1

CHARTIS

Artificial intelligence in healthcare: Implications on accreditation and regulatory compliance

Monthly webinar series

July 17, 2025

The webinar will start at the top of the hour.

2

MONTHLY INSIGHTS

Webinar schedule and topics

THE 3RD THURSDAY OF EVERY MONTH:

10AM Pacific, 1PM Eastern

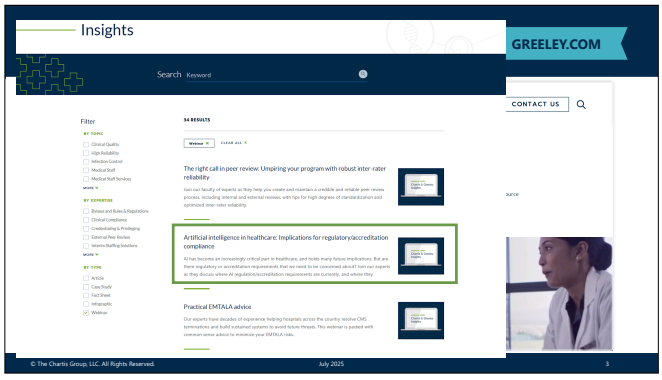
August 2025

The right call in peer review: Umpiring your program with robust inter-rater reliability

September 2025

Joint Commission Accreditation 360 Update

3



4

Navigating the Zoom interface

Handouts:

Check the chat function for copies of the slides for note taking and any other handouts.

Questions and comments:

Please participate in the discussion by asking question through the Q&A function during the webinar.

There will also be a survey you will receive immediately after the webinar that will give you an opportunity to ask additional questions or make comments.

Any questions not answered during the webinar will be addressed in a follow-up email or posting.

5

Healthcare challenges are not siloed. *Neither are we.*

Chartis has **six lines of business** that together craft **singular solutions**.

- 1000+ Professionals
- Mission: to materially improve healthcare
- Ranked Best Overall Management Consulting Firm by KLAS
- Charis acquires Greeley in 2019, became Chartis Clinical Quality Solutions in 2022
- Greeley brand brought back in 2024 to cover Medical Staff Services Related Offerings and now part of Clinical Transformation

6

High reliability care

UNPARALLELED BREADTH AND DEPTH

Our clients are all striving toward the same goal of providing safe, high-quality care—something that's becoming even more important with the many distractions and disruptions in healthcare today. We help clients achieve their organizational reliability, quality, and safety goals, leading to results in areas that matter most—improved care outcomes, staff engagement, operational stability, and total cost of care, enhanced reputation, and better patient experience.

High reliability organization (HRO)

- High reliability organizational design and infrastructure
- Quality, value, and performance improvement
- Quality ratings and rankings optimization
- Patient safety/harm reduction/ safety and reliability culture
- Adverse event response and remediation/RCA
- High fidelity measurement/Clinical Documentation Integrity (CDI)
- Care facilitation

Clinical compliance, regulatory, and physical environment solutions

- Adverse event response
- Adverse action regulatory response and remediation
- Accrediting body readiness assessment
- Regulatory readiness rehearsal/mock surveys
- Life safety and environment of care assessment
- Policy simplification
- Infection prevention program

Bylaws, rules and regulations, and peer review

- Bylaws and rules and regulations assessment and redesign
- Peer review assessment and redesign
- Medical staff/medical director structure and governance
- Credentialing, OPPE

External peer review

- Physician/advanced practice professional external peer review
- Focused Professional Practice Evaluation (FPPE)
- Ongoing case review in support of OPPE/FPPE
- Medical necessity reviews
- Patient safety/carequality case reviews

MEMBERSHIP AND PROFESSIONAL EDUCATION SERVICES

7

Today's *discussion*

This program will provide a high-level overview of the current state of AI in healthcare. Included in the discussion will be a discussion on current and potential future regulatory and accreditation expectations. The speakers will wrap up with next step suggestions, especially for organizations without an AI strategy.

Steve Chinn
Partner
Chartis

Christian Dankers
Partner and Associate Chief Medical and Quality Officer
Chartis

"Keeping up with change, planning for tomorrow

8

Today's *agenda*

High Level Overview of Current State

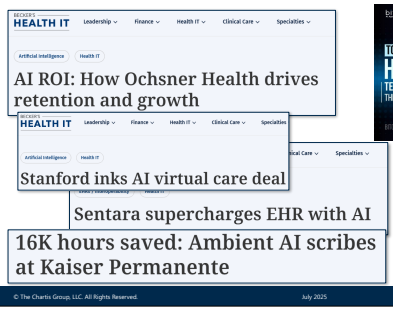
Current Status of Regulatory and Accreditation Expectations

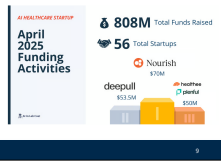
Suggestions for Next Steps

Questions should be posted in the webinar interface throughout the presentation.
We will respond to any unanswered questions in writing following the webinar.

9

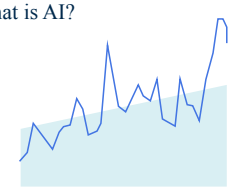
Beckers Health IT issue June 23, 2025





10

What is AI?



https://www.syskit.com/glossary/agentic-ai/

11

Key attributes of agentic AI vs. generative AI

Agentic AI		Generative AI
Autonomous action and decision-making	MAIN PURPOSE	Content creation based on training data in response to user prompts
High; acts independently to set and pursue goals	AUTONOMY	Low; reacts to user input and cannot set its own goals
Can adjust its behavior in response to changing conditions of real-world or virtual environments	ADAPTABILITY	Shows some adaptability, but cannot independently adapt to fully new or unstructured environments
Capable of setting its own goals	GOAL SETTING	No independent goal setting; operates within predefined constraints
Minimal; able to function with little to no human intervention	HUMAN OVERSIGHT	Necessary; operates based on user-provided prompts

12

Uses of AI

- Medical record documentation
- Translation services
- Billing and collection
- Appointment management
- Preventative health screenings
- Diagnostic assistance
- Treatment guidance/protocols

Kaiser Permanente Northern California Region experience (https://catalyst.nejm.org/doi/full/10.1056/CAT.25.0040)

13

Four things from the research:

- Some physicians were particularly heavy AI scribe users, with nearly 3,500 of them employing the technology in at least 100 patient appointments.
- AI scribe users were most likely to work in mental health, emergency medicine, primary care, allergy or cardiology, and least likely to specialize in infectious disease, OB-GYN or urology.
- In a survey of 102 Permanente Medical Group physicians, two-thirds said they used the technology five days a week while 8% hadn't used it. Eighty-four percent had a positive experience with ambient AI, citing reduced mental workload and better recall of appointment details.
- In a survey of 118 patients, 47% said their physician spent less time looking at the computer. Meanwhile, two-thirds were comfortable with the technology, 26% were neutral and 8% were uncomfortable with it.

Ethical Concerns

14

- Equity from access and availability
- Bias inadvertently built into the tool
- Informed recipient of use of AI
- How is the data going to be used?
- How secured is the data?

FYI

15

General discomfort:

- A study by Pew Research Center found that 60% of U.S. adults would be uncomfortable if their doctor used AI for diagnosis and treatment recommendations.

Mistrust in healthcare systems:

- A study by the University of Minnesota indicated that 65.8% of individuals expressed low trust in their healthcare system's ability to use AI responsibly.

Data privacy concerns:

- A survey by Urology Times revealed that 63% of patients are worried about their health information being at risk due to increased AI usage.

Dankwa-Mullan I. Health Equity and Ethical Considerations in Using Artificial Intelligence in Public Health and Medicine. Prev Chronic Dis 2024;21:240245. DOI: http://dx.doi.org/10.5888/pcd21.240245

Risk Concerns

16

- AI diagnosis is not always superior to human diagnosis
- AI programs may be difficult to understand and overly ambitious
- Implementation issues
- Transparency issues and risks with data sharing
- Biases
- Mistakes in disease diagnosis or AI cannot be held accountable
- Data availability and accessibility
- Social challenges
- Regulatory concerns

Chustecki M Benefits and Risks of AI in Health Care: Narrative Review, Interact J Med Res 2024;13:e53616 doi: 10.2196/53616

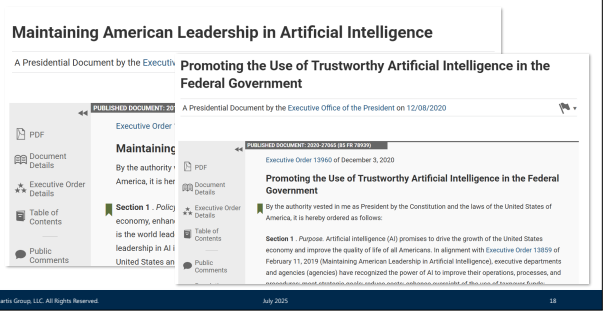
Regulatory/Accreditation Ramifications

17

- Privacy and security of data
- Technology infrastructure
- Quality controls and assurance
- Patient rights
- Staff/practitioner adoption
- Governance

Executive Orders

18



Regulatory Activity

American Health Information Management Association (AHIMA)'s
2024 Artificial Intelligence Regulatory Resource Guide

19

Areas of Focus for Decision Support Intervention Requirements

- Details and output of the DSI;
- Purpose of the intervention;
- Cautioned out-of-scope use of the intervention;
- Intervention development details and input features;
- Process used to ensure fairness in development of the intervention;
- External validation process;
- Quantitative measures of performance;
- Ongoing maintenance of intervention implementation and use; and
- Updates and continued validation or fairness assessment schedule.

American Health Information Management Association (AHIMA)'s 2024 Artificial Intelligence Regulatory Resource Guide
The Office of the National Coordinator for Health Information Technology (ONC) released the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1)6 final rule in December 2023,

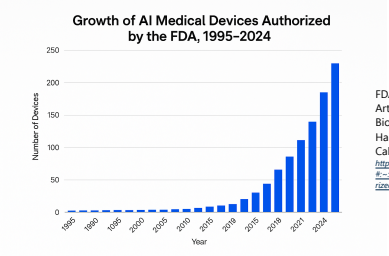
20

Regulatory Activity

- In 2024, U.S. federal agencies introduced 59 AI-related regulations—more than double the number in 2023—and issued by twice as many agencies. Globally, legislative mentions of AI rose 21.3% across 75 countries since 2023, marking a ninefold increase since 2016. (Source: https://hai.stanford.edu/ai-index/2025-ai-index-report)
- There are no comprehensive Federal AI regulations in place.
- Colorado: Senate Bill 24-205 aka Colorado Artificial Intelligence Act (CAIA)
- California: California Consumer Privacy Act (CCPA) and the California Invasion of Privacy Act (CIPA) are being applied to AI systems that process personal data. Additionally, there are proposed bills addressing specific AI concerns, such as AB 1008, which focuses on consumer rights related to AI-generated or processed data, and a bill (AB-489 Bonta) aimed at preventing AI from impersonating licensed healthcare professionals.

21

Food and Drug Administration



FDA Perspective on the Regulation of Artificial Intelligence in Health Care and Biomedicine
Haider J Warraich, Troy Tazbaz, Robert M Califf
https://pubmed.ncbi.nlm.nih.gov/39405330/#:~:text=Observations%3A%20The%20FDA%20has%20authorized,in%20their%20discovery%20and%20development.

22

Key Trends and Facts

Rapid growth:

- The number of FDA-approved AI/ML medical devices has increased dramatically in recent years, particularly since 2016.

Radiology dominance:

- Radiology accounts for a large portion of the approved devices, with 723 devices approved as of mid-2024.

Diverse applications:

- AI/ML technologies are being applied across various medical specialties, including cardiology, neurology, and ophthalmology.

FDA authorization pathways:

- The FDA uses different submission types for these devices, including 510(k) premarket notification, premarket approval (PMA), and the De Novo classification process.

Examples of FDA-approved AI medical devices:

- These include devices for cancer diagnosis, stroke detection, and risk prediction for breast cancer.

No generative AI yet:

- While there's significant interest, the FDA has not yet authorized any devices using generative AI or large language models, according to The Medical Futurist.

23

Examples of AI-powered medical devices approved by the FDA

- **Clairity Breast:** The first AI-powered platform to predict breast cancer risk using only a mammogram, according to the Breast Cancer Research Foundation.
- **Operating Rooms:** The FDA has approved AI-powered devices for use in the operating room, including devices for surgical guidance and monitoring.
- **Cancer Diagnosis:** AI-powered tools are being used to assist in the diagnosis of various cancers, including breast and lung cancer.
- **Stroke Detection:** AI algorithms are being used to analyze MRI images to help detect and diagnose strokes.
- **Risk Prediction:** Beyond breast cancer, AI is being used to assess and predict risks for other conditions.

24

Coming Soon To Your Organization…

INDUSTRY DIVE

Joint Commission, CHAI partner to develop guidance on health AI

Healthcare Dive
Emily Olsen
13 June 2025

- TJC and Coalition for Health AI (CHAI) have partnered to accelerate the development and adoption of AI best practices and guidance across the U.S. healthcare system.
- They will work together to create AI playbooks, tools, and a new certification program.
- This partnership aims to help healthcare organizations utilize AI safely and responsibly.
- The goal is to have something applicable for organizations of all sizes

25

Resources

American Health Information Management Association (AHIMA)
2024 Artificial Intelligence Regulatory Resource Guide
https://www.ahima.org/media/twjmtnq4/2024-artificial-intelligence-regulatory-resource-guide-axs.pdf

American Medical Association (AMA)
Augmented Intelligence Development, Deployment, and Use in Health Care
https://www.ama-assn.org/system/files/ama-ai-principles.pdf

Stanford Medicine Responsible AI for Safe and Equitable (RAISE) Health
https://www.youtube.com/playlist?list=PLVKEERwuGN08e0d7xWc9G0OnnDaIoIo7o

26

Next steps

1. Assess current applications in your organization (and who is using them)
2. Define how the application is being used
3. Evaluate resourcing needs (Training, IT, Clinical Informatics)
4. Process to evaluate new applications
5. Consider approvals and oversight (especially if it is being used as part of a clinical guideline or pathway)
6. Establish an overall governance structure

27

Acknowledgements

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28

Questions ?

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29

Thank *you*

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30