



AI in Healthcare: Policy Recommendations and Voting

Presented by Ms. Jodi Kuhn, Executive Director

Agenda

- Study Overview
- Summary of key findings
- The case for legislation
- Policy recommendations
- Vote

Study Overview

Timeline	4-6 months; interviews conducted over 6 weeks (Jul-Aug)
Source material	Literature review & subject matter expert interviews
Scope	Focus: enterprise applications and adoption of AI in healthcare settings (hospitals and health systems) & clinical support tools used for mediating clinician-patient relationship (diagnosis, communication, etc.)
Advisory Group	Dr. Sylvester Johnson, Northwestern University (fmr. Virginia Tech) Dr. Sandra Soo-Jin Lee, Columbia University Dr. Sarah Henrickson Parker, Virginia Tech

KEY FINDINGS

- (1) AI is not new in the healthcare sector, but the newest AI is front-of-mind;
- (2) The dominant business case for adopting new AI technologies is clinician burnout;
- (3) Good AI governance is a top priority, but it is uneven, institution-specific, and voluntary;
- (4) Multiple and messy external vendor dependencies characterize AI adoption;
- (5) Humans are staying in the loop;
- (6) Developers, deployers, and end-users want regulatory clarity and harmonization.

KEY FINDINGS

(1) AI is not new, but there are new AI applications rapidly changing how healthcare is delivered

KEY FINDINGS

(2) The business case for
AI adoption is often
clinician burnout

KEY FINDINGS

(3) Good AI governance is a top priority, but it's uneven, institution-specific, and largely voluntary

KEY FINDINGS

(4) Multiple and messy
external vendor dependencies
characterize AI adoption

KEY FINDINGS

(5) Humans are staying in
the loop to provide
oversight of AI models

KEY FINDINGS

(6) Developers, deployers,
and end-users could
benefit from regulatory
clarity and harmonization

Challenges & Controversies

The “black box”

Negative outcomes for
patients

Lack of transparency

Data privacy and security

Patchwork of binding and
non-binding policy

Data quality

Complicated role of
humans in the loop

The Case for Legislation

- **Mitigate risks**, address known challenges and controversies
- Provide developers/deployers/end-users **clarity** for long-term planning
- **Standardize governance** expectations and frameworks
- **Promote AI adoption** by establishing clear guardrails
- Create an opportunity for **sharing knowledge** for other states and federal regulation

Policy Recommendations

Legislative	Roadmap for Responsible Regulation
1. AI governance processes for healthcare providers 2. Model transparency standards 3. Model validation and evaluation standards 4. Adverse event reporting 5. Specific requirements for humans in the loop 6. Public disclosures about AI use 7. Enforcement and investigation mechanisms and oversight agency	• Address the need for regulation to be agile, adaptive, and accountable for outcomes • Accommodate the rapidly evolving AI landscape by making room for regulatory changes and updates • Provide opportunities for intentional and iterative consultation to ensure compliance requirements are feasible and outcome-driven • Share learnings openly to facilitate inter-state harmonization and regulatory coherence

Policy Recommendations

(1) **AI governance** processes for healthcare providers

Explanation

For Deployers: Documented AI governance processes that detail internal standards for decision making processing for adopting AI systems, including designating an accountable AI officer or committee.

(2) Model **transparency** standards

Explanation

For Developers and Deployers: Standards should apply to modifications made to AI models in recognition of the complex dependencies that results from software integration. Transparency standards should be developed in consultation with diverse stakeholders but may include training data, model weights, and performance metrics/benchmarks.

Policy Recommendations

(3) Model **validation and evaluation** standards

Explanation

For Developers and Deployers: Requires independent impact assessments, testing, and evaluation of phases of models, encompassing both before and after deployment assessments to evaluate model performance in real-world settings.

(4) Adverse event reporting

Explanation

For Deployers: Requires reporting information about serious incidents and negative events that result from the development or deployment of technology. Definition of categories of incidents that required reporting should be defined in regulatory guidance, and reporting should be continuous throughout the lifecycle of an AI product.

Policy Recommendations

(5) Specific requirements for humans in the loop and clarity on liability

Explanation

For Deployers: Requirements such as user-centered design in the development of AI models, requiring AI literacy training for human oversight of AI models, and requiring ongoing workforce development plans for entities procuring AI solutions. To address clinician concerns about liability, clarify the roles and responsibilities of developers, deployers, and end-users.

(6) Public disclosures about AI use

Explanation

For Deployers: Provide patients with information about how their data is managed and protected in relation to generative AI and when AI is being used in their care. Disclosures should provide comprehensible, clear, and actionable information to patients, which may include opt-in or opt-out mechanisms.

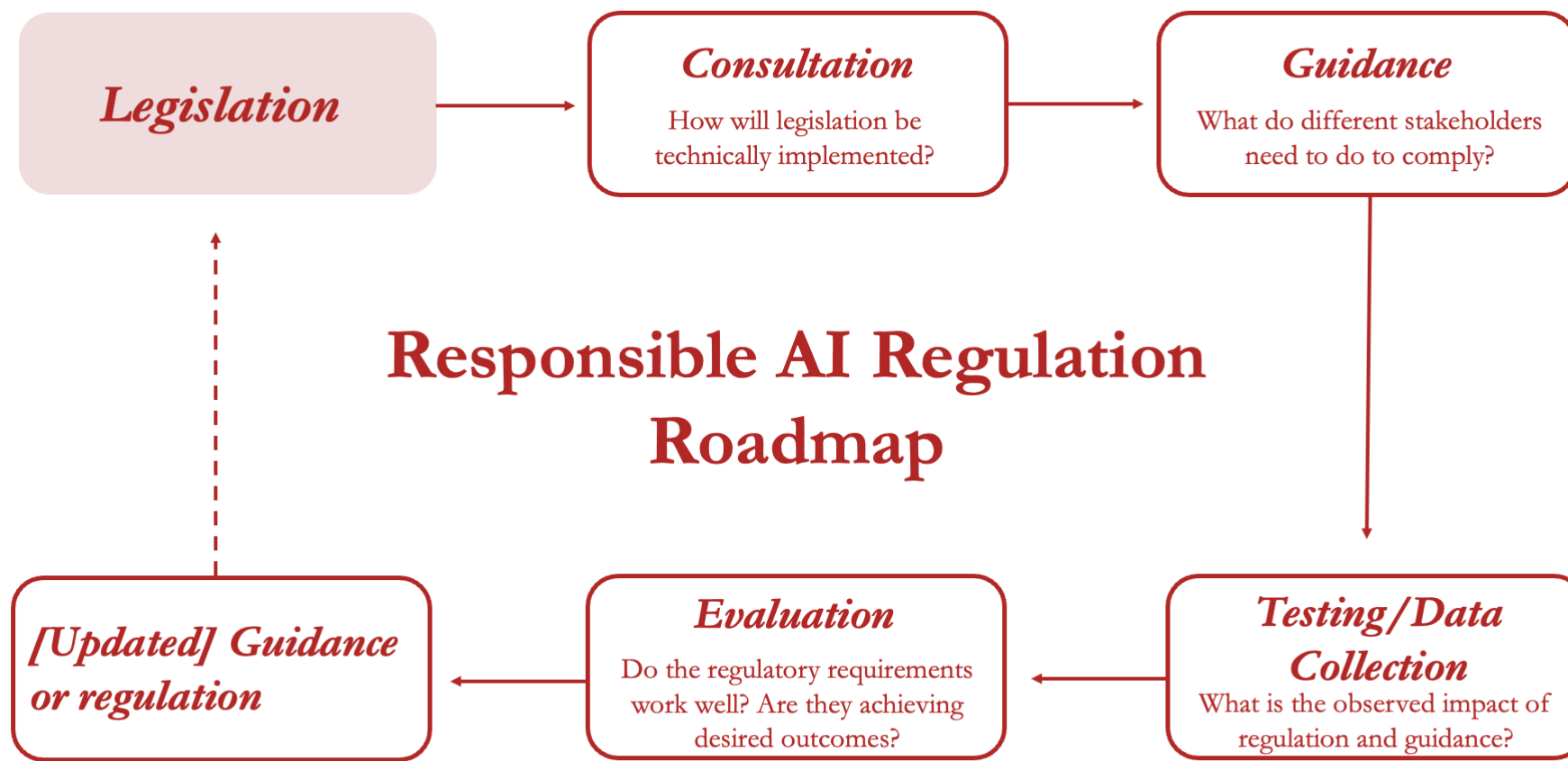
(7) Enforcement and investigation mechanisms and oversight agency

Explanation

An entity (e.g., section within the Office of the Attorney General) that can receive complaints and concerns from patients or members of the public, proactively investigate non-compliance or violations of established regulation, and impose penalties.

The Roadmap:

Regulation as a process, not an endpoint



Policy Recommendations

Legislative (Combined or individual bills)	Roadmap (Potential Study Topic)
1. AI governance processes for healthcare providers 2. Model transparency standards 3. Model validation and evaluation standards 4. Adverse event reporting 5. Specific requirements for humans in the loop 6. Public disclosures about AI use 7. Enforcement and investigation mechanisms and oversight agency	• Address the need for regulation to be agile, adaptive, and accountable for outcomes • Accommodate the rapidly evolving AI landscape by making room for regulatory changes and updates • Provide opportunities for intentional and iterative consultation to ensure compliance requirements are feasible and outcome-driven • Share learnings openly to facilitate inter-state harmonization and regulatory coherence