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Health AI and Nondiscrimination Due Diligence: Key Considerations if the Section 1557 Regulation Is Rescinded

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In May 2024, the Biden administration finalized its revised regulation under Section 1557 of the Affordable Care Act (ACA), and, in doing so, promulgated a new regulatory standard of ongoing due diligence as it relates to promoting nondiscrimination in the use of health artificial intelligence (AI).[1] And although no court has addressed whether this regulatory standard would survive a legal challenge under *Loper Bright* (or any other basis), this new regulatory standard is currently set to go into effect on May 1, 2025. But in the likely event that the Trump administration changes course and renounces this regulatory standard, what nondiscrimination laws would govern a hospital or health system's use of health AI?

As explained below, pre-existing federal statutory law—Section 1557 of the ACA itself and its referenced civil rights statutes—would continue to apply to a hospital or health system's use of health AI. And of most relevance here, certain legal frameworks associated with these longstanding laws may still allow for institutional liability for discrimination resulting from the use of health AI. Given this potential risk, hospitals and health systems should continue taking steps to mitigate any known instances or risks of discrimination in the use of health AI.

Regulatory Due Diligence Standard

The final revised regulation under Section 1557 issued by the Department of Health and Human Services (HHS) last year purported to impose a new regulatory standard of ongoing due diligence as it relates to nondiscrimination in the use of "patient care decision support tools"—including health AI.[2] This new due diligence standard (which, as noted above, goes into effect on May 1, 2025, barring a successful legal challenge or action by the Trump administration) consists of two main parts: an ongoing duty to take reasonable efforts to *identify* tools that employ factors that measure (or serve as a proxy for) race, color, national origin, sex, age, or disability; and a related ongoing duty to take reasonable efforts to *mitigate* the risk of discrimination from those tools.[3]

In the preamble to this regulation, HHS elaborated on its expectations around these two interrelated obligations. First, HHS expressed its view that health systems "must exercise due diligence when *acquiring* and *using* such tools to ensure compliance" with the regulation. According to HHS, a health system could satisfy this "due diligence" requirement by consulting the disclosures required by certified health IT developers,

reviewing resources published by HHS, monitoring published academic literature on health care AI, reviewing reports in media outlets, and participating in professional and hospital associations.

And when evaluating whether a health system has taken "reasonable efforts" to identify potential risks, HHS stated that it would consider: (1) the system's size and resources; (2) whether the system used the tool in a manner and under the conditions intended by the developer and approved by regulators (or whether the tool was customized by the health system); (3) whether the system reviewed the product information from the certified developer of health care IT regarding the potential for discrimination; and (4) whether the system has a methodology or process in place for evaluating the tools it adopts (e.g., the "due diligence" concept just discussed).

In terms of satisfying a health system's ongoing mitigation efforts, HHS encouraged health systems to: (1) establish written policies and procedures for the use of these tools in decision making, including governance measures; (2) monitor potential impacts and develop ways to address complaints; and (3) train staff on the purpose of these tools' use in clinical decision making.

The question then is this: if the Trump administration revises or altogether rescinds Section 92.210 of the current regulation, what becomes of this "ongoing due diligence" standard for nondiscrimination in health AI? Put differently, apart from this portion of the regulation, are there any statutory schemes that otherwise create a similar framework?

Litigants or regulators may argue that the answer is "yes." As explained below, pre-existing federal civil rights laws would continue to apply to the use of health AI such that hospitals and health systems should continue to consider the reasonable steps necessary to mitigate any known instances or risks of discrimination in the use of particular health AI tools.[4]

Federal Civil Rights Laws and the "Deliberate Indifference" Standard for Intentional Discrimination

Federal Civil Rights Statutes Would Continue to Apply

Federal statutes continue to apply even when a particular regulation promulgated under those statutes is rescinded. Here, the first statute to consider is the ACA itself. Section 1557 of the ACA (entitled "Nondiscrimination") standing alone prohibits discrimination on the basis of race, color, national origin, disability, sex, and age in federally funded health programs and activities. Enacted against a backdrop of longstanding federal nondiscrimination law, Section 1557 incorporates by reference[5] the following pre-existing civil rights statutes:

- Title VI of the Civil Rights Act of 1964 (race, color, national origin)

- Title IX of the Education Amendments of 1972 (sex)
- The Age Discrimination Act of 1975 (age); and
- Section 504 of the Rehabilitation Act of 1973 (disability).

So, of relevance here, apart from any regulation, Section 1557 and the longstanding civil rights statutes that it incorporates would continue to apply to entities that accept federal financial assistance—most health care providers—and, by extension, to a hospital or health system's use of health AI.[6]

And given that federal courts have consistently recognized that private causes of action exist under each of these statutes, hospitals and health systems should continue to take steps to mitigate any known instances or risks of discrimination in the use of health AI.

"Deliberate Indifference" Standard for Intentional Discrimination

For example, one way that litigants may argue for imposing institutional liability for discrimination resulting from the use of health AI may be by way of the longstanding "deliberate indifference" standard for intentional discrimination under federal civil rights law.[7]

A recent Fourth Circuit opinion illustrates the point. In that case, the plaintiff alleged that she was terminated as a patient from a Virginia hospital after complaining of racial discrimination to hospital managers.[8] The Fourth Circuit held that the plaintiff had adequately stated a claim of intentional racial discrimination under Section 1557 of the ACA, because she alleged that the hospital "acted with deliberate indifference" to the discrimination of its agents.[9] According to the court, this "deliberate indifference" standard requires a "deliberate or conscious choice to ignore something."[10] Critically, this type of "deliberate indifference" has also been held to constitute intentional discrimination under the Americans with Disabilities Act, Title VI, and Title IX.[11]

The relevance of this "deliberate indifference" standard to the use of health AI seems readily apparent.[12] Although not yet established in any case law, litigants are likely to argue that this "deliberate indifference" theory should be applied where a hospital or health system does not undertake efforts to mitigate any known instances or risks of discrimination through their use of health AI.

As a result, to minimize the potential risks of "deliberate indifference" claims of discrimination under this framework, hospitals and health systems should consider what proactive steps may be necessary to rectify known instances of disparities or discrimination that flow from the deployment of a particular health AI tool. Otherwise, the failure to do so may risk exposure to a cause of action for intentional discrimination on the basis of "deliberate indifference."

Practical Recommendations in Response to Known Risks of Discrimination

Given the discussion above, hospitals and health systems would be wise to continue to invest in the talent and governance structures that will enable them to adequately respond to known risks of discrimination in their deployment of health AI.

Ultimately, what that could look like in practice may (paradoxically) follow HHS' recommendations in the preamble of the current Section 1557 regulation: (1) establishing written policies and procedures for the use of particular health AI tools in decision making; (2) monitoring the impacts and developing ways to address complaints related to particular health AI tools; and (3) training staff on the purpose of a particular health AI tool in clinical decision making.

Considering these potential steps in response to a known risk of discrimination in the use of a particular health AI tool may go a long way to reducing the risk of a "deliberate indifference"-style intentional discrimination claim under Section 1557 of the ACA.

About the Author

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[1] 89 Fed. Reg. 37522, https://www.govinfo.gov/content/pkg/FR-2024-05-06/pdf/2024-08711.pdf.

[2] Per the "Definitions" section of the regulation, "patient care decision support tools" include "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.

[3] *See* 45 C.F.R. § 92.210.

[4] This article's focus is on the impact of pre-existing federal civil rights law, and, therefore, the impact (if any) of any future federal legislation or state legislation is outside this article's scope.

[5] The text of Section 1557 reads in relevant part:

[A]n individual shall not, on the ground prohibited under title VI of the Civil Rights Act of 1964, title IX of the Education Amendments of 1972, the Age Discriminatio n Act of 1975, or section 504 of the Rehabilitation Act of 1973, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an Executive Agency or any entity established under this title (or amendments). The enforcement mechanisms provided for and available under such title VI, title IX, section 504, or such Age Discrimination Act shall apply for purposes of violations of this subsection.

Pub. L. No. 111-148, § 1557, 124 Stat. 119, 260 (2010) (codified as amended at 42 U.S.C. § 18116).

[6] *See, e.g.*, Sharona Hoffman and Andy Podgurski, *Artificial Intelligence and Discrimination in Health Care*, 19 Yale J. Health Pol'y, L. & Ethics 1 (2020). It is worth noting, however, that Title IX did not independently apply to the health care industry until Congress passed the ACA.

[7] This article's focus is on intentional discrimination claims, as opposed to unintentional discrimination claims (disparate impact). With the potential exception of Section 504 of the Rehabilitation Act (disability), following the U.S. Supreme Court's 2001 ruling in the *Sandoval* case, a private individual may only bring a discrimination claim under Section 1557 and its incorporated statutes for intentional discrimination. *See Alexander v. Sandoval*, 532 U.S. 275 (2001). The federal government, however, may continue to assert claims based on unintentional discrimination (disparate impact). That the federal government could assert claims for disparate impact discrimination in health care should, in theory, further prompt hospitals and health systems to mitigate the risks of discrimination in health AI, but it is not clear at this time whether the Trump administration intends to police potential disparate-impact discrimination in the use of health AI.

[8] *Lucas v. VHC Health*, No. 24-1128, 2025 WL 395728 (4th Cir. Feb. 5, 2025).

[9] *See id.* at *5.

[10] *See id.*

[11] *See id.*

[12] *See, e.g.,* Hoffman and Podgurski *supra* note 6 (noting "if health-care providers become aware that their AI disproportionately deprives minority patients of referrals to high-risk management programs or underestimates their risk of contracting serious diseases and do not intervene to rectify the problem, they could face intentional discrimination claims under Title VI or Section 1557.").