Compliance Services Alert

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Biden administration delivers new proposed rules on ACA's Section 1557 nondiscrimination provision

Just last week, the Department of Health and Human Services – Office of Civil Rights (HHS-OCR) issued much-anticipated proposed rules revising the ACA's Section 1557 nondiscrimination regulations. The proposed rules affirm and expand protections against discrimination on the basis of sex, including sexual orientation and gender identity, and those seeking reproductive healthcare services. Specifically, the rules apply to health programs and activities that receive federal funding. Under these rules, a covered entity must not, in providing or administering health insurance coverage or other health-related coverage, discriminate against any protected class.

What you need to know:

- The current proposal expands the scope of Section 1557 to apply to health insurance issuers and other health programs or activities that receive funds from federal agencies or in relation to federal programs such as federal or state exchanges, Medicare and Medicaid, and other HHS programs. These rules will directly or indirectly apply to fully insured plans and to health insurance carriers acting as third-party administrators for self-insured plans. They would also apply to self-insured plans that receive federal funding through the Retiree Drug Subsidies program.
- The rules define discrimination on the basis of sex to include discrimination on the basis of sex stereotypes; sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; and gender identity. This will effectively ban covered entities from applying blanket exclusions for gender-affirming care.
- Most covered entities must implement written policies and procedures to ensure compliance with Section 1557, appoint a "Section 1557 coordinator" to coordinate compliance efforts and investigate any grievances regarding nondiscrimination, and implement reasonable steps to accommodate those with limited English proficiency including providing language assistance services and auxiliary aids free of charge.
- A covered entity must provide a notice of nondiscrimination to participants, beneficiaries, enrollees and applicants of its health programs and activities, as well as members of the public.
- HHS-OCR will adopt a process by which those with religious objections may inform the Department of their views to seek an exemption.

- These are proposed rules and will not be effective until 60 days following finalization. For plans requiring design changes to comply, this means the final rules will apply to plan years beginning on or after the rules are finalized. While we wait on these rules to be finalized, remember that both the Section 1557 statute and the final regulation from June 12, 2020, are still in effect. However, entities that believe they will be covered entities or will need to expand their policies and procedures to comply with new final rules may want to get a head start on reviewing their plans and programs for compliance. See our suggestions for next steps below.

Purpose of the Section 1557 rules

HHS finally delivered on its stated intent to revamp the Section 1557 regulations to not only remake them in their own image, but also align with the 2020 U.S. Supreme Court decision in *Bostock v. Clayton County*. *Bostock* held that the prohibition of discrimination on the basis of sex under Title VII of the Civil Rights Act includes discrimination on the basis of sexual orientation and gender identity.

> **Lockton comment:** Our previous alert highlighted the various interpretations of these rules since 2016 and advised plan sponsors that HHS intended to realign the rules with the 2020 U.S. Supreme Court ruling in *Bostock v. Clayton County*.

HHS-OCR has twice reminded us that nondiscrimination principles related to *Bostock* and Section 1557 have been in force since 2020, and HHS-OCR is actively fielding public complaints to identify instances of healthcare discrimination by certain covered entities based on the patient's race, color, national origin, age, disability, or sex, including gender and gender identity. These newly proposed HHS rules expand the scope of entities that are required to comply with Section 1557 and further articulate its interpretation of nondiscrimination principles and protections for sex stereotypes and sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; and gender identity to align with *Bostock*.

Covered entities

Covered entities include health programs and activities receiving federal financial assistance, such as through Medicare and Medicaid, administered by a federal executive agency, and any entity established under Title I of the ACA, such as the health insurance marketplaces. Covered entities include any health program or activity that receives federal financial assistance from HHS (including credits, subsidies or contracts of insurance) and programs administered by HHS.

The proposed rules apply a broader "covered entity" definition than the definition included in the currently effective 2020 final rules. While the rules do not directly apply to group health plans unless they receive federal funding (such as self-funded plans receiving the retiree drug subsidy), many group health plans will be indirectly affected as the rules include any entity that provides or administers health-related services including health benefits (including telehealth benefits) offered by health insurance carriers in relation to fully insured group health plans as well as the carrier's TPA services provided to self-insured plans. The rules also apply to entities that are principally engaged in the provision of healthcare such as hospitals, physician practices, pharmacies, health clinics, nursing facilities, community-based healthcare providers, and state or local health agencies.

HHS cautioned entities that if it receives a complaint regarding a group health plan's perceived discrimination under Section 1557, it will evaluate the facts on a case-by-case basis to determine whether the group health plan or its service provider is a covered entity.

> **Lockton comment:** As we have cautioned previously, even if Section 1557 does not apply to the group health plan, other laws likely will (such as Title VII of the Civil Rights Act), so employers still need to watch and be cautious of EEOC knocking on their door if an employer-sponsored plan is discriminating against individuals based on sex, including gender identity, when they seek care.

Religious exemption

HHS asserts that it is committed to respecting federal conscience and religious freedom laws. The proposed regulations would provide a process for recipients of federal financial assistance to notify HHS of their belief that the application of Section 1557 would violate their rights under such laws. HHS proposes that it would consider those views in responding to complaints or determining whether to proceed with enforcement activity and would determine whether a recipient should receive an exemption or modification from certain provisions of the regulations.

Prohibitions on discrimination based on sex

The proposed rules attempt to articulate the types of discriminatory actions prohibited by the rules once final. Activities include covered entities that discriminate in health coverage, benefit design, claims adjudication, marketing, cost sharing, or place other limits on benefits based on an individual's race, color, national origin, sex, age, or disability. This includes provisions or policies that take into account the individual's sex at birth, sexual orientation, gender identity, or gender that is otherwise recorded in formal records.

This means that covered entities cannot have categorical coverage exclusions for health services related to gender transition or other gender-affirming care. Even if the plan terms do not have blanket exclusions for these types of benefits, coverage cannot be denied under the guise that the treatment is experimental in nature. This is not to say that covered entities must provide all services related to gender-affirming care for transgender individuals—or all medically necessary services generally. Covered plans retain flexibility in designing their benefits packages but must apply standards in a consistent, neutral, nondiscriminatory manner that does not limit or deny services to individuals based on a protected basis. However, a covered entity cannot deny care based on assigned gender. For example, a transgender male who is able to become pregnant cannot be denied pregnancy care. These rules also explicitly prohibit discrimination in the use of clinical algorithms which many claims adjudicators use to support claims review and decision-making in covered health programs and activities.

> **Lockton comment:** Gender-affirming care and treatment for gender dysphoria were originally included in the 2016 rules but noticeably absent in the 2020 final rules. This latest rendition of the rules protects this type of care once again. However, the rules preserve the right of the plan to only cover services that are based on a genuine medical necessity determination from a qualified medical professional on a case-by-case basis. It's also important to note that gender identity disorder (GID) is widely recognized by medical professionals as a serious medical condition and that mental health professionals consider hormone therapy and gender reassignment surgery as appropriate and effective treatments for individuals with GID. Unlike cosmetic surgery, this type of gender-affirming care for individuals with GID qualifies as a 213(d) medical expense under the Internal Revenue Code and enjoys tax-free status, if received.

Covered entities required to implement nondiscrimination policies and procedures

The new rules, once finalized, will require covered entities to comply with Section 1557 rules in written policies as well as operations. To ensure covered entities have a continued focus on these requirements, the rules require covered entities with more than 15 employees to appoint a Section 1557 coordinator whose responsibility is to implement written civil rights policies and procedures that prevent and address discrimination.

Grievance process and record retention

Covered entities must develop and implement a grievance process that allows affected individuals to lodge complaints regarding discriminatory policies or practices and seek redress. All documentation related to the grievance must be retained for at least three years from the date the grievance is filed. The records must include the grievance; the name and contact information of the complainant (if provided by the complainant); the alleged discriminatory action and alleged basis (or bases) of discrimination; the date the grievance was filed; the grievance resolution; and any other pertinent information. Pertinent information includes, to the extent relevant to a particular complaint, information related to the complainant's national origin (including limited English proficiency and primary language), sex (including pregnancy, sexual orientation, gender identity, or sex characteristics), etc.

Language services

The rules require covered entities to take reasonable steps to assess and meet the needs of individuals with limited English proficiency (LEP) that may be directly affected by the services provided by the covered entity and provide them with language assistance and other services. This requirement is intended to ensure LEP individuals have sufficient access to services and understand critical information that affects their medical care. The need for LEP language services be assessed on a case-by-case basis but would include language assistance for at least 15 languages most commonly spoken in the covered entity's relevant state or states and auxiliary aids must be provided. For example, a surgeon would likely determine that it is a reasonable step to provide an interpreter when discussing the risks and aftercare of a particular procedure with an LEP individual in order to afford that individual meaningful access; however, a hospital may determine that reasonable access can be provided via sight translation of a generic brochure for an LEP patient rather than providing a fully translated version.

Training

Covered entities must also routinely train staff on nondiscrimination policies and procedures. The Section 1557 coordinator will ensure that the relevant employees within the health program or activity are trained on the covered entity's Section 1557 policies and procedures to ensure staff is knowledgeable about the nondiscrimination policy, grievance procedures, and processes by which to obtain language assistance services for LEP individuals, and to ensure effective communication with and provide reasonable modifications for individuals with disabilities. Given the diversity of entities covered by the Section 1557 rules, HHS did not prescribe specific training methods a covered entity must use or the nature of a covered entity's training program. However, as noted in the rules, the more thoroughly a covered entity trains its staff on its Section 1557 policies and procedures, the more likely it is that the covered entity will successfully provide services to individuals in a nondiscriminatory manner and avoid potential liability.

Annual notice

Once the rules are finalized, covered entities will be required to provide an annual notice of nondiscrimination along with a notice of the availability of language assistance services to participants, beneficiaries, enrollee, and applicants of its health programs and activities. The notice must be provided annually, upon request, and posted prominently on the entity's website and in a conspicuous physical location where it's reasonable to expect individuals who are seeking or accessing services to read or hear the notice.

Next steps

As we await the finalization of the Section 1557 rules, plan sponsors and other entities may want to begin evaluating whether the rules apply to them as a covered entity. The rules will ultimately require covered entities to submit assurances to HHS that all covered health programs and activities have implemented compliant policies and procedures and will be operated to comply with Section 1557's nondiscrimination provisions. It may make sense for certain covered entities to start selecting a Section 1557 coordinator so they may begin working on some of the heftier requirements as implementing grievance procedures, language services and training may take some time to implement once the rules are effective. For plan sponsors that are covered by Title VII or Section 1557, they should start reviewing group health plan documents to ensure there are no categorical exclusions of benefits based on sex. This would include exclusions to treat gender dysphoria or provide gender-affirming care.

HHS is accepting comments on these proposed rules for at least the next 60 days regarding the impact, structure or requirements imposed by these rules on covered entities.

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