Biden Administration Proposes Significant Revisions to Trump-Era Nondiscrimination Regulations

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Key Takeaways:

- The Biden administration released a its long-awaited "Nondiscrimination in Health Programs and Activities" proposed rule which would restore, and in certain cases strengthen, many of the nondiscrimination protections eliminated by the Trump administration.
- While the rule is far reaching, it is most notable for its focus on restoring protections for discrimination based on sexual orientation and gender identity.
- In the wake of the Supreme Court decision in *Dobbs v. Jackson Women's Health Organization*, HHS is also seeking feedback on ways in which the agency can address discrimination on the basis of pregnancy-related conditions.
- The rule also proposes to adopt a number of new protections, including with respect to accessibility for buildings and facilities, for the use of clinical algorithms, and with respect to health services delivered through telehealth.

On July 25, 2022, the Department of Health and Human Services (HHS) Office for Civil Rights (OCR) released a long-awaited proposed rule on Section 1557 of the Affordable Care Act (ACA), the nondiscrimination protections enacted by Congress in 2010.[1] The Proposed Rule follows on the heels of a 2020 Final Rule promulgated by the Trump administration which significantly rolled back many Obama-era regulatory protections first adopted in 2016, perhaps most notably by eliminating the prohibition on discrimination based on gender identity and sex-stereotyping. HHS states the 2022 Proposed Rule is necessary to better align Section 1557 regulations with the underlying statute, reflect recent developments in civil rights case law, address unnecessary confusion in compliance and enforcement resulting from the Trump-era 2020 Final Rule, and better address issues of discrimination that contribute to negative health outcomes.

BACKGROUND

Section 1557 of the ACA seeks to protect against discrimination in the provision of health care services by extending a series of existing civil rights laws,[2] and providing that individuals may not be excluded on the basis of race, sex, age or disability from participation in, be denied the benefits of, or be subjected to discrimination under any "health program or activity" that receives "federal financial assistance."

In May 2016, the Obama administration issued the first final rule implementing Section 1557 (2016 Final Rule).[3] Among other provisions, the 2016 Final Rule defined discrimination "on the basis of sex" to cover, among other things, discrimination on the basis of sex stereotyping, gender identity, and termination of pregnancy.[4] Furthermore, the 2016 Final Rule included protections for individuals with limited English proficiency (LEP), such as requiring covered entities to include with all "significant" documents certain "non-discrimination notices" that include the top 15 languages spoken by individuals with LEP in the state and that indicate the availability of language assistance services.[5]

On June 12, 2020, the Trump administration (in the wake of ongoing lawsuits challenging the Obama-era regulation) issued a new final rule interpreting Section 1557.[6]The 2020 Final Rule made significant changes to the 2016 rulemaking. For example, it withdrew the 2016 Final Rule's definition of discrimination "on the basis of sex" that included discrimination based on gender identity or termination of pregnancy. HHS stated that it would interpret "sex" solely as "biological sex," meaning a person's genetic sex at birth. (It should be noted that subsequent to the publication of the 2020 Final Rule, in *Bostock v. Clayton County Georgia*, the Supreme Court in a 6-3 decision held

that discrimination based on transgender status or sexual orientation "necessarily entails discrimination based on sex" within the context of Title VII of the Civil Rights Act.[7]). The 2020 Final Rule also narrowed the scope of language access requirements for patients with LEP, arguing that this would "particularly reduce the economic burden imposed on healthcare providers and insurers."[8]

2022 PROPOSED RULE

HHS now proposes to revise the 2020 Final Rule to "reinstate regulatory protections from discrimination on the basis of race, color, national origin, sex, age, or disability in covered health programs and activities, consistent with the statutory text of Section 1557 and Congressional intent." HHS proposes to apply the new rule to:

(1) every health program or activity, any part of which receives "federal financial assistance," directly or indirectly, from HHS;

(2) every health program or activity administered by HHS; and

(3) every program or activity administered by a Title I entity.

This scope is largely a reinstatement of the scope of the Obama-era 2016 Final Rule. HHS proposes to define "federal financial assistance" to include grants, loans, and other types of assistance from the Federal Government. HHS also proposes to specifically include credits, subsidies, and contracts of insurance. Examples of HHS programs that provide federal financial assistance subject to 1557 include but are not limited to Medicaid and CHIP, Medicare Part A, Part B (discussed below), Part C, Part D and HHS grant programs.

Medicare Part B. Notably, HHS also proposes to reverse its longstanding position regarding whether Medicare Part B payments constitute federal financial assistance for purposes of the relevant federal civil rights laws. HHS' longstanding position has been that Medicare Part B funding does not constitute federal financial assistance for the purpose of Title VI, Title IX, Section 504, the Age Act, and Section 1557, meaning that Part B providers were not bound by these civil rights obligations solely on the basis of their receipt of funds under Medicare Part B. HHS now states that it has reevaluated this policy, and is proposing to change its position and treat Medicare Part B funds as "federal financial assistance to the providers and suppliers subsidized by those funds." Under this new reinterpretation, providers that are enrolled in the Part B program (both participating and non-participating providers) will now be subject to these existing civil rights laws, including Section 1557.

Sex Discrimination. HHS proposes to 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." While the 2022 Proposed Rule largely reinstates the 2016 definition of sex discrimination, it goes further by including references to both "sex characteristics" and "intersex traits." HHS says it is proposing to include "sex characteristics" in the definition of sex discrimination because discrimination based on anatomical or physiological sex characteristics (such as genitals, gonads, chromosomes, hormone function, and brain development/anatomy) is inherently sex-based. Furthermore, according to HHS, discrimination on the basis of intersex traits is similarly prohibited sex discrimination because the individual is being discriminated against based on their sex characteristics. If their sex characteristics were different—i.e., traditionally "male" or "female"—the intersex person would be treated differently. Moreover, like gender identity and sexual orientation, intersex traits are "inextricably bound up with" sex, and "cannot be stated without referencing sex."

HHS states it is also considering whether this proposal should include a provision to specifically address discrimination on the basis of pregnancy-related conditions. The agency states it believes it could be beneficial to include a provision specifically prohibiting discrimination on the basis of pregnancy-related conditions as a form of sex-based discrimination. The agency is seeking comment on whether and how it should do so. HHS also seeks comment on what impact, if any, the Supreme Court decision in *Dobbs v. Jackson Women's Health Organization* has on the implementation of Section 1557 and these regulations.

Equal Program Access on the Basis of Sex. HHS proposes to reinstate a section clarifying covered entities' obligation to ensure equal access to their health programs and activities without discrimination on the basis of sex, including pregnancy, sexual orientation, gender identity, and sex characteristics. This provision would primarily relate to covered entities that are directly engaged in the provision of health care services, such as hospitals, physical and mental health care providers, and pharmacies. While the 2016 Final Rule included a section on equal program access on the basis of sex, the 2020 Final Rule did not.

Notice of Nondiscrimination. HHS points out that the 2016 Final Rule received criticism for failing to provide a definition of "significant publications or significant communications" subject to the rule's notice and tagline requirements. HHS also notes that it received substantial feedback regarding the financial burden imposed by these requirements. The 2020 Final Rule cited these concerns in repealing

the 2016 Final Rule's provisions on notices and taglines in their entirety.

HHS states that although it acknowledges the additional responsibilities placed on covered entities through the 2016 Final Rule requirements relating to the notice of nondsicrimination, it believes that the 2020 Final Rule did not adequately consider some of the harms and burdens incurred by individuals and health care systems without these notice provisions. As such, HHS proposes to again require covered entities to provide a notice of nondiscrimination, relating to their health programs and activities, to participants, beneficiaries, enrollees, and applicants of their health programs and activities, and to members of the public.

In contrast to the 2016 Final Rule, however, the Proposed Rule would require covered entities to *provide the notice on an annual basis and upon request*, rather than in all "significant" communications. Similar to the 2016 Final Rule requirements, HHS proposes that the notice also be placed at a conspicuous location on the covered entity's health program or activity 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 or activity to be able to read or hear the notice. The agency states it believes the proposal addresses the burdens raised by covered entities in response to the 2016 Final Rule notice requirements by providing specific occurrences (annual basis and upon request) and locations (conspicuous location on website and prominent physical location) for when and where the notice must be provided rather than the ambiguity caused by the 2016 Final Rule.

Notice of Availability of Language Assistance Services and Auxiliary Aids and Services. The 2016 Final Rule required covered entities to include "taglines" in at least the top 15 languages spoken by LEP individuals in the relevant state or states in significant publications and communications and at various locations. The 2020 Final Rule repealed this provision, citing costs, confusion, and waste, but stated that covered entities were still required "to provide taglines whenever such taglines are necessary to ensure meaningful access by LEP individuals to a covered program or activity."

The 2022 Proposed Rule seeks to find a middle ground between the 2016 and 2020 regulations. It would require that the Notice of Availability be provided 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. While the standard of providing the statement in these "top 15" languages is the same as that required by the 2016 Rule, the 2022 Proposed Rule seeks "to alleviate burdens" here by also proposing an explicit list of the relevant materials that must include the Notice of Availability, as well as providing options for covered entities to allow individuals to "opt out" of receipt of the Notice of Availability or to provide communication to individuals in their primary language in lieu of a Notice of Availability.

Meaningful Access for Limited English Proficient Individuals. The 2022 Proposed Rule would also require covered entities "take reasonable steps to provide meaningful access to each [LEP] individual eligible to be served or likely to be directly affected by its health programs and activities." This language is nearly identical to the 2016 Final Rule, which required a covered entity to take reasonable steps to provide meaningful access to each LEP individual "eligible to be served or likely to be encountered."

Under the 2022 Proposed Rule, language assistance services must be provided free of charge, be accurate and timely, and protect the privacy and independent decision-making ability of an LEP individual. This provision is similar to those included in the 2016 and 2020 Final Rules. The 2022 Proposed Rule also outlines specific requirements regarding interpreter and translation services and the use of machine translation. HHS seeks comment on the use of machine translation in health programs and activities generally, other possible approaches to address this issue, and whether there should be an exception to allow for the limited use of machine translation in exigent circumstances.

Accessibility for Buildings and Facilities. The 2022 Proposed Rule adds a new general provision, not in the 2016 or 2020 Final Rules, "establishing that no qualified individual with a disability shall, because a covered entity's facilities are inaccessible to or unusable by individuals with disabilities, be denied the benefits of, be excluded from participation in, or otherwise be subjected to discrimination under any health program or activity … consistent with the Department's Section 504 regulation covering federally assisted and federally conducted programs and activities."

Clinical Algorithms. HHS additionally proposes provisions related to nondiscrimination in the use of clinical algorithms in health care decision-making and in telehealth services. According to HHS, this is a new provision, and this topic has not been addressed in previous rulemaking (2016 or 2020).

Telehealth. The 2022 Proposed Rule also, for the first time, addresses nondiscrimination in the delivery of health programs and activities specifically through telehealth services. According to HHS, this duty includes ensuring that such services are accessible to individuals with disabilities and provides meaningful program access to LEP individuals.

Procedural Requirements. The 2022 Proposed Rule seeks to create consistent procedural requirements for covered health programs and activities by requiring grievance procedures (for employers with 15 or more employees), the designation of a responsible employee (for employers with 15 or more employees), and the affirmative provision of civil rights notices. According to HHS, "the absence of such consistency [in the 2016 and 2020 Final Rules] leaves individuals with different procedural protections in covered programs and activities depending on whether their complaint is based on race, color, national origin, sex, age, and/or disability."

Section 1557 Coordinator. The 2022 Proposed Rule would also reinstate the requirement that covered entities with 15 or more employees designate at least one employee to serve as a Section 1557 coordinator to coordinate their efforts to comply with and carry out the covered entity's responsibilities under Section 1557 with regard to their health programs and activities. The 2016 Final Rule similarly required covered entities of this size to designate a compliance coordinator for Section 1557, but the 2020 Final Rule repealed this requirement.

Training. The 2022 Proposed Rule would also require covered entities to train relevant employees in their health programs and activities on their Section 1557 Policies and Procedures. This proposal is "designed to help covered entities and their employees take measures to prevent discrimination by ensuring that staff are knowledgeable about" Section 1557 requirements. Neither the 2016 nor the 2020 Final Rules included a training requirement.

Benefit Design and Marketing Practices. The 2022 Proposed Rule proposes to reinstate specific provisions related to the prohibition against 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. This proposal would also specify that health insurance and other health-related coverage offered through the Exchanges and Medicaid must be provided in a nondiscriminatory manner. According to HHS, this is consistent with the 2016 Final Rule, which similarly prohibited discrimination in health-related insurance and other health-related coverage. The 2020 Final Rule had rescinded this provision.

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[1] https://www.hhs.gov/sites/default/files/section-1557-nprm.pdf.

[2] 42 U.S.C. § 18116 (e.g., Title VI of the 1964 Civil Rights Act; Title XIX of the Education Amendments of 1972, Section 504 of the Rehabilitation Act, the Age Discrimination Act of 1973).

[3] *Nondiscrimination in Health Programs and Activities*, 81 Fed. Reg. 31375 (May 18, 2016).

[4] 81 Fed. Reg. at 31467.

[5] 81 Fed. Reg. at 31469.

[6] 85 Fed. Reg. 37160 (June 19, 2020).

[7] *Bostock v. Clayton County, Georgia*, 140 S. Ct. 1731, 1747 (2020).

[8] 85 Fed. Reg. at 37241.

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