relates to the benefit design of a self-insured group health plan did not originate with the TPA, but rather with the plan sponsor, the complaint will be referred to the Equal Employment Opportunity Commission or the Department of Justice for potential investigation, in instances where the group health plan is not a covered entity.

Application to excepted benefits and grandfathered group health plans

HHS notes that neither Section 1557 nor the 2022 Proposed Rule provides an exception for excepted benefits, such as limited-scope dental and vision plans, or for grandfathered plans. The 2022 Proposed Rule applies to insurers and TPAs for these plans that are covered entities.

Requirements Imposed on Covered Entities

The 2022 Proposed Rule would prohibit an individual from being excluded from participation in, being denied the benefits of, or otherwise being subject to discrimination under any health program or activity operated by a covered entity on the basis of race, color, national origin, sex, age, or disability. The 2022 Proposed Rule clarifies that discrimination on the basis of sex includes, but is not limited to: discrimination on the basis of sex stereotypes; sex characteristics, including intersex traits; pregnancy or related conditions (including "pregnancy termination"); sexual orientation; and gender identity.

Examples of benefit design features that must be considered include, but are not limited to: coverage, exclusions, and limitations of benefits; prescription drug formularies; cost-sharing (including copays,

coinsurance, and deductibles); utilization management techniques (such as step therapy and prior authorization); medical management standards (including medical necessity standards); provider network design; and reimbursement rates to providers and standards for provider admission to participate in a network.

The 2022 Proposed Rule clarifies that it is prohibited discrimination to deny or limit coverage or impose additional cost-sharing or other limitations or restrictions on coverage to an individual based upon the individual's sex at birth, gender identity, or gender otherwise recorded. More specifically, the 2022 Proposed Rule would prohibit a covered entity from denying coverage of any claim (not just for sex-specific services) on the basis that the enrollee's sex assigned at birth is different than their gender identity. However, an insurer or TPA may confirm that treatment related to pregnancy is medically necessary for an enrollee whose recorded sex is male, for example.

Coverage of gender-affirming services

Although the 2022 Proposed Rule does not require coverage of any particular procedure or treatment, it does prohibit any categorical coverage exclusion or limitation for all health services related to gender transition or other gender-affirming care. A covered entity cannot impose discriminatory limits on coverage for health services related to gender transition or other gender-affirming care if such limits are not applied when that type of health service is not related to gender transition. For example, a health plan that covers a mammoplasty for a participant whose sex assigned at birth is a female could not categorically exclude such service for a participant whose sex assigned at birth is male. It is unclear how this proposed rule would interact with state laws that prohibit the coverage of gender transition or other gender-affirming care.

Covered entities can use reasonable medical management techniques, including medical necessity standards, to determine if a particular treatment is medically appropriate under current generally accepted standards of care for an individual or whether the treatment is experimental or cosmetic, as long as the medical management standards are not discriminatory and are not otherwise prohibited under other applicable federal and state law.

Policies and grievance procedures

Covered entities would be required to adopt and implement a nondiscrimination policy, grievance procedures, language access procedures, auxiliary aids and services procedures, and procedures for reasonable modifications for individuals with disabilities. Covered entities must retain records related to grievances filed and processed for at least three years. In addition, covered entities must train relevant employees on the Section 1557 policies and procedures, document completion of such training, and retain such documentation for at least three years.

Notice of nondiscrimination

The 2022 Proposed Rule requires covered entities to provide a notice of nondiscrimination to participants, beneficiaries, enrollees, applicants, and to the public. The covered entity must provide the notice annually, upon application of enrollment, and upon request. The notice would also have to be posted in a conspicuous location on a health program or activity website (for example, a medical

insurer's website), if applicable, and in clear and prominent physical locations where it is reasonable to expect individuals seeking service from the health program to be able to read or hear the notice.

Notice of availability of language assistance services and auxiliary aids and services

The 2022 Proposed Rule requires an annual notice of availability of language assistance services and auxiliary aids and services (Notice of Availability) to be provided to participants, beneficiaries, enrollees (including late and special enrollees), and applicants in English and at least the 15 most common languages spoken by LEP individuals of the relevant state or states, and in alternate formats for individuals with disabilities who request auxiliary aids and services to ensure effective communications. The notice must also be provided upon request. The Office of Civil Rights will provide a sample Notice of Availability for covered entities to use, as well as the 15 most common non-English languages spoken by LEP individuals for each state and territory. The Notice of Availability would also be required to be provided at a conspicuous location on the covered entity's health program website, if it has one, and in clear and prominent physical locations where it is reasonable to expect individuals seeking service from the health program to be able to read or hear the notice. This notice must also be accessible to individuals with disabilities who require auxiliary aids and services.

The Notice of Availability is proposed to be included with the following documents that are issued by covered entities:

- Notice of nondiscrimination;
- HIPAA notice of privacy practices;
- Application forms;
- Notices of denial or termination of eligibility, benefits, or services, including Explanations of Benefits, and notices of appeal and grievance rights;
- Communications related to a person's rights, eligibility, benefits, or services that require or request a response from a participant, beneficiary, enrollee, or applicant; and
- Patient and member handbooks.

Telehealth

While not specifically addressed in prior Section 1557 rulemaking, the 2022 Proposed Rule includes a provision that would prohibit discrimination in the delivery of health programs and activities through telehealth services. The addition clarifies the affirmative duty that covered entities have in ensuring that telehealth services are accessible to individuals with disabilities (e.g., auxiliary aids and services) and provide meaningful program access to LEP individuals.

Potential Exemption Due to Application of a Federal Conscience or Religious Freedom Law

The 2022 Proposed Rule offers an exemption procedure that will allow the Office of Civil Rights to review whether an applicant is exempt from certain provisions or modified application of Section 1557 based on a federal conscience or religious freedom law. HHS requests comment on this case-by-case

approach to exemption and whether additional procedural information is needed to balance federal conscience and religious freedom laws and Section 1557's civil rights protections.

Effective Date

Provisions of the 2022 Proposed Rule that would require changes to health insurance or group health plan benefit designs would become effective on the first day of the first plan year beginning on or after the year immediately following the effective date of the final rule in the *Federal Register*. The final rule would become effective 60 days after publication in the *Federal Register*. HHS intends to issue a final rule by the end of 2022.

For More Information

The 2022 Proposed Rule is available here.

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