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Artificial Intelligence in Medicine: *Policy, Governance, and the Path from Innovation to Implementation*

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Innovation in Healthcare

Innovation in healthcare has always raised concerns about the impact on the clinical practice

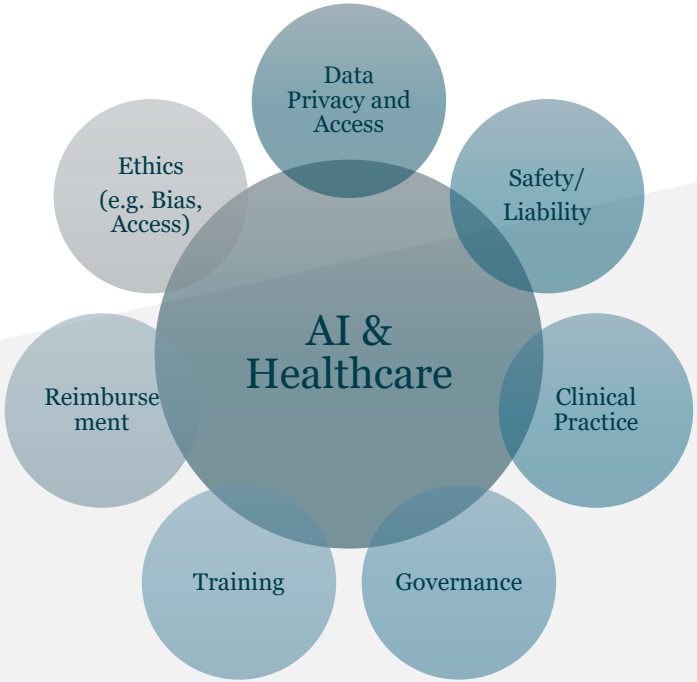
- What ubiquitous technology was considered by many doctors as “unnecessary and cumbersome” and created a barrier to connection to patients?

“*AI Will Be as Common in Healthcare as the Stethoscope.*”
Dr. Robert Pearl, former CEO of the Permanente Medical Group

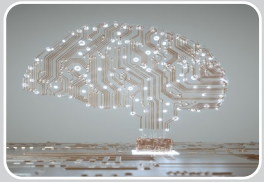
My View on AI & Healthcare

Work at the intersection of law, policy, and strategy to support innovation in healthcare

- Focus on legal and policy issues related to health tech and data for over 25 years
- Former federal regulator
- Advise innovative start-ups, tech companies, and health systems
- Not technology expert <u>but</u> experienced on the building blocks on which the technology depends for success



Our Discussion



What AI is and Use in Healthcare

Regulatory Landscape

Opportunities & Risks

Practical Guidance

What's Ahead

What is AI and Use in Healthcare

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What is AI?

Predictive Analytics

Algorithm

Machine Learning

Generative AI

Augmented Intelligence

Agentic AI

LLMs

Neural Networks

Chatbots

Explainability

Transparency

Bias

Hallucinations

Autonomous

Human in the Loop

What is AI? – Some Key Considerations in Healthcare

Locked vs. Adaptive Algorithms

Decision Support vs. Decision Making

Narrow AI vs. Foundational Models

AI and Healthcare

How AI is being used to support healthcare

Ambient technology	Diagnostic & clinical decision support	Administrative	Direct-to-Consumer	Agentic AI and autonomous decision-making
•Clinical documentation and coding •E.g., Nuance DAX, Abridge, Suki	•1300+ FDA-cleared devices, dominated by radiology and cardiology	•E.g., Call centers, utilization management, prior authorization	•Health management tools •AI assistants •Chatbots	•Autonomous care for routine decisions •E.g., renewing prescriptions, changing dosages based on clinical guidelines

Regulatory Landscape

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Congressional Activity

Focused on general regulations over healthcare specific regulations

- Limited
- Some reactive – e.g. oversight hearings on the use of AI chatbots
- Broader use of AI – consider various concepts, including regulatory sandboxes and state law moratoria
- Health AI hearing – Areas of Interest
  - Mental Health (AI chatbots)
  - Data Privacy
  - Denials in Care (prior auth)
  - Payment/reimbursement

Themes Related to Federal Agency Oversight of AI and Healthcare

- ***White House leading the broad approach – promoting AI innovation***
- ***Agencies are removing regulatory burdens***
- ***Growing discussions re regulatory sandboxes and post-deployment surveillance***
- ***Continued push for greater access to health data to support AI***

- ***BUT… New concerns could lead to some oversight***

Issues Regulators are Addressing Related to Health AI

1. ***Safety and Effectiveness Oversight***
2. ***Reimbursement & Billing***
3. ***Interoperability, Data Exchange, Information Blocking and Infrastructure***
4. ***Privacy and Security of Data***
5. ***Licensing and Practice of Medicine***
6. ***Product Claims and Transparency***

Oversight of Safety and Effectiveness (FDA)

FDA oversight was not designed for adaptive technology

- Software as a Medical Device (SaMD) and the 510(k) pathway
  - Designed for static devices, not continuously learning systems
- Predetermined Change Control Plans (PCCPs)
  - The agency's best answer to adaptive AI
  - Allows post-market updates without full re-review if the change envelope was pre-specified
- Digital Health Center of Excellence
- Focus: Reducing regulatory burden
  - Recent guidance increases "enforcement discretion"
  - TEMPO Model

Key Gaps and Challenges:

- Regulatory Fit for Evolving Technology
- Burden and uncertainty in regulatory pathways
- Post-market monitoring gaps
- Limited workforce

Reimbursement for AI-Enabled Care (CMS)

The payment gap results in an adoption gap

- Most clinical AI has no independent reimbursement pathway
- Approaches being used - but all limited:
  - New Technology Add-On Payments (NTAP)
  - Transitional Coverage for Emerging Technologies (TCET)
  - Coverage with Evidence Development
- CMS Innovation Center pilots as the proving ground for value-based AI reimbursement models (e.g., ACCESS Model)
- Value-based care can provide indirect payment where tools improve outcomes
- Leads to more DTC technology

Efficiency Paradox:

If AI makes physicians more efficient, payers capture that value, not physicians. May discourage adoption.

The Infrastructure – EHRs, Interoperability, and Health Information Exchange (ONC)

Health IT Standards and Certification of EHRs

- Requirements for EHR technology including data standards (USCDI) and exchange standards (FHIR)
- Required certified EHRs to provide transparency related to predictive decision support interventions (e.g., provide source attributes)
  - But proposal to remove this requirement is pending
- Many certification requirements are being proposed to be removed – will enable innovators to enter the EHR market more easily

Information blocking rules - Prohibition on interfering with access, exchange or use of electronic health information (EHI)

- Guidance that access to EHI includes through automated technologies
- Increased resources for enforcement

Health Information Exchange

- Continued focus on the Trusted Exchange Framework and Common Agreement (TEFCA)
- CMS Health Tech Ecosystem

Privacy and Health Data

OCR: HIPAA Privacy and Security Rules were promulgated before AI

- HIPAA was not designed for AI training on PHI
- HIPAA de-identification safe harbor was not designed to withstand modern re-identification techniques
- No AI-specific guidance
- HIPAA Privacy and Security Rule modifications are coming

FTC: Enforcing Data Privacy

- FTC enforcement increasingly applied to health technology
  - Health Data Breach Notification Rule
  - FTC Act: unfair and deceptive practices authority

State health data privacy laws

- In addition to comprehensive privacy laws, states are passing health data laws
  - Washington My Health My Data Act, Nevada, Connecticut
  - Laws regarding sensitive health data

State AI Laws

- Use of AI-Enabled Chatbots
- Use of AI-Enabled Chatbots Specific to Mental Health
- AI and Unauthorized Practice of Medicine
- AI in Clinical Care
- Payer Use of AI (Decisionmaking and Oversight)
- AI Transparency - Consumer Interactions, Patient Communications & Content
- AI Transparency - Training Data & Catastrophic Risks
- Transparency Regarding Algorithmic Decision Making

Opportunities and Risks

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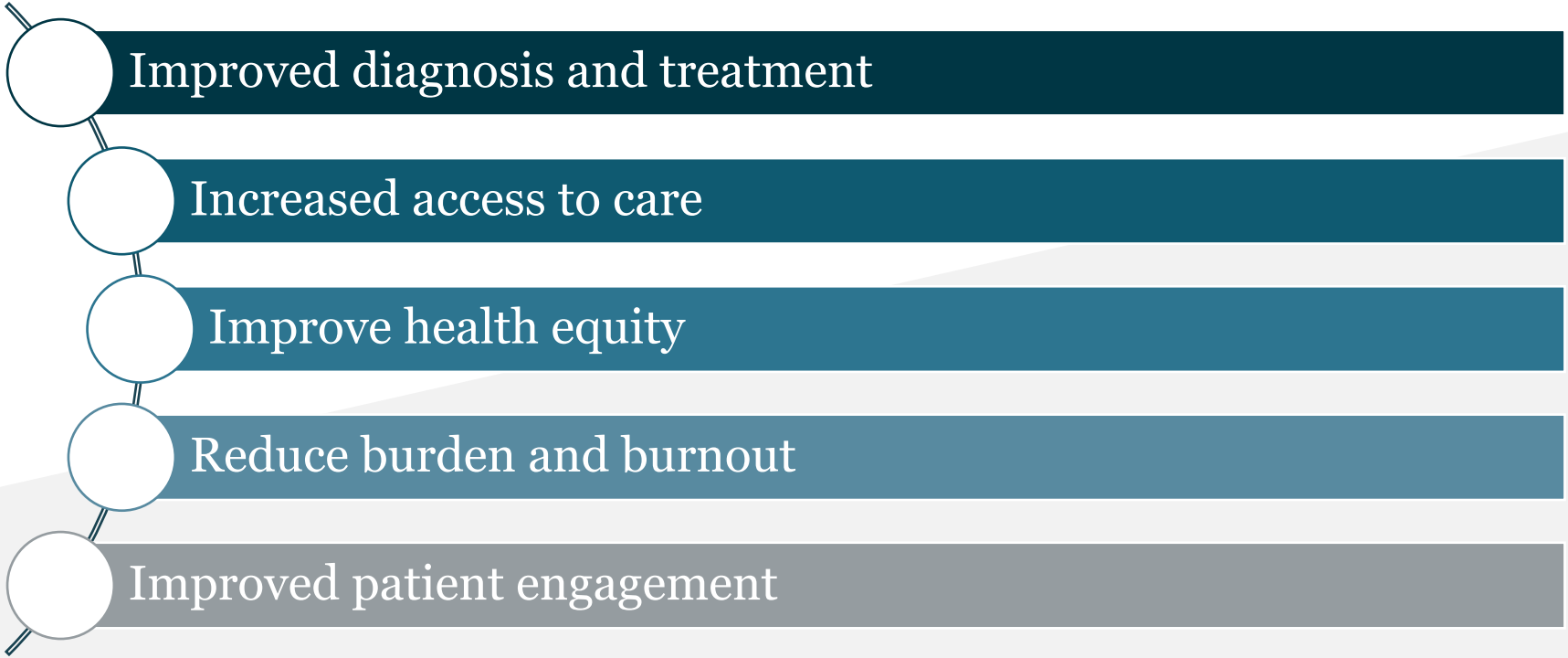
Opportunities for AI in Health



Risks for AI in Health

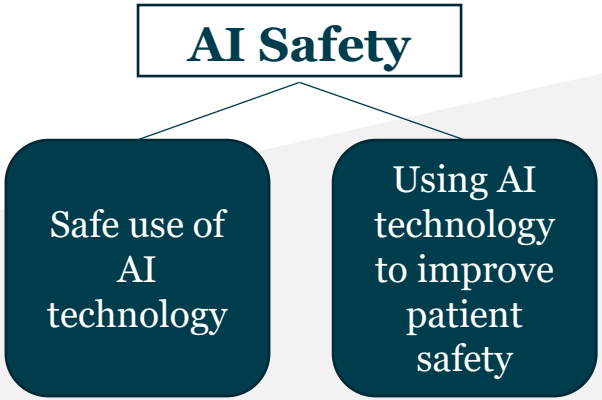
Errors at scale	Bias	Over-reliance	Challenges in training new clinicians
Inconsistent/ unreliable results	Disparate access to technology	Limited access to human clinicians based on ability to pay	Loss of trust
Security breaches	Liability	Cost	Reduced payment for clinical care

Tangled Liability Profile for AI

- Hardware defect
- Software defect
- Failure of AI algorithm
- Connectivity issue
- Security issue
- False or inaccurate information provided
- User error

Liability Risks of Using AI in Health (or Not)

- ***What's the standard of care?***
- ***Medical malpractice: duty, breach of duty, harm, causation***
- ***How does the standard of care evolve with integration of AI technology and become implemented?***



Practical Guidance

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AI Governance and Policies

1. AI Policies and Governance Structures
   - Oversight, AI design/development/deployment, etc.
2. Risk and Bias Assessment
   - Use, benefit, risk tolerance, etc.
3. Privacy Security and Data Use Protections
   - Protect privacy of health data in the use and development of AI
   - Protect against new security risks
4. Transparency
   - With patients and clinicians
5. Deployment
   - Ongoing quality monitoring
   - AI safety-related event reporting
   - Education and training

Industry Guidance

- National Institute of Standards and Technology (NIST)
  - AI Risk Management Framework
- Joint Commission (JC) and Coalition for Health AI (CHAI)
  - Guidance on the Responsible Use of AI in Healthcare

Develop a Data Strategy

You do not have an AI strategy unless you have a health data strategy

Mitigating Risks for AI in Healthcare

1. ***Consider regulatory oversight requirements***
2. ***Conduct regular risk assessments and mitigate risks***
3. ***Clarify data ownership***
   - Who owns algorithms trained on your data?
   - Will those algorithms be shared with competitors?
4. ***Set contractual limitations and indemnities***
5. ***Obtain insurance coverage***
6. ***Think about "fail safes" (e.g., clinician training, clinician review/customization of technology)***
7. ***Monitor and comply with emerging regulations and think about contract modification***

What’s Ahead

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State and Federal Policy Supporting Use of AI in Clinical Care

CMS

Health Tech Ecosystem: LIVE!

First Wave Launch APRIL 9, 2026

CMS HEALTH TECH ECOSYSTEM MVP

Today, we are proud to welcome a distinguished group of Health Tech Ecosystem pledge companies who have met the March 31, 2026 Minimum Viable Product (MVP) deadline, demonstrating their commitment to transforming health care through cutting-edge innovation.

Altera Health (Paragon EHR): Provides healthcare IT solutions, including the Paragon Electronic Health Record (EHR) system designed for community and rural hospitals. Their platform focuses on streamlining clinical workflows and improving patient care coordination.

Atlanticare: A regional health system based in New Jersey offering a wide range of medical services, including hospital care, cancer treatment, and behavioral health. They are committed to improving community health outcomes through integrated care delivery.

Athena Health: A cloud-based healthcare technology company offering EHR, practice management, and patient engagement solutions. Their platform helps medical practices and health systems streamline administrative and clinical operations.

Brado: A healthcare marketing and consumer insights company that helps health organizations better understand and connect with patients. They specialize in digital strategy, brand development, and patient journey optimization.

Bwell: A digital health platform that empowers individuals to manage their health and wellness through personalized tools and resources. Their solution integrates health data to support proactive care and engagement.

Cigna: A global health services company offering medical, dental, behavioral health, pharmacy, and supplemental insurance plans. They serve millions of customers worldwide with a focus on improving health, well-being, and peace of mind.

Cleveland Clinic: A nonprofit, multispecialty academic medical center renowned for its expertise in cardiology, oncology, and complex surgical procedures. It consistently ranks among the top hospitals in the United States and operates facilities globally.

Clover Health: A Medicare Advantage-focused health insurance company that uses a proprietary data-driven software platform to improve patient outcomes. The company leverages technology and analytics to manage costs and enhance care quality for seniors with complex conditions.

Connxus: Connecting organizations, policymakers, and stakeholders across all sectors in Central Texas to better address pressing health challenges. With decades of experience as a Health Information Exchange, it has become a catalyst for collaboration and innovation.

CVS/Health 100: One of the largest healthcare companies in the U.S., operating retail pharmacies, MinuteClinics, and the Aetna insurance brand. Health100 is a health technology services subsidiary of CVS Health that will launch a new AI-native consumer engagement platform powered by Google Cloud's AI technologies.

CyrenCare: A digital health company focused on providing personalized care management solutions for individuals with chronic conditions. Their platform leverages data and technology to support better health outcomes and care coordination.

DaVita: A leading American healthcare company specializing in kidney care and dialysis services, operating thousands of outpatient dialysis centers across the United States and internationally. As one of the largest providers of renal care, DaVita works closely with Medicare and Medicaid programs.

Doctronic: An AI-powered healthcare platform that enables patients to access medical guidance and connect with clinicians digitally. Their solution aims to make healthcare more accessible and efficient through intelligent automation.

eClinicalWorks: A leading provider of cloud-based EHR and practice management software used by thousands of healthcare providers across the U.S. Their platform supports clinical documentation, population health management, and patient engagement.

Fasten Health: A health tech startup focused on enabling patients to aggregate and control their personal health records from multiple providers into a single, unified platform. The company leverages open health data standards to give individuals seamless access to their medical history.

Fitbit by Google: Acquired by Google in 2021, Fitbit is a wearable technology brand that produces smartwatches and fitness trackers designed to monitor health metrics. Integrated with Google's ecosystem, the devices and app help users track their overall wellness.

Flexpa: A healthcare workforce solutions company that connects healthcare organizations with flexible, on-demand clinical talent. They help address staffing shortages by providing scalable workforce management tools.

Fruit Street: A telehealth company offering a CDC-recognized Diabetes Prevention Program delivered via live video sessions with registered dietitians. Their program helps individuals at risk for type 2 diabetes make sustainable lifestyle changes.

HabitNu: A digital health company offering a CDC-recognized Diabetes Prevention Program focused on lifestyle coaching and behavior change. Their platform delivers group-based virtual coaching to help participants reduce their risk of developing type 2 diabetes.

HealthEx: A health data exchange platform designed to facilitate secure and interoperable sharing of patient information across healthcare organizations. Their technology supports compliance with data-sharing regulations and improves care coordination.

Health Tree: A patient-centered platform focused on supporting individuals with blood cancers such as multiple myeloma and leukemia. They provide research tools, community support, and personalized health tracking to empower patients and accelerate research.

BUT…

State of Utah
Utah Medical Licensing Board

20 April 2026

Utah Department of Commerce
Office of Artificial Intelligence Policy

To Whom It May Concern,

On January 6, 2026, the State of Utah and Doctronic entered into an agreement to introduce an artificial intelligence (AI)-powered system to "automate routine, guideline-based prescription renewals" for Utah residents. This system will allow "30-, 60-, or 90-day renewals for medications that have already been prescribed by a licensed provider." The Utah Medical Licensing Board (Medical Board) was made aware of this agreement only after its implementation, once the system was already live and available for use.

The Medical Board is tasked with protecting the public in the State of Utah. While we support the legislative mandate to explore AI implementation, we also have a stewardship to protect Utah citizens. Collectively, the board has decades of medical experience across a variety of specialties, positioning us to understand the potential consequences of implementing what may seem like an innocuous task of AI-driven prescription refills.

Overseeing prescription refills is a task reserved for properly licensed medical practitioners for critical safety and clinical reasons. Each refill requires reassessment and clinical decision-making to safely adjust doses, monitor for side effects, contraindications, or new drug interactions, and ensure the medication remains effective. Patients who continue refilling medications without assessment may remain on outdated or suboptimal therapy for months or years. There is a reason prescription refills require physician authorization.

Proceeding with this agreement without consulting the Medical Board potentially places Utah citizens at risk and remains a major concern of the board. It is imperative that professionals with medical backgrounds review all proposals prior to implementation to ensure these programs do not compromise patient safety. We must not allow AI or other financial motivations to override this obligation, yet that is precisely what occurred here.

It is the strong recommendation of the Utah Medical Licensing Board that this program be immediately suspended pending further discussion.

We look forward to working with the Office of Artificial Intelligence Policy to explore ways to safely implement AI in the practice of medicine.

Sincerely,

Utah Medical Licensing Board

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More to Come…

Exploring promotion of adoption and use of AI for clinical care	• Dec. 2025 - RFI on AI and clinical care focused on regulation, reimbursement and research and development
ARPA-H funding	• Funding for FDA-authorized agentic AI that connects to patient records: Agentic AI-Enabled Cardiovascular Care Transformation (ADVOCATE) Program
Updates to federal and state laws	• New federal and state approaches to spur AI innovation and limit risks are being considered

Technology is moving fast

Thank you

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Chair, Health Regulatory Practice

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