Summary: Nondiscrimination in Health Programs and Activities Final Rule
Updated: May 2024

Background

The US Department of Health and Human Services (HHS) Office for Civil Rights (OCR) and the Centers for Medicare & Medicaid Services (CMS) released the Nondiscrimination in Health Programs and Activities final rule on April 26, 2024. The final rule modifies Section 1557 of the Affordable Care Act (ACA) which prohibits certain practices in healthcare to protect against discrimination. Included in the final rule are provisions related to the use of algorithms and the potential for bias within those algorithms. The applicability date for requirements contained in the Nondiscrimination in the Use of Patient Care Decision Support Tools section of the final rule is March 2, 2025.

Key Provisions

- Covered entities are prohibited from discriminating in their health programs and activities, including through the use of AI and other tools.

- Defines a “patient care decision support tool” 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.”

- OCR and CMS clarify the definition applies to tools that are used by a covered entity in clinical decision-making that impact the care a patient receives. Under this definition, tools used for prior authorization and medical necessity analysis are included.

- Discrimination in the context of this rule is described as based on race, color, national origin, sex, age, or disability by a covered entity in its health programs or activities through the use of patient care decision support tools.

- Covered entities are required to make reasonable efforts to identify uses of patient care decision support tools used in its health programs and activities that employ input variables or factors that measure race, color, national origin, sex, age, or disability.

- A covered entity must make reasonable efforts to mitigate the risk of discrimination resulting from the use of any of the tools identified.
• Covered entities are not required to obtain data from a developer to determine if the tool discriminates against patients. However, a covered entity should consult publicly available sources or request information if it believes the tool’s use could result in discrimination on or uses variables in its decision-making including race, color, national origin, sex, age, or disability.

• OCR will review each case of potential discrimination through the use of these tools on a case-by-case basis.

• OCR may use the following factors to determine compliance:
  ○ The covered entity’s size and resources.
  ○ Whether the covered entity used the tool in the manner or under the conditions intended by the developer and approved by regulators, and if the covered entity has adapted or customized the tool.
  ○ Whether the covered entity received product information from the developer of the tool regarding the potential for discrimination or identified that the tool’s input variables include race, color, national origin, sex, age, or disability.
  ○ Whether the covered entity has a methodology or process in place for evaluating the patient care decision support tools it adopts or uses. This may include seeking information from the developer, reviewing relevant medical journals and literature, obtaining information from membership in relevant medical associations, or analyzing comments or complaints received about patient care decision support tools.

• When an investigation reveals a covered entity has appropriately identified its use of a patient care decision support tool, OCR will determine whether the entity took reasonable efforts to mitigate the risk of discrimination from the use of the tool.

If you have additional questions on the contents of this final rule or would like to discuss this FAQ further, please contact advocacy@ahima.org.