



January 10, 2025

## **Re: Ensuring Nondiscrimination Through the Use of Artificial Intelligence and Other Emerging Technologies**

Dear Colleagues:

As the landscape for artificial intelligence (AI) continues to develop, the U.S. Department of Health and Human Services' (HHS) Office for Civil Rights (OCR) is committed to ensuring non-discrimination on the basis of race, color, national origin, sex, age, and disability through the use of these tools. OCR recognizes the potential of AI—in reducing clinician burnout and increasing access to quality care, among other benefits. As a result, OCR has sought to balance those benefits with the need for the responsible use of these tools.

OCR is a federal regulator and law enforcement agency that is uniquely positioned to safeguard the public's trust in the use of AI and other emerging technologies in health care. Unlike other federal agencies that regulate the tools themselves,<sup>1</sup> OCR regulates the *use* of these tools when providers use them to make health care and benefits decisions.

Accordingly, OCR is sharing information in this letter about how Section 1557 of the Affordable Care Act (Section 1557) applies when health programs and activities utilize patient care decision support tools.<sup>2</sup> Patient care decision support tools, including AI, are used by covered entities, such as hospitals, providers, and payers (e.g., health insurance issuers), in their health programs and activities for functions like screening, risk prediction, diagnosis, prognosis, clinical decision-making, treatment planning, health care operations, and allocation of resources, all of which affect the care that individuals receive.

On May 6, 2024, OCR published the final rule implementing Section 1557 ("final rule") (codified at 45 Code of Federal Regulations (C.F.R.) part 92). Section 1557 prohibits discrimination on the basis of race, color, national origin, age, sex, and disability in health programs or activities that receive Federal financial assistance from HHS, health programs or activities established under

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<sup>1</sup> See e.g., *Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing*, Final Rule, 89 FR 1192 (January 9, 2024) <https://www.federalregister.gov/d/2023-28857> issued by the Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology; <https://www.fda.gov/media/166704/download>, issued by the Food and Drug Administration; and [https://ai.cms.gov/assets/CMS\\_AI\\_Playbook.pdf](https://ai.cms.gov/assets/CMS_AI_Playbook.pdf), issued by the Centers for Medicare & Medicaid Services.

<sup>2</sup> "Patient care decision support tool" means 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. 45 C.F.R. § 92.4. Though the use of patient care decision support tools could also implicate other civil rights laws, including Titles II and III of the Americans with Disabilities Act and Section 504 of the Rehabilitation Act, this letter only addresses nondiscrimination obligations under Section 1557 of the ACA.

Title I, such as State-based Exchanges, and HHS-administered health programs or activities, including the Federally-facilitated Exchanges. OCR is committed to assisting covered entities understand their obligations under the final rule, including with regard to their use of patient care decision support tools.

The final rule makes clear that Section 1557's nondiscrimination protections apply to the use of AI and other emerging technologies such as clinical algorithms and predictive analytics. Specifically, the final rule:

- Applies Section 1557's general nondiscrimination requirements to the use of AI and other emerging technologies in patient care.
- Requires covered health programs and activities to take reasonable steps to identify and mitigate the risk of discrimination when they use AI and other emerging technologies in patient care that use race, color, national origin, sex, age, or disability as input variables.

## **1. Nondiscrimination in the Use of AI and Other Emerging Technologies in Patient Care**

The Section 1557 final rule applies to the use of AI and other emerging technologies in patient care, which the final rule captures under the term “patient care decision support tools.”<sup>3</sup> Specifically, the final rule provides: “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.”<sup>4</sup> This provision applies longstanding civil rights principles to the use of these tools in health care to make clear that these protections do not cease when the technology changes.

*Example 1: A hospital relies on a Crisis Standards of Care<sup>5</sup> flowchart for triage guidance when patients are admitted for emergency care. Such a flowchart may result in discrimination if, for example, it screens out individuals with disabilities, prohibiting them from equally accessing a health care service, program, or activity that a covered entity offers by assessing an individual's potential response to life-saving care without making an individualized assessment of the individual's health and without providing modifications for how an individual's disability or age could affect the assessment factors used in the algorithm or the time needed for the individual to respond to treatment.*

## **2. Identifying and Mitigating Risks of Discrimination**

The Section 1557 final rule also has two regulatory requirements for covered entities in their use of AI and other emerging technologies in patient care (i.e., patient care decision support tools).

*First*, the final rule places an ongoing duty on users to make reasonable efforts to identify risk of discrimination when the tools they use contain inputs that measure race, color, national origin, sex, age, or disability.<sup>6</sup> The final rule does not prescribe which steps a covered entity must take to

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<sup>3</sup> *Id.*

<sup>4</sup> 45 C.F.R. § 92.210(a).

<sup>5</sup> Crisis Standards of Care inform decision-making designed to accomplish the best outcome for a group of patients rather than focusing on an individual patient.

<sup>6</sup> 45 C.F.R. § 92.210(b).

identify such risks—rather, it requires that the covered entity make reasonable efforts. Such efforts to identify risk may include the following measures:

- Review OCR’s discussion of risks in the use of such tools in the Section 1557 final rule, including categories of tools used to assess risk of heart failure, cancer, lung function, and blood oxygen levels;<sup>7</sup>
- Research published articles of research studies in peer-reviewed medical journals or from health care professional and hospital associations, including those put out by HHS<sup>8</sup>;
- Utilize, implement or create AI registries for safety that are developed by nonprofit AI organizations or others, including use of internal registries by the covered entity to determine use cases within an organization; and,
- Obtain information from vendors about the input variables or factors included in existing patient care decision support tools.

When reviewing whether a covered entity made reasonable efforts to identify risk of discrimination, OCR will conduct a case-by-case analysis that may consider, among other factors:

- The covered entity’s size and resources (e.g., 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);
- The available information at the time of use, to determine whether there was notice of the potential discriminatory use of a product used input variables on the basis of race, color, national origin, sex, age, or disability;
- Whether the covered entity used the tool in the manner intended by the developer and approved by regulators, if applicable, or whether 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; and
- Whether the covered entity has a methodology or process in place for evaluating the patient care decision support tools it adopts or uses.

Additionally, covered entities may benefit from implementing policies and procedures for identifying whether the use of a patient care decision support tool risks discrimination.

*Example 2:* A covered entity could adopt a policy to determine whether it uses any of the patient care decision support tools discussed in the preamble to the Section 1557 final rule (e.g., the race-adjusted estimated glomerular filtration rate (eGFR) equation, pulse oximeters, and Crisis Standards of Care plans).<sup>9</sup> The covered entity’s policy could also require its procurement personnel to obtain information from vendors about the input variables or factors included in existing patient care decision support tools and for patient care decision support tools that the entity intends to procure, adopt, and/or implement in the future. The entity’s policy might indicate a preference for procuring tools for which vendors provide information about the input variables and factors included in the tools. In addition, the entity could provide training to staff on its policy as well as review of uses of patient

<sup>7</sup> See 89 Fed. Reg. 37642-51 (further outlining examples of what constitutes reasonable efforts under the rule).

<sup>8</sup> See e.g., <https://psnet.ahrq.gov/perspective/artificial-intelligence-and-patient-safety-promise-and-challenges>

<sup>9</sup> See 89 Fed. Reg. 37644, 45, and 47.

*care decision support tools to ensure nondiscrimination.*

*For covered entities that develop their own patient care decision support tools, an internal policy might require their internal developers to document whether the tools under development measure race, color, national origin, sex, age, or disability. Additionally, an entity's policy could require appropriate staff to determine whether an existing tool's output varies depending on the tool's measurements of race, color, national origin, sex, age, or disability. For technological tools not yet introduced to an entity's production environment, the entity's policy could require IT staff to develop tests intended to identify whether the tool includes input variables or factors that measure race, color, national origin, sex, age, or disability (if the entity is unable to obtain this information from vendors). Again, one such test might be to determine whether the output of a technological tool—not yet introduced to the production environment—varies depending on the tool's measurements of race, color, national origin, sex, age, or disability.*

**Second**, after covered entities identify the risk of discrimination that their use of these tools presents, the final rule requires covered entities to make reasonable efforts to mitigate the risk of discrimination posed by the use of these tools.<sup>10</sup> The final rule does not require covered entities to take any specific actions in its mitigation efforts—rather, they are required to make mitigation efforts that are reasonable.

Such efforts to mitigate risk may include the following measures:

- Establish written policies and procedures governing how patient care decision support tools are used in decision-making, as well as governance measures;
- Monitor potential impacts and develop ways to address complaints of alleged discrimination;
- Maintain internal AI registry or reference AI registries developed by nonprofit AI organizations or others to provide the covered entity with information regarding what is being used internally and to facilitate regulatory compliance;
- Utilize staff to override and report potentially discriminatory decisions made by a patient care decision support tool, including a mechanism for ensuring “human in the loop” review of a tool’s decision by a qualified human professional;
- Train staff members, including how to report results and how to interpret decisions made by the tool, including factors required by other Federal rules;<sup>11</sup>
- Establish a registry of tools identified as posing a risk of discrimination and review previous decisions made by these tools;
- Audit performance of tools in “real world” scenarios and monitor the tool for discrimination; and
- Disclose to patients a covered entity’s use of patient care decision support tools that the entity has identified as posing the risk of discrimination.

*Example 3: To illustrate how § 92.210’s requirements work with respect to identifying uses of tools that risk discrimination and to making reasonable efforts to mitigate that risk, consider providers’ use of the race-adjusted eGFR equation. The race-adjusted eGFR has been shown to lead to lower referrals to kidney specialists and reduced placements on*

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<sup>10</sup> 45 C.F.R. § 92.210(c).

<sup>11</sup> See e.g., [89 Fed. Reg. 1192](https://www.healthit.gov/topic/laws-regulation-and-policy/health-data-technology-and-interoperability-certification-program) (Jan. 9, 2024); <https://www.healthit.gov/topic/laws-regulation-and-policy/health-data-technology-and-interoperability-certification-program>.

*kidney transplant lists because the equation's output differs based on a provider's selection of "Black" or "non-Black" as an input variable.<sup>12</sup> Under § 92.210, given the public information on this patient support tool, covered entities must make efforts to mitigate risk of racial discrimination in its use. Covered entities who elect to use this tool must make reasonable efforts to ensure that patients for whom they select "Black" as an input variable do not receive reduced referrals to kidney specialists, placements on transplant lists, or other services for which they would otherwise be qualified if the provider had instead selected "non-Black" as an input variable. Covered entities could mitigate the risk of the race-adjusted eGFR by discontinuing use of the race-adjusted equation and instead using an updated eGFR equation that does not adjust for race.<sup>13</sup> Covered entities could also implement measures that ensure staff follow proper protocols when using the race-adjusted eGFR to avoid discrimination.*

*Example 4: Another example of a patient care decision support tool that raises the risk of discrimination for which mitigation efforts may be required is use of a pulse oximeter. Readings from pulse oximeters that are not sufficiently trained on representative populations have been shown to overestimate blood oxygen levels in patients of color, leading to delayed or denied care for patients of color as compared to patients with lighter skin. Covered entities could mitigate the risk of discrimination posed by pulse oximeters by educating staff about the potential for inaccurate, elevated blood oxygen level readings for patients of color and by training staff on policies and procedures that require staff to consider additional indicators of respiratory stress (beyond pulse oximeter readings) to ensure patients of color receive appropriate care, including emergency/inpatient admissions, referrals, etc. Further, covered entities could audit the use of this tool by their staff, to determine compliance with these trainings, actual use and/or to continue to monitor its use.*

Whether a covered entity took reasonable efforts to mitigate discrimination risks may differ depending on several factors, including the context in which the tool was used, steps taken by the provider to understand the risks, size of the provider, and policies used to address complaints. A covered entity's mitigation efforts under § 92.210(c) may vary based on the input variable or factor, as well as the purpose of the tool in question. OCR acknowledges that some input variables may generate greater scrutiny, such as race, which is more suspect, as compared to other variables, such as age, which is more likely to have a clinical and evidence-based purpose, and may not require extensive mitigation efforts.

The Section 1557 final rule general prohibition of discrimination under § 92.210 took effect July 5, 2024. The final rule's affirmative requirements to make reasonable efforts to identify and mitigate risks of discrimination in use of patient support tools in AI and emerging technologies takes effect May 1, 2025. OCR encourages all entities to review their use of such tools to ensure compliance with Section 1557 and to put into place measures to prevent discrimination that will help ensure all patients benefit from technological innovations in clinical decision-making.

To review the Section 1557 final rule preamble discussion for § 92.210, please visit: <https://www.federalregister.gov/d/2024-08711/p-1647>. We also recommend reviewing the National Institute for Standards and Technology's (NIST): (1) AI Risk Management Framework (RMF),

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<sup>12</sup> <https://jamanetwork.com/journals/jama/article-abstract/2735726>.

<sup>13</sup> [https://www.kidney.org/professionals/gfr\\_calculator](https://www.kidney.org/professionals/gfr_calculator).

[https://airc.nist.gov/AI\\_RM\\_F\\_Knowledge\\_Base/AI\\_RM\\_F](https://airc.nist.gov/AI_RM_F_Knowledge_Base/AI_RM_F); and (2) AI RMF: Generative AI Profile, <https://nvlpubs.nist.gov/nistpubs/ai/NIST.AI.600-1.pdf>.

OCR is committed to helping covered entities understand their Federal civil rights obligations and to collaborate in navigating the responsible integration of tools such as AI and other emerging technologies into health care. In addition to complying with their Federal civil rights obligations with respect to AI, health care providers, health plans, and health care clearinghouses must also ensure their compliance with the Health Insurance Portability and Accountability Act (HIPAA) with respect to their use of AI and other tools. Accordingly, we recommend the following HIPAA resources:

- October 2024 OCR Cybersecurity Newsletter, <https://www.hhs.gov/hipaa/for-professionals/security/guidance/cybersecurity-newsletter-october-2024/index.html>.
- Cyber Security Guidance Material, <https://www.hhs.gov/hipaa/for-professionals/security/guidance/cybersecurity/index.html>.
- HIPAA FAQs for Professionals, <https://www.hhs.gov/hipaa/for-professionals/faq/index.html>.
- HIPAA Basics for Providers: Privacy, Security, & Breach Notification Rules, <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/HIPAAPrivacyandSecurity.pdf>.

Sincerely,

/s/

Melanie Fontes Rainer  
Director, Office for Civil Rights