U.S. Based Artificial Intelligence Regulations:
Federal Guidance & State Laws

As of February 18, 2025

Whitepaper

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Table of Contents

Executive Summary

This whitepaper provides a general overview of the evolving landscape of Artificial Intelligence (AI) U.S. based regulations at the federal and state levels, with a particular focus on the healthcare industry. As AI continues to transform healthcare operations, compliance programs, and internal audit groups, understanding the legal framework surrounding its use is critical.

Currently, there are no overarching federal laws specifically governing AI in healthcare. However, multiple existing regulations, such as HIPAA, the 21st Century Cures Act, and the Affordable Care Act (ACO) address AI applications in different capacities. Regulatory bodies, including the Food and Drug Administration (FDA), the Department of Justice (DOJ), the Centers for Medicare and Medicaid Services (CMS), the Federal Trade Commission (FTC), and the Equal Employment Opportunity Commission (EEOC), have issued guidelines affecting AI use in areas like data privacy, patient care, compliance, and employment practices.

In addition to federal oversight, individual states have enacted their AI-related regulations, which vary widely in scope and application. A number of States have implemented specific laws addressing AI in employment, consumer protection, facial recognition, and healthcare applications. This fragmented regulatory environment underscores the importance of staying informed about both federal and state-level requirements.

As AI regulations rapidly evolve, healthcare organizations must proactively develop compliance strategies that align with emerging legal and ethical considerations. This includes implementing robust data governance policies, ensuring transparency in AI-driven decision-making, and mitigating risks related to both perceived and actual bias and discrimination. Organizations should also monitor ongoing regulatory updates to adapt to new requirements effectively.

This whitepaper serves as a first step guide for healthcare professionals, compliance officers, and policymakers to help locate US based AI regulations and guidance.

Introduction

AI refers to the simulation of human intelligence in machines, enabling them to perform tasks that typically require human cognition. These tasks include learning, reasoning, problem-solving, perception, language understanding, and decision-making. AI technologies encompass machine learning, deep learning, natural language processing, computer vision, and robotics.

The integration of AI into the healthcare industry has led to significant advancements in diagnostics, treatment planning, and medical research. AI enhances operational efficiency by automating administrative tasks, optimizing resource allocation, and improving patient outcomes through data-driven insights. As AI applications continue to evolve, they bring both opportunities and challenges, particularly in areas such as compliance, ethical considerations, and regulatory oversight.

Given AI's growing role in healthcare, organizations must stay informed about emerging laws and best practices. This paper explores the current regulatory landscape governing AI, examines key federal and state-level regulations, and provides high-level insights for compliance and risk mitigation.

Current Landscape of AI Regulations

The regulatory landscape for AI in healthcare is rapidly evolving, with various federal and state laws addressing different aspects of AI deployment, compliance, and oversight. While there is no single federal law governing AI in healthcare, several existing regulations and regulatory bodies provide guidance on specific AI applications.

At the federal level, multiple agencies have established guidelines and enforcement mechanisms:

- **The Department of Justice (DOJ)[1]** issued the *Evaluation of Corporate Compliance* (updated September 2024), which emphasizes the role of AI in compliance monitoring and the need for organizations to integrate data analytics and AI-driven risk assessment tools. Part of the use of these tools is to answer the following three questions:

  1. Is the corporation's compliance program well designed?
  2. Is the program being applied earnestly and in good faith?
  3. Does the corporation's compliance program work in practice?

  One of the key elements addressed in this document is the use of data analytics tools and models and if compliance personnel have sufficient and direct access to these tools and data for timely and effective monitoring and/or testing of policies, controls, and transactions. Conversely, the document also specifies management of emerging risk to ensure compliance with applicable laws. As AI laws and regulations are actively changing, organizations also need to mitigate risk associated with the use of new AI technology.

  As part of a recent SunHawk Consulting survey of healthcare compliance professionals regarding the use of AI within healthcare organizations, over 80% of respondents did not have a program in place to track internal use of AI by employees.

- **HIPAA** does not deviate from the already established Privacy Rule, Security Rule, Business Associate Agreements (BAAs), and Breach Notification Rule. The same applications of HIPAA would apply to any software used for the safeguard of patient information.

- **21st Century Cures Act** provides guidelines for the access to electronic health information (EHI) and interoperability requirements (*e.g.,* HL7 and FHIR standards). However, like HIPAA,

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[1] The *Evaluation of an Effective Compliance Program,* dated September 2024.
https://www.justice.gov/criminal/criminal-fraud/page/file/937501/dl?inline=

the rules and guidance are similar to the use of other software applications in the healthcare space.

- **The Centers for Medicare and Medicaid Services (CMS)[2]** provides guidance on using algorithms or AI to make coverage determination decisions. AI alone cannot be used as the basis to deny admission or downgrade to an observation stay (§422.101(c)), and predictive algorithms or software tools cannot apply other internal coverage criteria that have not been explicitly made public and adopted in compliance with the evidentiary standard in (§ 422.101(b)(6)).

- **The Office for Civil Rights Office of the Secretary**, **Department of Health and Human Services (HHS)[3]** issued a Final Rule on May 6, 2024, within Section 1557 of the Affordable Care Act (ACA) prohibiting the use of AI from discrimination and bias and authorizes the Secretary of the Department of HHS to promulgate regulations to implement the nondiscrimination requirements.

- **Food and Drug Administration (FDA)[4]** published draft guidance proposes both lifecycle considerations and specific recommendations to support marketing submissions for AI-enabled medical devices. Notably, this draft guidance is specific to AI-enabled medical devices. Additionally, the FDA makes recommendations with regards to the use of AI in supporting the development of drug and biological products.

- **The Equal Employment Opportunity Commission (EEOC)[5]** enforces federal laws that make it illegal for an employer, union, or employment agency to discriminate against an applicant or employee. In addition to the EEOC's enforcement activities on discrimination related to AI and automated systems, the EEOC issued a technical assistance document explaining how the Americans with Disabilities Act applies to software, algorithms, and AI in making employment-related decisions about job applicants and employees.

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[2] CMS *Frequently Asked Questions Related to Coverage Criteria and Utilization Management Requirements in CMS Final Rule (CMS-4201-F),* dated February 6, 2024.
https://www.aha.org/system/files/media/file/2024/02/faqs-related-to-coverage-criteria-and-utilization-management-requirements-in-cms-final-rule-cms-4201-f.pdf
[3] Nondiscrimination in Health Programs and Activities, CFR 42, CFR 45, and section 1557 of the Affordable Care Act, dated May 6, 2024.
https://www.federalregister.gov/documents/2024/05/06/2024-08711/nondiscrimination-in-health-programs-and-activities
[4] FDA, Draft Guidance: Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations, dated January 7, 2025.
https://www.fda.gov/media/184856/download
[5] EEOC, *What is the EEOC's role in AI?,* dated April 29, 2024.
https://www.eeoc.gov/sites/default/files/2024-04/20240429_What%20is%20the%20EEOCs%20role%20in%20AI.pdf

- **Federal Trade Commission (FTC) Act**[6] has made statements regarding AI and unfair or deceptive changes in terms and conditions. It may be unfair or deceptive for a company to adopt more permissive data practices. For example, to start sharing consumers' data with third parties or using that data for AI training, and to only inform consumers of this change through a surreptitious, retroactive amendment to its terms of service or privacy policy. The FTC Act prohibits companies from unilaterally applying material privacy policy changes to previously collected data.

- **The Consumer Financial Protection Bureau (CFPB)**[7] published a circular confirming that federal consumer financial laws and adverse action requirements apply, regardless of the technology used (*e.g.,* machine learning and AI). The circular also made clear that the fact that the technology used to make a credit decision is too complex, opaque, or new is not a defense for violating these laws.

- **Federal Communication Commission (FCC)**[8] has made AI-generated voices in robocalls illegal as of February 8, 2024, as part of the Telephone Consumer Protection Act (TCPA).

- **President Trump's AI Executive Order**[9] *Removing Barriers to American Leadership in Artificial Intelligence,* dated January 23, 2025, revoked the October 30, 2023 Biden Executive Order which discussed eight principles and priorities governing AI. President Trump's AI Executive Order states the administration aims to "develop AI systems that are free from ideological bias or engineered social agendas" and to solidify the United States' position as the global leader in AI.

- **Federal Agencies**[10] *Joint Statement on Enforcement of Civil Rights, Fair Competition, Consumer Protection, and Equal Opportunity Laws in Automated Systems* was published April 4, 2024, which includes guidance and links to specific agencies' statements, and commitments to enforcements to protect civil rights, fair competition, consumers and equal opportunity from unlawful bias and discrimination.

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[6] FTC, AI (and other) Companies: Quietly Changing Your Terms of Service Could Be Unfair or Deceptive, dated February 13, 2024.
https://www.ftc.gov/policy/advocacy-research/tech-at-ftc/2024/02/ai-other-companies-quietly-changing-your-terms-service-could-be-unfair-or-deceptive

[7] CFPB, Consumer Financial Protection Circular 2022-03, *Adverse action notification requirements in connection with credit decisions based on complex algorithms*, dated May 26, 2022.
https://www.consumerfinance.gov/compliance/circulars/circular-2022-03-adverse-action-notification-requirements-in-connection-with-credit-decisions-based-on-complex-algorithms/

[8] FCC, *FCC Confirms that TCPA Applies to AI Technologies that Generate Human Voices*, dated February 8, 2024.
https://www.fcc.gov/document/fcc-confirms-tcpa-applies-ai-technologies-generate-human-voices

[9] AI Executive Order, *Removing Barriers to American Leadership in Artificial Intelligence*, dated January 23, 2025.
https://www.whitehouse.gov/presidential-actions/2025/01/removing-barriers-to-american-leadership-in-artificial-intelligence/

[10] Federal Agencies, *Joint Statement on Enforcement of Civil Rights, Fair Competition, Consumer Protection, and Equal Opportunity Laws in Automated Systems*, dated April 4, 2024.
https://www.justice.gov/crt/media/1346821/dl?inline

- **HHS Secretary Advisory Committee of Human Research Protection[11]** *Institutional Review Board (IRB) Considerations on the use of Artificial Intelligence in Human Subjects Research,* dated October 19, 2022, addresses the concern for AI or AI validation activities as they might meet the Common Rule definition of research that is "designed to develop or contribute to generalizable knowledge" and Common rule exemptions found in 45 CFR 46.104 (d)(4). "Similarly, information gleaned from "de-identified" medical records was collected during the course of medical care, and such collection is a condition of receiving care, depriving individuals of the ability to choose whether or not to participate in research. Further, the value of de-identification is questionable, given advancing technology and the ability to combine disparate sources of data, leaving subjects vulnerable to harms consequent on exposure of sensitive and identifiable personal data."

State & Local Laws

State & Local laws governing AI in the U.S. vary widely, as different localities have approached AI regulation with distinct priorities. Here are some key areas where state & local AI laws passed:

- **California**
  - **SB-942,** *Consumer Protection: Generative Artificial Intelligence, the California AI Transparency Act,* **enacted September 19, 2024:[12]** The California AI Transparency Act defines deepfakes and requires covered providers (developers) to provide a manifest disclosure to AI-generated image, video, or audio. Additionally, it assigns civil monetary penalties to violations (e.g., $5,000/violation). The provisions of this bill will be operative on January 1, 2026.
  - **SB-926,** *Distribution of intimate images,* **and SB-981,** *Sexually explicit digital images,* **enacted September 19, 2024:[13]** Criminalizes malicious deepfake videos used to manipulate elections or distribute fake pornography.
  - **AB-3030,** *Health care services: artificial intelligence,* **enacted September 28, 2024:[14]** This bill adds to Section 1339.75, Division 2 of the Health and Safety Code related to health care services. This requires a health facility, clinic, physician's office, or office of a group practice that uses generative AI to disclose its use to patients.
  - **AB-2013,** *Generative artificial intelligence: space training, data transparency,*

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[11] U.S. Department of Health and Human Services, *IRB Considerations on the Use of Artificial Intelligence in Human Subjects Research*, dated October 1, 2022.
https://www.hhs.gov/ohrp/sachrp-committee/recommendations/irb-considerations-use-artificial-intelligence-human-subjects-research/index.html

[12] California SB-942 *Consumer Protection: Generative Artificial Intelligence*, enacted September 19, 2024.
https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=202320240SB942

[13] California, SB-926, *Distribution of intimate images,* and SB-981, *Sexually explicit digital images,* enacted September 19, 2024.
https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=202320240SB926 &
https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=202320240SB981

[14] California, AB-3030, *Health care services: artificial intelligence, enacted September 28, 2024.*
https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=202320240AB3030

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enacted September 28, 2024:[15] This bill adds to Section 3110, Part 4 of Division 3 of the Civil Code, relating to disclosure of the data used to train generative artificial intelligence on her after January 1, 2022. The bill includes provisions on automated decision-making and requires businesses to provide transparency and opt-out rights for AI-driven profiling.

- **AB-2885, *Artificial intelligence,* enacted September 28, 2024:**[16] This bill amends the Business and Professions, Education, and Government Code relating to artificial intelligence. This bill provides definitions for artificial intelligence.

- **Colorado**
  - **SB 24–205, *Consumer Protections for Artificial Intelligence,* enacted May 17, 2024:**[17] Under the law, both developers and deployers must exercise "reasonable care to protect consumers from any known or reasonably foreseeable risks of algorithmic discrimination" in their high-risk AI systems. In addition, the law provides for a rebuttable presumption that the developer or deployer used reasonable care if they comply with the bill's requirements.
  - **HB 24–1468, *Artificial Intelligence & Biometric Technologies*, enacted June 6, 2024:**[18] The act establishes an AI impact task force in the issues of study for the task force.

- **Illinois**
  - **820 ILCS 42, *Artificial Intelligence Video Interview Act,* enacted January 1, 2020:**[19] This Act regulates the use of AI in analyzing job interview videos, requiring disclosure, consent, and the option for candidates to delete recordings.
  - **HB3773, *Limit Predictive Analytics Use,* enacted January 1, 2026:**[20] This Act restricts the use of predictive data analytics to determine a consumer's credit worthiness and the use of information about the consumer that is used to assign specific risk factors to the consumers (e.g., race or ZIP Code) resulting in rejection of credit.

- **Maryland**
  - **HB1202, *Use of Facial Recognition Services Prohibition,* enacted October 1, 2020:**[21] The act prohibits an employer from using certain facial recognition services during an applicant's interview for employment unless the applicant consents.

- **Massachusetts**

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[15] California AB-2013, *Generative Artificial intelligence: training, data transparency,* enacted September 28, 2024. https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=202320240AB2013

[16] California AB-2885, *Artificial intelligence, enacted September 28, 2024.* https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=202320240AB2885

[17] Colorado, SB 24–205, Consumer Protections for Artificial Intelligence, enacted May 17, 2024. https://leg.colorado.gov/bills/sb24-205

[18] Colorado, HB 24–1468, *Artificial Intelligence & Biometric Technologies*, enacted June 6, 2024. https://leg.colorado.gov/bills/hb24-1468

[19] Illinois, 820 ILCS 42, *Artificial Intelligence Video Interview Act,* enacted January 1, 2020. https://www.ilga.gov/legislation/ilcs/ilcs3.asp?ActID=4015&ChapterID=68

[20] Illinois, HB3773, *Limit Predictive Analytics Use,* enacted January 1, 2026. https://www.ilga.gov/legislation/publicacts/fulltext.asp?Name=103-0804

[21] Maryland, HB1202, *Use of Facial Recognition Services Prohibition,* enacted October 1, 2020 https://mgaleg.maryland.gov/mgawebsite/Legislation/Details/HB1202?ys=2020RS

- o **General Law – Part 1, Title II, Chapter 6, Section 220,** *The Massachusetts Police Reform Law, enacted* **December, 31, 2020:**[22] Restricts the use of facial recognition by law enforcement without a court order.
- **New York City,**
  - o **NYC Local Law 144,** *Automated employment, decision tools***, enacted December 11, 2021:**[23] Mandates bias audits for automated employment decision tools to prevent discrimination.
- **Texas**
  - o **Tx. Pen. Code § 21.165,** *Unlawful Production or Distribution of Certain Sexually Explicit Videos,* **enacted November 21, 2023, February 5, 2025**:[24] The law bans deepfake videos (*i.e.,* pornography).
- **Utah**
  - o **S.B. 149,** *Artificial Intelligence Amendments***, enacted March 13, 2024:**[25] this bill establishes liability for use of artificial intelligence that violates consumer protection laws, if not properly disclosed, create the Office of Artificial Intelligence Policy and a regulatory AI analysis program, enables temporary mitigation of regulatory impacts during AI pilot testing, establishes the Artificial Intelligence Learning Laboratory Program to assess technologies, risks, and policy, requires disclosure when an individual interacts with AI in a regulated occupation, and granted the office role making authority over AI programs and regulatory exemptions.

Conclusion

AI continues to reshape the healthcare industry, providing innovative solutions to improve patient care, operational efficiencies, and compliance monitoring. However, these advancements also introduce significant challenges, particularly in navigating the complex and evolving regulatory landscape. As AI technologies progress, healthcare organizations must adopt a proactive approach to compliance by integrating ethical AI governance, transparent decision-making processes, and ongoing legal assessments.

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[22] Massachusetts, General Law – Part 1, Title II, Chapter 6, Section 220: *The Massachusetts Police Reform Law, enacted* December, 31, 2020
https://malegislature.gov/Laws/GeneralLaws/PartI/TitleII/Chapter6/Section220#:~:text=(b)%20Any%20law%20enforcement%20agency,the%20Federal%20Bureau%20of%20Investigation.
[23] New York City, NYC Local Law 144, *Automated employment decision tools*, enacted December 11, 2021. https://legistar.council.nyc.gov/LegislationDetail.aspx?ID=4344524&GUID=B051915D-A9AC-451E-81F8-6596032FA3F9&Options=ID%7cText%7c&Search=
[24] Texas, Texas, Tx. Pen. Code § 21.165, *Unlawful Production or Distribution of Certain Sexually Explicit Videos*, enacted November 21, 2023. https://casetext.com/statute/texas-codes/penal-code/title-5-offenses-against-the-person/chapter-21-sexual-offenses/section-21165-unlawful-production-or-distribution-of-certain-sexually-explicit-videos
[25] Utah, S.B. 149, *Artificial Intelligence Amendments*, enacted March 13, 2024 https://le.utah.gov/~2024/bills/static/SB0149.html

Both federal and state governments are taking active steps to establish guidelines that address privacy, bias, and ethical concerns in AI applications. While regulations continue to evolve, it is crucial for healthcare professionals and compliance officers to stay informed about new laws and best practices. Organizations should develop internal policies that align with regulatory expectations, ensuring that AI is deployed responsibly and in a manner that upholds patient safety and data integrity.

Looking ahead, collaboration between regulatory bodies, healthcare providers, and technology developers will be essential in shaping AI policies that balance innovation with ethical responsibility. By embracing a forward-thinking regulatory approach and fostering industry-wide cooperation, healthcare stakeholders can harness the full potential of AI while mitigating risks associated with its use.