Health Care in Motion
Timely, Substantive Updates on Policy Shifts · Actionable Advocacy to Protect Health Care

May 2, 2024

Section 1557 ACA Non-Discrimination Rule Finalized: What the Rule Means for Health Care Access

At long last, the Biden Administration has finalized its rule clarifying the protections laid out in Section 1557 of the Affordable Care Act (ACA), the part of the law that forbids federally funded health care activities and programs from discriminating on the basis of sex, race, color, national origin, age, or disability. The scope of Section 1557 protections has expanded and retracted over three Presidential Administrations. In this new final rule, the Biden Administration restores – and builds on – many of the original protections of the 2016 rule that were eliminated in 2020. At the same time, there are several discrete topics in which the new rule falls short of the expectations of advocates for health care access, and in other areas it refuses to offer any position at all. For a deeper dive into how we got here, see our previous Health Care in Motion summarizing the twists and turns of Section 1557 rulemaking over the last eight years. Read on for an overview of what's new in the Biden Administration's final rule and how it will impact access to health care.

What's In and What's Out of the Final 1557 Rule?

The new final rule departs significantly from the Trump era rule, restoring and expanding non-discrimination protections, including in the following areas.

Covered entities

The scope of covered entities that must comply with Section 1557 protections went from a fairly expansive interpretation under the Obama Administration's 2016 rulemaking to a very restrictive interpretation under the Trump Administration's 2020 rule that excluded health insurance from 1557 protections. Under the new final rule, covered entities include health care providers (e.g., hospitals, clinics, pharmacies, doctor's offices) *and* issuers selling health insurance plans.

CHLPI's Recent 1557 Advocacy

- CHLPI comments on discriminatory use of clinical algorithms and proposed 1557 protections (October 2022)
- HHCAWG comments on 1557 proposed rule (October 2022)
- CHLPI and Quinnipiac Legal Clinic Urge Federal Appeals Court to Hold Firm on ACA Civil Rights Protections for Transgender and Reproductive Health Care (October 2020)

The new final rule also reinstates the interpretation that applies Section 1557 protections to every facet of a covered entity's operations, not just the part accepting federal financial assistance. For example, all health

insurance products sold by an issuer that receives federal funding through Advance Premium Tax Credits (APTCs) would be subject to Section 1557, including health insurance that the issuer provides to a fully-insured group health plan, third-party administrator activities the issuer provides to a self-funded group health plan, and even short-term limited duration insurance plans and excepted benefits plans. This is an important interpretation that expands non-discrimination protections to a far greater number of stakeholders across the health care landscape.

Discrimination on the basis of sex

The definition of discrimination on the basis of sex was eliminated by the Trump Administration's Section 1557 rule. Under the new final rule, the regulatory definition of "on the basis of sex" was restored and modified. The new final rule clarifies that discrimination on the basis of sex explicitly includes discrimination on the basis of sex stereotypes and sex characteristics, including intersex traits, pregnancy or related conditions, sexual orientation, and gender identity. The new final rule retains the details included in the proposed rule related to gender identity discrimination, including examples of prohibited plan design discrimination based on gender identity.

Before finalizing the rule, the Biden Administration requested comments on whether it should clarify that discrimination based on "pregnancy or related conditions," includes termination of pregnancy. A clear statement like that would have been a strong showing from the Administration as to how it plans to enforce the new final rule. Instead, the administration opted not to include any examples, noting in the preamble that sex discrimination protections include termination of pregnancy. It will be important going forward to see how the Administration balances this interpretation of sex discrimination with their interpretation of federal laws regarding a provider's refusal to provide an abortion.

> ***Discrimination based on gender identity (example)***
>
> *A covered entity that routinely provides OB/GYN care cannot deny an individual a pelvic exam because the individual is a transgender man or nonbinary person; covered entities are also prohibited from having categorical coverage exclusions of gender-affirming care.*

Discriminatory plan design

The 2020 rule eliminated sections prohibiting benefit designs and marketing practices that discriminate on the basis of race, color, national origin, sex, age, and disability. The new final rule reinstates these provisions and prohibits covered entities from denying, cancelling, or limiting health coverage based on these impermissible bases. The new final rule opts not to define "benefit design" but instead notes in the preamble that non-discriminatory plan design protections apply to plan marketing, cost-sharing design, utilization management, and provider networks. While advocates requested more details on what constitutes discriminatory plan design, including specific examples of prohibited designs, the final rule is largely silent on specifics. HHS will conduct a fact-specific inquiry in cases of alleged discrimination, and the covered entity may provide a legitimate, nondiscriminatory reason for the action or practice in response. The final rule also applies plan design protections to short-term limited duration insurance (STLDI) plans and other excepted benefits (e.g., hospital indemnity plans and Medigap plans). The effect of this is to focus increased pressure on the U.S. Department of Health and Human Services Office of Civil Rights, which will be responsible for responding to complaints and conducting investigations arising from allegations of discriminatory plan design.

Patient care decision support tools

The final rule includes a section prohibiting covered entities from discriminating against individuals on the basis of race, color, national origin, sex, age, or disability through the use of "patient care decision support tools." Under the proposed rule, these tools were referred to as "clinical algorithms," but the new final rule opts for a more specific term and definition. The final rule defines these support tools as "any automated or non-automated tool, mechanism, method, technology, or combination thereof used by a covered entity to support clinical decision-making in its health programs or activities." The rule clarifies that these tools could be used to assess health status, recommend care decisions, and conduct utilization management.

> ***Discriminatory patient care decision support tool (example)***
>
> *Clinical tools that evaluate kidney function have been found to undercount kidney disease in Black people. The algorithm used to assess kidney function adjusts the score for Black patients based on a biased assumption based on race, making their kidneys register as healthier than white patients despite Black Americans being four times as likely to have kidney failure as white Americans.*

This protection was not part of previous Section 1557 rules. The Biden Administration now includes this part of the new final rule to address rising concerns that patient care support tools based on faulty or biased assumptions about race and ethnicity will lead to discriminatory denial of necessary care and treatment.

Many examples of how this discrimination plays out were included in the proposed rule's preamble, including the kidney functioning algorithm discussed in the pull-out box. The new final rule clarifies that providers will not be held liable for discriminatory elements included in clinical algorithms, but they will be accountable for ensuring that they are not making discriminatory health care decisions based on algorithms.

Language access

Recognizing the large number of people in the United States for whom English is not the primary language, the new final rule reinstates many of the language access protections that had been included in the 2016 rule, but largely erased from the Trump Administration rule. The new final rule requires covered entities to take steps to provide "meaningful access" to individuals with limited English proficiency (LEP) and provide notices in different languages to ensure individuals are aware of their Section 1557 non-discrimination rights and are aware of the availability of language services. Covered entities will be required to use a "Notice of Availability," alerting consumers with LEP about language access resources. This notice must be available in at least the 15 most common languages spoken by individuals with LEP in the relevant state and in alternate formats for individuals with disabilities who request auxiliary aids and services. The notice must be included on "significant documents," and the final rule provides a list of documents considered significant. Finally, the final rule adds the requirement that a qualified human translator must review a machine translation (i.e., use of artificial intelligence to automatically translate text from one language to another) in certain circumstances.

Enforcement

The final rule clarifies that the enforcement mechanisms available to individuals who experience impermissible discrimination are the same enforcement mechanisms in the federal civil rights laws referenced in the law (Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, section 504 of the Rehabilitation Act of 1973, and the Age Discrimination Act of 1975). The preamble to the rule explicitly

notes that a private right of action is also available. Other, more specific proposals made by advocates to expand enforcement capabilities using a more robust interpretation of Section 1557 were deferred to the courts by the new final rule.

Religious freedom and conscience exemptions

In a change from the proposed rule, the final rule adds new language repeatedly emphasizing that any entity subject to Section 1557 may "rely" on applicable Federal statutes protecting religious freedom and conscience. Additionally, the final rule strengthens a process by which a religious entity may seek exemptions from Section 1557 for certain services, provided they are able to point to a basis in federal law for such an exemption, and if providing the service would violate the entity's religious or conscience beliefs. On the one hand, this process could be seen as balancing existing federal laws protecting religious freedom and conscience with Section 1557's vital civil rights protections; on the other, the broad availability of the religious exemption leaves open questions about how exactly the department intends to enforce the rule, and whether OCR intends to countenance pretextual invocations of religious freedom and conscience protections as a *de facto* license to discriminate.

What's Next?

The ACA's Section 1557 non-discrimination provision is self-implementing, meaning it does not require a regulation to go into effect and has been in effect continuously since the passage of the ACA. The rule's general prohibition on discrimination on the basis of race, color, national origin, sex, age, and disability go into effect 60 days after publication of the final rule (scheduled for May 9, 2024). However, HHS has adopted a phased approach for covered entities to develop the policies, procedures, and operational changes needed to come into compliance, described in the table below.

1557 provision	**Date by which covered entities must comply**
Appointment of Section 1557 Coordinator	Within 120 days of effective date
Development of compliance policies & procedures	Within 1 year of effective date
Development of training	Following implementation of policies & procedures; no later than 1 year of effective date
Notice of nondiscrimination	Within 120 days of effective date
Notice of availability of language assistance service and auxiliary aids and services	Within 1 year of effective date
Nondiscrimination in health insurance coverage	By first day of the first plan year beginning on or after January 1, 2025
Use of patient care decision support tools	Within 300 days of effective date

Education on the rule's non-discrimination protections – for covered entities, consumers, and regulators – will be critical, as will a commitment from OCR to aggressively enforce the rule's protections.

Subscribe to all Health Care in Motion Updates

Health Care in Motion is written by Carmel Shachar, Health Law and Policy Clinic Faculty Director; Kevin Costello, Litigation Director; Elizabeth Kaplan, Director of Health Care Access; Maryanne Tomazic, Clinical Instructor; Rachel Landauer, Clinical Instructor; Johnathon Card, Staff Attorney; Suzanne Davies, Senior Clinical Fellow; and Anu Dairkee, Clinical Fellow. This issue was written with the assistance of Amy Killelea of Killelea Consulting.

*For further questions or inquiries please contact us at **chlpi@law.harvard.edu**.*