Under Section 1557 final rule, nondiscrimination mandates are coming soon

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Compliance

The finalization of the Section 1557 rule from HHS' Office for Civil Rights (OCR) means that practices will have to take practical steps — including training staff and designating a 1557 "coordinator" — with urgency, as the rule has an effective date of July 5 and tight deadlines.

The main points of the final rule, "Nondiscrimination in Health Programs and Activities," published on May 6, are nearly identical to those of the proposed rule that HHS issued in 2022 (*PBN 8/8/22*). They extend and codify the requirements of covered health care entities to protect the rights of patients to equal access to treatment under the provisions of Section 1557 of the 2010 Affordable Care Act. Section 1557 prohibits discrimination on the basis of multiple attributes recognized in civil rights law, including race and national origin.

The new rule, however, does not cover every single one of these areas, and repeatedly refers to other rules and laws that offer protection from discrimination on those bases. The rule instead focuses on accommodations for patients with limited English proficiency and with disabilities such as low vision or hearing, as well as an expanded understanding of "sex discrimination," which in HHS' reading includes discrimination on the basis of "pregnancy, sexual orientation, gender identity, and sex characteristics."

The first rule to broach 1557 topics, issued in 2016 under President Obama, was scaled back in 2020 by a rule issued under President Trump (*PBN 7/13/20*). The most notable aspect of the Trump administration's rule was its recission of any reference to transgender patients' rights, leaning on a "plain meaning of the word 'sex' as male or female and as determined by biology."

Rule broadens definitions; Part B swept in

The 2020 rule also limited the definition of covered entities for purposes of the rule to specific lines of business of a "health program or activity" that received "federal financial assistance," rather than the entire business running those lines; this largely exempted, for example, private health care issuers (*PBN blog 7/14/20*). The 2020 rule also said that Part B Medicare reimbursement was not federal financial assistance, exempting many medical practices.

The new rule greatly broadens the definitions of covered entities: It reads 1557's definition of a "health program or activity" covered by the rule "to include all of the operations of any entity principally engaged in the provision or administration of health projects, enterprises, ventures, or undertakings."

For example, private health insurance issuers may now be covered, as they "exercise significant control over enrollees' access to health care and play a critical role in the business of health care," the rule says, "as insurance is an essential component of ensuring that people receive care in the current health care system."

Also, it reverses the previous rule's judgment on Part B Medicare, meaning providers, groups and systems that accept Part B reimbursement for any part of their business are now considered covered by this rule.

"While many Part B providers were already subject to Section 1557 and other civil rights laws by virtue of their acceptance of Medicaid, there are many who were not," says Leon Rodriguez, partner with Seyfarth Shaw LLP in Washington, D.C. and chair of the firm's government relations policy group. "This will now include a broad range of health care businesses in the ambit of Section 1557, from solo providers all the way up to very large providers and other businesses."

These responsibilities cannot be offloaded, OCR warns: "Covered entities are responsible for the conduct of their subcontractors and cannot contract away their civil rights obligations through contractual arrangements with subcontractors."

The rule does exempt certain auxiliary health care businesses such as pharmacy benefit managers. And covered entities, which include health care providers, are exempt if they have fewer than 15 employees, or if, in some cases, have a legitimate religious or moral objection to its provisions.

LGBTQI+ coverage

Like the proposed rule, the final rule refers throughout to LGBTQI+ patients — lesbian, gay, bisexual, transgender, queer, intersex and others — to underline the breadth of its definition of sex discrimination. It includes several references to the U.S. Supreme Court 2020 decision in *Bostock v. Clayton County, Ga.*, which found that discrimination based on sex includes sexual orientation and gender identity in the context of employment law.

In response to commenters to the proposed rule who insisted that "sex is an immutable, biological binary," OCR says that while "OCR recognizes that sex has biological components and knowledge of an individual's biological attributes is an essential component of providing high quality health care for all patients … health care providers are highly trained in issues of biology, anatomy, and physiology" and "there is no evidence that demonstrates that compliance with civil rights protections, including on the basis of sex, has caused any confusion in the medical field."

Note: The Mississippi and Tennessee Attorneys General have announced a suit against HHS, in which they have been joined by several other states, to block these provisions, arguing in part that the rule "would require every health care worker to use gender-affirming pronouns and punish providers for the use of biologically accurate pronouns."

The rule also prohibits discrimination due to pregnancy and "marital, parental, or family status."

OCR offers some examples of the protections the rule affords. For example, "a medical practice may not refuse to see a prospective female patient based solely on the fact that the patient has a female spouse if they otherwise accept married individuals into their practice."

By the same logic, the rule "does not mandate coverage of gender dysphoria; however, it requires that decision about such coverage not be based on discriminatory criteria," according to Rodriguez. Either declining to refer the patient, or failing to instruct the patient about the existence of treatments, could constitute a violation of 1557, Rodriguez says.

This also applies to pregnant patients if the provider ordinarily treats such patients. OCR specifies, however, that "this rule should not be read to override any [restrictive] State abortion laws."

OCR notes that the rule does not override laws allowing conscience and religious exemption from these standards, and that such entities may apply to an administrative appeal process under OCR.

If they need help, give it

Language interpretation and translation requirements are also codified in this rule. OCR had previously specified a 15-most-used-non-English-languages guideline for providers, though the agency mainly used this as a way to make sure providers were attentive to local needs (*PBN 6/6/16*). In the new rule, OCR specifies that the 15-language standard only applies to a requirement that a "notice of availability" of language assistance services and auxiliary aids and service (such as braille, etc.) be supplied.

However, OCR says, "covered entities are reminded that they must still take reasonable steps to provide meaningful access to all individuals with LEP, regardless of whether the individual's primary language is one of the 15 most frequently spoken non-English languages in their State or States." Therefore, when "interpreter services are required under this [rule], a covered entity must offer a qualified interpreter … [and] when translation services are required under this [rule], a covered entity must use a qualified translator."

The requirement, that is, has to do with the individual needs of each patient. This also applies to patients with disabilities, which may vary according to the nature of their limitation. For example, OCR says, a patient who cannot use a phone may require communication with the provider by email, even if the provider does not normally offer the option. "Making reasonable modifications to [the covered entity's] policies, practices, or procedures when necessary to avoid discrimination on the basis of disability" is part of the rule.

Machine translation, addressed in this rule for the first time, is acceptable as the sole means of translation in a pinch — for example, "as a temporary measure while finding a qualified interpreter in an emergency." Otherwise, if you use machine translation, the results "must be reviewed by a qualified human translator when the underlying text is critical to the rights, benefits, or meaningful access of an individual with LEP; when accuracy is essential; or when the source documents or materials contain complex, non-literal, or technical language."

Train and coordinate

Perhaps the most visible change in covered entities' 1557 responsibilities is the requirement to put in compliance measures, including staff training and a coordinator to oversee compliance.

The rule requires that covered entities maintain a suite of administrative functions associated with civil rights enforcement programs, including relevant policies and procedures; a notice of nondiscrimination available to the public; a grievance process; and staff training, along with the aforementioned notice of availability.

OCR refers to materials at HHS' 1557 page that are suitable source material for these mandates (*see resources, below*). But it's not just cut and paste. The rule specifies that "training required under [this rule] must be based on the covered entity's own policies and procedures."

Overseeing compliance in each organization will be a 1557 coordinator, chosen from among current employees. The coordinator's minimum requirements are listed in the rule:

1. Receives, reviews and processes grievances, filed under the grievance procedure.
2. Coordinates the covered entity's recordkeeping requirements.
3. Coordinates effective implementation of the covered entity's language access procedures.
4. Coordinates effective implementation of the covered entity's effective communication procedures.
5. Coordinates effective implementation of the covered entity's reasonable modification procedures.
6. Coordinates training of relevant employees as set forth in [the rule] including maintaining documentation required by [it].

There's nothing in the rule to suggest the coordinator needs special training in law, says Stefanie Doyle, a health care regulatory and compliance attorney with Baker Donelson in Washington, D.C.
"I do not recall there being a great deal of guidance about how the 1557 coordinator should be qualified," Doyle says. "That being said, the whole point of the coordinator is that the person will understand and coordinate and ensure those covered by the rule are in compliance. I think clerical skills would be part of it, just to keep up with the paperwork."

Doyle adds, "I think people can do a good job if they read and understand the rule, are dedicated to ensuring the organization complies with the rule, receive proper training, and ask questions when they have them."

Implementation: Coming up fast
Perhaps mindful of the reverses suffered by previous 1557 finals, OCR has put these requirements on an expedited basis.

The rule specifies that the coordinator must be up and running within 120 days of the July 5, 2024, effective date — that is, by November 2, 2024. The same date serves as the implementation deadline for the notice of nondiscrimination.

The entity's notice of availability of language assistance services and auxiliary aids and services, its 1557 policies and procedures and its English proficiency program must be ready by a year after the effective date — that is, by July 5, 2025.

"If the covered entity was already in compliance with the 2020 rule, they may need to make adjustments to align with the finalized rule's specific requirements," says Paul F. Schmeltzer of the Clark Hill law firm. "This could involve updating existing policies and procedures to reflect the expanded protections for LGBTQI+ patients and the enhanced language assistance services for ESL patients. Additionally, the covered entity may need to revise their staff training programs to incorporate new guidance and ensure that all employees are aware of their responsibilities under the updated rule."

Resources
- HHS/OCR, "Nondiscrimination in Health Programs and Activities," final rule, May 5, 2024: *www.federalregister.gov/documents/2024/05/06/2024-08711/nondiscrimination-in-health-programs-and-activities*
- HHS 1557 page: *www.hhs.gov/civil-rights/for-individuals/section-1557/index.html*
- Tennessee Attorney General's Office, "TN and MS AGs Lead Multi-State Suit to Protect Healthcare Providers and States' Residents from Department of Health and Human Services' Unlawful 'Rule,'" May 30, 2024: *www.tn.gov/attorneygeneral/news/2024/5/30/pr24-46.html*