Licensure and Regulatory Implications in the Face of the AI Revolution in Healthcare

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I. Introduction

As technology evolves, health care systems have adapted, integrating AI into their daily practices of medicine. AI has rapidly spread into hospitals and clinics around the world, as more than 1,000 health-related AI tools have been authorized by the FDA.[1] In 2024, it was reported that nearly two-thirds of doctors are using AI in their health care practices.[2] This represents a nearly 30% increase from 2023, in which only 38% of doctors were using AI.[3] If this trend continues, nearly all doctors will have integrated AI into their practices in the next few years.

The health care world relies on licensing and regulatory standards to ensure patient safety. Since the colonial era, states have regulated medical fields through legislative medical practice acts.[4] However, when these acts were written, and when health policy reforms took place in the 1900s,[5] AI was not in existence, nor did law makers consider that it may develop. As a result, the licensure and regulatory frameworks have not established clear standards as to how AI may be used in health care.

With this rapid integration of AI into health care in recent years, there is a growing need for legal reform. AI is taking on key responsibilities of doctors, presenting issues of compliance with licensing and regulations.[6] If they're not updated, health systems and their doctors will soon face lawsuits, accusing them of falling below the standard of care and failing to comply with regulations.[7]

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[1] Murali Doraiswamy and Marc Benioff, *AI Is Revolutionizing Healthcare. But It Can't Replace Your Doctor*, TIME (September 18, 2025). https://time.com/7315960/ai-healthcare- murali-Doraiswamy-Marc-benioff-essay/ [https://perma.cc/Y7JB-24EK].

[2] Marc Zarefsky, *Using AI to heal the system, not replace the physician*, AMERICAN MEDICAL ASSOCIATION (September 17, 2025). https://www.ama-assn.org/practice-management/digital-health/using-ai-heal-system-not-replace-physician [https://perma.cc/Q4QL-7XHL].

[3] *Id.*

[4] INSTITUTE OF MEDICINE (US) COMMITTEE TO STUDY THE ROLE OF ALLIED HEALTH PERSONNEL, ALLIED HEALTH SERVICES: AVOIDING CRISES.

[5] Katherine Smith, *A (Brief) History of Health Policy in the United States*, DELAWARE JOURNAL OF PUBLIC HEALTH, NATIONAL LIBRARY OF MEDICINE (September 20, 2025). https://pmc.ncbi.nlm.nih.gov/articles/PMC10810293/ [https://perma.cc/CY3L-HNTP].

[6] *State Oversight of AI in Healthcare: Status and Impacts*, AVALERE HEALTH (September 18, 2025) https://advisory.avalerehealth.com/insights/state-oversight-of-ai-in-healthcare-status-and-impacts [https://perma.cc/BUH6-ZDXV].

[7] *See* B. Scott McBride and Sydney Menack, AI in Healthcare: Opportunities, Enforcement Risks and False Claims, and the Need for AI-Specific Compliance, MORGAN LEWIS (September 19, 2025) https://www.morganlewis.com/pubs/2025/07/ai-in-healthcare-opportunities-enforcement-risks-and-false-claims-and-the-need-for-ai-specific-compliance [https://perma.cc/B5YD-MG6F].

II. How AI is Changing Health Care Models

The integration of AI can significantly lighten the workloads of doctors.[8] It can be used for "drafting doctor's notes, suggesting diagnoses, helping to read x-rays and MRI scans, and monitoring real-time health data such as heart rate or oxygen level."[9] With AI to perform tasks such as these, doctors can focus more attention on direct patient interaction. Jefferson Health, a hospital system in the Philadelphia area, conducted a pilot project in which AI was used to listen to conversations between doctors and patients and summarize them, leaving doctors with more face-to-face contact with their patients.[10] Jefferson Health has also implemented an AI symptom checker for patients to use to identify issues and recommend next steps, such as calling a doctor or visiting an urgent care center.[11] This allows doctors to already have a sense of patient needs before meeting them, therefore allowing them to give more personalized care to every patient they see.

Beyond patient care, AI is being used to identify abnormalities that may be missed by the human eye and more precisely target radiation beams in cancer treatments.[12] As a result, health care systems are seeing greater operational efficiency and effectiveness.[13] However, it is important to remember that "the promise of AI in medicine will only be realized if it is built and used responsibly."[14] There are challenges and ethical considerations that must be at the forefront of the AI health care revolution, including: data privacy and security, algorithmic bias and fairness, transparency and explainability, integration with legacy systems, workforce impact and resistance, patient resistance and trust, & regulatory and ethical oversight.[15]

III. Legal Implications of the Rapidly Expanding Use of AI

As it currently stands, AI use in healthcare is regulated by Software as a Medical Device (SaMD), the framework for use of medical devices.[16] This framework follows a soft-law approach

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[8] Doraiswamy and Benioff, *supra* note 1.
[9] Robert H. Shmerling, MD, *Can AI answer medical questions better than your doctor?* HARVARD HEALTH PUBLISHING (September 17, 2025). https://www.health.harvard.edu/blog/can-ai-answer-medical-questions-better-than-your-doctor-202403273028 [https://perma.cc/8DKJ-6YBF],
[10] Zarefsky, *supra* note 2.
[11] *Id.*
[12] *Id.*
[13] *Id.*
[14] Doraiswamy and Benioff, *supra* note 1.
[15] Michael Brenner, *The AI-Powered Doctor Will See You Now: How AI Is Revolutionizing Healthcare*, WORKDAY (September 20, 2025), https://blog.workday.com/en-us/the-ai-powered-doctor-will-see-you-now-how-ai-is-revolutionizing-healthcare.html [https://perma.cc/4XSQ-FC25].
[16] Katitha Palaniappan, Elaine Yan Ting Lin, and Silke Vogel, *Global Regulatory Frameworks for the Use of Artificial Intelligence (AI) in the Healthcare Services Sector*, NATIONAL LIBRARY OF MEDICINE (September 19, 2025). https://pmc.ncbi.nlm.nih.gov/articles/PMC10930608/ [https://perma.cc/R7PS-3XVZ].

and includes professional guidelines, voluntary standards, as well as codes of conduct.[17] However, until very recently, there were no regulatory frameworks specifically for AI in medicine.[18]

With AI rapidly becoming commonplace in the medical field, lawmakers and policymakers have been left to play catch up. In the past year, state lawmakers have begun to implement legislation to regulate the use of AI, and "as of August 2025, at least 29 states and the District of Columbia (DC) have passed at least one bill addressing the use of AI in healthcare."[19] The legislation enacted thus far tends to fall into three categories: (1) prior authorization/claims (2) disclosure & operations requirements and (3) scope of practice.[20] In each category, the regulations aim to limit how much influence AI has and ensure that there remains human oversight.[21]

Without proper oversight, AI technologies pose serious risks to patient safety and health care operations.[22] Some key issues include potential for misdiagnoses stemming from AI hallucinations or bias, overlooking individual patient needs, and data breaches that may expose sensitive and confidential health information.[23] Doctors and hospital systems have a duty of care when it comes to their patients[24] and must ensure that their use of AI does not lead to breaches in such care. HIPAA regulations are also at play here, as medical records can only be accessed by authorized parties and patients have the right to know who has access to their health information.[25] The potential for data breaches that comes with the use of AI threatens this right and must be protected against.[26]

IV. Conclusion

The rapid development of AI and its use in health care, while offering many benefits, poses many risks to the regulatory system of health care that has been established. If the law does not keep up with the practices of AI, there will be a growing risk of patient harm, opening the door for potential legal ramifications for doctors and health systems for going against licensure and

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[17] *Id.*
[18] *Id.*
[19] *State Oversight of AI in Healthcare: Status and Impacts, supra* note 6.
[20] *Id.*
[21] *Id.*
[22] Mitchell Goldenberg, MBBS, PhD, Can Artificial Intelligence Replace Doctors? KECK MEDICINE OF USC (September 18, 2025). https://www.keckmedicine.org/physician-hub/can-artificial-intelligence-replace-doctors/ [https://perma.cc/X6E5-LDW2].
[23] McBride and Menack, *supra* note 7.
[24] Cara E. Davies and Randi Zlotnik Shaul, Physicians' legal duty of care and legal right to refuse to work during a pandemic, CANADIAN MEDICAL ASSOCIATION JOURNAL, NATIONAL LIBRARY OF MEDICINE (September 20, 2025). https://pmc.ncbi.nlm.nih.gov/articles/PMC2817323/ [https://perma.cc/79W8-ZNPR].
[25] *Your Rights Under HIPPA*, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (September 17, 2025). https://www.hhs.gov/hipaa/for-individuals/guidance-materials-for-consumers/index.html [https://perma.cc/Z5WZ-V6QJ].
[26] McBride and Menack, *supra* note 7.

regulatory measures. AI is here to stay and the legal framework surrounding health care must continue to stay on pace to mitigate the risks.

For there to be long-term success in the inclusion of AI in healthcare, lawmakers and policymakers alike must establish measurable goals to demonstrate AI's value, build collaborative teams in which doctors work alongside AI, and take proper steps to refine both the AI technology and the law before complete deployment of AI systems.[27] If the licensure and regulatory frameworks in healthcare continue to develop, AI can be an excellent tool to improve medical care and patient safety. However, without the continued implementation of strict regulations and licensure requirements, the use of AI will become a source of many lawsuits for doctors and health systems alike.

[27] Brenner, *supra* note 15.