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Biden Administration Proposal Restores, Updates Obama-Era Affordable Care Act Section 1557 Rules

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On August 4, 2022, the Biden Administration published its long-anticipated proposed rulemaking on Affordable Care Act ("ACA") Section 1557's nondiscrimination in health programs and activities requirements ("Proposed Rule"). Strengthening civil rights protections and language access via Section 1557 is a centerpiece of the Department of Health and Human Services' Equity Action Plan, in furtherance of the Administration's Inauguration Day Executive Order 13985, Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, which identified health equity and nondiscrimination as a domestic policy priority. Comments on the Proposed Rule closed October 3, 2022.

Background

ACA Section 1557 prohibits discrimination on the basis of race, color, national origin, sex, age, or disability, for any health program or activity, any part of which receives federal funding or assistance, or under any program or activity that is administered by an executive agency or any program or activity administered by an entity established by title I of the ACA. In so doing, Section 1557 incorporates both the protections and the remedies available under 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. The extent to which prior law for those four acts is incorporated or controlling for Section 1557 is addressed via both Section 1557's implementing regulations and emerging case law.

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Finalized in the 2016, the Obama Administration's Section 1557 regulations created broad, detailed requirements for health insurance issuers, group health plans, third-party administrators ("TPAs"), and providers. The Trump Administration took a narrower approach in its 2020 rulemaking, reducing the scope of covered entities and lifting certain nondiscrimination requirements. Section 1557's scope and meaning, as interpreted in regulations, are one of the most consequential and contested aspects of the ACA, with legal challenges to both the Obama Administration's and the Trump Administration's regulations. Now, as detailed below, the pendulum swings back toward a more expansive interpretation of Section 1557.

Summary of Select Provisions

Broad Application to Programs and Activities

The Proposed Rule would apply to every health program or activity any part of which receives federal financial assistance ("FFA"), directly or indirectly from HHS; every health program or activity administered by HHS, and every program or activity administered by an ACA Title I entity (Exchanges, both FFE and state-based, including those on the federal platform). FFA includes monetary and nonmonetary subsidies, but not all government payments to beneficiaries are FFA (for example, Social Security payments and veterans' pensions do not constitute FFA). The Proposed Rule includes the following non-exhaustive list of HHS programs providing FFA: Medicaid and CHIP, Medicare Parts A, B, C, and D, and HHS grant programs. The addition of Medicare Part B as FFA for purposes of 1557 and Title VI, Section 504, Title IX, and the Age Act is new in the Proposed Rule.

The Proposed Rule adopts a broad interpretation of "health program or activity," defined as:

> any project, enterprise, venture or undertaking to provide or administer health-related services, health insurance coverage, or other health-related coverage; provide assistance to persons in obtaining health-related services, health insurance coverage, or other health-related coverage; provide clinical, pharmaceutical, or medical care; engage in health research; or provide health education for health care professionals or others.

This includes "all of the operations of any entity principally engaged in the provision or administration of health projects, enterprises, ventures, or undertakings" described above. In contrast to the Trump Administration's narrower interpretation, the Proposed Rule applies to health insurance issuer operations, including when acting as a TPA for a group health plan.

Consistent with the Obama Administration rules, the Proposed Rule will apply to health insurance issuers' TPA operations for self-funded plans when the issuer is a recipient of FFA. Similarly, it "will engage in a fact-specific analysis to evaluate whether a third party administrator is appropriately covered under Section 1557 as a recipient of Federal financial assistance in circumstances where the third party administrator is legally separate from the issuer that receives Federal financial assistance." *See* 87 Fed. Reg. 47,876.

GROOM INSIGHT: The Proposed Rule also suggests that TPAs subject to Section 1557 may be held liable for Section 1557 violations when the allegedly discriminatory act or

feature originated with the TPA. For example, if a group health plan adopts a template plan document provided by the TPA, the TPA could be found liable. This appears to be the case even in the event the plan sponsor formally adopts the document or benefit design as the plan settlor.

Group health plans are not necessarily in scope for the Proposed Rule; it depends on whether the group health plan receives FFA, such as the retiree drug subsidy. Although a group health plan may be engaged in providing or administering a health program or activity, the group health plan itself may not be a recipient of FFA and, therefore, would be outside the scope of Section 1557. If the group health plan receives FFA, however, then it is subject to 1557. The Proposed Rule explained that HHS will evaluate Section 1557 complaints against group health plans on a case-by-case basis. Generally, the Proposed Rule appears to indirectly apply to insured group health plans via the issuer's receipt of FFA and to self-insured group health plans via the TPA if the TPA develops the group health plan document or other policy documents, as often occurs.

The Proposed Rule also does not apply to an employer with respect to its employment practices, including its provision of employee health benefits. This is a departure from both the 2016 and 2020 regulations, which applied to employment in certain limited circumstances (employee health benefit programs). A health insurance issuer's employee-sponsored health plan, however, would be subject to Section 1557 because the regulation applies to all of the issuer's operations.

HHS requested comments about how a group health plan may receive funds considered FFA from HHS—such as the retiree drug subsidy—and whether to add additional examples of entities that would qualify as principally engaged in the provision or administration of health programs or activities.

Prohibited Discrimination in Health Insurance Coverage and Other Health-related Coverage

The Proposed Rule, "prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in the provision or administration of health insurance coverage and other health-related coverage." Consistent with the Supreme Court's ruling in *Bostock v. Clayton County*, 140 S. Ct. 1731 (2020) and the Obama-era regulations, the Proposed Rule construes discrimination on the basis of sex broadly to prohibit, *inter alia*:

- Denying coverage for sex-specific services based on an individual's sex at birth, gender identity, or gender otherwise recorded;
- Having or implementing a categorical exclusion or limitation for all health services related to gender transition or gender-affirming care; or
- Otherwise deny, limit, or impose additional cost sharing on specific health care services related to gender transition or gender-affirming care if such denial or limitation results in discrimination on the basis of sex—though the provisions do not require coverage of specific procedures or treatments for gender transition or gender-affirming care that are not otherwise covered under the plan, exclusions that limit care to one class of gender transition or gender-

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affirming care *may* violate this provision (*e.g.*, depending on the policy or plan, the categorical exclusion of certain procedures for gender dysphoria discriminates on the basis of sex).

The Obama-era rule did not incorporate Title IX exceptions because Section 1557 does not unambiguously require it to do so. The 2020 Rule was less clear, it asserted that Section 1557 incorporated the scope of Title IX, but stopped short of expressly incorporating a religious exemption of other specific Title IX exceptions. The Proposed Rule also does not incorporate Title IX exceptions, reasoning that Section 1557 only prohibits discrimination on a basis prohibited under one of the four incorporated acts. Even so, HHS notes that it "is fully committed to respecting conscience and religious freedom laws when applying this rule" and points to newly proposed § 92.302, discussed below.

The Proposed Rule also would include a new provision prohibiting covered entities from discriminating on the basis of sex regarding an individual's marital, parental, or family status. Similar to HHS's Title IX regulation, 45 C.F.R. § 86.40(a), the Proposed Rule would prohibit covered entities from considering an individual's current, perceived, potential, or past marital, parental, or family status. HHS added this requirement based, in part, on complaints alleging that covered entities automatically assigned a male spouse as the guarantor when a female spouse received medical services but did not apply a similar assignment when the male spouse received medical services.

Proposed Rule § 92.302 is new and intended to address a recipient's concern that applying the 1557 regulations to it violates federal conscience or religious freedom protections. The rule allows recipients to raise these concerns and requires OCR to promptly consider those concerns and hold in abeyance any relevant ongoing investigation or enforcement activity regarding the recipient pending resolution of the concerns. The Proposed Rule clarifies that OCR has the discretion to determine—on a case-by-case basis—whether a recipient is entitled to an exemption or modification of the 1557 regulations based on federal conscience or religious freedom laws.

As proposed, OCR "must assess whether there is a sufficiently concrete factual basis for making a determination and apply the applicable legal standards of the referenced statute." OCR would then communicate its determination, which would not otherwise limit the application of any other aspect of the 1557 regulations aside from those specifically identified—to the recipient. The Proposed Rule does not address the process by which recipients could challenge adverse determinations or whether an investigation or enforcement action would remain stayed pending a recipient's appeal of such determination.

HHS requested comment on this approach, including whether to provide additional procedural information, whether to consider additional factors when considering the relationship between Section 1557 and federal conscience and religious freedom protections, potential alternatives, and the burdens of this proposal on recipients and third parties.

Subsequently, on August 26, a three-judge panel from the United States Court of Appeals for the Fifth Circuit unanimously affirmed a district court's permanent injunction prohibiting HHS from requiring the Plaintiff religious organizations to perform gender-reassignment surgeries or abortions in violation of their sincerely held religious beliefs based on the Religious Freedom Restoration Act. *Franciscan Alliance Inc. et al. v. Becerra et al.*, No. 21-11174 (5th Cir. Aug. 26, 2022). The Fifth Circuit dismissed as moot the plaintiffs' Administrative Procedure Act claim to vacate the Obama-era regulation because it

had been vacated in part by the district court and subsequently rescinded by the Trump Administration. As a result, the Biden Administration's proposed rulemaking's nondiscrimination protections on the basis of sex may have limited impact on religiously affiliated organizations that challenge the rule.

The Biden Administration requested comments about whether to include a provision specifically addressing discrimination based on pregnancy-related conditions. HHS also sought comments on how *Dobbs v. Jackson Women's Health Organization*, 142 S. Ct. 2228 (2022), may impact Section 1557 or these rules. Additionally, HHS solicits input on other means to ensure nondiscriminatory access to care.

GROOM INSIGHT: Battle over the scope of abortion rights and access is ongoing, with the Biden Administration and states each exploring options to restrict or expand access in the wake of *Dobbs*. Section 1557 may provide a limited basis for protecting abortion rights. More broadly, the Fifth Circuit's ruling in *Franciscan Alliance* portends strong headwinds for application of nondiscrimination provisions to religiously affiliated organizations despite their receipt of FFA.

The Proposed Rule also prohibits discriminatory marketing practices and benefit designs that discourage enrollment in a plan, such as not advertising in a region populated by a majority of people of color or using cost sharing and formulary design that affect persons with certain health conditions.

Clinical Algorithms Used in Decision-Making

Given the increasing use of clinical algorithms to support utilization management and clinical decision-making, the Proposed Rule applies Section 1557's nondiscrimination requirements to clinical algorithms. Notably, covered entities would not be liable for clinical algorithms that they did not develop, but would be responsible for discriminatory decisions the covered entities made on the basis of the algorithms. The Proposed Rule frames this provision against the backdrop of the COVID-19 pandemic and growing research on the unintended consequences of clinical algorithms. Similar concerns had been expressed by commenters in response to the 2023 Notice of Benefit and Payment Parameters proposed rulemaking's discussion on the use of clinical evidence to support nondiscriminatory benefit design. In that context, commenters cited concern with "embedded systemic racism and bias" pervasive in medical research underlying clinical evidence.[1]

GROOM INSIGHT: Covered entities may need to make reasonable modifications to how clinical algorithms are used—unless that would cause a fundamental alteration to the covered entity's health program or activity. Algorithms that rely on protected characteristics may, in some circumstances, be appropriate, such as to identify health disparities or advance health equity. That said, HHS cautions against over reliance on

[1] 87 Fed. Reg. at 27,299.

clinical algorithms and highlights the importance of a provider's independent clinical judgment applied to the specific needs and medical history of the patient.

Application to Telehealth Services

The Proposed Rule introduces additional accessibility requirements for the provision of telehealth services. Given the rapid expansion of telehealth utilization during the COVID-19 pandemic, the federal government has been focused on potential discriminatory effects in the provision and use of telehealth services. For example, the 2023 Notice of Benefit and Payment Parameters final rule also included discussion on how the use of telehealth may impact nondiscriminatory access to essential health benefits.[2] The Proposed Rule requires telehealth services to be accessible to individuals with disabilities, such as by including support for third-party services providing real-time captioning or additional video feeds to support interpreters and decision makers.

Meaningful Access for Limited English Proficient Individuals and Effective Communication for Individuals with Disabilities

Covered entities must "take reasonable steps to provide meaningful access to each limited English proficient individual eligible to be served or likely to be *directly affected* by its health programs and activities." Individuals likely to be directly affected include persons in the covered entity's service area and who are eligible for the covered entity's benefits or services or may be directly affected by its conduct. Language access services must be: provided free of charge, accurate and timely, and protect the LEP individual's privacy and independent decision-making. Likewise, subject to certain limited exceptions, covered entities cannot rely on individuals that are not qualified interpreters to provide LEP individuals assistance. The Proposed Rule reinstates, with some modifications, the Obama Administration notice requirements, including the publication of a notice of nondiscrimination and notice of availability of language assistance services and auxiliary aids and services (*i.e.*, taglines) in English and the top 15 most common languages spoken by LEP individuals in the state.

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Additionally, the Proposed Rule restored the Obama-era regulations' requirement that covered entities with more than 15 employees designate a Section 1557 Coordinator. The Proposed Rule identifies specific responsibilities for the coordinator, delineates compliance and grievance policies and procedures, and newly introduces an explicit training requirement. Finally, the Proposed Rule reiterates that Section 1557 includes a private right of action in addition to investigation and enforcement by HHS OCR.

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[2] *Id*. at 27,300-301.