To: Robert F. Kennedy Kr, secretary of Health and Human Services

From: Michael Tan

Date: July 24, 2025

Re: Federal Regulation for Safe and Ethical Use of Artificial Intelligence in Clinical Medicine

Statement of Issue: What federal policies or regulations can be implemented to ensure that the use of artificial intelligence in clinical settings within the U.S. healthcare system is safe, evidence-based, equitable, and well-regulated without compromising patient trust and safety?

Recent technological advancements have significantly enhanced medical care, with artificial intelligence (AI) now playing a major role in data analysis and clinical decision-making. Although rapid adoption of AI in medicine has introduced significant benefits, alongside there are complex ethical and legal challenges. Its rapid integration has raised concerns about liability, accountability and data privacy in the event of patient harm. Additionally, AI algorithms may perpetuate health disparities due to biased training data, setting a precedent for unequal distribution of quality care. Current federal laws like the Health Insurance Portability and Accountability Act (HIPAA) do not directly address AI specific data-privacy concerns.

- In 2018, the FDA approved the first autonomous AI system for diagnosing diabetic retinopathy, raising legal questions over who is liable when it causes harm to patients: the provider, the medical institution, or the AI developer
- Raising concerns about an increased risk of misdiagnosis or unequal distribution of care as most AI systems are trained on historical health data that may be racially or socioeconomically biased
- Medical malpractice lawsuits usually involve negligence on part of the physician. Liability may also fall onto AI developers. However, AI companies can often offload liability through contracts or insurance, leaving providers or hospitals vulnerable to malpractice suits
- HIPAA lacks provisions specific to AI's use of large-scale health datasets, raising concerns about privacy and transparency.

Policy Options

1. **Establish a federal regulated framework for AI in Healthcare commission (FDA/HHS)**

A federal body under the FDA or HHS to regulate AI in clinical medicine would set standards for safety, transparency, human oversight, and ethical use. Similar to the EU AI act and Brazil's draft AI legislation, this regulated body will help maintain a public registry of approved use of AI tools in medicine.

Advantages: Ensures national consistency in how AI is regulated through a federal body, protects patient safety, and establishes clear accountability for both developers and healthcare personnels. Can enhance public trust by mandating transparency and mitigating bias in AI algorithm training. Encourages AI innovation within the scope of ethical and legal guidelines.

Disadvantages: Establishing a federal body requires legislative approval and allocation of budget and workforce. There can be potential duplications of roles within FDA and HHS unless clearly delineated. Legal compliance can unintentionally slow the pace of AI innovation. Legislative implementation can be time-consuming, and these regulation frameworks may lag behind emerging technologies.

2. **Modernizing HIPPA provisions to include AI-specific data governance**

Include guidelines for use of patient data in AI machine learning which requires informed consent for health data used to train AI. Mandate documentation of how data and Protected Health Information (PHI) is de-identified and utilized. Additionally, audit data-sharing contracts and procedures with AI vendors.

Advantages: Enhances transparency and builds patient trust by clearly informing them about how their PHI is used in AI training. Reduces risk of HIPPA violations and data breaches through enforcement of strong privacy protection. Making data-sharing practices more accountable and auditable encourages ethical partnerships with AI vendors. Protects patient privacy; encourage responsible handling of PHI.

Disadvantages: May increase administration burden and costs on healthcare organizations and developers. Regulations may potentially limit access to wide and diverse range of data, and slow AI algorithm development. The process of acquiring informed consent where patient understand the relevance of the information, can be complex process.

3. **Mandating equity, bias and performance audits for FDA/HHS approved AI tools**

Mandate that all AI tools used in clinical care undergo periodic audits to assess bias, safety, equity, and efficacy across diverse patient populations. Audits are conducted by independent and/or external third-party organizations. Findings will be published in a transparent database accessible to patients and clinicians.

Advantages: Ensure AI tools deliver equitable care across diverse racial, ethnic, socioeconomic patient populations. Encourages AI developers to proactively address algorithmic bias. Promote continues quality improvement and life-long learning for clinicians and developers.

Disadvantages: May pose a financial burden on developers; especially on smaller companies. Can unintentionally stifle innovation by pushing smaller research companies out of the AI-healthcare market. Developers may feel hesitant and resist public disclosure audit findings.

Policy Recommendation: A federal oversight framework, combined with modernization of HIPAA, are necessary to ensure the ethical and equitable use of AI in clinical medicine. While shared liability and regular bias audits are important safeguards, federal regulation is essential to establish consistent national standards for safety, privacy, and transparency. This approach protects both patients and providers while supporting ongoing innovation. As AI become more autonomous and integrated into clinical decision-making, proactive policy measures are essential to address legal, ethical, data control challenges, and to preserve public safety and trust.

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