

## New final rule strengthens nondiscrimination protections under Section 1557 of the Affordable Care Act

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**S**ection 1557 of the Affordable Care Act and related regulations prohibit discrimination on the basis of race, color, national origin, sex, age, or disability in health programs or activities that receive federal assistance. On April 26, 2024, the U.S. Department of Health and Human Services (HHS) Office of Civil Rights (OCR) issued a Final Rule under Section 1557 to strengthen certain nondiscrimination protections, reduce access barriers to healthcare and address bias in health technology. Some of the provisions of the Final Rule reinstate protections that were previously eliminated in other rulemaking under Section 1557, while other provisions are intended to strengthen certain existing requirements. This alert provides a summary of some of the key updates and actions required under the Final Rule, which took effect on July 5, 2024.

### Expanded Applicability under Section 1557

The Final Rule applies to health programs or activities that receive HHS funding, health programs or activities administered by HHS (e.g., Medicare Part D program), and the health insurance Marketplace.

Previously, Medicare Part B payments were excluded from the definition of “Federal financial assistance” under Section 1557. However, the Final Rule modified OCR’s interpretation of Section 1557 to include Medicare Part B payments as a form of Federal financial assistance subject to Section 1557. Accordingly, physicians accepting Federal financial assistance from HHS, including, but not limited to, payment under any Medicare Part A, B, C, and D plan or Medicaid must comply with the provisions of Section 1557.

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## Action Required for Covered Physicians

Physicians and medical practices covered under Section 1557 (hereinafter “Covered Entities”) must comply with the following requirements within the deadlines specified in the Final Rule:

### Within 120 Days of Effective Date (By November 2, 2024):

Consistent with previous rulemaking, Covered Entities with 15 or more employees must have a designated compliance coordinator responsible for carrying out their responsibilities under Section 1557. While practices may assign one or more individuals to carry out these responsibilities, the designated Coordinator must retain ultimate oversight for ensuring compliance.

- All Covered Entities must post a notice of nondiscrimination which contains certain specified information to inform people that language and accessibility services are available at no cost to patients.
- The notice must be provided on an annual basis or upon request, must be posted in a conspicuous location on the Covered Entity’s website if it has one, and posted in clear and prominent physical locations in no smaller than 20-point sans serif font where it is reasonable to expect individuals seeking service from the Covered Entity to be able to read or hear the notice.
- While Covered Entities can create their own notice, to assist Covered Entities, OCR has prepared sample notices in English and 47 other languages that can be used by the Covered Entity, which is available here. Covered Entities which previously developed a nondiscrimination notice in compliance with prior rulemaking should review their notice to ensure it is updated in compliance with the new Final Rule.

### Within 300 days of Effective Date (By April 1, 2025):

Covered Entities must train relevant employees on its Section 1557 policies and procedures as necessary and appropriate for the employees to carry out their functions within the Covered Entity. The required training must be provided to each employee no later than 30 days following the Covered Entity’s implementation of the required Section 1557 policies and procedures and no later than April 1, 2025. Thereafter, Covered Entities must provide the training to each new relevant employee within a reasonable time after the employee joins the Covered Entity’s workforce and to all relevant employees within a reasonable time after any material change is made to the Covered Entity’s policies and procedures that affects the functions of the relevant employee. Covered Entities must also document the completion of such training and retain such documentation for at least 3 calendar years.

Covered Entities that already furnish training on Section 1557 policies and procedures should review their training materials to ensure they are updated and in compliance with the requirements of the Final Rule.

The Final Rule prohibits Covered Entities from discriminating on the basis of race, color, national origin, sex, age or disability through its use of “patient care decision support tools.”

The Final Rule defines “patient care decision support tools” to mean “any automated or non-automated tool, mechanism, method, technology, or a combination thereof used by a Covered Entity to support clinical decision making in its health care programs or activities.” The Final Rule clarifies that the definition includes AI as well as other clinical algorithms, predictive analytics and other tools used to support clinical decision making. However, the Final Rule also provides examples of tools that are unrelated to clinical decision making and outside of the scope of the rule, including automated and non-automated tools used for medical coding, patient scheduling, supply chain management, and employment and staffing-related activities.

The Final Rule imposes an ongoing duty upon Covered Entities to make reasonable efforts to identify uses of patient care decision support tools in its practice that employ input variables or factors that measure race, color, national origin, sex, age or disability. From there, Covered Entities must make reasonable efforts to mitigate the risk of discrimination resulting from the identified tool’s use in its practice.

### Within 1 year of Effective Date (By July 5, 2025):

Covered Entities must implement written policies and procedures that are designed to comply with the requirements under Section 1557. The policies and procedures must include an effective date and be reasonably designed after taking into account the size, complexity and activities undertaken by the Covered Entity.

The written policies must include a nondiscrimination policy that, at a minimum, states:

- that the Covered Entity does not discriminate on the basis of race, color, national origin (including limited English proficiency and primary language), sex, age, or disability;
- that the Covered Entity provides language assistance services and appropriate auxiliary aids and services free of charge, when necessary for compliance with Section 1557;
- that the Covered Entity will provide reasonable modifications for individuals with disabilities; and
- the current contact information for the designated Coordinator (if applicable).

Additional written procedures that Covered Entities must implement include:

- written language access procedures describing the Covered Entity's process for providing language assistance services to individuals with limited English proficiency when required.
- written effective communication procedures describing the Covered Entity's process for ensuring effective communication for individuals with disabilities when required.
- written procedures describing the Covered Entity's process for making reasonable modifications to its policies, practices, or procedures when necessary to avoid discrimination on the basis of disability when required.

Specific requirements for each of these written procedures are set forth in the Final Rule, which is available [here](#).

Covered Entities with 15 or more employees must further implement written grievance procedures that provide for the prompt and equitable resolution of grievances alleging any action that would be prohibited under Section 1557. Such Covered Entities must retain records related to filed grievances for no less than 3 years from the date the Covered Entity resolves the grievance. The identity of the individual who filed the grievance must be kept confidential except as required by law or to carry out the purpose of this requirement.

All Covered Entities must post a notice of the availability of language assistance services and auxiliary aids and services that, at a minimum, states that the Covered Entity provides language assistance services and appropriate auxiliary aids and services free of charge, when necessary for compliance with Section 1557 to patients. The notice must be provided in English and at least the 15 languages most commonly spoken in Michigan and in alternate formats for individuals with disabilities who require auxiliary aids and services to ensure effective communication.

The top 15 non-English languages for Michigan are: Spanish, Arabic, Chinese, Syriac, Vietnamese, Albanian, Korean, Bengali, Polish, German, Italian, Japanese, Russian, Serbo-Croatian and Tagalog.

The notice must be provided to patients annually or upon request, and posted both in a conspicuous location on the Covered Entity's website and in a clear and prominent location at the Covered Entity's physical location in no smaller than 20-point sans serif font where it is reasonable to expect patients to be able to read or hear the notice.

The notice must further be provided in the following electronic and written communications when these forms are provided by a Covered Entity:

- Notice of nondiscrimination (see above);
- HIPAA Notice of Privacy Practices;
- Application and intake forms;
- Notices of denial or termination of services, and notices of appeals and grievance rights;
- Communications related to an individual's rights, eligibility, benefits or services that require or request a response from the patient;
- Communications related to a public health emergency;
- Consent forms and instructions related to medical procedures or operations, medical power of attorney, or living will (Covered Entities may provide one notice for all documents bundled together);
- Discharge papers;
- Communications related to the cost and payment of care with respect to a patient, including medical billing and collection materials and good faith estimates under the No Surprises Act;
- Complaint forms; and
- Patient handbooks.

Covered Entities which previously created similar notices in compliance with earlier rulemaking should review their notice and posting procedures to ensure they are updated in compliance with the new Final Rule (e.g., content, formatting, frequency, etc.).

The Final Rule permits Covered Entities to allow patients to opt-out of receiving the notice, provided certain documentation and information criteria is met.

## Other Changes under Final Rule

The Final Rule includes some additional clarifications regarding certain nondiscrimination provisions, including, but not limited to:

- Covered activities offered via telehealth (including via videoconferencing, the internet, store-and-forward imaging, streaming media, and terrestrial and wireless communications) must also be accessible to individuals with limited English proficiency and individuals with disabilities.
- The Final Rule reinstates protections under Section 1557 for LGBTQI+ and pregnant patients, affirming that discrimination on the basis of sex includes discrimination on the basis of gender identity and pregnancy or related conditions.
- The Final Rule reinstates the application of Section 1557 to health insurance plans.

Additional information regarding the Final Rule, including a fact sheet and FAQs issued by OCR, is available [here](#).