



# LEADING WITH RESPONSIBLE AI

*Day 2: Navigating a Rapidly  
Evolving AI Regulatory  
Landscape*

## The State of AI Regulation in Healthcare

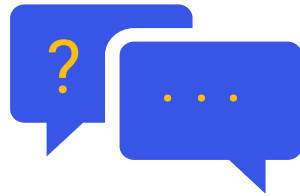
 Clearwater

# Meeting Logistics



## Microphones

All attendees are on mute.



## Questions

Type your questions in the Q&A box.



## Resources

Upcoming events, slides & resources linked.



## Recording

Recording will be provided after event.



## Survey

Survey will prompt at the end of webinar.

# Agenda

- Welcome + Introductions
- Presentation Content: The State of AI Regulation in Healthcare
- Q+A



**Andrew Mahler, JD, CIPP/US,  
AIGP, CHC, CHPC, CHRC**

Vice President of Privacy &  
Compliance Services  
Clearwater



**Frank Meyers**

Deputy Legal Counsel  
**Federation of State  
Medical Boards**



**Adam Greene**

Partner  
**Davis Wright  
Tremaine LLP**

# The State of AI Regulation in Healthcare

Andrew Mahler, Vice President Privacy & Compliance Services, Clearwater

Frank Meyers, Deputy Legal Counsel, Federation of State Medical Boards

Adam Greene, Partner, Davis Wright Tremaine LLP





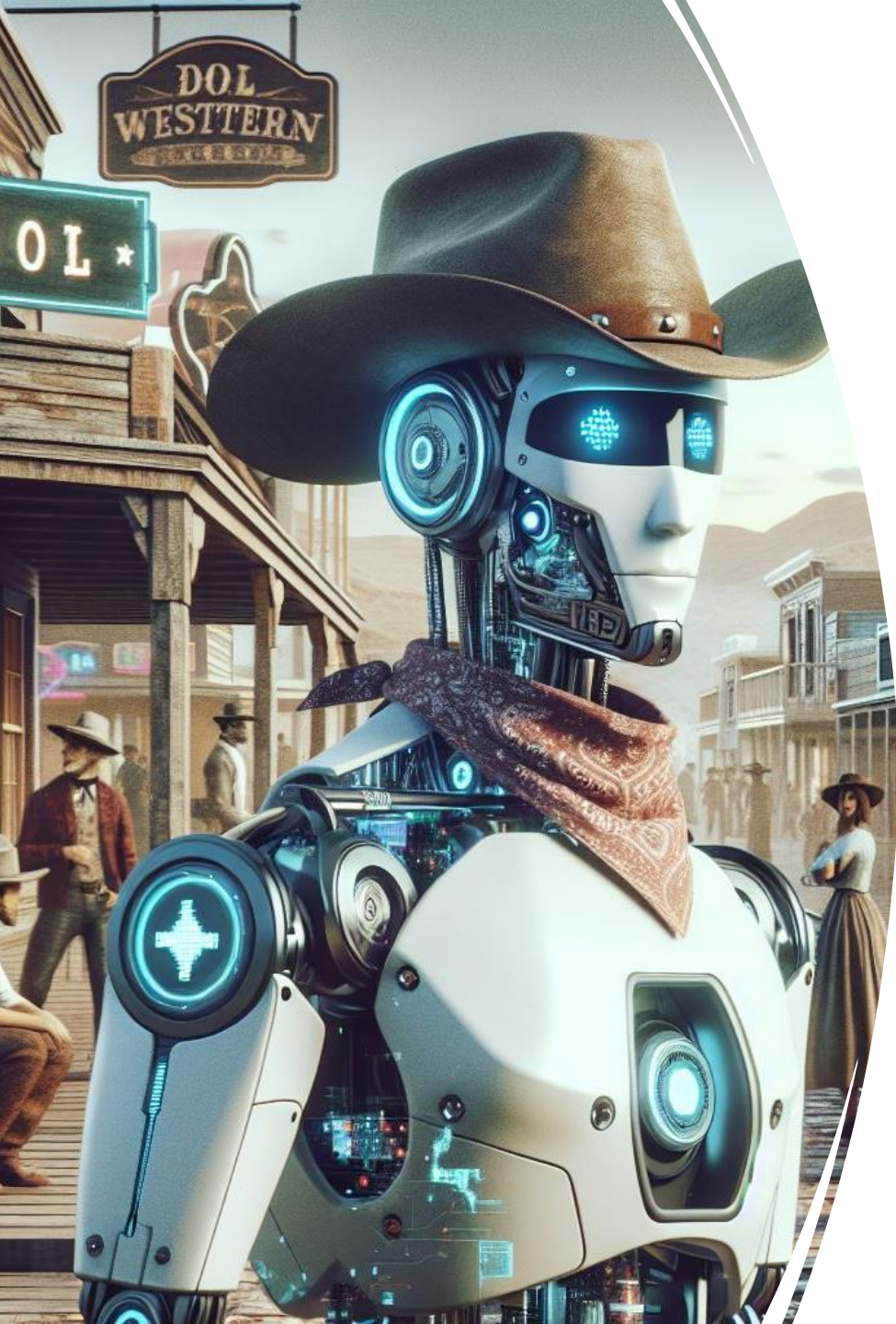
# Adam Greene's Perspective



# The Wild West of AI Regulation

- AI has been around for some time.
- Before ChatGPT launched in 2022, regulation of AI was not a significant focus.





# New Sheriff in Town

## Impact of ChatGPT and GenAI

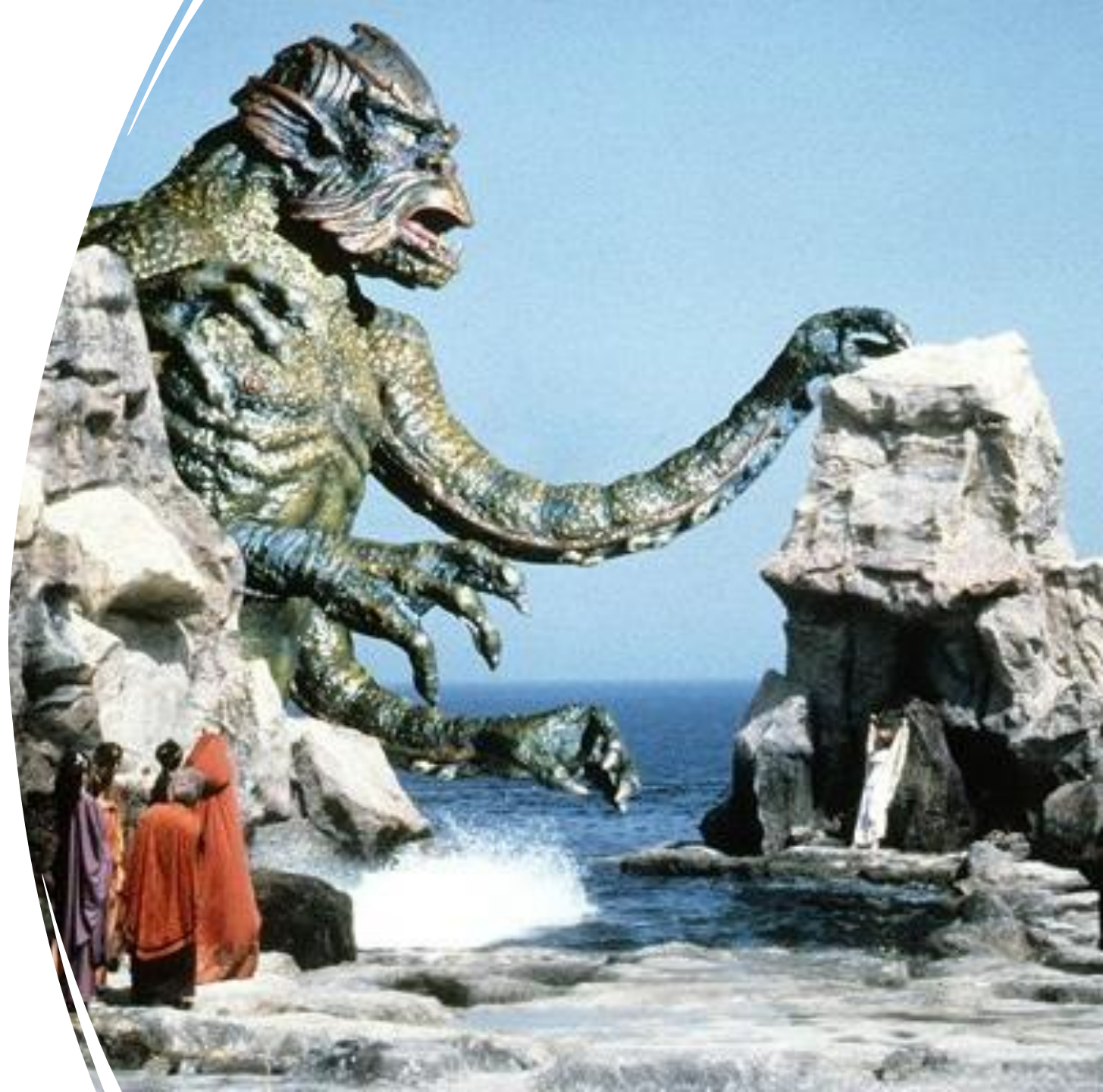
The launch of ChatGPT and rise of GenAI highlighted the immense benefits and potential risks of AI technology to the general public.

## The Biden Administration sought to promote AI innovation while addressing risks.

- EO 14110 – Safe, Secure, and Trustworthy Development and Use of AI (Oct 30, 2023)
- EO 14141 – Advancing US Leadership in AI Infrastructure (Jan. 14, 2025)
- Numerous federal legislative proposals to regulate AI, including the AI Accountability Act of 2023 failed to pass both chambers.
- NIST released an AI Risk Management Framework (Jan. 26, 2023)

# Release the Kraken

- Trump administration has sought to minimize regulation of AI
  - Trump rescinds Biden EO 14110 on AI (Jan. 20, 2025)
  - EO 14179 – Removing Barriers to American Leadership in AI (Jan. 31, 2025)
  - Office of Science and Technology Policy working on AI Action Plan
  - House passes budget bill with 10-year moratorium on state AI regulation



# Regulating AI in Healthcare



## FDA Oversight

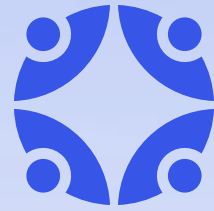
In the US, the FDA oversees AI applications in medical devices, ensuring they meet safety and efficacy standards.

## Electronic Health Records Certification Standards

ONC's Health Data, Technology, and Interoperability (HTI) rule include requirements to "improve transparency, promote trustworthiness, and incentivize the development and wider use of fair, appropriate, valid, effective, and safe Predictive [Decision Support Interventions] to aid decision-making in healthcare." (Jan. 9, 2024)

## State Regulations

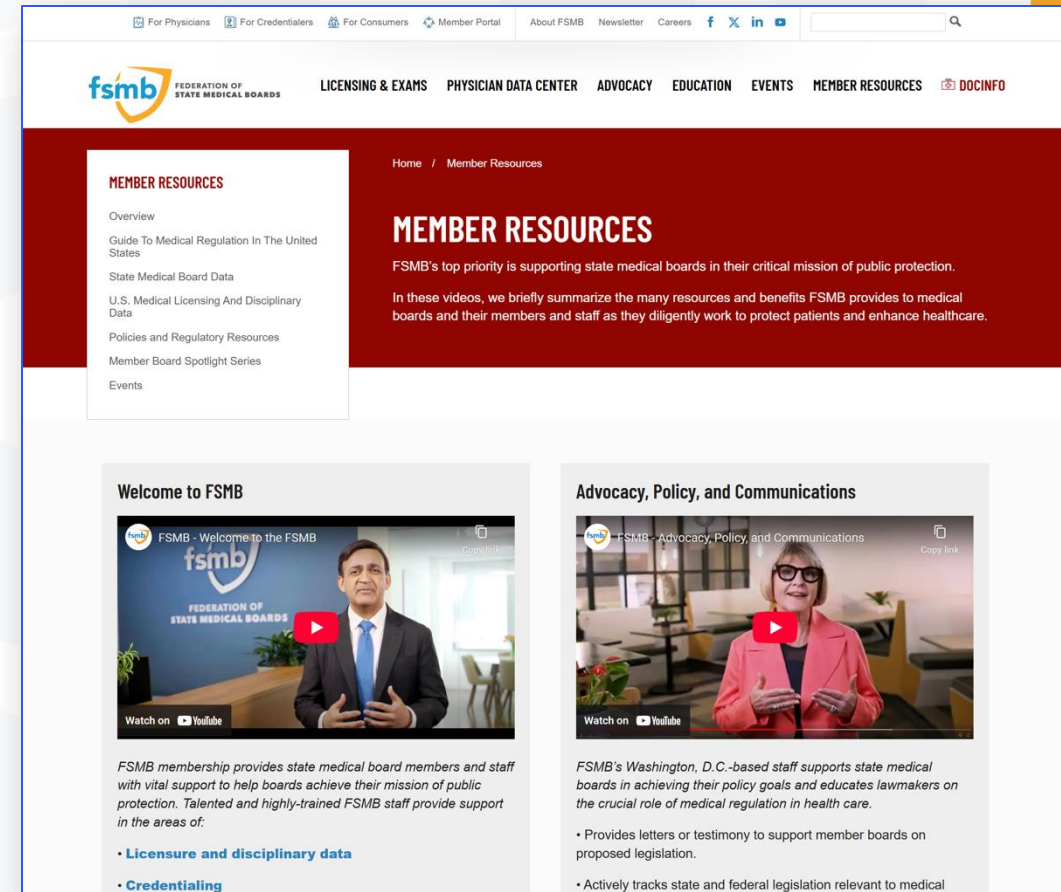
- California and Colorado AI laws impact the use of AI in high-risk areas such as health care.
- Utah passed a law specifically regulating "mental health chatbots."
- State consumer privacy laws often provide opt-out rights to "automated decision-making technology" or profiling, which impacts use of AI to make health care decisions (although HIPAA exemption generally applies)



# Frank Meyers' Perspective



- **Comprehensive Support for Medical Boards:** FSMB offers state medical boards access to essential services, including licensure and disciplinary data, credentialing, education, physician assessment, research, technology, and advocacy.
- **Advocacy and Policy Assistance:** The FSMB team in Washington, D.C., aids member boards by tracking relevant legislation, providing testimony, and offering public relations support to enhance the role of medical regulation in healthcare.
- **Educational Programming and Resources:** FSMB delivers high-quality, in-person and virtual programming, on-demand CME courses, and scholarships for board members and staff to attend the FSMB Annual Meeting, fostering the sharing of best practices among medical regulators.



**#1:** Many states introduced language that was modeled on Colorado SB205, a consumer protection law signed with reservations by Colorado Governor Jared Polis in May 2024.

**#2:** In 2025, there has been a very significant increase in bills legislating payer use of AI, particularly related to utilization management and physician oversight of adverse decisions. Over 56 bills were introduced that would govern payer use of AI.

**#3:** States are grappling with the role of AI in clinical delivery, in particular what provider oversight should be required when using AI tools in clinical decision-making and how providers should communicate the use of AI to patients. Over 20 bills regulating provider use of AI were introduced.

## Manatt Health: Health AI Policy Tracker

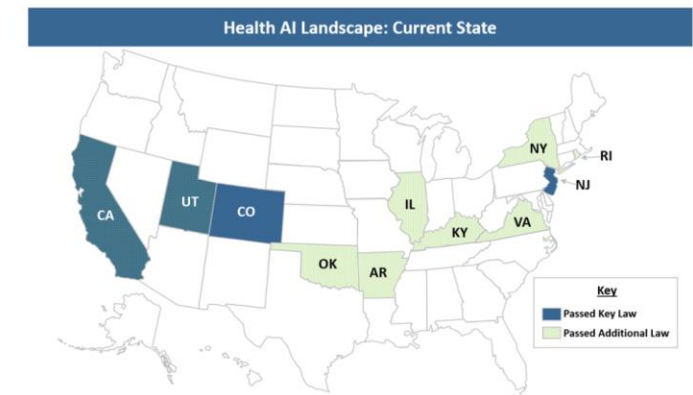
*Purpose: The purpose of this tracker is to identify key federal and state health AI policy activity and summarize laws relevant to the use of AI in health care. The below reflects activity from January 1, 2025 through March 31<sup>st</sup>, 2025. This is published on a quarterly basis.*

It has been an active start to 2025 – the past 18 months have seen a whirlwind of state legislative activity on AI in health care – and there are no signs of slowing down. In the first three months of 2025 alone, states have introduced over 250 AI bills impacting health care stakeholders, well exceeding the number of AI bills introduced in all of 2024 (~100). As of March 31, 2025, forty-two states had introduced some relevant legislation and six bills has been signed into law: Utah [SB 226](#), Utah [HB 452](#), and Utah [SB 332](#), Kentucky [SB 4](#), Mississippi [SB 2426](#), New York [SB 822](#). These signed laws are primarily focused on transparency / disclosure requirements (Utah [HB 452](#), Utah [SB 226](#) (essentially modifying Utah [SB 149](#), which passed last year)) or mandating the state inventory departmental use of AI and/or create an AI task force to support future policy making (Kentucky [SB 4](#), New York [SB 822](#), Mississippi [SB 2426](#)). Virginia's [HB 2094](#) – a bill heavily modelled off of a Colorado law passed last year, which would have imposed significant requirements on developers and deployers of high-risk AI systems – was vetoed. See table below for additional information on all passed bills. Because many legislative sessions end in Q2 2025, we expect the next quarter to be equally active.

At a federal level, AI continues to be discussed as a promising tool to root out fraud and abuse in health care and reduce costs, including by Dr. Oz who has publicly endorsed potentially using AI to assist with health care. The Trump administration has thus far taken a strong de-regulatory stance, reversing many Biden-era policies, including revoking President Biden's executive order on addressing AI risks, and replacing it with its own [executive order](#). The few regulations previously adopted that address AI in health care remain in effect, but could be repealed or rescinded; in early April, CMS [chose not to include](#) proposed regulatory provisions related to artificial intelligence in the Medicare Advantage final rule.

There are three sections in this report-out:

1. Key Takeaways from Q1 State Health-Related AI Activity
2. Key Federal Activity
3. Summary of all Passed Health-Related AI Bills



The map does not include bills we categorize as "Other: State Activity Laws," which generally are bills that create councils or tasks forces to study AI or related to narrow state activity (as further discussed below).

## ***Navigating the Responsible and Ethical Incorporation of Artificial Intelligence into Clinical Practice***

*Adopted by FSMB House of Delegates, April 2024*







### **EXECUTIVE SUMMARY**

Artificial Intelligence (AI) holds tremendous potential to aid healthcare providers in diagnosis, treatment selection, clinical documentation, and other tasks to improve quality, access, and efficiency. However, these technologies introduce risks if deployed without proper “guardrails” and understanding which may impact considerations in clinical practice as well as regulatory processes of state medical boards. By taking a proactive and standardized governance approach anchored in ethical principles, state medical boards can promote safe and effective integration of AI, in its various forms, while prioritizing patient wellbeing.

This report summarizes expert opinion and proceedings to develop guidance from the FSMB Ethics and Professionalism Committee to aid physicians and state medical boards in navigating the responsible and ethical incorporation of AI centered on (1) education, (2) emphasizing human accountability, (3) ensuring informed consent and data privacy, (4) proactively addressing responsibility and liability concerns, (5) collaborating with experts, and (6) anchoring AI governance in ethical principles.

Clinical systems and processes making use of AI must be continually monitored and refined. This should not occur in a vacuum but should be the focus of collaborative efforts among physicians, health systems, data scientists, and regulatory agencies, *including state medical boards*. By thoughtfully addressing the opportunities and challenges posed by AI in healthcare, state medical boards can promote the safe, effective, and ethical use of AI as a tool to enhance, but generally not replace, human judgment and accountability in medical practice. In fulfilling their missions to ensure that patients benefit from and are not harmed by applications of AI in their care, it is essential that state medical boards avoid over-regulation and regulatory overreach by attempting to regulate that which is not in their purview. With focused efforts on the current and future state of the use of AI by licensees, state medical boards may sustain regulatory efficiency, achieve consistency across jurisdictions in the regulation of AI in clinical practice, help secure the benefits of AI, and proactively safeguard patients while upholding professional standards.

Medical Boards

-  Education is critical.
-  Physicians remain accountable.
-  Informed consent and data privacy are paramount.
-  Proactively address bias and access.
-  Anchor AI governance in ethics.
-  Collaboration is key.



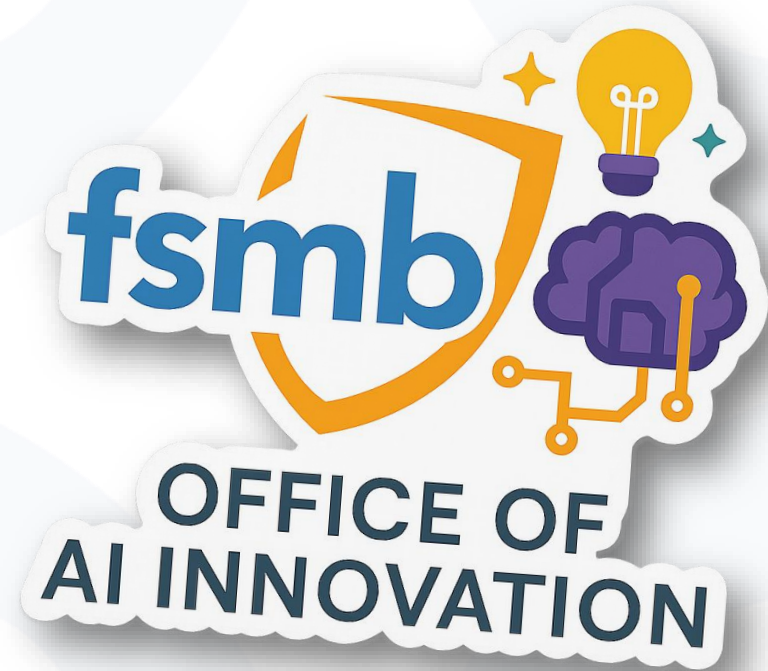
Centralizes AI initiatives across FSMB to enhance internal operations and regulatory support for state and territorial boards.



Drives practical AI applications, such as tools for research, complaint triage, and operational efficiency.

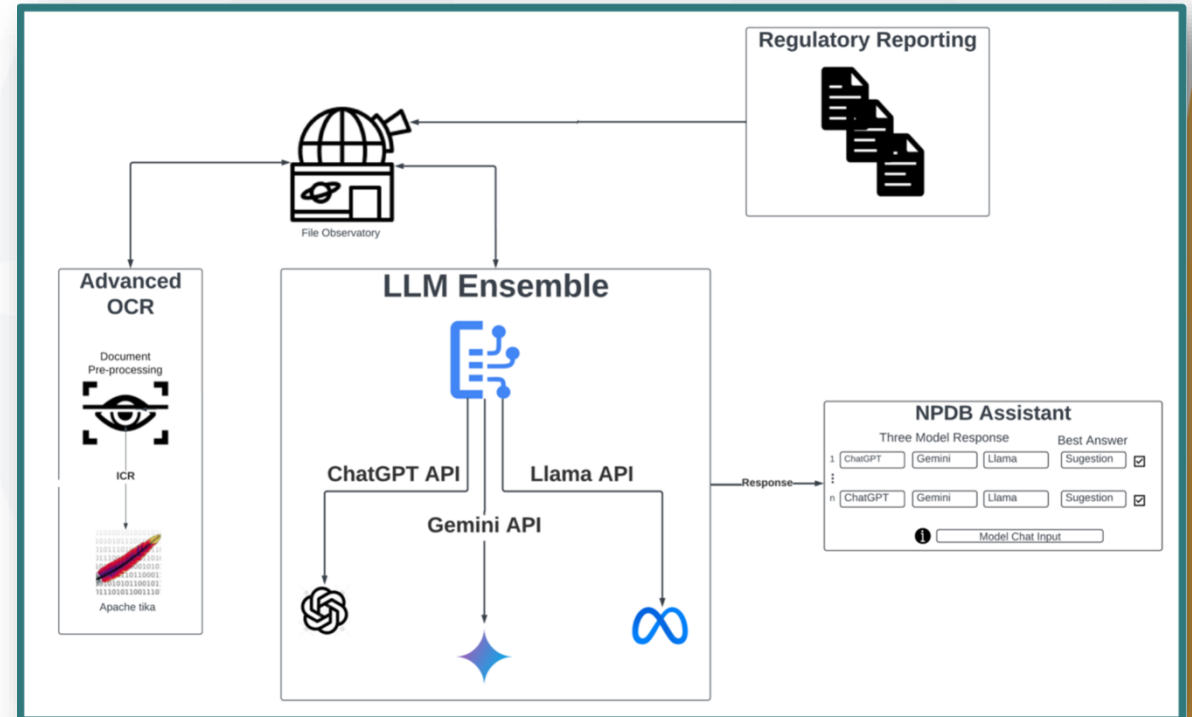


Engages cross-functional leaders in hands-on AI innovation, including legal, IT, and executive leadership.



- **Board Order Analysis**
  - Narrative and reporting summarization.
  - Automates text extraction.
- **NPDB Reporting**
  - Uses advanced methods to minimize errors and maximize precision.
  - Ideal for both recurring tasks and one-time reporting needs.

## Project Endeavour



- **Technical Capabilities**
  - Automates the processing and summarization of diverse complaint formats (handwritten, typed, scanned materials) to reduce processing times.
- **Regulatory & Compliance Features**
  - Maintains regulatory integrity through clear citation trails and structured analysis.
  - Preserves human oversight while ensuring consistent complaint categorization.

Triage Summary Report - 1700983954
February 11, 2025

---

## Dr. Emily Smith

NPI 1700983954

⚠ Triage Level: **Yellow**

<b>Submission Date</b>	06/12/2024
<b>Complainant</b>	John Doe
<b>Location of Care</b>	Dallas, TX
<b>Medical Facility</b>	Green Valley Medical Center
<b>Complaint Category</b>	<a href="#">Category II: Minimal Standards of Care</a> • <a href="#">Category XI: Miscellaneous Violations</a>

### SUMMARY

The attached complaint was submitted by John Doe on October 15, 2023, alleging Dr. Emily Smith may have engaged in behavior, that if true, may be a violation of the laws and regulations governing Minimal Standards of Care and Miscellaneous Violations. Specifically, the complaint alleges that on October 15, 2023, Dr. Smith provided care that did not meet their expectations, including long wait times, perceived lack of attention, dismissive responses to concerns, and limited explanation of treatment.

### PRIORITY ASSESSMENT

<b>Unethical Behavior</b>	<b>Substandard Care</b>	<b>Bedside Manner</b>	<b>Non Urgent Delay</b>
<a href="#">Ref: P1.6</a>	<a href="#">Ref: P1.6</a>	<a href="#">Ref: P1.5</a>	<a href="#">Ref: P1.4</a>

### MAIN ALLEGATION

Accused Party: Dr. Emily Smith

**Long Wait Time:** The complainant reports waiting over 45 minutes past the scheduled appointment time without receiving an explanation or apology<sup>(1)(2)</sup>.

[Ref: P1.4](#) • [Ref: P1.8](#)

**Lack of Attention:** The complainant perceives that Dr. Smith appeared rushed and distracted during the consultation<sup>(1)(2)</sup>, noting that she spent significant time typing on her computer<sup>(1)(2)</sup> and did not make consistent eye contact<sup>(1)(2)</sup>.

[Ref: P1.5](#) • [Ref: P1.9](#)


**Dismissive Attitude:** The complainant feels that their concerns about the severity and potential causes of their headaches, including a history of migraines, were not adequately addressed<sup>(1)(2)</sup>.

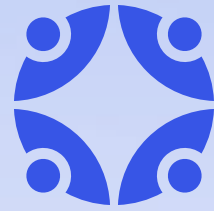
[Ref: P1.6](#) • [Ref: P2.0](#)

**Inadequate Explanation:** The complainant states that the prescribed medication was not explained in detail<sup>(2)</sup>, and potential side effects<sup>(1)(2)</sup> or alternative treatments<sup>(1)(2)</sup> were not discussed.

[Ref: P1.5](#) • [Ref: P2.1](#)

① This report has been generated with the assistance of artificial intelligence (AI) technology. The AI has been utilized to classify and summarize the provided document. While every effort has been made to ensure the accuracy and reliability of the information presented, there is a possibility that the content may contain errors or misrepresentations. Users are strongly advised to verify the information independently before taking any action based on this report. The use of AI is intended to support, not replace, professional judgment and expertise.

 2025 - Private & Confidential, Not for Distribution
01



# Fireside Chat





Q&A



# Contact Information



E: [andrew.mahler@clearwatersecurity.com](mailto:andrew.mahler@clearwatersecurity.com)

**Andrew Mahler, JD, CIPP/US,  
AIGP, CHC, CHPC, CHRC**

Vice President of Privacy &  
Compliance Services  
Clearwater



E: [fmeyers@fsmb.org](mailto:fmeyers@fsmb.org)

**Frank Meyers**

Deputy Legal Counsel  
**Federation of State  
Medical Boards**



E: [AdamGreene@dwt.com](mailto:AdamGreene@dwt.com)

**Adam Greene**

Partner  
**Davis Wright  
Tremaine LLP**

# Today's Agenda – Day 2 – Coming Next

## June 24

**12:00 am – 12:45 pm CT**

AI, Privacy, and the Future of Healthcare:  
Legal Perspectives with Thomas Nachbar

Andrew Mahler, Vice President of Privacy & Compliance Services, Clearwater  
Thomas Nachbar, F.D.G. Ribble Professor of Law, University of Virginia Law School



**1:00 pm – 1:45 pm CT**

The Compliance Officer's Guide to Managing  
the Use of AI

Jon Moore, Chief Risk Officer & SVP Consulting Services, Clearwater  
Leah Voigt, Chief Compliance Officer, Corewell Health





We are here to help.

*Moving healthcare organizations to a more secure, compliant, and resilient state so they can achieve their mission.*



# Clearwater

Healthcare – Secure, Compliant, Resilient

[www.ClearwaterSecurity.com](http://www.ClearwaterSecurity.com)

800.704.3394

LinkedIn | [linkedin.com/company/clearwater-security-llc/](https://www.linkedin.com/company/clearwater-security-llc/)



## Legal Disclaimer

Although the information provided by Clearwater Security & Compliance LLC may be helpful in informing customers and others who have an interest in data privacy and security issues, it does not constitute legal advice. This information may be based in part on current federal law and is subject to change based on changes in federal law or subsequent interpretative guidance. Where this information is based on federal law, it must be modified to reflect state law where that state law is more stringent than the federal law or other state law exceptions apply. This information is intended to be a general information resource and should not be relied upon as a substitute for competent legal advice specific to your circumstances. YOU SHOULD EVALUATE ALL INFORMATION, OPINIONS AND RECOMMENDATIONS PROVIDED BY CLEARWATER IN CONSULTATION WITH YOUR LEGAL OR OTHER ADVISOR, AS APPROPRIATE.

## Copyright Notice

All materials contained within this document are protected by United States copyright law and may not be reproduced, distributed, transmitted, displayed, published, or broadcast without the prior, express written permission of Clearwater Security & Compliance LLC. You may not alter or remove any copyright or other notice from copies of this content.

\*The existence of a link or organizational reference in any of the following materials should not be assumed as an endorsement by Clearwater Security & Compliance LLC.