

States seek AI guardrails in health care

By Brett Mason, Esq., and Emma Trivax, Esq., Troutman Pepper

JULY 9, 2024

AI is poised to revolutionize the health care industry with its capacity to make complex health decisions — whether it's making an insurance coverage determination or identifying the most optimal medical treatment for a patient.

But is the AI risk worth the reward? With health care access and patient safety on the line, there's an ever-growing need for AI guardrails and many state legislators, including those in Georgia, have answered the call.

Earlier this year, Georgia introduced HB 887, which proposed to regulate the use of AI in three primary health care areas: insurance coverage, patient care, and public assistance determinations. Although the bill was not enacted, it illustrates the shifting trend in state AI legislation and the challenging cost-benefit analysis lawmakers must consider as AI continues to advance.

And without any federal framework in sight, providers and other health care industry participants are now facing a patchwork of state regulations that are constantly in flux, which could ultimately stymie the use of AI and its potential health care benefits.

AI biases are top of mind

AI can efficiently and quickly sift through large volumes of data to make recommendations to insurance providers on coverage determinations and aid health care providers in making medical decisions.

But AI can also have blind spots, which is why Georgia's proposed AI legislation required a secondary meaningful review by an authorized individual for decisions resulting from AI in these circumstances. In particular, algorithms can inadvertently perpetuate or exacerbate existing biases in health care, leading to disparities in access, treatment, and outcomes.

It's no surprise that this is the focus for new legislation, as the Centers for Medicare and Medicaid Services (CMS) has already taken steps to address these concerns. Last year, CMS prohibited Medicare Advantage organizations from relying on a computer algorithm or software that does not take individual circumstances into account when making certain medical necessity determinations.¹

Even without AI-targeted legislation, state AGs have already been cracking down on potential bias across the industry, whether it's addressing potential racial bias in health care computer algorithms or pushing for consumer warnings regarding reduced drug or medical device efficacy for people of color.

Additionally, consumers themselves have initiated class action lawsuits against insurers over their alleged use of algorithms to deny coverage.

As the use of AI tools becomes more prevalent, health care industry participants should be proactive in implementing appropriate risk mitigation strategies and fail safes to address potential bias in AI algorithms.

Expect enforcement actions from state AGs on issues related to bias under consumer protection laws to continue, in addition to more targeted legislation to combat potential AI biases across the sector.

Patient safety and allocation of risk

As the health care industry navigates the complexities of AI integration, it is crucial to consider the implications for patient safety and the allocation of risk. Patient safety is a paramount concern, and rightly so. AI systems must be rigorously tested to ensure they do not cause harm and inaccurate diagnoses or treatment recommendations.

But questions remain — who is responsible when AI steers a medical provider to an incorrect or harmful course of action?

Accountability and determining liability when AI systems fail or cause harm is complex. Georgia's proposed legislation required any health care decision-making process that included the usage of an AI tool to be reviewed by an individual with the authority to override the AI's recommendation, although the bill did not specifically identify what health care credentials would qualify an individual.

While this "trust, but verify" approach is a sound one, does it hamstring the efficiency and analytical benefits if a second review is required? And will providers be hesitant to utilize AI if they are liable for relying on an AI misstep?

There's also a question of where a health care provider's liability ends, and an AI developer's liability begins. In states like Colorado, newly enacted legislation has created additional enforcement against the latter.

In particular, it places requirements on both developers and deployers of "high-risk" AI systems by requiring certain disclosures to the consumers and attorney general, the development and implementation of a risk management programs, as well impact assessments.

Health care providers must also carefully evaluate the scope of their medical malpractice insurance coverage. Presently, many insurers have instituted policies to deny claims associated with AI-generated content, and only a handful, if any, have indicated a willingness to cover claims resulting from erroneous AI outputs.

Insurance regulations will also continue to evolve, so it is imperative for health care providers to remain vigilant and informed about any legal developments.

Informed consent is key to responsible AI in health care

By requiring deployers of AI to notify consumers of when AI is being used to make consequential decisions, Colorado's most recent legislation also highlights the importance of responsible AI use, including risk mitigation processes like disclosure and informed consent. And Colorado is not alone in these efforts.

In 2023, Georgia enacted HB 203, which regulates the usage of AI for certain eye assessments and requires an optometry prescriber to obtain informed consent when using AI for this purpose.² Although unsuccessful, Illinois attempted to enact legislation that would require hospitals to inform patients when their diagnosis derived from some form of AI or algorithm.³

And Pennsylvania has a proposed a bill that would require added transparency when health insurers are using AI.⁴

Disclosure and informed consent are a cornerstone of ethical practice in health care, and their importance is magnified when AI is involved. Transparency ensures that patients understand the potential benefits, risks, and limitations of AI-driven interventions and fosters trust between patients and health care providers, empowering patients to make educated decisions about their health.

Health care providers should consider implementing informed consent and disclosure measures as they incorporate AI into their practice, as we expect that informed consent will be a key priority in future state AI legislation.

Anticipating AI legal impacts

As AI continues to revolutionize health care, industry participants must proactively consider and anticipate legal issues to ensure compliance and ethical practice.

For example, AI systems often require vast amounts of patient data to function effectively, raising concerns about the security and confidentiality of sensitive health information. Ensuring compliance with regulations like HIPAA and implementing robust data protection measures are essential to mitigate these risks.

Additionally, it is crucial to establish clear boundaries and guardrails to prevent AI developers from inadvertently engaging in the unauthorized practice of medicine, which could lead to liability issues and undermine patient trust.

About the authors



Brett Mason (L), a partner at **Troutman Pepper**, primarily defends pharmaceutical and medical device companies in litigation involving mass tort, personal injury and wrongful death claims. She is based in Atlanta and can be reached at brett.mason@troutman.com. **Emma Trivax (R)**, a Detroit-based associate, represents a wide range of health care providers, including pharmacies, hospitals, clinical laboratories, skilled nursing facilities and behavioral health providers. She can be reached at emma.trivax@troutman.com. The authors would like to thank summer associate Camdyn E. Neal for her contribution to this article.

This article was first published on Westlaw Today on July 9, 2024.

By anticipating legal impacts and instituting comprehensive safeguards, health care providers and AI developers can mitigate risk as they navigate the complex and evolving regulatory landscape.

Missing federal framework leaves more questions than answers

With the rise of digital health care services and capabilities, it's become even more common for health care to be provided outside the walls of a provider's office — making health care more accessible than ever before.

But the lack of a federal framework to govern the use of AI presents significant challenges, particularly in ensuring consistent standards and protections across the industry. Without a unified regulatory approach, providers and industry participants such as technology vendors are faced with a patchwork of regulations that can be difficult to navigate. This fragmentation can stifle innovation and result in accountability gaps.

Conclusion

As AI continues to permeate the health care industry, it will require lawmakers and industry participants to constantly balance the risks and rewards of AI implementation. The integration of AI offers transformative potential, yet it also introduces complex questions of safety, accountability, and liability.

Legislation reflects a cautious approach, emphasizing oversight and responsibility for both health care providers and AI developers. Ultimately, the successful integration of AI in health care hinges on a collaborative effort to safeguard patient well-being, while traversing the intricate landscape of legal and ethical responsibilities.

Notes:

¹ Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly, 88 FR 22120.

² H.B. 203, 157th Gen. Assemb., Reg. Sess. (Ga. 2023); see also Georgia Joins List of States Looking to Limit AI in Health Decisions (govtech.com) <https://bit.ly/4eHE1sb>.

³ H. 1002, 103rd Gen. Assemb., Reg. Sess. (Ill. 2023).

⁴ H.B. 1663, Gen. Assemb., Reg. Sess. (Pa. 2023).