

Top 10 Things to Understand About Regulating Healthcare AI

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1. Most healthcare organizations aren't doing much governance.

PERSPECTIVE

How Academic Medical Centers Govern AI Prediction Tools in the Context of Uncertainty and Evolving Regulation

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Even well-resourced AMCs are struggling to effectively identify, manage, and mitigate the myriad potential problems and pitfalls related to implementing predictive AI tools. The range of governance structures we identified indicates a need for additional guidance, both regulatory and otherwise, for health systems as prediction models continue to proliferate. Rather than concentrating respon-

Based on participants' responses, the current regulatory landscape does not require more consistency or explicit evaluation of them in practice. Rather, the decision makers we interviewed perceive that extant regulation targets vendors, leaving health systems to design governance processes based on their own priorities and understanding of best practices from peer institutions rather than federal regulation. According to participants, this landscape results in inconsistent quality, confusion, and potential patient safety issues. Guidance and regulation are important for providing a roadmap for this evolving landscape.



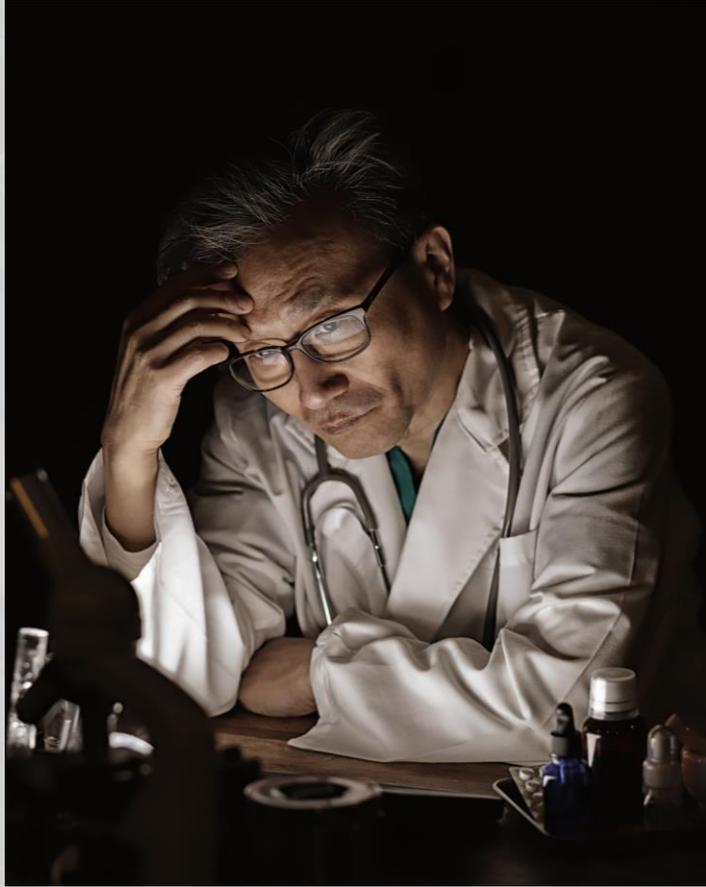
2. It's not just
about the model.



3. Robust
governance
is hard,
unrelenting,
and costly.

Assessing Decision Support Tools for Discrimination

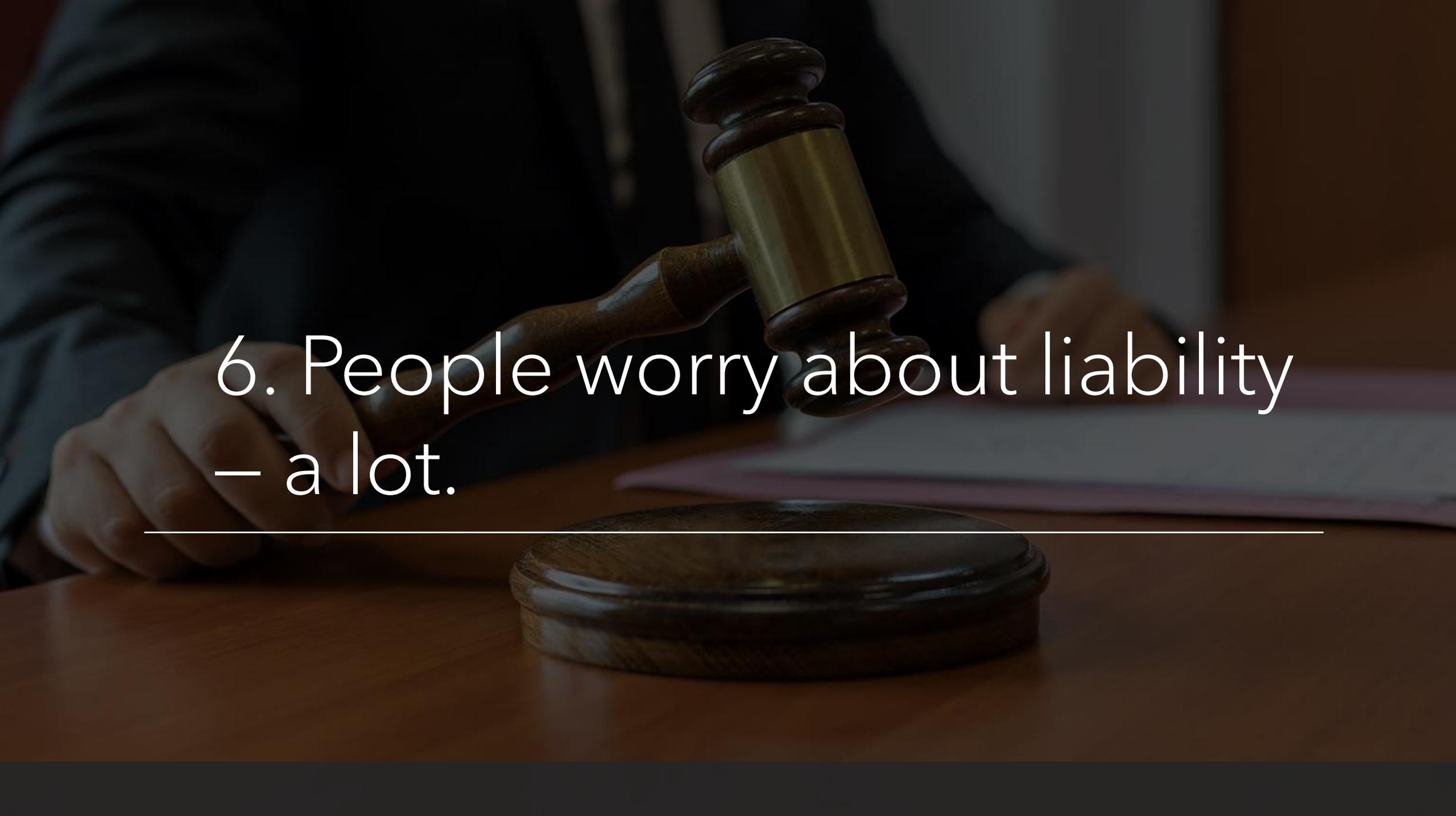
Section 92.210 sets a minimum requirement for each covered entity to make reasonable efforts to mitigate the risk of discrimination resulting from the covered entity's use of a decision support tool. This will impose a cost on covered entities to review for potential discrimination in their decision support tools and to then make reasonable steps to mitigate the risk of discrimination. To estimate the cost of review, the Department assumes that all covered entities, or 266,297 entities, would on average take 1 hour to review decision support tools in year 1 and 0.5 hours in each year 2–5. The Department assumes



4. Using AI has many benefits, but saving money isn't usually one of them.

5. Consider the
counterfactual



A hand holding a wooden gavel over a wooden block on a table. The gavel has a dark wood handle and a brass head. The block is also made of dark wood. The background is a blurred office setting with papers and a person's hand.

6. People worry about liability
– a lot.

What healthcare providers hear from lawyers

“can be a disaster for health care providers”



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7. The “human in the loop” isn’t Superman.





8. More disclosure isn't always better.



9. The legal environment
abhors a vacuum

10. Careful state regulation can make a positive contribution.



Require governance processes as a condition of healthcare facility licensure



Make disclaimers / limitations of warranties and liability unenforceable in the state

Thank you

FOLLOW-UP QUESTIONS WELCOME

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