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New Section 1557 regulations: Focused on health care industry but indirectly impact employee benefits

On April 26, the Office for Civil Rights (OCR) issued new final regulations, including a list of FAQs, under Section 1557, which prohibits discrimination within certain health programs and activities on the basis of a protected status, including race, color, national origin, sex, disability, and age. The new rules have a direct impact on organizations in the health care industry and will, in most situations, have an indirect impact on employer-sponsored benefits.

This is the third iteration of the regulations, with the first round in 2016, soon followed by lawsuits and an injunction, a second round in 2020, which was enjoined before it became effective, and now a third round released in 2024. Moreover, if the administration changes next year, we may likely see another round in the future.

These final regulations take a similar approach to the 2016 regulations — broadly interpreting discrimination on the basis of sex to include sexual orientation, gender identity, sex stereotyping, sex characteristics including intersex traits, pregnancy, and pregnancy-related conditions, such as termination. The regulations also clarify how these rules apply to plan sponsors and provide an exemption for entities with religious objections.

Covered entities

The 1557 regulations apply to “covered entities,” which are “health programs or activities” that receive “federal financial assistance” from the Department of Health and Human Services (HHS), and also includes the Marketplace, and the Department itself. A “health program or activity” is an entity that administers or provides individuals with health-related services, health insurance coverage, or other health-related coverage; provides clinical, pharmaceutical, or medical care; engages in health or clinical research; or provides health education to health care professionals.

Covered entities include, but are not limited to, health care providers participating in CHIP and Medicaid, hospitals, nursing homes, home health care providers, Medicare Advantage Plans, and Medicare Advantage Drug Plans that receive Medicare funding or payments, and insurers participating in the Marketplace.

When a covered entity is principally engaged in providing or administering health programs and activities, all the entities' operations are subject to the law. For example, a hospital that accepts Medicare will be subject to the rules in its business operations and when administering its group health plan for its employees unless the plan is legally independent from the recipient of the funds.

Insurers, TPAs, and PBMs

Since Marketplace insurers are subject to the rules, and they are principally engaged in health programs and activities, the insurer's entire operations will be impacted, including its third-party administrator (TPA) and pharmacy benefits manager (PBM) services. Only when a TPA or PBM can prove it is legally separate from the insurer (or other covered entity) will that TPA or PBM be exempt from covered entity status. To determine whether entities are legally separate, OCR will look at their interrelatedness, degree of common ownership, control between or among the entities, and whether the legal separation was solely to avoid Section 1557 application.

When an insurer is a covered entity, group health plans that it provides or administers will be affected, as well as its other plans that provide health care, such as an insurer's excepted benefits, including dental and vision, fixed indemnity, and certain employee assistance programs (EAPs), as will its telehealth and short-term limited duration insurance (STLDI) products. When an insurer, TPA, or PBM is not a covered entity, it is exempt from Section 1557.

Employer-sponsored plans

The 2024 regulations exempt employers and other group health plan sponsors, including boards of trustees, associations, or other groups regarding employment practices, including the provision of employee health benefits. However, when an organization is principally engaged in the provision or administration of a health program or activity, all its operations are subject to the requirements. For example, a hospital that accepts Medicare payments will be a covered entity. And, if that hospital, as an employer, sponsors a health plan for its employees, that plan is also subject to Section 1557 unless it is a separate legal entity, using the same considerations above.

Employer group waiver plans (EGWPs), which receive Medicare funding, and qualified retiree prescription drugs plans that receive a retiree drug subsidy (RDS) are covered entities under Section 1557 when the plan receives the funds. However, the plan sponsor's involvement in that process, including when the employer contracts directly with the Centers for Medicare & Medicaid Services (CMS), does not cause the employer to be a covered entity. When an employer offers an "800 series" EGWP through a Medicare Advantage organization or Part D sponsor, that entity or insurer would be subject to the rules for the EGWP due to the entity or insurer's receipt of the Medicare funding.

Impact on employee benefits

The Section 1557 nondiscrimination prohibitions impact employee health benefits even if the plan sponsor or the plan is not a covered entity. First, discrimination is prohibited for protected classes in employment, including in employee benefits, which is enforced by the Equal Employment Opportunity Commission (EEOC). The EEOC has taken a similar, broad stance on what encompasses discrimination on the basis of sex. Second, because most insurers will be covered entities, we expect they (and their TPA and PBM counterparts) will request that plan sponsors remove potentially discriminatory plan designs to avoid liability. Insurers, TPAs, and PBMs can be held responsible for discriminatory plan designs that they originated or controlled. Conversely, when a plan sponsor controls a discriminatory plan design, the plan sponsor can be held liable if it is a Section 1557 covered entity. When the plan sponsor or plan is not subject to Section 1557, OCR will refer the complaint to another enforcement agency (typically the EEOC). So, whether or not an employer is in the health care business, it is prohibited from protected status discrimination in providing employee benefits.

Discriminatory plan provisions

Plan sponsors should expect insurers, TPAs, and PBMs to notify them of these new regulatory changes to avoid potential liability. If based on a protected status, some examples of problematic limits and exclusions could be: limiting claim coverage, imposing additional cost sharing, categorical exclusions related to gender transition or gender-affirming care or to a specific disability or condition (e.g., autism or hearing loss), or benefit designs that do not provide or administer health coverage in the most integrated setting appropriate to the needs of individuals with disabilities.

The regulations' preamble also mentions other potential employee benefit issues, such as fertility benefits not available on an equal basis to same sex couples, excluding all providers that specialize in treating certain conditions from the plan's network, excessive utilization management on a particular condition, and denying coverage for medication or health services that may also be used in abortion care. Although these are issues to confront in plan provisions, the regulations make clear that plans are not required to provide specific health services when the covered entity has a "legitimate, nondiscriminatory reason for denying or limiting coverage." However, any coverage denial or limitation cannot be based on unlawful animus or bias.

Plans may continue to use reasonable medical management techniques, such as medical necessity and utilization management; however, those methods also cannot be discriminatory. For example, the preamble states that excessive use of utilization management that targets a particular disability or protected status will be discriminatory, and appeals processes that subject participants to excessive administrative burdens to access coverage could also be discriminatory. Insurers may need to update their claims processing and medical management software, as potentially discriminatory software programming was an issue addressed in the regulations.

Covered entity requirements

When an organization is a covered entity, it must take specific steps to ensure the nondiscriminatory delivery of health care, including the following:

- **Make assurances** when applying for HHS funds that it will be in compliance with Section 1557.
- **Do not discriminate on the basis of any protected status**, including marital, parental or familial status or based on association with an individual with protected status.
- **Provide meaningful access for individuals and their companions with limited English proficiency** that is free, accurate and timely, and protects the privacy of the individual. A qualified interpreter is required. Machine translation may be used, but should be reviewed by a qualified interpreter when the messaging is critical. An adult that is not a qualified interpreter may be used in limited circumstances. Video and audio remote interpretation is permissible if compliant with additional requirements.
- **Establish effective communication for individuals with disabilities** to ensure communications are as effective as communications to individuals without disabilities, including free auxiliary aids and services, provided in a timely manner, and respecting the individual's privacy.
- **Ensure buildings and facilities are accessible**.
- **Make communication technology available to individuals with disabilities**, including on the covered entity's website and mobile applications.
- **Make reasonable modifications for individuals with disabilities** to policies, practices, and procedures to avoid discrimination unless such modification would fundamentally alter the program or activity.
- **Provide a notice of nondiscrimination** that is available annually, upon request, in a conspicuous location on its website, and in physical locations in 20-point font (model notice will be available).
- **Provide a notice of availability of language assistance and auxiliary aids** on an annual basis, upon request, conspicuously on the entity's website, and in physical locations in 20-point font, in each of the 15 required languages (model notices will be available).

Covered entities with 15 or more employees must also:

- **Name a 1557 coordinator** to promote compliance and be available for grievances.
- Establish and implement **policies and procedures** (OCR will make templates available in the future at www.hhs.gov/1557).

- Establish a **grievance process** that enables a prompt and equitable resolution that is accessible by individuals with limited English proficiency and disabilities and retain records for three years after the resolution.
- Establish written **language access procedures** for individuals with limited English proficiency or disabilities.
- Establish **reasonable modifications** for individuals with disabilities.
- **Train employees** on the policies and procedures within one year of the law's effective date and new employees within a reasonable period.

Religious exemptions

Covered entities are expressly exempt from particular provisions of Section 1557 when their rights are protected by federal religious freedom and conscience laws. Also, religious entities may, but are not required to, seek assurances from OCR on their exemption by submitting a notification explaining the legal and factual basis of the asserted exemption to the OCR Director — whether before or during an investigation. If OCR agrees, it will provide assurance of the exemption, which will also exempt the entity from administrative investigations and enforcement of the provision. If OCR disagrees, the entity may appeal, and if denied, may request judicial review.

It is not clear how a covered entity insurer, TPA, or PBM will be able to work with entities with religious objections. One comment in the preamble alludes to religious plan sponsors with objections to provisions of Section 1557 finding insurers and TPAs that are not covered entities to maintain plan provisions that discriminate on the basis of the expanded definition of sex.

Effective dates

The law becomes effective 60 days after publication, which is July 5, 2024. Since there are numerous requirements under Section 1557 that require substantial undertakings for the covered entity and others that will not, OCR has delayed the effective dates for some requirements.

Insurers (and their TPAs and PBMs that are not legally separate) must adjust the health plans that they provide or administer by the first day of the plan (or policy) year beginning on or after January 1, 2025.

Within 120 days of the effective date, covered entities must name a coordinator and disclose the notice of nondiscrimination. Within one year of the effective date, covered entities must adopt and implement policies and procedures and begin to provide notice of availability of auxiliary aids. Finally, within 300 days of the effective date, the covered entity must train individuals on their Section 1557 policies and procedures and review their patient care decision support tools.

Employer action steps

Covered entity organizations (insurers, hospitals, etc.) should review the requirements and begin determining first steps. Noncovered entity plan sponsors should discuss with their insurer, TPA, or PBM any potential upcoming plan changes that are needed to protect the employer and its plan service providers from potential discrimination complaints. Plans that previously removed blanket exclusions for gender-affirming care after the first round of regulations in 2016 may not need to make many changes, but expect insurers, TPAs, and PBMs to come to the table with suggestions.

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