# Artificial Intelligence: Use in the Provision of Medicine: Benefits and Regulatory Concerns

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Legislative Science, Technology and Telecommunications Committee

# Concepts and terminology

**NLP: Natural language processing:** analyzes and processes free text into structured language data. NLP tasks can include translation, semantic analysis, automatic summarization, question-answering and speech recognition.

**CV**: computer vision – AI that uses visual data inputs to analyze and interpret images/videos.

**ML: Machine learning:** enables computer programs to learn from data by identifying patterns and improving performance through experience. Often requires large datasets and benefits from iterative feedback and fine-tuning

**DL: deep learning**: subfield of ML that uses deep neural networks (DNNs) for data analysis, pattern recognition and decision-making. Distinct capability of autonomously learning crucial features for predictions with minimal human intervention.

**DNN: deep neural networks**: multiple layers of weighted, interconnected nodes trained through supervised or unsupervised learning. DNNs can extract features from raw data using a learning algorithm called "backpropagation". As a result, they have the capacity to learn from mistakes and adjust their course over time to solve problems. They are more powerful than traditional ML algorithms but require large amounts of data and computational resources.

**ANN: Artificial neural networks:** algorithms with architecture inspired by the human brain and biological neural networks. Consist of interconnected nodes or artificial "neurons" in layers. Can learn from examples of relationships in data and are capable of complex pattern recognition and decision-making

**Recurrent neural networks: RNN**: Networks designed to process sequential data with temporal dependencies such as time series or natural language by utilizing internal loops that allow information to persist (a memory).

**Self-attention:** an iterative mechanism that enables models to assign varying degrees of importance to different parts of the input during processing- useful to focus on relevant information for making predictions. Use widely in NLP tasks such as sentiment analysis where the relationships between words in a sentence are important. Combined with RNN-like structures, it forms the backbone of transformer models, which are the central component of chatbot technologies.

**LLM**: **large language models:** LLMs are designed to understand and generate text like a human, in addition to other forms of content, based on the vast amount of data used to train them. They have the ability to infer from context, generate coherent and contextually relevant responses, translate to languages other than English, summarize text, answer questions (general conversation and FAQs) and even assist in creative writing or code generation tasks**. Generative pre-trained transformer 4 – GPT-4** is the most well-known LLM with NLG capability (natural language generation) trained on over 1.75 trillion parameters. Large language models utilize transformers to process long text sequences using self-attention and RNNs

**Autonomous agents:** can perform tasks and make decisions independently without human intervention. They perceive their surroundings through sensors, process them, reason about them, and take action to achieve their goals.

# Multiple AI applications are currently in use in healthcare

Some common examples of such applications include:

- Computer vision systems to analyze medical images.
- Natural language processing to review clinical notes.
- Voice recognition to support clinical documentation.
- Predictive algorithms and advanced data analytics to forecast clinical trends.
- Chatbots to provide patient education and triage.
- Robots (diligentrobots.com) assist clinical staff with non-patient-facing tasks (deliver lab samples, fetching items).

Many of these tools analyze large datasets to identify patterns, classify information, and make predictions to support clinical decision-making.

# NLP (Natural language processing) and CV (Computer Vision)

Facilitate analysis of text, images, and other qualitative data for optimized workflows and patient engagement

- Automated analysis of retinal images to detect diabetic retinopathy/macular degeneration
- Detection of pneumonia, tuberculosis, and other thoracic disease from chest x rays
- Sentiment analysis of patient feedback to identify care experience improvements
- Extraction of social determinants of health from clinical notes
- Automated coding of medical procedures from clinical documentation
- Chatbots to provide treatment reminders to patients

# Machine Learning and Neural Networks

Enable the detection of complex data patterns to inform clinical decision-making and medical discoveries

- Predict patient outcomes and trajectories using large electronic health record datasets
- Optimizing hospital logistics such as bed assignments, operating room schedules
- Powering clinical decision support systems with updated recommendations

# RL (Reinforcement Learning)

Provides a framework for iterative improvement of targeted tasks

- Optimizing sepsis care and ventilator settings for critically ill patients
- Improving chemotherapy regimens through iterative learning
- Personalizing glucose control for diabetes patients
- Optimizing stroke rehabilitation strategies based on patient response

| AI capability | Description | Example clinical scenario | Potential role of AI |
|---|---|---|---|
| **Identification** | Identifying objects, patterns, and/or characteristics within data (often images). | A physician orders an X-ray for a patient who presents with pain, swelling, and limited leg mobility. | An AI tool reviews the X-ray and identifies an incidental nodule for further analysis by a radiologist. |
| **Translation** | Translating data inputs into another data type or data format (often between modalities or languages), often using natural language processing. | A radiologist reviews an MRI for a patient at-risk of breast cancer and dictates observations via an audio recording. | An AI tool converts the radiologist's audio dictation into a structured summary and applies the BIRADS classification scheme automatically. The AI produces a 'plain language' interpretation for the patient. The AI could also translate the report into a different language. |
| **Summarization** | Summarizing data inputs into shorter and more accessible outputs. | A patient is admitted to an emergency department in status epilepticus. A team of admitting health care professionals review the patient's medical file to understand the patient's medical history, current medications, previous allergic reactions and potential triggering factors. | An AI tool reviews the patient's medical history in totality, near-instantly identifying and summarizing key information for current clinical needs, such as recent medication changes affecting seizure threshold and a list of contraindicated drugs based on allergy history. |
| **Prediction** | Predicting or forecasting future events based on historical data and patterns. | A patient is discharged after hospitalization for heart failure. A patient is discharged after hospitalization for heart failure. | Using historic heart failure readmission rates and the patient's clinical data, an AI tool predicts the risk of the patient's hospital readmission. |
| **Suggestion** | Providing recommendations, guidance or advice. In some systems, suggestions may automatically lead to a specific downstream action. | A patient sees a provider every few months for a routine check-in; clinical team conducts retrospective analysis of blood glucose measures from the past few months. | An AI tool continually monitors a patient's blood glucose levels and (1) sends an alert to patient and clinician when deviations occur and (2) provides recommended course of action (e.g., insulin level recommendation). |

# AI and Mental Health

# Treatment possibilities in mental health

- Genetic predisposition analysis, past treatment responses, behavioral patterns and real-time physiological data can be analyzed allowing AI to customize treatment plans to individual patients
- In the context of addiction treatment, AI can continuously observe and analyze a patient's behavioral patterns, triggers, stressors, and substance use.  This proactive approach allows for timely interventions and modification of treatment strategies
- Algorithms continuously analyze patient progress and adjust treatment plans in real time

# Machine learning algorithms/ Predictive Analytics

- Sift through vast patient data including medical histories, diagnostic tests and clinical notes to identify patterns suggesting a mental health condition: machine learning can be autonomous
- AI-powered predictive analytics (takes in data, looks at patterns to predict outcomes)

- These algorithms can flag patients at risk. For example, the work of Dr. Joel Stoddard at Colorado Children's Hospital:
    - https://www.childrenscolorado.org/advances-answers/recent-articles/suicide-prevention-with-ai/
    - With the help of artificial intelligence (AI), Children's Hospital Colorado psychiatrist Joel Stoddard, MD, MAS, is driving research that could finally predict suicide risk in kids. Dr. Stoddard serves as principal investigator at Children's Colorado's Emotion and Development Lab, which seeks to understand the neurological underpinnings of social emotional challenges in children and adolescents.
    - In the lab, Dr. Stoddard and his team will use AI to learn which patterns are most likely to lead to a suicide attempt. Then, the AI tool helps the team create models that predict future suicidal thoughts and behaviors as well as the potential interventions that might work best to save a patient's life.
    - "Pattern detection is really important. You can do it as a human, but it takes a long time — it's like finding the needle in the haystack," Dr. Stoddard says. "We're actually able to predict people's clinical outcomes much faster using data about them, which includes both clinical impressions and computer-derived measures of their behavior."

# Usefulness of AI in mental health disorders: Natural language processing techniques

- Sentiment analysis: identifies nuanced changes in an individual's emotional condition (social media posts, chat logs, written diary)
  - Woebot
- Voice analysis: alterations in speech patterns which might serve as indicators of anxiety, depression or other mental health condition.
  - Cogito
- Facial expression analysis (coupled with computer vision) can provide insights into an individual's emotional state. AI can detect micro-expressions and subtle changes that may indicate underlying psychological conditions
  - Affectiva, Kintsugi

# Predictive modeling

- Models consider a wide range of factors including genetics, environmental factors, lifestyle choices, social determinants of health.
  - Ginger: utilized predictive analytics to identify individuals at risk of developing mental health conditions. If a user displays concerning behaviors, Ginger's predictive model may prompt a mental health coach to offer assistance.
  - IBM's "Watson for Drug Discovery" uses AI to analyze vast genetic and chemical information datasets to identify potential drug candidates for mental health conditions such as schizophrenia and bipolar disorder. This accelerates drug development, potentially offering more effective treatments for these conditions.
  - Many predictive models integrate wearable technology and mobile health apps for patients.

# Virtual Therapists and Chatbots

- Address a critical gap in mental healthcare access
- Can engage in empathetic conversations, offer coping strategies and connect users to human therapists or crisis helplines
- Provide discrete and stigma-free platform for individuals to engage with mental health support
- Can provide therapy for children with autism spectrum disorder using facial recognition technology to adjust interactions

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Enhancing mental health with Artificial Intelligence: Current trends and future prospects
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# AI tools: Chatbot-based therapy

Woebot is a chatbot that provides cognitive-behavioral-based therapy for depression and anxiety. It has been shown to be effective in reducing symptoms of depression and anxiety in clinical trials.  Now Woebot Health.

Wysa is a chatbot that provides therapy support for a variety of mental health conditions, including depression, anxiety, stress, and loneliness. It uses a combination of CBT (cognitive-behavioral therapy), mindfulness, and positive psychology to help users improve their mental health.  Has partnered with the NHS (UK).

Talkspace is an online therapy platform connecting patients with licensed therapists through video, text, and audio messaging. It uses AI to match patients with therapists best suited to their needs.

BetterHelp is an online therapy platform that connects patients with licensed therapists. It uses AI to match patients with therapists but offers a broader range of therapeutic approaches, including cognitive-behavioral therapy (CBT) and psychodynamic therapy.

# AI tools: Smart mental health tools

Kintsugi utilizes facial and voice analysis to provide real-time emotional feedback to therapists, aiding in the early detection of emotional distress.

IBM's Watson Health employs AI to predict disease progression and treatment outcomes by analyzing comprehensive patient data.

Cerebral utilizes AI to support therapists in refining personalized treatment plans for patients with mental health conditions.

Mindstrong Health employs AI to analyze smartphone keyboard interactions during teletherapy, providing therapists with insights into emotional states.

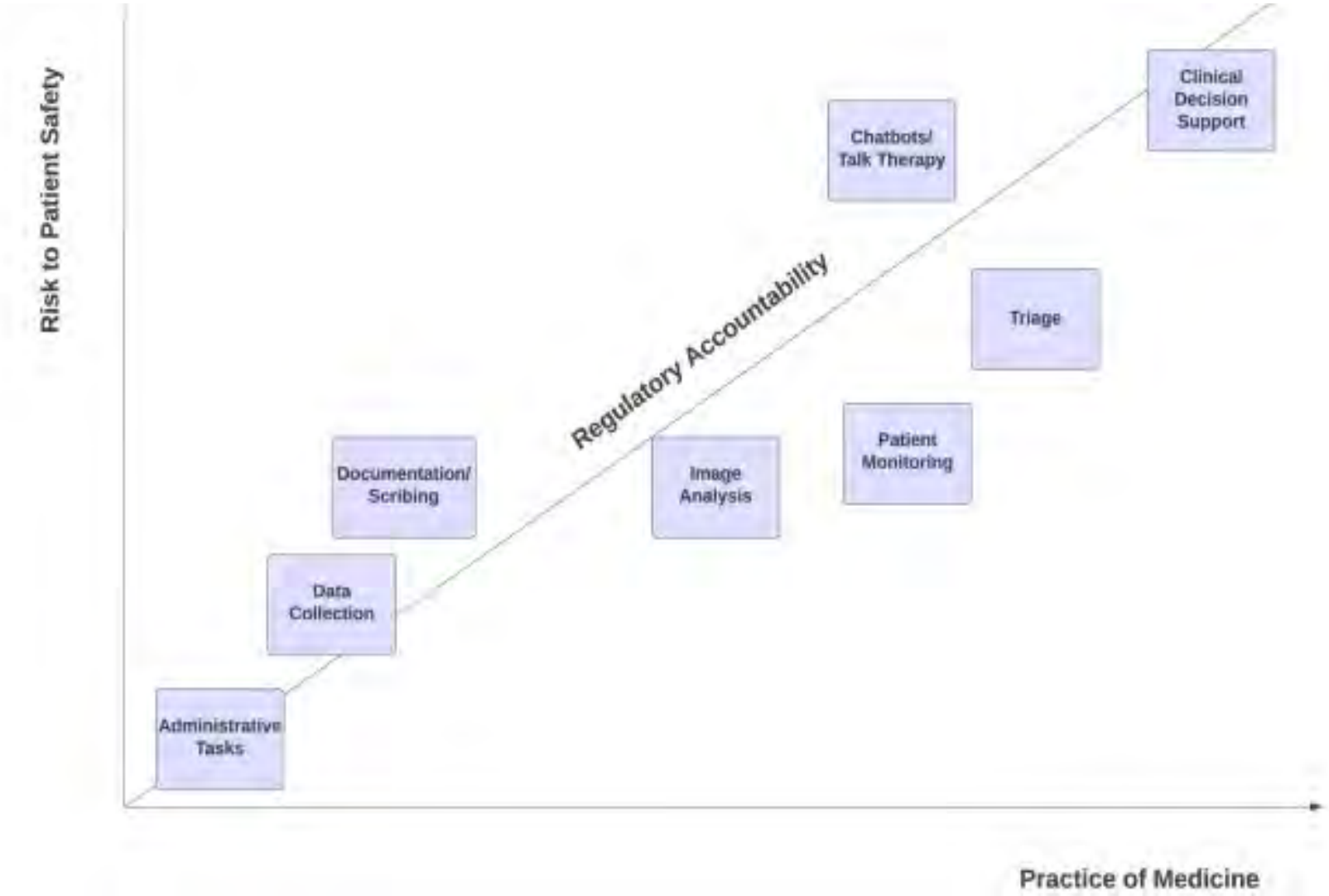
Smartwatches equipped with AI algorithms monitor changes in sleep patterns, physical activity, and heart rate, offering valuable insights for mental health monitoring.

# AI tools: Emotional health apps

- Moodfit is an app that uses AI to track and analyze users' moods and emotions. It can help users to identify patterns in their moods and to develop strategies for managing their emotions.
- Happify is an app that uses AI to help users build resilience and happiness. It offers a variety of games, activities, and exercises designed to improve users' mood, well-being, and resilience.
- Headspace is an app that offers guided meditation and mindfulness exercises. It uses AI to personalize the meditation experience for each user. Calm is an app offering guided meditation and mindfulness exercises. It also offers other relaxation and sleep-aid features, such as sleep stories and ambient sounds.
- Shine is an app that provides personalized daily inspiration and support. It uses AI to learn about users' needs and interests and then provides content and resources tailored to each user.
- DBT Coach is an app that provides users with tools and resources to help them practice dialectical behavior therapy (DBT), which teaches people how to manage their emotions, thoughts, and behaviors healthily.
- CBT Companion is an app that helps users practice cognitive-behavioral therapy (CBT), which teaches people how to identify and change negative thought patterns and behaviors.
- MindShift CBT is an app that helps users practice CBT techniques for anxiety and depression. It offers a variety of interactive exercises and tools to help users manage their symptoms and improve their mood.
- PTSD Coach is an app that provides users with tools and resources to help them manage post-traumatic stress disorder (PTSD), a mental health condition that can develop in people who have experienced or witnessed a traumatic event.
- SuperBetter is an app that helps users build resilience and achieve their goals by gamifying the process. It offers a variety of challenges and rewards to help users stay motivated and make progress.

*Computers will overtake humans with AI at some point within the next 100 years. When that happens, we need to make sure the computers have goals aligned with ours."*

Stephen Hawking 2015




Federation of State Medical Boards

# Table 3 A list of regulatory challenges related to the rise of LLMs.

## From: The imperative for regulatory oversight of large language models (or generative AI) in healthcare

| Regulatory challenge | Short description |
|---|---|
| Patient Data Privacy | Ensuring that patient data used for training large language models are fully anonymized and protected from potential breaches. This poses a significant regulatory challenge, as any violation could lead to serious consequences under privacy laws like HIPAA in the US. |
| Intellectual Property | If an LLM generates content similar to proprietary medical research or literature, it could lead to issues regarding intellectual property rights. |
| Medical Malpractice Liability | Determining who is responsible when an AI's recommendations lead to patient harm. Is it the AI developers, the healthcare professionals who used it, or the institutions that adopted it? |
| Quality Control & Standardization | Regulation is required to ensure the reliability and consistency of AI-generated medical advice, which can vary based on the data used to train the AI. |
| Informed Consent | Patients need to be informed and give consent when AI tools are used in their healthcare management. This is challenging because it can be difficult for patients to fully understand the implications of AI use. |
| Interpretability & Transparency | Regulations need to ensure transparency about how decisions are made by the AI. This is particularly challenging with AI models that are often termed as "black boxes" due to their complex algorithms. |
| Fairness and Bias | Regulation is needed to prevent biases in AI models, which could be introduced during the training process using patient data. This can lead to disparities in healthcare outcomes. |
| Data Ownership | It can be challenging to define and regulate who owns the data that large language models learn from, especially when it comes to patient data. |
| Over-reliance on AI Models | Over-reliance on AI could lead to decreased human expertise and potential errors if the AI malfunctions or provides incorrect information. Regulations are needed to balance the use of AI and human expertise. |
| Continuous Monitoring & Validation | Ensuring the continuous performance, accuracy, and validity of AI tools over time and across different populations is a critical regulatory challenge. |

# United States: Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence E.O.14110

**On October 30, 2023, the Biden Administration released Executive Order (E.O.) 14110 on Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence. It establishes a government-wide effort to guide responsible artificial intelligence (AI) development and deployment through federal agency leadership, regulation of industry, and engagement with international partners.**

The E.O. directs over 50 federal entities to engage in more than 100 specific actions to implement the guidance set forth across eight overarching policy areas.

• **Safety and security.** The E.O. promotes the development and implementation of repeatable processes and mechanisms to understand and mitigate risks related to AI adoption, including with respect to biosecurity, cybersecurity, national security, and critical infrastructure.

• **Innovation and competition**. The E.O. compels actions to attract AI talent to the United States, understand novel intellectual property (IP) questions, protect inventors and creators, and promote AI innovation, including at startups and small businesses.

• **Worker support**. The E.O. states that AI adoption may be disruptive to the workforce and directs agencies to research and develop potential mitigations against such disruptions. • Consideration of AI bias and civil rights. The E.O. states that AI models may perpetuate biases and their implementation may lead to civil rights violations. The E.O. includes a section on equity and civil rights considerations for use of AI in the criminal justice system and the administration of federal government programs and benefits.

• **Consumer protection**. The E.O. instructs agencies to enforce existing, technology-agnostic authorities in an effort to minimize harms to consumers, and to identify needed authorities related to AI.

• **Privacy**. The E.O. calls for the evaluation and mitigation of privacy risks—potentially exacerbated by AI— associated with the collection, use, and retention of user data.

• **Federal use of AI**. The E.O. requires the Office of Management and Budget (OMB) to establish an interagency council to coordinate AI use by federal agencies and develop guidance on AI governance and risk management activities for agencies. It acknowledges the ubiquity of generative AI (GenAI) tools, and directs agencies to move toward adoption with safeguards in place. The E.O. also calls for additional agency hiring and training activities to increase the AI workforce capacity across the federal government.

• **International leadership**. The E.O. declares that the United States should be a global leader in AI development and adoption by engaging with international allies and partners, leading efforts to develop common AI regulatory and accountability principles, and advancing responsible global technical standards for AI.

R47843 April 3, 2024 Laurie Harris Analyst in Science and Technology Policy Chris Jaikaran Specialist in Cybersecurity Policy

# EU Artificial Intelligence Act: August 2024

https://artificialintelligenceact.eu/the-act/

# EU Risk Categories

### Unacceptable Risk

1

Highest level of risk prohibited in the EU. Includes AI systems using e.g. subliminal manipulation or general social scoring.

### High Risk

2

Most regulated AI systems, as these have the potential to cause significant harm if they fail or are misused, e.g. if used in law enforcement or recruiting.

### Limited Risk

3

Includes AI systems with a risk of manipulation or deceit, e.g. chatbots or emotion recognition systems. Humans must be informed about their interaction with the AI.

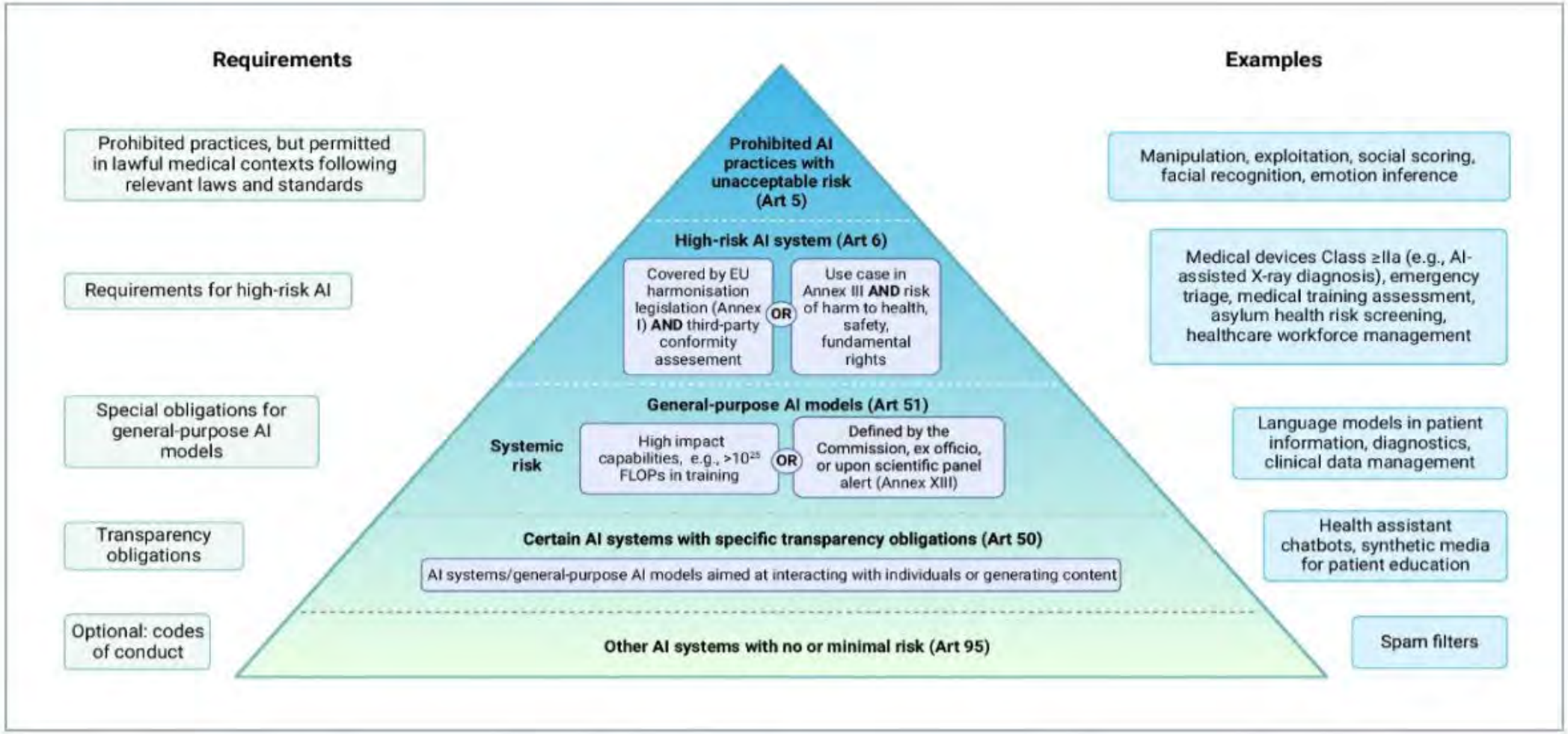
### Minimal Risk

4

All other AI systems, e.g. a spam filter, which can be deployed without additional restrictions.

## Fig. 1: Schematic illustration of the risk-based approach of the EU AI Act, including relevant definitions, requirements, and examples.

From: Navigating the European Union Artificial Intelligence Act for Healthcare




The pyramid structure illustrates the hierarchy of risk, with the most critically regulated or prohibited AI applications at the top and the least or unregulated AI applications at the bottom. This illustration does not necessarily correspond to the actual market share proportions of the individual risk categories. AI artificial intelligence, *Art* article, *EU* European Union. Created with biorender.com.

# FDA Regulation

**How Are Artificial Intelligence and Machine Learning (AI/ML) Transforming Medical Devices?**

- AI/ML technologies have the potential to transform health care by deriving new and important insights from the vast amount of data generated during the delivery of health care every day. Medical device manufacturers are using these technologies to innovate their products to better assist health care providers and improve patient care. One of the greatest benefits of AI/ML in software resides in its ability to learn from real-world use and experience, and its capability to improve its performance.

**How Is the FDA Considering Regulation of Artificial Intelligence and Machine Learning Medical Devices?**

- The FDA reviews medical devices through an appropriate premarket pathway, such as premarket clearance (510(k)), De Novo classification, or premarket approval. The FDA may also review and clear modifications to medical devices, including software as a medical device, depending on the significance or risk posed to patients of that modification. Learn the current FDA guidance for risk-based approach for 510(k) software modifications.
- The FDA's traditional paradigm of medical device regulation was not designed for adaptive artificial intelligence and machine learning technologies. Many changes to artificial intelligence and machine learning-driven devices may need a premarket review.
- On April 2, 2019, the FDA published a discussion paper "Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) - Discussion Paper and Request for Feedback" that describes a potential approach to premarket review for artificial intelligence and machine learning-driven software modifications.
- In January 2021, the FDA published the "Artificial Intelligence and Machine Learning Software as a Medical Device Action Plan" or "AI/ML SaMD Action Plan." Consistent with the action plan, the FDA later issued the following documents:
- October 2021 - Good Machine Learning Practice for Medical Device Development: Guiding Principles
- April 2023 - Draft Guidance: Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions
- October 2023 - Predetermined Change Control Plans for Machine Learning-Enabled Medical Devices: Guiding Principles
- On March 15, 2024 the FDA published the "Artificial Intelligence and Medical Products: How CBER, CDER, CDRH, and OCP are Working Together," which represents the FDA's coordinated approach to AI. This paper is intended to complement the "AI/ML SaMD Action Plan" and represents a commitment between the FDA's Center for Biologics Evaluation and Research (CBER), the Center for Drug Evaluation and Research (CDER), and the Center for Devices and Radiological Health (CDRH), and the Office of Combination Products (OCP), to drive alignment and share learnings applicable to AI in medical products more broadly.
- June 2024 - Transparency for Machine Learning-Enabled Medical Devices: Guiding Principles

# A Regulation To Promote Responsible AI In Health Care: ONC HTI-1 Final Rule

- The Department of Health and Human Services through the Office of the National Coordinator for Health Information Technology (ONC) in March 2024 published the "Health Data, Technology, and Interoperability," (HTI-1) final rule, which includes first-of-its-kind federal requirements for artificial intelligence (AI) and machine learning (ML)-based predictive software in health care.
- This rule impacts a wide range of technologies—referred to as predictive decision support interventions (predictive DSIs)—and directly applies to health information technology, including electronic health records (EHRs), which ONC certifies as having specific technical capabilities. Certified EHRs, which more than 96 percent of hospitals and 78 percent of office-based clinicians use nationwide, are the foundation of digital health care in the US.
- The ONC's vision is for better health enabled by data, and policies established in our recent history have supported an explosion of health data made available through EHRs. Today, we believe that AI and ML—increasingly powered by data from certified health IT and injected into day-to-day workflows within certified health IT—will have a growing impact on how health decisions are made—particularly those directly affecting patients' lives.
- And while we are AI optimists, we also recognize the potential for negative impacts from AI. A primary goal of the HTI-1 final rule is to address these concerns by promoting the development and **use of AI in health care that is fair, appropriate, valid, effective, and safe (FAVES).**

## Rapidly Growing Consensus

- We designed the HTI-1 final rule based on a rapidly growing industry consensus that greater transparency into how AI is developed, evaluated, and performs is a crucial first step to achieving responsible and safe use in health care. Requiring greater information transparency should create incentives for software developers to follow industry best practices in building predictive DSIs and make it easier for those considering these tools—health system leaders, clinicians, and others—to evaluate whether the developer followed best practices.
- To be clear, the ONC is not testing or approving predictive DSIs; rather, we are enabling users to have the information. And with that information, they can determine whether their predictive DSI is FAVES. These requirements are conceptually parallel to other efforts to enhance consumer information, such as nutrition labels and vehicle history reports.
- The final rule **includes two primary policies to enhance transparency and promote FAVES predictive DSIs in health care**.

# A Regulation To Promote Responsible AI In Health Care: Two Primary Policies:

- **First, users of certified health IT must be able to access complete and up-to-date technical and performance information—referred to as source attributes—for predictive DSIs made available to them**. Our selection of source attributes was guided by more than 15 industry- and academia-developed model reporting guidelines in health care. These selected attributes should provide meaningful and interpretable information to health IT users; focus on health equity and model fairness; and show whether the predictive DSI performs effectively in the local setting where it is deployed.
- **Second, the final rule requires that developers of certified health IT apply risk management and governance practices to predictive DSIs supplied in their health IT.** Experience from the financial services sector indicates that transparency regarding the performance of quantitative models is insufficient. To instill trust, we also need continuous, iterative processes to manage risk throughout the entire lifecycle of AI systems. Drawing closely from the NIST Artificial Intelligence Risk Management Framework, **the rule specifies that risk management practices must cover topics including validity, reliability, robustness, fairness, intelligibility, safety, security, and privacy**. The rule requires that a summary of these practices be made publicly available on the ONC's Certified Health IT Product List.
    - The HTI-1 final rule complements existing and emerging policies across HHS and the federal government. As directed by President Joe Biden in his recent "Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence," our final rule supports the "availability of documentation to help users determine appropriate and safe uses of AI in local settings in the health and human services sector." Moreover, we have worked closely with HHS and other federal partners to align programs and policies.
    - For example, our requirements for source attributes could serve, at least in part, as the technical means to enable users to "independently review" a software function, which is one criterion that would lead the function to be excluded from the Food and Drug Administration's (FDA's) definition of a medical device. Final rule requirements for technical and performance information and risk management closely mirror numerous recommendations included in other FDA guidance documents. Furthermore, final rule requirements could help users comply with non-discrimination proposals, if finalized, from the HHS Office of Civil Rights on the use of clinical algorithms in decision making. Importantly, the rule also covers areas—for instance, technology that do not meet the definition of medical devices or clinical algorithms—that regulations from the FDA, OCR, and our other federal partners do not cover. We recognize that transparency is just an initial step toward prudent and critical guardrails for AI innovation in health care to proceed responsibly. And we understand the need for urgent action: The ONC has prioritized these requirements on a faster timeline than other components of HTI-1, so that **developers of certified health IT will need to meet them by January 1, 2025.** Our requirements for a consistent approach to transparency and risk management for predictive DSIs will establish an industrywide foundation to build upon. However, wide adoption of responsible AI in health care is a shared responsibility across numerous stakeholders. We hope that our regulation catalyzes a rich information ecosystem that optimizes AI in health care for the benefit of all.

Authors' Note: The authors are all part of the Office of the National Coordinator for Health Information Technology, which published the described HTI-1 regulation.

Health Affairs Forefront, February 28, 2024.DOI

# Navigating the responsible and ethical incorporation of artificial intelligence into clinical practice. Federation of State Medical Boards April 2024

**EXECUTIVE SUMMARY**

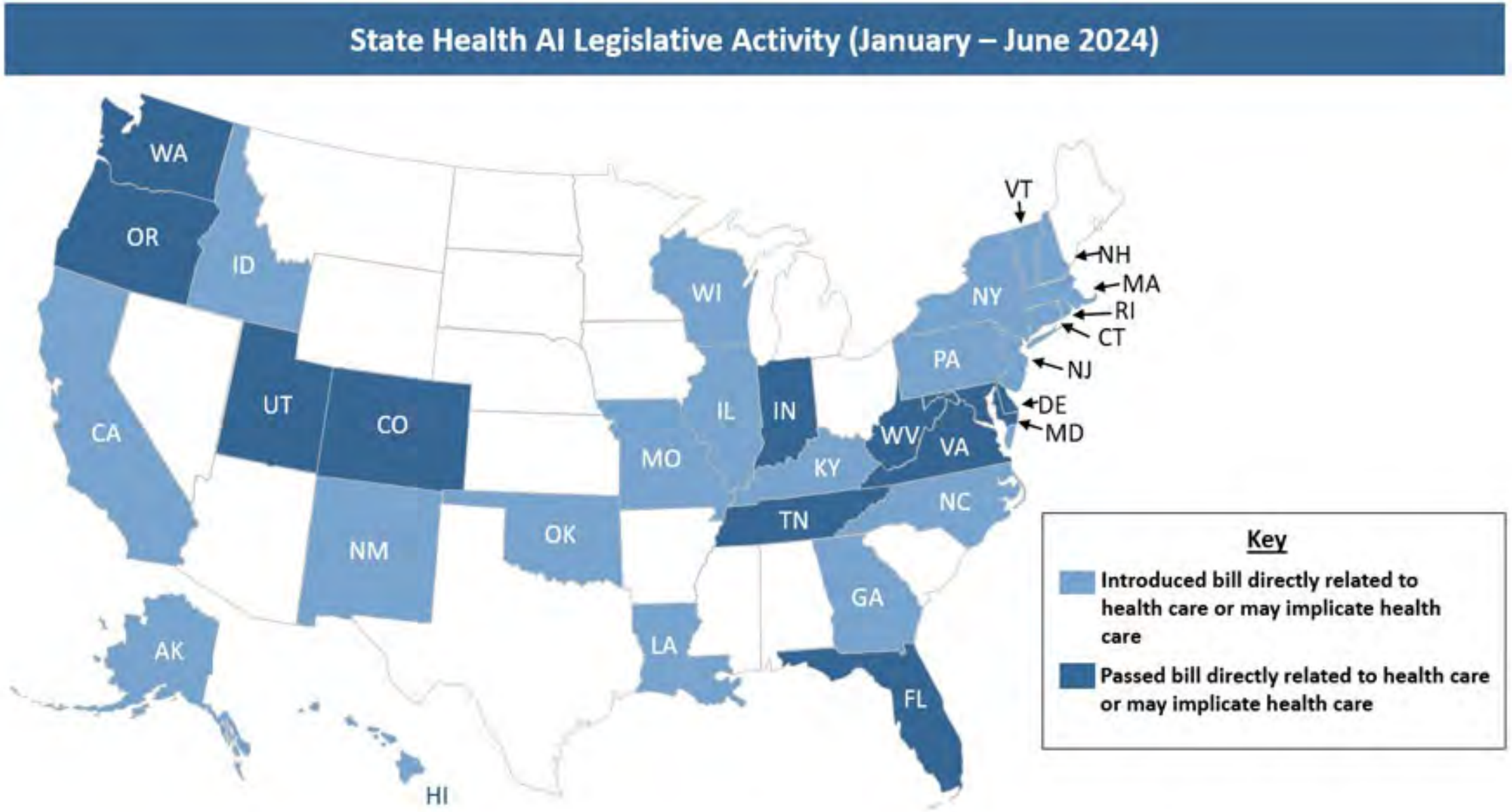
- **Artificial Intelligence (AI) holds tremendous potential to aid healthcare providers in diagnosis, treatment selection, clinical documentation, and other tasks to improve quality, access, and efficiency.**
- **However, these technologies introduce risks if deployed without proper "guardrails" and 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.**

**https://www.fsmb.org/siteassets/advocacy/policies/incorporation-of-ai-into-practice.pdfm**

# Governance

- **AI governance for medicine should be anchored in ETHICS**

- **“Medical boards should focus on governing the use of AI through established ethical principles, including respect for patient autonomy, nonmaleficence, beneficence, and justice, that have served as the foundation of professional expectations and demonstrated applicability in a variety of situations, regardless of treatment modalities or technology involved.” FSMB Policy Paper April 2024**




https://www.manatt.com/insights/newsletters/health-highlights/manatt-health-health-ai-policy-tracker

# Utah Artificial Intelligence Policy Act (UAIP)

- In effect May 1, 2024
- Imposes certain disclosure requirements on entities using generative AI tools with their customers
  - Generative AI “an artificial system that is (a) trained on data;(b)interacts with a person using text, audio or visual communication; and(c)generates non-scripted outputs similar to outputs created by a human, with limited or no human oversight.”
- Limits an entity’s ability to “blame” generative AI for statements or acts that constitute consumer protection violations
- Those in “regulated occupations” must prominently disclose that a consumer is interacting with generative AI, or materials created by generative AI, at the beginning of any communication

le.utah.gov S.B. 149

# Colorado SB24-205 Consumer Protections for Artificial Intelligence

- Requires disclosures and limits on AI used in high-risk areas, ranging from employment and lending services to housing and insurance.
- “Use reasonable care to protect consumers from any known or reasonably foreseeable risks of algorithmic discrimination in the the high-risk system”
- In effect on or after February 1,2026

# Georgia

- **Georgia's Act to amend Article 1 of Chapter 24 of Title 33 of the Official Code of Georgia Annotated (HB887)** was introduced January 2024 to amend the Georgia code with prohibitions for the use of AI-driven decision making for insurance coverage and healthcare.
- A new section is added to the code to prohibit insurance coverage decisions from being solely based on AI or automated decision tools and requires that any coverage decisions that were made using AI be meaningfully reviewed and overridden where necessary.
- The same requirements are set out for healthcare, where healthcare decisions should not be made solely on the basis of AI or automated decision tools, and decisions made with the support of these tools should be meaningfully reviewed by someone with the authority to override the decision. Moreover, the Georgia medical board will be required to adopt rules and regulations governing and establishing the standards necessary to implement these requirements.
- Similar provisions are also set out for public assistance decisions.

# Massachusetts and Illinois

**Massachusetts has put forth a bill titled "An Act Regulating the use of artificial intelligence in providing mental health services" (H1974).** This bill seeks to promote the safety and well-being of individuals seeking mental health treatment and responsible AI practices.

- The Act requires that any licensed mental health professional that desires to use AI to provide mental health services must seek approval from the relevant licensing board. Those licensed to do so must disclose the use of AI to their patients and provide informed consent, as well as provide them with the option to receive treatment from a human instead.
- Moreover, AI systems used in the provision of mental health services must be designed to prioritize patient safety and well-being. Mental health professionals must also continuously monitor the system for its safety and effectiveness.

**The Illinois Safe Patients Limit Act (SB2795)** was first introduced in 2023 and reintroduced in January 2024 for the new session, the Act seeks to set limits on the safe number of patients that may be assigned to a registered nurse in specified situations, as well as placing restrictions on the use of AI.

- Hospitals, long-term acute care hospitals, ambulatory surgical treatment centers, and other health care facilities are prohibited from adopting a policy that substitutes independent nursing judgements from a registered nurse for decisions or recommendations made by algorithms, artificial intelligence, or machine learning.

# California

- The “Physicians Make Decisions Act”

- CA SB1120 proposes to require that a “health care service plan shall ensure that a licensed physician supervises the use of artificial intelligence decision making tools when those tools are used to inform decisions to approve, modify, or deny requests by providers for authorization prior to, or concurrent with, the provision of health care services to enrollees”.

# Summary of Physician Sentiments on AI

## There is enthusiasm around augmented intelligence and its role in health care.

- • 65% of physicians see an advantage to AI.
- • The greatest enthusiasm is around AI tools that can help reduce administrative burdens including documentation (54%) and prior authorization (48%).

## There is both excitement and concern about the potential for AI in healthcare.

- 41% of physicians responded that they were both equally excited and concerned.
- Physicians indicated that they see the most promise for AI to support diagnosis (72%) and workflow (69%).
- Physicians are most concerned about the impact to the patient-physician relationship (39%) and patient privacy (41%).
- Only 38% of physicians are currently using AI in practice, with the most common uses being for various forms of documentation, translation services, and assisting with diagnosis
- 56% of physicians indicated that AI can best help with administrative burdens through automation.
- Generation of patient messages and chart summaries, and prediction of demand and associated workforce needs are top areas where physicians plan to implement AI within the next 5 years. Resources and support will be crucial for physician adoption of AI.
- Data privacy assurances, being not liable for AI model errors, and malpractice insurance coverage are most important for advancing adoption.
- 35% of physician respondents indicated that clinical evidence was the most helpful resource.

# New Mexico: AI and medicine: what problems are we trying to solve? Mostly administrative/ non-clinical tasks

- Patient preventative care (health maintenance):
  - AI reminders via text for vaccines, labs, screenings, medicine refills or reminders
  - Online scheduling for clinic appointment, lab draw, radiology, screenings (mammography, colonoscopy, glucose levels)
- Complete insurance prior authorizations for studies, medications and referrals
  - AI programs can access entire chart, studies, specialist notes and provide basis for prior authorization request to insurance companies
- Continuity of care:  access to schedule with same provider, give chart synopsis, specialty recommendations/results
- Act as a “virtual” scribe for practitioner, minimizing charting (pajama) time
- Improve coding/billing and payment systems
- Support practitioners to make better clinical decisions

# Artificial intelligence in medicine

- AI has tremendous promise. It will undoubtedly advance the standard of care, and clinicians who carefully embrace AI tools will ultimately detect pathologic subtlety, improve accuracy, and spend more quality time in face-to-face patient care than those who do not.
- AI can improve patient access and engagement by shifting administrative tasks away from the clinician while simultaneously increasing empathy shown to patients in spite of pervasive health care provider shortages.

From: Oregon Medical Board: Statements of Philosophy

# Artificial intelligence in medicine: Key Regulatory Points

- **Education**: learning safe and effective use of AI in medicine is necessary.
- **Accountability:** where does responsibility/liability lie? The New Mexico Medical Board (and other regulatory agencies) licenses a **person** to practice medicine, not a machine. The practice of medicine is by a professional, licensed clinician.
- **Highest regulatory risk:** clinical decision-making, standard of care must be followed.
- **Transparency**: companies are currently making up their own benchmarks. We need **key metrics** for use and must understand the development, training, operation and deployment of the AI system.
- **Consent and data privacy** must be ensured.
- **Equity bias** must be monitored.

# Thank you.