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Publications

Back to the Future: HHS Publishes ACA Section 1557 Nondiscrimination Final Rule Similar to 2016-Era Regulations

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On May 6, 2024, the Department of Health and Human Services ("HHS") Office for Civil Rights ("OCR") and the Centers for Medicare and Medicaid Services ("CMS") published the long-awaited Nondiscrimination in Health Programs and Activities Final Rule ("Final Rule") implementing Affordable Care Act ("ACA") Section 1557's protections against discrimination in healthcare.[1] Originally proposed on August 4, 2022 (see our prior alert here), the Biden Administration issued the politically charged Final Rule in an election year just prior to the potential lookback period for the Congressional Review Act.

The Final Rule is effective July 5, 2024. But covered entities have until July 5, 2025 to comply with the Final Rule's policies and procedures and notice of availability requirements. The Final Rule provides a table that outlines the effective dates of specific provisions. Notably, health insurance coverage or other health-related coverage, including coverage that was *not* subject to Section 1557 prior to the Final Rule's publication, must make changes to their benefit designs by the first day of the first plan year (in the individual market, the policy year) beginning on or after January 1, 2025.[2]

The Final Rule re-establishes several policies originally implemented under the Obama Administration's 2016 Section 1557 regulations (the "2016 Rule"), such as applying Section 1557 broadly to all operations of a covered entity. The Trump Administration adopted a narrower interpretation of Section 1557 in its 2020 regulations (the "2020 Rule"). As detailed more fully below, the Final Rule once again broadly defines "covered entities," reaching "all of the operations of any entity principally engaged in the provision or administration of health projects, enterprises, ventures, or undertakings . . . ." Likewise, the Final Rule includes OCR's interpretation of Section 1557's prohibition against discrimination on the basis of sex to include pregnancy or related conditions, sexual orientation, gender identity, sex stereotypes, and sex characteristics, including intersex traits ("LGTQI+") discrimination.

The Final Rule does not merely rehash the 2016 Rule, however, it also introduces new wrinkles for compliance and access. For example, instead of the 2016 Rule's notices

and taglines requirement, the Final Rule includes a required notice of availability regarding not only language access but also auxiliary aids and services. The Final Rule also addresses standards to mitigate the risk of unlawful discrimination in "patient care decision support tools," which include both new technologies, such as artificial intelligence and clinical algorithms, as well as less technologically-based tools.

The Final Rule also amends CMS exchange regulations on: nondiscrimination (45 C.F.R. § 155.120), Federally-Facilitated Exchange standards of conduct (45 C.F.R. § 155.220), Essential Health Benefit prohibition on discrimination (45 C.F.R. § 156.125), Qualified Health Plan ("QHP") participation (45 C.F.R. § 156.200), direct enrollment with a QHP issuer (45 C.F.R. § 156.1230), and guaranteed availability of coverage (45 C.F.R. § 147.104).

Background

Section 1557 was enacted as part of the ACA in 2010. This provision of the statute prohibits discrimination on the basis of race, color, national origin, sex, age, or disability by incorporating by reference Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, the Age Discrimination Act of 1975, and Section 504 of the Rehabilitation Act of 1973. Entities subject to Section 1557 include any: (1) health program or activity that, in any part receives federal funding or assistance; or (2) program or activity that is administered by an executive agency or by an entity established by Title I of the ACA.

Section 1557 regulations have faced serious challenges to regulatory continuity, resembling something of a policy ping-pong match with major shifts in policy from the Obama, Trump, and now Biden Administrations. Against that backdrop, numerous legal challenges to both the Obama Administration and Trump Administration rulemakings resulted in nationwide injunctions of certain provisions and an industry whipsawed by dramatic shifts in scope, application, and requirements. This trend may continue, as the Final Rule itself already faces a legal challenge in federal court filed the same day it was published in the Federal Register, discussed in brief at the end of this alert.

Expansion of Section 1557's Scope

The Final Rule expands the applicability of Section 1557 to healthcare-related entities both by re-adopting policies established under the Obama Administration and adding new provisions that clarify the extent of Section 1557's application. Notably, the Final Rule explains that Section 1557 applies to health insurers across their books of business if they receive, in any part, federal financial assistance ("FFA") from HHS. FFA includes credits, subsidies, and other types of assistance from the Federal government. As a result, for insurers that participate in Medicare Advantage or Medicaid Managed Care, or offer QHPs on an exchange and, therefore, receive FFA, the Final Rule applies to *all* of the insurer's operations—including fully insured large group commercial coverage, grandfathered and grandmothered plans, excepted benefits (including Medigap), short-term, limited duration insurance ("STLDI"), third party administrator services, and, potentially, each of the insurer's affiliates, even if those affiliates themselves do not receive FFA.

GROOM INSIGHT: This change in policy is notable for health insurance issuers that directly or indirectly receive FFA and that also have affiliated third party administrators ("TPAs") or pharmacy benefit managers ("PBMs"), or offer excepted benefits or STLDI. Covered entities and any affiliates should examine whether they are now subject to Section 1557 and if any of their practices may conflict with the statute's nondiscrimination provisions. OCR notes in the Final Rule preamble that it will carefully consider the facts and circumstances of a challenged action or practice, and the health insurance issuer may provide a legitimate, nondiscriminatory reason for the benefit design, and, in certain instances, the issuer can demonstrate that modifying a plan to comply with Section 1557 would result in a fundamental alteration to their health program or activity. For TPA services, if the allegedly discriminatory benefit design or act originates with a TPA and applies to a self-funded plan, even if the plan sponsor requested—but did not design—the allegedly discriminatory feature, OCR suggests that it will hold the TPA liable.

OCR will perform a fact-specific analysis to determine whether an affiliate of a covered entity, such as a health insurance issuer's TPA affiliate, is sufficiently distinct that it is not subject to the Final Rule. As part of that analysis, OCR will consider how interrelated the covered entity and the affiliate's operations, controls, management, and employees are to one another. Covered entities should consider potential Section 1557 exposure as part of their merger and acquisition strategy.

The Final Rule explicitly notes that receipt of Medicare Part B payments constitutes a form of FFA that subjects the receiver to Section 1557's nondiscrimination mandate. The Final Rule also provides that Section 1557 applies to all of HHS's health programs and activities.

Importantly, the Final Rule includes an express exception for "any employer or other plan sponsor of a group health plan" and provides a non-exhaustive list that includes a board of trustees and associations (or other groups) with regard to their employment practices—including the provision of health benefits to employees.

GROOM INSIGHT: The Final Rule explained that employers that directly contract with CMS to offer a Medicare Advantage or Part D plan as an Employer Group Waiver Plan ("EGWP") and receive FFA for that EGWP or that offer qualified retiree prescription drug plans (also known as retiree drug subsidy or "RDS" plans) nevertheless are not subject to the Final Rule with respect to their employment practices. Even so, the group health plan itself would be subject to the Final Rule if, after OCR's "fact-specific analysis," OCR determines that the group health plan is a recipient, subrecipient, or indirect recipient of FFA. In contrast, if the employer contracted with a Medicare Advantage Organization ("MAO") or Part D Plan ("PDP") sponsor to offer an 800 series EGWP, then the MAO or PDP sponsor would be the FFA recipient and covered by the Final Rule.

Enhanced Discrimination Protections

This Final Rule reverts to policies established under the Obama Administration concerning discrimination on the basis of sex—specifically, LGBTQIA+ and pregnancy-related discrimination. Under both the Trump and Biden Administrations, the application of Section 1557 to LGBTQIA+ and pregnancy-related discrimination has been a target of legal challenges.

In the 2020 Rule, OCR removed the provisions detailing the particularities of sex discrimination. That same year, the Supreme Court issued a ruling that found, under Title VII of the Civil Rights Act of 1964 (which is *not* incorporated by reference into Section 1557), that sex discrimination covers both sexual orientation and gender identity.[3] OCR issued guidance in the following year explaining that it would interpret Title IX, as incorporated by reference under Section 1557, in alignment with the Supreme Court's holding in *Bostock*. This Final Rule cements this policy by including provisions addressing sex discrimination involving sex characteristics, sexual orientation, gender identity, and sex stereotypes. Covered entities subject to Section 1557 are now prohibited from taking the following actions:

- Denying or limiting health care-related services on the basis of an individual's sex assigned at birth, gender identity, or gender otherwise recorded;
- Denying or limiting a healthcare provider's ability to provide those services if this action has the effect of excluding individuals from participation in, denying them the benefits of, or otherwise subjecting them to discrimination on the basis of sex under a covered health program or activity;
- Adopting or applying a policy that treats individuals differently or separates them on the basis of their sex if this practice or policy results in more than *de minimis* harm (including to the extent a policy prevents an individual from participating in a health program or activity consistent with the individual's gender identity); and
- Denying or limiting gender affirming or gender transition care that would be provided to an individual for other purposes solely on the basis of an individual's sex assigned at birth or gender identity.

The Final Rule explicitly includes exceptions for "the provision of any health service" or "coverage of any health service" "where the covered entity has a legitimate, nondiscriminatory reason for denying or limiting" that service or coverage. OCR noted that this exemption is not intended to enable denials of healthcare services or coverage for such services due to unlawful animus or bias. OCR also included an exemption to protect religious freedom and conscience whereby covered entities can submit documentation to avoid compliance with particular provisions in the Final Rule if the covered entity provides legal and factual support for the exemption.

The Final Rule also explicitly includes language that prohibits discrimination on the basis of "pregnancy or related conditions." "Related conditions" are not explicitly defined in the text of the Final Rule, but OCR noted in the preamble that this term is intended to include "termination of pregnancy." The agency explained it declined to provide more specific examples of the definition of "related conditions" in the regulations.

GROOM INSIGHT: The provisions in the Final Rule concerning sex discrimination are likely to lead to legal challenges in states where the availability of gender-affirming or gender transition care has been limited. Indeed, Florida already has filed a legal challenge on this point.

Language Assistance Services and Removal of Telehealth Barriers

The Final Rule requires entities subject to Section 1557 to ensure that their health programs and activities available via telehealth are accessible to those with disabilities and limited English proficiency. The Final Rule also requires covered entities to inform individuals that language assistance services and auxiliary aids are available at no cost. Covered entities must post this information in a prominent location on their health program or website (if applicable), provide the notice upon an individual's request, and share it annually with enrollees and applicants. This Notice of Availability must be provided in English and in at least 15 of the most common languages spoken by people with limited English proficiency in the state where the covered entity operates.

Individuals may opt-out of receiving the Notice of Availability after being asked about their language needs. Covered Entities may document an individual's primary language and any necessary auxiliary aids and services and then provide information in accordance with that selection.

OCR has provided sample notices in English and 47 other languages that covered entities may use.[4] Additionally, the Final Rule requires covered entities to implement policies and training to ensure individuals with limited English proficiency may access their services.

Patient Care Decision Support Tools

The Biden Administration issued Executive Order 14110 in November 2023 that directed HHS to evaluate the regulatory actions it should take to ensure safe and responsible usage of artificial intelligence by healthcare entities. HHS addresses artificial intelligence in the Final Rule by adding a nondiscrimination provision specifically applicable to "patient care decision support tools," which are defined as "automated or non-automated tool[s], mechanism[s], method[s], technolog[ies], or combination thereof used by a covered entity to support clinical decision-making in its health programs or activities."

GROOM INSIGHT: The Final Rule's reference to "patient care decision support tools" includes non-automated patient care decision support tools, such as flowcharts, as well as technology-based tools, such as predictive decision support interventions.[5] As a result, covered entities should analyze not only algorithms and technology-driven supports, but other decision support tools and documentation for compliance, as well.

Covered entities are obligated to "make reasonable efforts to identify uses" of these tools that employ input variables or factors that account for race, color, national origin, sex, age, or disability and "make reasonable efforts to mitigate the risk of discrimination" that could result from such tools. Importantly, the Final Rule regulates the *usage* of patient care decision support tools, *not* the development of these tools (which is subject to separate regulation by HHS). This provision has a delayed effective date of May 1, 2025 (*i.e.*, within 300 days of the effective date of the Final Rule).

OCR requested additional comment on whether to engage in additional rulemaking to expand the scope of this provision and, if so, how.

Notice of Nondiscrimination and Civil Rights Grievance Procedures and Coordinator

Entities subject to Section 1557 must post a Notice of Nondiscrimination that informs individuals, including the public, of their civil rights under Section 1557. Covered entities with 15 or more employees are also required to establish grievance procedures as well as designate an employee to be the "Section 1557 Coordinator" who will oversee the covered entity's compliance with this Final Rule.

Religious Freedom and Conscience Protection Exemptions

The Final Rule implements a notification process by which recipients of FFA from HHS may affirmatively request an assurance of exemption from application of the Final Rule to the entity. Additionally, the FFA recipient could raise this exemption request as a defense to an ongoing OCR investigation. OCR will acknowledge the request within 30 days, during which time the requestor may rely on a temporary exemption while OCR adjudicates the request.

The general process for requesting an assurance of exemption is as follows:

- Identify the provision of care to which the covered entity objects, specifying whether the objection is to the service overall or to the provision of care in a specific circumstance;
- Explain the legal basis supporting the claim, including the applicable federal religious freedom and conscience protections and requirements; and
- Provide the factual basis supporting the claim including the conflict between the recipient's religious or conscience beliefs and the requirements of section 1557.

OCR will conduct a case-by-case consideration of facts, the appropriate legal standard (*e.g.*, Religious Freedom Restoration Act ("RFRA"), Church Amendment, etc.), any potential harm an exemption could have on third parties, and whether imposing burdens on a covered entity is the least restrictive means of furthering a compelling government interest. An exemption may apply in specific contexts, to particular procedures, or health services generally.

Enforcement

The Final Rule provides that the enforcement mechanisms in the underlying Civil Rights laws shall apply for purposes of Section 1557, and OCR clarifies that it is the agency within HHS that investigates and enforces 1557 complaints. The preamble to the Final Rule also notes that courts have recognized that Section 1557 authorizes a private right of action under any of the bases for discrimination.