

HHS Publishes New Rules to Enhance Federal Anti-Discrimination Rules in Artificial Intelligence



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Navigating the evolving landscape of healthcare regulations can be a complex task for covered entities, particularly in regard to the increasing use of Artificial Intelligence (AI). A final rule recently adopted by the Department of Health and Human Services (HHS) Office for Civil Rights (OCR) on May 6, 2024 (the “Anti-Discrimination Final Rule”) introduces new requirements on health care providers to ensure that AI technologies do not violate federal non-discrimination protections, including new protections based on a person’s sex.¹ The Anti-Discrimination Final Rule has varied effective dates to allow covered entities time to prepare for compliance, which preparation may include designating a 1557 Coordinator, creating policies and procedures to implement the Anti-Discrimination Final Rule, training of staff, and developing and publishing certain notices.² As it relates to the anti-discrimination provisions in the use of AI, covered entities have 300 days from the July 5, 2024 effective date to comply with the risk identification and mitigation requirements.

BACKGROUND ON THE ANTI-DISCRIMINATION FINAL RULE

Section 1557 of the Affordable Care Act (ACA), 42 U.S.C. 18116, prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in a health program or activity, any part of which is receiving Federal financial assistance.³ The Anti-Discrimination Final Rule follows a long history of rulemaking that began in 2013. The goal of the AI portion of the Anti-Discrimination Final Rule is to eliminate discrimination in health care resulting from algorithms. As was seen from the comments on the Anti-Discrimination Final Rule, there is concern from the public that there is a “prevalence of ethic and racial bias in clinical algorithms that result in fewer health care services provided to Black, Hispanic/Latino, Asian, and American

Indian/Alaska Native patients” as well as other discriminatory practices impacting patients with disabilities and older individuals, which the Anti-Discrimination Final Rule seeks to eliminate.⁴

FINAL REGULATION

The Final Regulation found in Section 92.210 as described in the Anti-Discrimination Final Rule is as follows:

92.210 Nondiscrimination in the use of patient care decision support tools.

(a) General prohibition. A covered entity must not discriminate on the basis of race, color, national origin, sex, age, or disability in its health programs or activities through the use of patient care decision support tools.

(b) Identification of risk. A covered entity has an ongoing duty to make reasonable efforts to identify uses of patient care decision support tools in its health programs or activities that employ input variables or factors that measure race, color, national origin, sex, age, or disability.

(c) Mitigation of risk. For each patient care decision support tool identified in paragraph (b) of this section, a covered entity must make reasonable efforts to mitigate the risk of discrimination resulting from the tool’s use in its health programs or activities.⁵

PATIENT CARE DECISION SUPPORT TOOLS

As it relates to the use of AI in healthcare, the Anti-Discrimination Final Rule prohibits discrimination on the basis of race, color, national origin, sex, age, or disability through the use of patient care decision

support tools, which replaces the concept of “clinical algorithms” that was in the proposed rule. The term “Patient care decision support tools” is broadly defined 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.”⁶

In order to comply with the Anti-Discrimination Final Rule, the covered entity must first learn how to identify a patient care decision support tool and have policies and procedures that allow its workforce to easily make such identification. In the commentary to the final rule, HHS-OCR confirms that patient care decision support tools subject to regulation include automated decision systems and AI used to support clinical decision-making. HHS-OCR further clarifies in a recently updated Section 1557 Final Rule: Frequently Asked Questions that “this updated rule recognizes the growing importance of telehealth and patient care decision support tools in the health care marketplace – including artificial intelligence and machine learning – and applies nondiscrimination protections to the use of these technologies.”⁷ This would include any tools that are used for “screening, risk prediction, diagnosis, prognosis, clinical decision-making, treatment planning, health care operations, and allocation of resources,”⁸ as well as tools used to “recommend care, provide disease management guidance, determine eligibility, and conduct utilization review.”⁹

HHS-OCR also provided specific examples that health care providers should review to ensure that they understand what constitutes a patient care decision support tool. For example, a physician that uses an algorithm to assess a patient’s risk of a severe cardiac event or a hospital that uses a treatment protocol based on geographic area due to variations produced by risk adjustment modeling, would all

be considered a patient care decision support tool.¹⁰ Similarly, tools used for prior authorizations and medical necessity analysis that impact clinical decision making would also be considered a patient care decision support tool, in addition to predictive decision support interventions as defined in the Office of the National Coordinator for Health Information Technology's (ONC) final rule for "Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing," which final rule is applicable to health IT developers. Importantly for health care providers, patient care decision support tools include non-automated patient care decision support, such as a flowchart for triage guidance.¹¹ As seen above, the definition of patient care decision support tools is extremely broad and will require health care providers and other covered entities to carefully look at their organization to determine what constitutes a patient care decision support tool for purposes of compliance.

RISK IDENTIFICATION AND RISK MITIGATION

The Anti-Discrimination Final Rule imposes an ongoing duty to make reasonable efforts to identify uses of patient care decision support tools in a provider's health program or activities that employ input variables or factors that measure race, color, national origin, sex, age, or disability. For the tools that are identified, a covered entity must then make "reasonable efforts" to mitigate the risk of discrimination resulting from the tool's use in its health programs or activities.

HHS-OCR emphasizes that covered entities must exercise due diligence when acquiring and using patient care decision support tools. In determining whether a covered entity has made reasonable efforts to identify a patient care decision support tool, HHS-OCR will review the covered entity's size and resources, adherence to

the tool developer's approved conditions or whether the covered entity customized the tool, receipt of product information from the tool developer, and the presence of a methodology or process for evaluating patient care decision support tools. For example, whether the covered entity seeks information from developers, relevant medical journals, and literature from medical associations.¹² In the commentary, HHS-OCR specifically stated that "a large hospital with an IT department and a health equity officer would likely be expected to make greater efforts to identify tools than a smaller provider without such resources, which may be an indication of how HHS-OCR will view these matters during enforcement."¹³

HHC-OCR specifically declined to require covered entities to take specific risk mitigation efforts but did make general recommendations. Mitigation of risk may be achieved by: (1) establishing governance measures and written policies and procedures concerning these tools and how they will be used in decision making; (2) monitoring potential impacts and developing a way to address complaints; and (3) instituting staff training on the proper use of these tools in decision making.¹⁴ HHS-OCR also emphasized that covered entities should not be over-reliant on patient care decision support tools and such tools should not replace a provider's independent medical judgment.¹⁵

WHAT'S NEXT?

The Anti-Discrimination Final Rule is effective July 5, 2024, but HHS-OCR has delayed the applicability date. Providers now have 300 days from the effective date of the final rule to comply with the risk identification and mitigation requirements. Until then, covered entities should consider cataloging their use of patient care decision support tools – both at the individual patient level and population health level – as well as seek additional information from any

third-party vendors providing a tool covered by the final rule. Additionally, to support operationalizing compliance, covered entities should review policies, procedures, and governance practices to support identifying potential discrimination risks and how such risks can be mitigated. Covered entities should also keep an eye out for technical assistance from HHS-OCR prior to the compliance date. Once effective, HHS-OCR will review each complaint on a case-by-case basis to determine if covered entities took reasonable steps to identify patient care decision support tools and, if so, whether the covered entity took reasonable steps to mitigate the risk of discrimination resulting from the use of the tool.¹⁶

Endnotes

1. Nondiscrimination in Health Programs and Activities, 89 Fed. Reg. 37522 (May 6, 2024).
2. *Id.* at 37525.
3. *Id.* at 37522.
4. *Id.* at 37644.
5. *Id.* at 37701.
6. *Id.* at 37544-45.
7. Section 1557 *Final Rule: Frequently Asked Questions*, U.S. Department of Health and Human Services (May 20, 2024), <https://www.hhs.gov/civil-rights/for-individuals/section-1557/faqs/index.html>.
8. 89 Fed. Reg. 37522, 37544-45 (May 6, 2024).
9. *Id.*
10. *Id.* at 37643.
11. *Id.* at 37644.
12. *Id.* at 37648.
13. *Id.*
14. *Id.* at 37649.
15. *Id.* at 37650.
16. *Id.* at 37650.

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