



# Legal tools to address discrimination by algorithm

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# The Problem: Discrimination by algorithm

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- Many clinical algorithms are flawed, either because:
  - they incorporate bias by design or
  - they are trained on biased data sets
- Use of biased AI can result in discrimination by algorithm
- To date, there has been little regulatory enforcement activities to combat discrimination by algorithm



# The Tool: Section 1557

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- ❑ Section 1557 of the Affordable Care Act (ACA) prohibits discrimination by covered health programs and activities on the basis of race, sex, color, national origin, age, or disability
- ❑ Covered entities include hospitals and physician groups that participate in Medicare and Medicaid and virtually all health plans
- ❑ Section 1557 was one of the last parts of the ACA to be implemented and has seen much political “back and forth”



# The Tool: Section 1557

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- ❑ Penalties for violating Section 1557 can be significant, including investigation by the Office for Civil Rights (OCR), suspension or termination of federal financial assistance from HHS, and compensatory damages
- ❑ Additionally, unlike HIPAA, Section 1557 includes a private right of action, allowing individuals to sue health care entities for discriminatory care



# The New Development: Section 92.210

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- Recent new proposed rule implementing Section 1557 includes § 92.210, which says that “a covered entity must not discriminate against any individual on the basis of race, color, national origin, sex, age, or disability through the **use of clinical algorithms in its decision-making.**”
- A covered entity would not be liable for a clinical algorithm it did not develop but maintains that it might be liable for a decision made in reliance on a biased clinical algorithm



# The Problem: Does Section 92.210 chill innovation?

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- ❑ HHS states in its proposed rulemaking that “[t]he intent of proposed § 92.210 is not to prohibit or hinder the use of clinical algorithms”
- ❑ But § 92.210, if rigorously enforced in the ML/AI space, will likely do just that by placing the burden on providers to understand complex algorithms



# The Problem: Does Section 92.210 chill innovation?

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- ❑ In the proposed rulemaking, HHS focuses on non-AI/ML algorithms.
- ❑ It is often very difficult (if not impossible) to identify sources of bias and discriminatory outputs in AI/ML algorithms
- ❑ HHS attempts to acknowledge this challenge, urging physicians to consult with the American Medical Association (AMA) framework.



# The Problem: Does Section 92.210 chill innovation?

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- Can providers truly evaluate available algorithms, develop necessary oversight protocols, and ensure meaningful oversight?
  - This may be beyond the practical capabilities of most providers except in the largest health care organizations.
  - It also raises equity issues because organizations with fewer resources to evaluate their technological tools will have to choose between exposing themselves to higher liability or forgoing the use of products to help keep the competitive.





# Alternative Solutions

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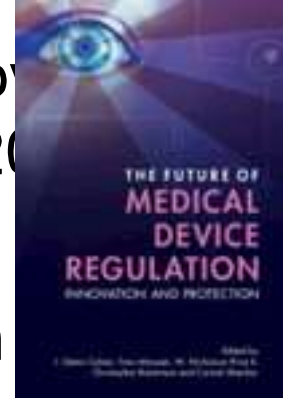
- ❑ HHS could consider establishing a “safe harbor” (standard of care) for health care providers
- ❑ HHS should coordinate its efforts with the FDA, clarifying how to best evaluate clinical algorithms to develop checklist/standards to evaluate bias
- ❑ Providers need to advocate on their own behalf to ensure the responsibility of addressing discrimination by algorithm does not fall just on them



# Acknowledgements and Further Reading

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- ▣ Collaborator: Prof. Sara Gerke, Assistant Professor of Law, Penn State Dickson Law and former Research Fellow on the Project on Precision Medicine, Artificial Intelligence, and the Law
- ▣ The Future of Medical Device Regulation: Innovation and Protection (Cambridge University Press, 2020)
- ▣ This research is supported by a Novo Nordisk Foundation-grant for a Collaborative Research Programme (grant agreement number NNF17SA0027784)





# Thanks!

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