ALLIANCE
FOR HEALTH POLICY

The Insider's Guide to Health Care AI Policy in 2025: Unique Needs, Evolving Approaches

Thursday, December 4, 2025

allhealthpolicy.org

Welcome Remarks

Sydney Shepherd
Senior Educational Program Manager
Alliance for Health Policy

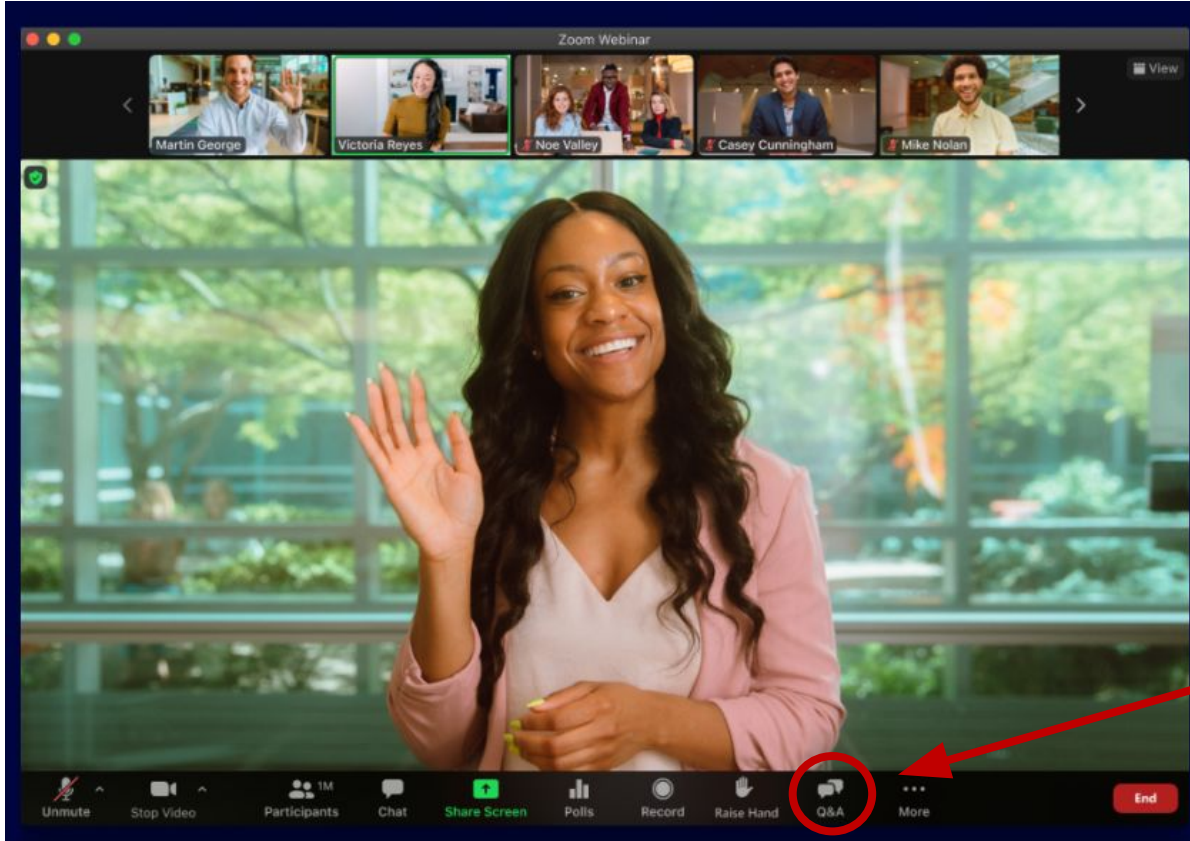# Thank You to Our Sponsors!

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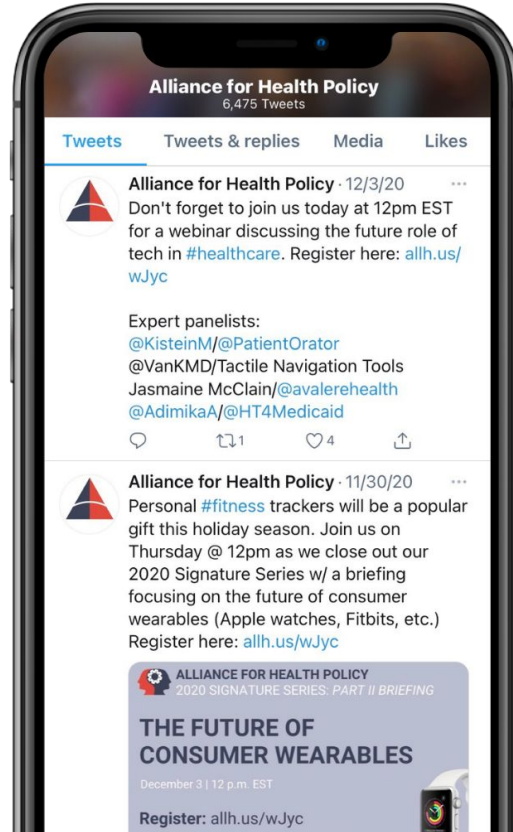FOR HEALTH POLICY

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Alliance for Health Policy · 12/3/20
Don't forget to join us today at 12pm EST for a webinar discussing the future role of tech in #healthcare. Register here: allh.us/wJyc

Expert panelists:
@KisteinM/@PatientOrator @VanKMD/Tactile Navigation Tools Jasmaine McClain/@avalerehealth @AdimikaA/@HT4Medicaid

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Alliance for Health Policy · 11/30/20
Personal #fitness trackers will be a popular gift this holiday season. Join us on Thursday @ 12pm as we close out our 2020 Signature Series w/ a briefing focusing on the future of consumer wearables (Apple watches, Fitbits, etc.) Register here: allh.us/wJyc

ALLIANCE FOR HEALTH POLICY
2020 SIGNATURE SERIES: *PART II BRIEFING*

THE FUTURE OF CONSUMER WEARABLES

December 3 | 12 p.m. EST

Register: allh.us/wJyc

ALLIANCE
FOR HEALTH POLICY

Today's Moderator

Claire Sheahan, M.Sc.
President and CEO
Alliance for Health Policy

For reference: 2024 AI Webinar
Demystifying AI Tools in Health Care:
An Introduction for Federal Policymakers

Rachel Snyder Good, J.D.
Strategic Counsel
Epstein Becker & Green

Lynn Shapiro Snyder, J.D.
Senior Member of the Firm, Epstein
Becker & Green
Chair, Women Business Leaders of the US
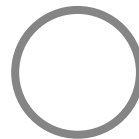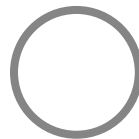Health Care Industry Foundation (WBL)

Maia Hightower, M.D.,
MPH, MBA
CEO and Founder
Equality AI

Nicoleta Economou, Ph.D.
Director of Duke Health AI Evaluation &
Governance, Duke Health
Scientific Director, Coalition for Health
AI (CHAI)

Today's Topics

Monica Massaro, MPP

- 2024 vs 2025- Big Picture in Healthcare AI
- Changes in Congress

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Jodi Daniel, J.D., MPH

- Federal Level updates:
  - White House
    - FDA
    - CMS
    - HHS/ONC

Jared Augenstein, M.A., MPHs

- State actions

Kev Coleman

- What's next: Four questions shaping the future of healthcare AI

Panelists

Jodi Daniel, J.D., MPH
Partner
Wilson Sonsini Goodrich & Rosati

Monica Massaro, MPP
Director, Government Relations and Public Policy
Hooper, Lundy & Bookman, PC

Kev Coleman
Research Fellow
Paragon Health Institute

Jared Augenstein, M.A., MPH
Senior Managing Director
Manatt Health

Learn More About Our Panelists!

Use the "Resources" tab on the Zoom toolbar

To learn more about our panelists, click the "Resources" icon on the bottom of your Zoom toolbar. Next, click the "Speakers" tab.

Monica Massaro, MPP
Director, Government Relations
and Public Policy
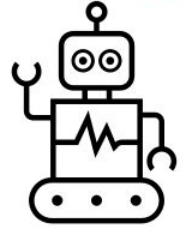*Hooper, Lundy & Bookman, PC*

AI State of Play: Where We Stand and What's Ahead in Congress

Monica Massaro

Director, Government Relations & Public Policy

Key Terms

+ Algorithm: Set of instructions followed in a specific order to complete a task

+ Machine Learning: Processing data to imitate the way that humans learn, improving AI accuracy over time

+ Artificial Intelligence: technology that enables computers and machines to simulate human intelligence and problem-solving capabilities

+ Generative AI: The class of AI models that emulate the structure and characteristics of input data in order to generate derived synthetic content. This can include images, videos, audio, text, and other digital content. FDA (Source: FedRAMP.gov)

+ Augmented Intelligence: Conceptualization of artificial intelligence that focuses on AI's assistant role, emphasizing that its design enhances human intelligence rather than replaces it (AMA, 2024)

Federal AI Health Policy Transition

A stark contrast in strategy across Federal Government

2024

- Government exploring uses of AI

- Several bipartisan Congressional Working Groups

- Presidential Executive Order: Safe, Secure, and Trustworthy Development and Use of AI (October 2023)

- Agency focus on transparency, bias

- Expanded role of the Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology

- Assurance Labs

2025

- Government utilizing AI

- Limited Congressional Activity

- Presidential Executive Order: Removing Barriers to American Leadership in Artificial Intelligence (January 2025)

- Agency focus on deregulation, interoperability

- Centers for Medicare and Medicaid (CMS) taking the lead on AI with Food and Drug Administration (FDA)

- Regulatory Sandboxes

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Congressional AI Activity (Federal)

- Congressional regulation of AI falls into two categories: General and industry specific regulations/safeguards

- There have been limited general Congressional hearings on AI this year
  - Senate Commerce
  - Senate Judiciary
  - House Energy and Commerce Committee
  - Interest from Armed Services Committees

- Some of these hearings have been **reactive**; with recent oversight hearings on the use of AI chatbots

- Some members of Congress looking at broader use of AI, considering the concepts of regulatory sandboxes and state law moratoria to promote innovation.

- Forward momentum is fading. Most Congressional interest has been responding to unfortunate situations.

Congressional AI Activity- Health Care

- First Health AI Hearing of the year held by House Energy and Commerce Committee in September offered a first look as to how legislators may address AI health policy in the 119th congressional session.

- Despite contrasting views, it was apparent during the hearing that Members of Congress from both sides of the aisle held a shared the belief that the unique nature of health care uses of AI may require a regulatory approach that departs from broader efforts to regulate (or not regulate) AI more generally.

- Bipartisan areas of interest:
  - Mental Health (AI chatbots, deceptive claims, inappropriate recommendations)
  - Data Privacy (Children's privacy, American Privacy Rights Act of 2024 (APRA), E & C Republican Working Group)
  - Denials in Care (Prior Authorization)
  - Payment (or lack thereof)

- Senate Health, Education, Labor and Pensions (HELP) Committee Chairman Bill Cassidy (R-LA) engaged on AI

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AI in Health Care: Themes & Questions

Members of Congress discussing AI in the health care space have focused on a few main questions:

1. Who should regulate?
2. Who should validate?
3. Who is liable?
4. What are the regulatory barriers to innovation?
5. Does FDA approval contribute to a certain status of validation?
6. What patient privacy protections must be updated outside of HIPAA?
7. Who will pay for AI utilization?
8. Should different policies be set for low vs high risk AI?
9. Who owns the data?
10. Do providers have the appropriate AI literacy to understand transparency information they receive?

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Federal AI Policy – Executive Branch
The Insiders' Guide to Health Care AI Policy
Alliance for Health Policy

Jodi Daniel

December 4, 2025

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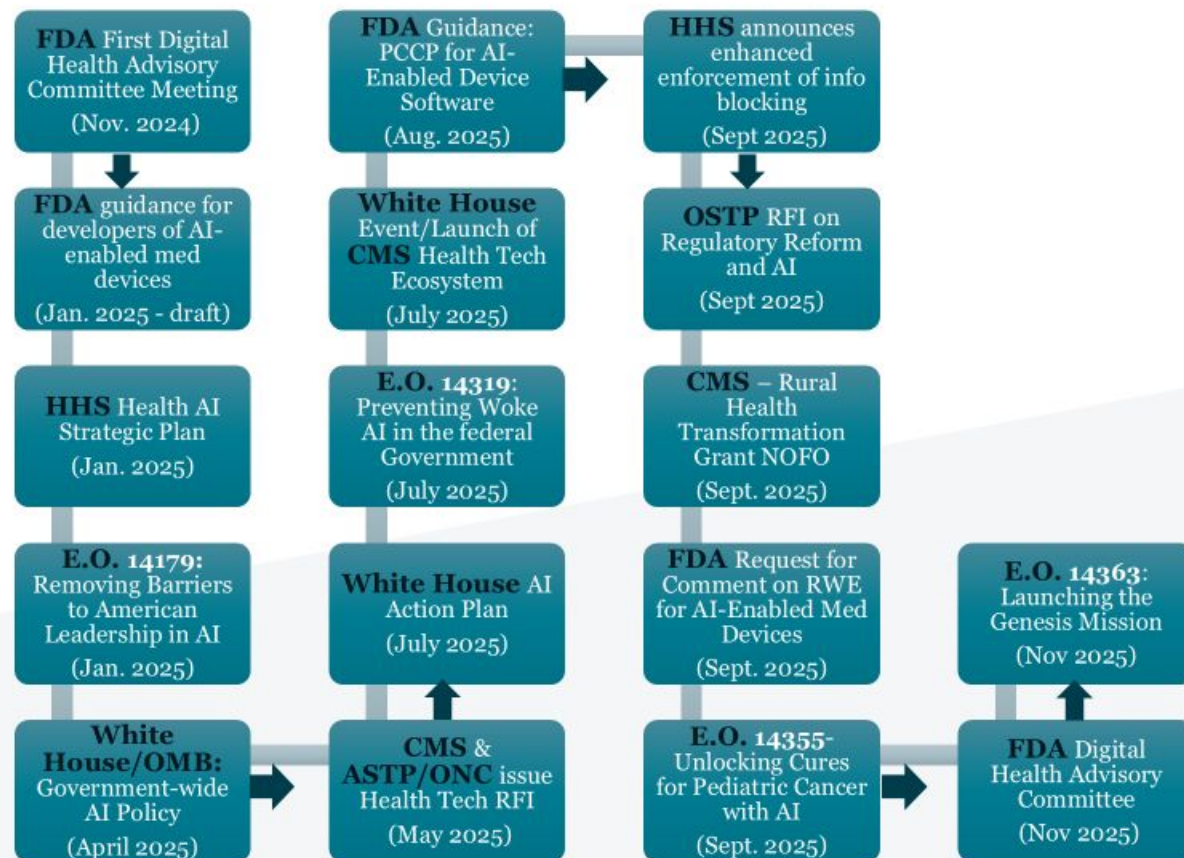# AI and Federal Policy Over the Past Year

Activities

- **Executive Orders**
- **Guidance**
- **HHS Policy Statements and Directives**
- **Requests for Information**
- **Committee Meetings**

Actors

- **White House**
- **FDA**
- **CMS**
- **ASTP/ONC**

AI and Federal Policy Over the Past Year

FDA First Digital Health Advisory Committee Meeting (Nov. 2024)

FDA guidance for developers of AI-enabled med devices (Jan. 2025 - draft)

HHS Health AI Strategic Plan (Jan. 2025)

E.O. 14179: Removing Barriers to American Leadership in AI (Jan. 2025)

White House/OMB: Government-wide AI Policy (April 2025)

FDA Guidance: PCCP for AI-Enabled Device Software (Aug. 2025)

White House Event/Launch of **CMS** Health Tech Ecosystem (July 2025)

E.O. 14319: Preventing Woke AI in the federal Government (July 2025)

White House AI Action Plan (July 2025)

CMS & ASTP/ONC issue Health Tech RFI (May 2025)

HHS announces enhanced enforcement of info blocking (Sept 2025)

OSTP RFI on Regulatory Reform and AI (Sept 2025)

CMS – Rural Health Transformation Grant NOFO (Sept. 2025)

FDA Request for Comment on RWE for AI-Enabled Med Devices (Sept. 2025)

E.O. 14355- Unlocking Cures for Pediatric Cancer with AI (Sept. 2025)

E.O. 14363: Launching the Genesis Mission (Nov 2025)

FDA Digital Health Advisory Committee (Nov 2025)

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White House – Overarching AI Policy: Executive Orders and Other Activities

- **E.O. 14179: Removing Barriers to American Leadership in AI (Jan. 2025)**

- **White House/OMB: Government-wide AI Policy (April 2025)**

- **White House: AI Action Plan (July 2025)**

- **E.O. 14319: Preventing Woke AI in the federal Government (July 2025)**

- **E.O. 14355: Unlocking Cures for Pediatric Cancer with AI (Sept. 2025)**

- **OSTP: RFI on Regulatory Reform and AI (Sept 2025)**

- **E.O. 14363: Launching the Genesis Mission (Nov 2025)**

Executive Branch – AI Action Plan

Strategy – Three Pillars

1. **Accelerate AI Innovation**

2. **Build American AI Infrastructure**

3. **Lead in AI Diplomacy and Security**

Impact on Healthcare

- Not health specific: HHS (incl. FDA, CMS, and ASTP/ONC) will have to figure out how to implement the plan for the healthcare sector

- Healthcare is noted as an industry slow to adopt AI due to "distrust or lack of understanding of the technology, a complex regulatory landscape, and a lack of clear governance and risk mitigation standards."

THE WHITE HOUSE

Winning the Race

AMERICA'S
AI ACTION PLAN

JULY 2025

FDA and AI: Guidance and Developing Policy

Risk-based approach to device software regulation; total lifecycle approach

- Draft Guidance: Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations (Jan 2025)

- Request for Public Comment: Measuring and Evaluating Artificial Intelligence-enabled medical Device performance in the Real-World (Aug 2025; Comments were due Dec. 1, 2025)

- Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Function (Aug 2025)

FDA Digital Health Advisory Committee considerations:

- Appropriate timeframes for demonstrating clinical benefit (pre-market)

- Intended use (adjunctive or stand alone; prescribed or over-the-counter; misuse)

- Risk controls, mitigations, testing and monitoring:
  - Device development
  - Safety by design
  - Verification & validation of risk control measures
  - Post-market monitoring

CMS Health Tech Ecosystem (with ASTP/ONC) - Improving Data Fluidity

CMS, in partnership with HHS and ASTP/ONC, uses federal government direction to encourage actions that would help modernize healthcare data exchange

- In May 2025, CMS issued an RFI to gather input from stakeholders to shape a patient-centric digital health ecosystem

- On July 30, 2025, CMS announced the launch of the Health Tech Ecosystem at the White House

- CMS launches an Interoperability Framework that is "a voluntary blueprint for modern health data exchange" that seeks to remove roadblocks to data access, sharing, and transparency.

Press Releases   Jul 30, 2025

White House, Tech Leaders Commit to Create Patient-Centric Healthcare Ecosystem

Administration

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Leading Healthcare, Tech Companies Pledge to Work on Interoperability & User-Friendly Apps

Today, the Trump Administration announced progress toward building a smarter, more secure, and more personalized healthcare experience in partnership with innovative private sector companies. During a White House "Make Health Tech Great Again" event hosted with the Centers for Medicare & Medicaid Services (CMS), the Administration secured commitments from major healthcare and information technology firms – including Amazon, Anthropic, Apple, Google, and OpenAI – to begin laying the foundation for a next-generation digital health ecosystem that will improve patient outcomes, reduce provider burden, and drive value.

"For decades, bureaucrats and entrenched interests buried health data and blocked patients from taking control of their health," **said HHS Secretary Robert F. Kennedy, Jr.** "That ends today. We're tearing down digital walls, returning power to patients, and rebuilding a health system that serves the people. This is how we begin to Make America Healthy Again."

CMS and ASTP/ONC Health Tech Ecosystem - Participants

- ## *CMS Aligned Networks*

  - Health information networks and exchanges and other health technology platforms that voluntarily commit to aligning with goals for interoperability

- ## *EHRs and Providers*

  - EHRs and providers that commit to making complete, timely patient data available, including both structured data and real-world clinical documentation and encounter signals

- ## *Payers*

  - Participating payers that commit to making claims data accessible to CMS Aligned Networks, and respond to patient, provider, and payer requests

- ## *Patient Facing Apps*

  - Patient facing apps must meet one of the following use cases: (i) "Kill the Clipboard"; (ii) **conversational AI assistants**; or (iii) diabetes & obesity prevention and management

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ASTP/ONC - Data Fluidity & Information Blocking Enforcement

Information Blocking:

- A practice that prevents or materially discourages access, exchange or use of electronic health information (EHI)
- Applies to health care providers, certified health IT developers, and health information exchanges and networks
- Includes a knowledge component and exceptions.

Announcement:

- September 3, 2025 - HHS announced that HHS would increase resources to enforce the information blocking prohibition under the 21st Century Cures Act

Significance:

- Developers, networks, and exchanges are subject up to $1 million penalty per information blocking violation.
- Providers are subject to disincentives by CMS.
- Aligns with goals of ensuring data is accessible to support AI development and deployment
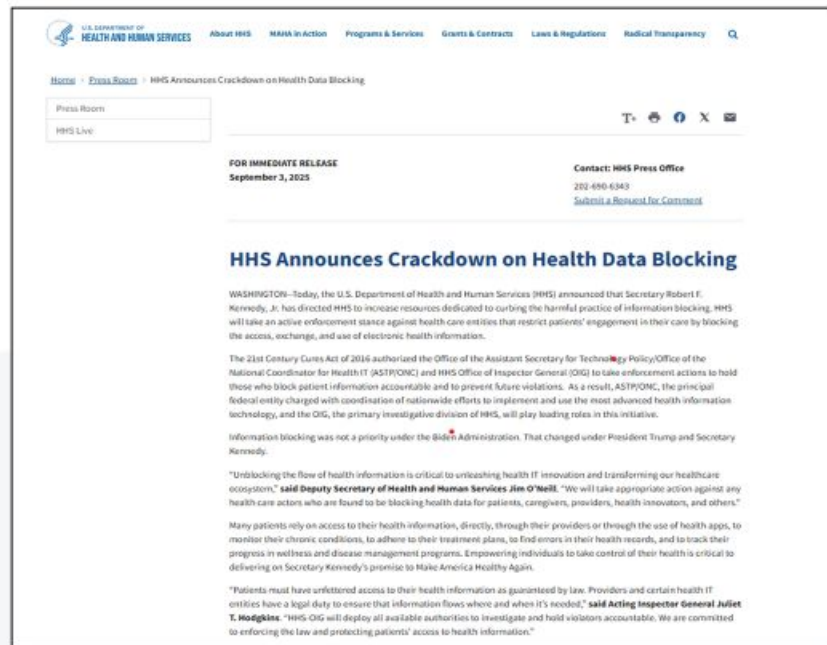
Rural Health Transformation (RHT) Program

- **RHT Program was authorized by the One Big Beautiful Bill Act (Section 71401 of Public Law 119-21)**

- **Purpose includes:**
  - "Tech innovation: Foster use of innovative technologies that promote efficient care delivery, data security, and access to digital health tools by rural facilities, providers, and patients. Projects support access to remote care, improve data sharing, strengthen cybersecurity, and invest in emerging technologies.

- **Notice of Funding Opportunity (NOFO) (CMS-RHT-26-001) – closing date 11/5/2025; awardees determined by 12/31/2025**

- **$50 billion to be allocated to approved states over 5 fiscal years**
  - Beginning in fiscal year 2026 and ending in fiscal year 2030
  - $10 billion of funding available each fiscal year
  - 50% to be distributed equally amongst all approved States
  - 50% will be allocated by CMS based on a variety of factors including rural population, the proportion of rural health facilities in the State, the situation of certain hospitals in the State, and other factors to be specified by CMS in the NOFO
  - Funding will be distributed in the form of a cooperative agreement

Existing Applicable Regulatory Frameworks Related to AI in Healthcare

Data Privacy and Security

- HIPAA, FTC Act, State Laws (including wiretapping (CIPA))

Interoperability and Information Blocking

- 21st Century Cures Act, State Laws
- Health data access via APIs

Licensing (Practice of Medicine/Professions)

- State Laws – AI technology could trigger state laws

Medical Device Safety/Liability

- FDA and 21st Century Cures Act
- State Laws

Non-Discrimination

- Sec. 1557 of ACA - nondiscrimination rule defines "patient care decision support tools"

Advertising

- HIPAA, FTCA

Reimbursement

- Federal and State Laws (Self-Referral/Anti-Kickback/Fee Splitting)

The Road Ahead: Things to Watch for Executive Branch Activities in 2026...

- **White House leading the broad approach**

- **Removing regulatory burdens**

- **Additional guidance for the healthcare industry**

- **Growing discussions re regulatory sandboxes and post-deployment surveillance**

- **Continued push for greater access to health data to support AI**

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Thank you!

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Senior Managing Director
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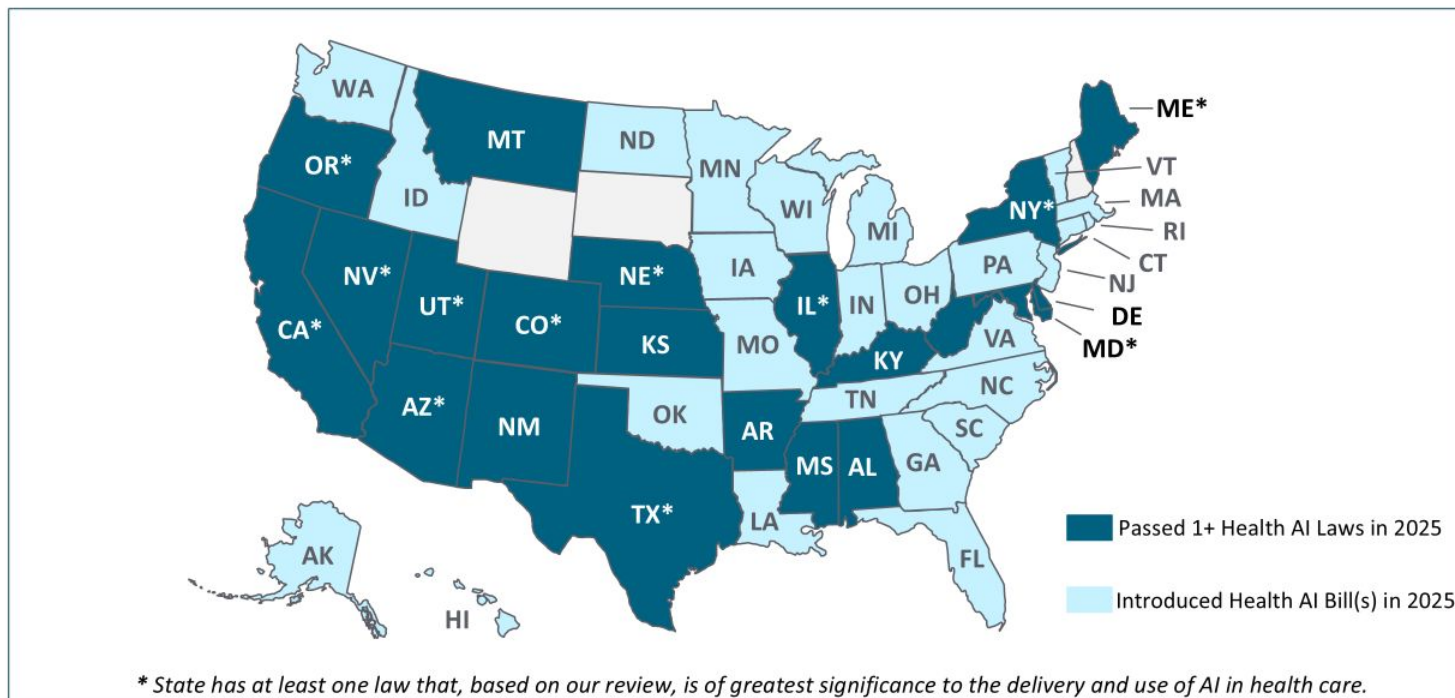# State of the States
Artificial Intelligence Policy Landscape

December 4, 2025

This year alone, 47 states introduced over 250 healthcare-specific bills (or general bills that implicate health) year.

33 bills have been passed into law in 21 states.

■ Passed 1+ Health AI Laws in 2025

■ Introduced Health AI Bill(s) in 2025

State has at least one law that, based on our review, is of greatest significance to the delivery and use of AI in health care.

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Use of AI-Enabled Chatbots

Six states passed seven laws that regulating AI-enabled chatbots, in response to growing concerns regarding chatbot misrepresentation, harmful or inaccurate responses, and the failure to detect crises. A subset of chatbot laws specifically focus on mental health.

AI in Clinical Care

Five states passed six laws addressing clinician use of AI tools, regulating provider oversight of AI outputs in clinical care, patient consent or disclosure mandates, and safeguards against bias and misuse of sensitive data.

Payer Use of AI

Four states passed laws (with over 60 bills introduced over the course of the year) establishing when payers may use AI tools to support decision-making (e.g., utilization management) and what oversight measures are necessary (e.g., clinician review).

Transparency

Some states passed broad AI transparency bills that will affect health care stakeholders, including providers, payers, and other actors in the health care ecosystem. Many of these bills target large and/or "high-risk" AI models.

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California S.B. 53
Enacted 9/29/2025, Effective 1/1/2026

- **Requires foundational model builders to develop and annually update a frontier AI framework applicable to their models**. The framework must include information on how developers incorporate national, international and industry-consensus best practices into model development; how developers identify and mitigate against the potential for catastrophic risk; as well as descriptions of cybersecurity practices, internal governance practices, and processes to report critical safety incidents.
- Requires developers to publicly **publish transparency reports.**
- Establishes **whistleblower protections for employees** that are responsible for assessing, managing, or addressing risk of critical safety incidents.

Colorado S.B. 4 (amending CO S.B. 205)

- CO S.B. 4 was passed during CO's special session in August 2025, **delaying the effective date of Colorado's sweeping transparency bill S.B. 205 (2024) from February 1, 2026, to June 30, 2026.**
- **S.B. 205 regulates developers and deployers of "high-risk" AI systems that make "consequential decisions," including healthcare stakeholders such as hospitals, insurers, and digital health companies**. It was signed with significant reservations from Colorado Governor Polis.
- The state legislature previously failed to pass S.B. 318 during the regular session, which would have substantially revised S.B. 205. **We expect to see additional efforts to revise S.B. 205 at the start of Colorado's 2026 legislative session.**

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Illinois H.B. 1906
Enacted 8/1/2025, Effective 8/1/2025

- Prohibits the **use of AI systems in therapy or psychotherapy to make independent therapeutic decisions, directly interact with clients in any form of therapeutic communication, or generate therapeutic recommendations or treatment plans without the review and approval by a licensed professional.**
- Prohibits licensed professionals from using AI tools for supplementary support unless the patient/legal representative is informed of the use and purpose of AI and **provide consent.**
- **Prohibits a chatbot** from **representing itself as a licensed mental health professional.**

Texas H.B. 149
Enacted 6/22/2025, Effective 1/1/2026

- **Requires that AI system deployed in relation to health care services or treatments must be disclosed** by the provider to the recipient of health services or their personal representative on the date of service, except in emergencies, when the provider shall disclose as soon as reasonably possible.
- Sets additional requirements on government agency use of AI (including requirements for clear and conspicuous disclosure to consumers) and non-governmental deployers and developers.

Three additional states have recently introduced similar legislation:

- **Florida H.B. 281** contains provisions banning the use of AI in mental health care outside of administrative or supplementary support and mandating that mental health providers may only use AI to record or transcribe a counseling or therapy session if written, informed consent is received at least 24 hours before services are provided.

- **Ohio H.B. 525** contains provisions requiring patient consent and prohibitions on the use of AI in clinical care and patient communications.

- **Pennsylvania H.B. 1925** requires disclaimers when AI is used to generate clinical communications and disclose when AI-based algorithms are used in clinical decision-making.
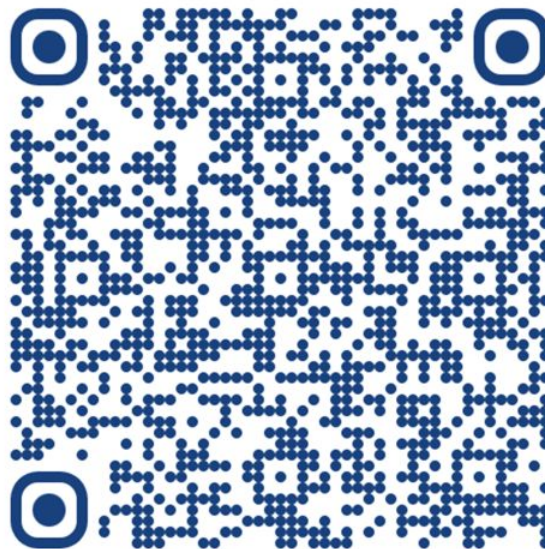
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Manatt AI Tracker

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4 Discussions Shaping the Future of Healthcare AI

Preamble: How AI Is Different
1.   Generalization/Localization
2.   Postmarket Surveillance?
3.   "Off Label" Uses in Healthcare?
4.   Encouraging innovation & Prevailing in International Competition

PARAGON
HEALTH INSTITUTE

How AI s/w Is Different

(A 60-second overview)

1. Generalization/Localization

2. Postmarket Surveillance?

3. "Off Label" AI Uses?

4. Innovation & Competition

Moderated Q&A

Closing Remarks

Sydney Shepherd
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