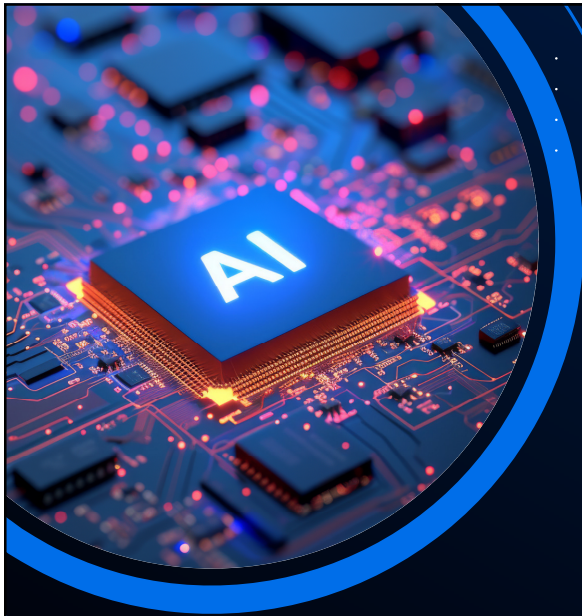




Navigating the Evolving AI Regulatory Landscape



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Laying the Groundwork

2

Foundations of AI Liability

Legal Doctrines for AI

1. Tort Law Principles
2. Product Liability
3. Negligence Theory

Who is a fault?



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Statutory Regimes Applied to AI in Healthcare

Anti-Kickback Statute – 42 U.S.C. § 1320a-7b

Prohibitions: Exchange of anything of value to induce referrals

Applications

- AI systems offering preferential recommendations of providers, services, or products in exchange for remuneration.
- Third parties provide remuneration to health IT developers to integrate AI that increases sales of the sponsor's products.
- EHR vendors use AI algorithms to steer clinical decision-making to increase profits.



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Statutory Regimes Applied to AI in Healthcare

False Claims Act – 31 U.S.C. §§ 3729-3733

Prohibitions: Submission of false claims, inducement by providing misleading information

Applications

- Machine-assisted coding and billing systems can trigger FCA enforcement when they generate false or inflated claims.
- Enforcement actions against providers using algorithms that suggest improper diagnostic codes or medically unnecessary treatments.
- Courts have accepted the theory that false claims can result from inaccurate AI-generated suggestions despite physician review.



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Statutory Regimes Applied to AI in Healthcare

Stark Law – 42 U.S.C. § 1395nn

Prohibitions: Physician referrals to entities with financial relationships for designated health services.

Applications

- AI systems that direct or influence referral patterns could trigger Stark violations if financial relationships exist between the parties.
- Automated referral systems could be subject to heightened scrutiny under Stark Law.



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Statutory Regimes Applied to AI in Healthcare

Civil Monetary Penalties Law – 42 U.S.C. § 1320a-7a(a)(5)

Prohibitions: Offering value to influence the selection of a provider or supplier.

Applications

- AI systems that offer incentives or recommendations to beneficiaries that steer them toward particular providers could trigger CMPL violations.
- Automated front-office services or patient engagement tools must avoid creating inducements prohibited under CMPL.
- The OIG is targeting “preferred provider” algorithms and automated outreach tools.



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Statutory Regimes Applied to AI in Healthcare

Corporate Practice of Medicine Doctrine – Varies by State

Prohibitions: Prevent corporations from practicing medicine.

Applications

- AI systems making or influencing clinical decisions without proper physician oversight may violate CPOM laws.
- Administrative AI implementations must maintain clear separation between clinical and administrative functions.
- AI-driven front-office automation must be structured to avoid corporate influence over medical decision-making.



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Statutory Regimes Applied to AI in Healthcare

Cybersecurity and Civil Cyber-Fraud Initiative

DOJ Initiative: Uses FCA against entities for deficient cybersecurity or misrepresentation.

Applications

- AI systems handling PHI must meet robust cybersecurity standards. Misrepresentations about AI security capabilities could trigger FCA liability.
- AI vendors making false certifications about security protocols may expose both themselves and their healthcare clients to liability.
- Automated systems can enhance compliance monitoring but must themselves adhere to security requirements.



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Federal Regulatory Efforts

Enacted

2020

- National Artificial Intelligence Initiative Act of 2020
- Identifying Outputs of Generative Adversarial Networks Act

2021

- Artificial Intelligence Capabilities and Transparency Act
- Artificial Intelligence for the Military Act

2022

- 2022 Omnibus Appropriations Bill
- Creating Helpful Incentives to Produce Semiconductors and Science Act



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Federal Regulatory Efforts

Introduced

- S.5289, Ethical Use of Facial Recognition Act
- H.R.4814, Consumer Safety Technology Act
- S.2293, AI LEAD Act
- H.R. 4639, Fourth Amendment is Not for Sale Act
- H.R.2225, National Science Foundation for the Future Act
- H.R. 8350, SELF DRIVE Act
- S.2134, Data Protection Act of 2021
- S.2763, Filter Bubble Transparency Act
- H.R.2438, Justice in Forensic Algorithms Act of 2021
- H.R.4039, Advancing Facial Recognition Technology Act
- S.2325, Algorithmic Justice and Online Platform Transparency Act
- H.R.4008, No Biometric Barriers to Housing Act
- S.3572, Algorithmic Accountability Act of 2022
- S.3599, Ban IRS Biometrics Act
- S.3668, No Facial Recognition at the IRS Act
- S.2559, Deepfake Task Force Act
- H.R.7983, B-VERIFY Act of 2022
- S.2052, Facial Recognition and Biometric Technology Moratorium Act of 2021
- H.R.8154, Facial Recognition Ban on Body Cameras Act
- H.R.9061, Facial Recognition Act of 2022
- S.3050, Artificial Intelligence Advancement Act of 2023
- H.R.6881, AI Foundation Model Transparency Act of 2023
- S.3554, Financial Artificial Intelligence Risk Reduction Act (FAIRR Act)
- S.3205, Federal Artificial Intelligence Risk Management Act of 2023
- S.3162, TEST AI Act of 2023
- S.2714, CREATE AI Act of 2023
- S.3312, Artificial Intelligence Research, Innovation, and Accountability Act of 2023
- S.3686, Preventing Algorithmic Collusion Act of 2025
- H.R.1692, Producing Advanced Technologies for Homeland Security (PATHS) Act
- H.R.334, Amendment to Communications Act of 1934
- S.321, Decoupling America's Artificial Intelligence Capabilities from China Act
- H.R.1569, Contraband Awareness Technology Catches Harmful Fentanyl Act
- H.R.1736, Generative AI Terrorism Risk Assessment Act
- H.R.1122, China Technology Transfer Control Act of 2025
- H.R.1734, Preventing Deep Fake Scams Act
- H.R.915, Small Business Technological Act of 2025
- H.R.1694, AI Accountability Act
- H.R.1283, Protecting Our Children in an AI World Act of 2025



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Agencies with Something to Say About It

- The White House
- The US Patent and Trademark Office
- The Federal Trade Commission
- The Equal Employment Opportunity Commission
- The Federal Aviation Administration
- Department of Transportation
- The National Highway Traffic Safety Administration
- Department of Commerce
- Department of Homeland Security
- National Security Commission on Artificial Intelligence
- National Institute for Standards and Technology (NIST)
- Office of Science and Technology Policy
- The Comptroller of the Currency
- Federal Reserve System
- Federal Deposit Insurance Corporation
- National Credit Union Administration
- Consumer Financial Protection Bureau



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Federal Regulatory Efforts

Summary

1. Federal Regulation is fragmented.
2. Attempts are high: over 700 AI-related bills in 2024; Over 40 already in 2025
3. Passage rate is low.

U.S. AI Regulation is likely to develop at the state level for the foreseeable future.



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Today's Environment



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The Present **Regulatory** Landscape

Executive Orders

E.O. 14110 (10/30/2023) – Safe, Secure, and Trustworthy Artificial Intelligence

- Established a comprehensive framework
- Required 50+ federal agencies to implement 100+ specific actions, including safety standards, bias mitigation, and watermarking of AI-generated content

E.O. 14179 (1/23/2025) – Removing Barriers to American Leadership in Artificial Intelligence

- Review and roll back existing AI regulations deemed barriers to innovation
- Develop a new national AI action plan within 180 days
- Ensure AI systems are "free from ideological bias or engineered social agendas"



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The Present **Regulatory** Landscape

Other Significant Federal Actions

Bipartisan House Task Force Report on AI (December 2024): Articulates guiding principles, key findings, and recommendations for Congress regarding AI advancements

White House OSTP and NSF Request for Information (February 6, 2025): Seeking public input on the AI Action Plan mandated by Trump's E.O. 14179, listing 20 AI policy topics for potential public comment



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Responsible AI Governance

Frameworks for AI Governance

1. **NIST-AI-100-1 AI Risk Management Framework** – “voluntary and to improve the ability to incorporate trustworthiness considerations into the design, development, use, and evaluation of AI products, services, and systems.”
 - NIST AI RMF Playbook
 - NIST Roadmap for the AI RMF
2. **NIST-AI-600-1 AI RMF: Generative AI Profile** – “help organizations identify unique risks posed by generative AI and proposes actions for generative AI risk management that best aligns with their goals and priorities.”

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Responsible AI Governance

Frameworks for AI Governance

3. **ISO/IEC 42001:2023** – First international standard for AI management systems focusing on governance, risk, and compliance
4. **OECD AI Principles** – Global ethical framework for trustworthy AI
5. **EU AI Act** – Risk-based regulatory framework with global impact



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Responsible AI Governance

Informative for AI Governance

Resource	Current Status	Key Focus
HHS Trustworthy AI Playbook	September 2021, active, not updated	Trustworthy, ethical AI in healthcare
CMS AI Playbook 2.0	October 2022, on hold, not updated	Practical AI deployment in CMS
HHS AI Strategic Plan (2025)	New in January 2025	Roadmap for all HHS AI activity
ONC-HTI-1 Final Rule	New in December 2023	Transparency in AI clinical decision tools
FDA AI Guidance	New/Updated 2024-2025	Oversight of AI in medical products
FUTURE-AI Guidelines	New in March 2025	International framework for trustworthy AI
HHS Chief AI Officer & Task Force	New 2024-2025	Centralized AI governance at HHS



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AI Governance Recommendations

Establish Core AI Governance Infrastructure

- Create a dedicated AI oversight committee that includes clinical, technical, legal, compliance, and patient advocacy representatives
- Designate AI accountability roles including an executive sponsor, AI governance leader, and operational team
- Develop and formalize AI policies that define what constitutes AI in your organization, acceptable use cases, and risk thresholds
- Implement an inventory system to track all AI systems in use, their functions, data sources, and risk profiles – beware SHADOW AI!



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AI Governance Recommendations

Adopt Transparent Development and Deployment Practices

- Create documentation standards for AI systems including “model cards” that explain how algorithms function, their limitations, and potential biases
- Establish audit trails for all AI-driven decisions
- Conduct regular fairness and bias assessments of AI systems to identify potential discrimination
- Implement explainability mechanisms that allow stakeholders to understand how AI recommendations or decisions are generated



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AI Governance Recommendations

Enhance Data Governance for AI Systems

- Develop [data governance policies](#) including role-based access controls, regular data quality assessments, and privacy safeguards
- Establish clear [data provenance tracking](#) to document the origin, processing, and transformations of all data used in AI systems
- Implement [data quality monitoring](#) to ensure AI systems are trained and operating on accurate, representative, and current information
- Create [data sharing agreements](#) that clearly outline responsibilities when using third-party AI systems or sharing data with external partners



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AI Governance Recommendations

Build Risk Management Frameworks

- Develop an [AI risk assessment methodology](#) that evaluates potential harms, compliance issues, and operational risks before implementation
- Create [contingency plans](#) for AI system failures or unexpected outputs, particularly for systems that affect clinical decision-making
- Establish [continuous monitoring](#) protocols for AI performance, with clear thresholds for human intervention
- Implement [version control and change management processes](#) to track modifications to AI systems and assess their impact



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AI Governance Recommendations

Ensure Regulatory Compliance and Preparedness

- Designate team members to [track evolving AI regulations](#)
- Conduct [gap analyses](#) between current practices and emerging regulatory requirements like ONC's algorithm transparency rules
- Review [existing laws](#) (AKS, False Claims Act, HIPAA) for applicability to AI use cases in your organization
- Consider adopting the [strictest state standards](#) when scaling AI nationally to simplify compliance across jurisdictions



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AI Governance Recommendations

Develop Human-AI Collaboration Protocols

- Establish clear "[human in the loop](#)" requirements for different types of AI applications, particularly those affecting clinical care
- Create [escalation pathways](#) for challenging cases or when AI recommendations conflict with clinical judgment
- Develop [training programs](#) for staff on AI capabilities, limitations, and appropriate use
- Implement [feedback mechanisms](#) to capture user experiences and improve AI system performance over time



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AI Governance Recommendations

Ensure External Transparency and Stakeholder Engagement

- Review and update [patient-facing materials](#) including Terms of Use and Privacy Policies to clearly disclose AI use
- Develop [patient education](#) resources about how AI is used in their care and benefits/limitations
- Create a [stakeholder engagement plan](#) to gather feedback from patients, providers, and payers on AI implementations
- Consider [external validation](#) of high-risk algorithms by third-party, conflict-free organizations



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AI Governance Recommendations

Build Evaluation and Improvement Cycles

- Establish [metrics to evaluate](#) AI effectiveness, safety, and fairness
- Conduct [regular AI audits](#) to assess performance, drift, and compliance with internal policies
- Create a [continuous improvement process](#) for refining AI models based on real-world performance
- Document [lessons learned](#) from AI implementations to inform future governance and deployment decisions



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Anticipating the Future of AI Regulation

CREATE AI ACT & NAIRR

- The National Artificial Intelligence Research Resource (NAIRR) established by EO and exists as a pilot program
- Three bills in Congress aim to codify and expand NAIRR
- Goals:
 1. Democratize access to AI research resources beyond large tech companies
 2. Ensure that AI development benefits society broadly, not just commercial interests
 3. Bring diverse stakeholders to the table to shape responsible AI development
 4. Strengthen U.S. global competitiveness in trustworthy AI development
 5. Support broad participation in AI innovation



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Anticipating the Future of **AI Regulation**

SAFE Innovation Framework (and other titles)

- Introduced by Senator Chuck Schumer (D-NY) in 2023
- DOA
- Four Pillars:
 - Security
 - Accountability
 - Foundations
 - Explainability



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Anticipating the Future of **AI Regulation**

Decoupling America's AI Capabilities from China Act of 2025

- Introduced by Senator Josh Hawley (R-MO)
- Sitting in the Senate Judiciary Committee
- Key Provisions:
 - Import/Export Restrictions
 - Research Limitations
 - R&D Prohibitions
 - Investment Restrictions



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Anticipating the Future of AI Regulation

U.S. AI ACT

- Proposed by Senators Richard Blumenthal (D-CT) and Josh Hawley (R-MO)
- Framework announced September 2023; full legislation still in development
- First comprehensive bipartisan legislative blueprint for enforceable AI protections



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Anticipating the Future of AI Regulation

U.S. AI ACT – Licensing & Oversight

- Mandatory registration for developers of general-purpose AI models
- Independent regulatory body with audit authority and enforcement powers
- Licensing requirements include:
 1. Robust risk management procedures
 2. Comprehensive model testing protocols
 3. Data governance frameworks
 4. Mandatory incident reporting mechanisms
- Goal: Prevent harmful AI systems from reaching market without oversight



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Anticipating the Future of AI Regulation

U.S. AI ACT – Enforcement

- Section 230 immunity does not apply to AI-generated content
- Regulatory actions by oversight body
- Private rights of action for affected individuals
- Focus on accountability for:
 - Privacy violations
 - Civil rights infringements
 - Algorithmic discrimination
 - Other AI-induced harms
- Consumer right to human review of consequential AI decisions



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Anticipating the Future of AI Regulation

U.S. AI ACT – National Security & International Competition

- Export controls to prevent transfer of advanced AI models to adversaries
- Sanctions against entities providing AI capabilities to human rights violators
- Balance between open innovation and protecting critical AI technologies
- Recognition of AI as critical infrastructure for national competitiveness
- Emphasis on maintaining U.S. leadership in responsible AI development



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Anticipating the Future of AI Regulation

U.S. AI ACT – Transparency Requirements

- Mandatory disclosures for AI developers regarding:
 - Training data composition and sources
 - Model limitations and performance boundaries
 - Safety assessments and mitigations
- Public database of:
 - Registered AI models and capabilities
 - Reported incidents and harms
 - Compliance status of licensed entities
- Technical requirements for identifying AI-generated content



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Anticipating the Future of AI Regulation

U.S. AI ACT – Consumer and Child Protection

- "Safety brakes" for high-risk AI applications
- Enhanced disclosure when AI is used in consequential decisions
- Special protections for children:
 - Strict limits on generative AI involving minors
 - Age-verification requirements
 - Stronger data protection for youth
- Clear notice requirements for AI-powered services



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Anticipating the Future of AI Regulation

Regulatory Implications for Healthcare

- Likely system classification as “high risk”
- Increased liability exposure for discriminatory practices or privacy violations
- Mandatory documentation and transparency
- Right to explanation and review
- Incident reporting and oversight
- Data governance and use controls
- Transparency of AI-generated work product



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