Health AI in California: The Role for State Policy

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CHCF

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Presentation Deck

Health AI in California: The Role for State Policy

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About this Project

On behalf of CHCF, the Duke Margolis Institute for Health Policy conducted a legislative review of AI in health care delivery.

The review covered federal, California state, and other relevant state bills affecting AI tools and uses in clinical settings.

This project had two core goals:

- Identify key concerns the California bills aim to address.
- Examine trade-offs and alternative approaches for lawmakers to consider going forward.

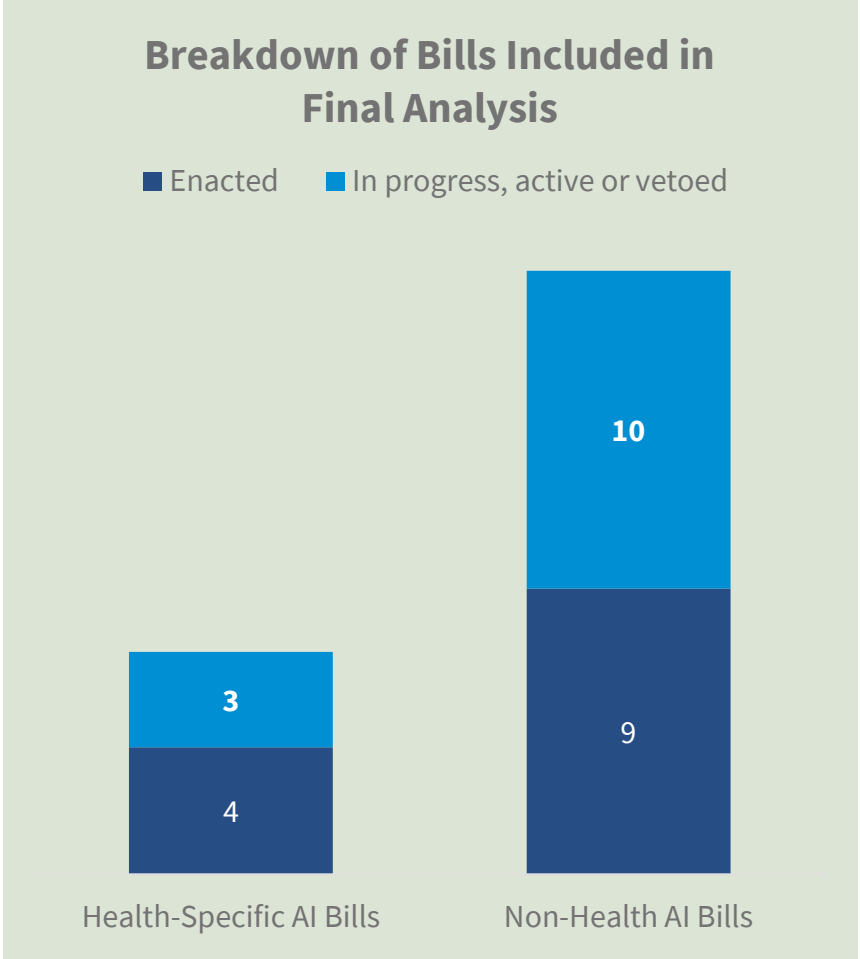
Overview of Federal & State Health AI Policy and Laws

- The current federal administration is emphasizing the importance of rapid innovation in the AI space, with a focus on reducing regulatory barriers and expanding AI use within agencies.
  - A December 2025 executive order discouraged states from enacting laws around AI.
  - Congress is divided on recently proposed state law moratoriums.
- All 50 states, Puerto Rico, the US Virgin Islands, and Washington, DC, introduced legislation on AI in 2025, with 38 states enacting ~100 laws. *

*Data from the National Conference of State Legislatures

Methodology

- Identified **41 California state bills** proposed through October 2025
- Narrowed analysis to **26 California state bills**
- Identified **four key themes** that were repeated through the bills
  - **Governance and risk management frameworks**
  - **Disclosing the use of AI**
  - **Transparency**
  - **Combatting bias**



Governance & Risk Management Frameworks

- **Nine bills focused in part on risk assessments and governance. Four were enacted.**
  - Generally required risk assessments but did not mandate or recommend specific methods or frameworks
- **Challenges:**
  - Lack of established best practices due to the technology's rapid evolution
  - Efficacy of specific risk mitigations is not well characterized
- **Potential solutions:**
  - Risk management frameworks:
    - Manage AI-related risk through standards that can evolve with technology more quickly
    - Incentivize responsible AI governance
  - Safe harbors:
    - Incentivize voluntary use of pre-identified, high-quality risk management frameworks
    - Reduce risk for regulated entities with less AI experience or fewer resources
    - Accommodate the use of alternative methods if regulated entities are willing to take on more risk

Disclosing the Use of AI

- **Thirteen bills included some type of disclosure requirement. Eight were enacted.**
  - Disclosure: a notification to a user or consumer that an AI system is being used with the consumer's data
  - Responsibility for disclosure was generally placed on the deployer of the tool
  - Often limited to specific use cases (e.g., mental health chatbot, high-risk decisions)
- **Disclosure can be an important risk mitigation and fairness tool.**
  - Informs users to prevent fraud and set appropriate expectations
  - Allows an option to speak with a human
  - Allows an opt-out or appeal of a decision
- **Challenges:**
  - Difficult to accurately convey what "human in the loop" means in any particular instance
  - Alert fatigue

Transparency

- **Seven bills included some type of transparency requirement. Three were enacted.**
  - Common elements included:
    - Explanation of the tool's purpose and its context for deployment
    - Summaries about the data used to train the model
    - Performance measures (e.g., accuracy, reliability)
    - Risk assessments and mitigation measures
    - Description of user information used by AI model
- **Transparency can help ensure AI solutions are trained and tested appropriately.**
  - Facilitates responsible deployment
- **Challenges:**
  - Compliance burden, trade secret disclosure, and information misuse
- **Possible solutions:**
  - Minimize information required to only those data elements with a clear safety purpose.
  - Consider trade secrecy implications and potential misuse.
  - Allow information to be provided confidentially to a trusted state agency or third-party body.

Combatting Bias

- **Four bills focused at least in part on concerns around discrimination and bias. None were enacted.**
  - Specified demographic/protected class bias or discrimination
  - Did not provide methods or frameworks to help regulated entities comply with the law
  - Did not specify what outcomes should be measured against or what allowances may be acceptable
- **Bias and discriminatory impacts are rightly a significant concern for AI tools.**
  - Potential for scaling
  - Ability to make bias less visible
- **Possible Solutions:**
  - Define bias and the comparator.
  - Clearly identify the range of tool types subject to the law.
  - Be realistic when setting requirements and compliance timetables.
  - Place responsibility and liability on the stakeholders most able to effect change.

Balancing Innovation & Regulation

- **Regulation is often perceived as a barrier to innovation.**
  - Small start-ups and under-resourced organizations find compliance more challenging than established companies.
  - Development becomes more expensive.
- **It's more complicated in the health technology space.**
  - **Most recent federal deregulatory actions focus on AI developers.**
    - This initially moves risk to the deployers (e.g., providers, health plans).
    - In the absence of clear laws, courts will ultimately determine liability.
  - **Rapid, unregulated innovation can present deployers with:**
    - Too many options, not enough information, no trusted "stamp of approval"
  - **This may push deployers towards large, well-established companies, even when small start-ups offer better solutions.**
    - Large companies have reputations at stake and more experience with cybersecurity compliance, data privacy, etc.
    - Deployers may be concerned about the viability of small start-ups to maintain AI tools over time.

The Importance of Definitions in Legislation

- **Consistent, clear definitions enable more rapid innovation and implementation.**
- **Definitions determine what types of AI tools are subject to enacted legislation.**
  - It is critical to use careful language to limit the scope to only the intended types of tools.
  - For example, removing “deterministic algorithms” from the definition of AI could inadvertently exclude all current FDA-authorized tools, which are designed to be stable (not to learn and change in real time).
- **California's AI-related definitions are generally clear and consistent.**
  - E.g., SB 53, Chapter 138, Statutes of 2025 defines foundation model as: "*an artificial intelligence model that is all of the following:*
    - *Trained on a broad data set.*
    - *Designed for generality of output.*
    - *Adaptable to a wide range of distinctive tasks."*

Key Takeaways for Health AI Policy

1. **Set the stage for success.**
   - Bills should give space for developers and deployers to use flexible, risk-based approaches to meet any requirements.
   - Legislation can incentivize best practices with safe harbor opportunities, which may also encourage the equitable deployment of AI across health systems.
2. **Reduce confusion and compliance cost.**
   - Carefully define and align key terms.
   - Harmonize definitions and standardize bill language across states, when possible.
3. **Incentivize innovation.**
   - Set out clear liability frameworks.
   - Assign accountability to the entities best positioned to drive change.
   - Balance transparency requirements with competitive concerns.
   - Prioritize state investments that focus on transformational impact.

About the Authors

Christina Silcox is the research director for digital health at the Duke-Margolis Institute for Health Policy, working on policy solutions to advance innovation in health by improving the regulation, reimbursement, and long-term evaluation of medical products. Silcox's portfolio extends across multiple areas in digital health policy, including the regulation, governance, and payment of AI-enabled clinical health tools and the value-based integration of patient-facing digital health tools (DHTs) into clinical care. Silcox has a PhD in medical engineering and medical physics from the Harvard-MIT Division of Health Sciences and Technology.

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Thank you!