

Artificial Intelligence in Health Care

Best Practices in This Brave New World

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February 26, 2024

Agenda



1. Definitions
2. Legal Landscape
3. AI Litigation / Enforcement Risk
4. Leveraging AI in the Health Care Industry
5. What Keeps You Up at Night? / Some Best Practices

Definitions

Artificial Intelligence and Gen-AI

Artificial Intelligence (AI) – *IBM*

AI “is technology that enables computers and digital devices to learn, read, write, talk, see, create, play, analyze, make recommendations, and do other things humans do.”

Gen-AI – *McKinsey*

“Gen-AI technology relies on deep-learning algorithms to create new content such as text, audio, code, and more. It can take unstructured data sets—information that has not been organized according to a preset model, making it difficult to analyze—and analyze them, representing a potential breakthrough for healthcare operations, which are rich in unstructured data such as clinical notes, diagnostic images, medical charts, and recordings. These unstructured data sets can be used independently or combined with large, structured data sets, such as insurance claims.”



Legal Landscape

AI Legal Landscape



- **November 2020, OMB Memo** on *Guidance for Regulation of AI Applications* directed that “[w]hen considering regulations or policies related to AI applications, agencies should continue to promote advancements in technology and innovation, while protecting American technology, economic and national security, privacy, civil liberties, and other American values, including the principles of freedom, human rights, the rule of law, and respect for intellectual property.”
- **December 2020, E.O. 13960** *Promoting the Use of Trustworthy AI in the Federal Government* stated, “The ongoing adoption and acceptance of AI will depend significantly on public trust. Agencies must therefore design, develop, acquire, and use AI in a manner that fosters public trust and confidence while protecting privacy, civil rights, [and] civil liberties.”
- **June 2021, GAO’s** *An Accountability Framework for Federal Agencies and Other Entities* outlined key principles and actions “[t]o help entities promote accountability and responsible use of AI systems.” This included outlining four principles for the framework, including governance, data, performance, and monitoring.

AI Legal Landscape



- **September 2022, Biden Admin's *Principles for Enhancing Competition and Tech Platform Accountability*** included a principle related to stopping discriminatory algorithmic decision-making.
- **October 2022, the Biden Admin's *Blueprint for an AI Bill of Rights*** outlines five principles that should guide the design, use, and deployment of automated systems to protect the American public in the age of AI. These principles are safe and effective systems, algorithmic discrimination protections, data privacy, notice and explanation, and human alternatives, consideration, and fallback.
- **February 16, 2023, E.O. 14091 *Further Advancing Racial Equity and Support for Underserved Communities Through the Federal Government*** requires the Federal Government to “promote equity in science and root out bias in the design and use of new technologies, such as artificial intelligence” and requires agencies to consider opportunities to “prevent and remedy discrimination, including by protecting the public from algorithmic discrimination.”

AI Legal Landscape



- **August 4, 2023, Proposed Rule on Section 1557 of the ACA** proposes to make explicit that CEs are prohibited from discriminating through use of clinical algorithms. ***Currently awaiting Final Rule.***
- **October 30, 2023, E.O. 14110** *Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence* directs HHS to issue a strategic plan on responsible deployment and use of AI that includes “development, maintenance, and availability of documentation to help users determine appropriate and safe uses of AI in local settings in the health and human services sector.” In addition, E.O. 14110 directs HHS to establish a safety program to receive reports of—and act to remedy—harms or unsafe healthcare practices involving AI.
- **HTI-1 Final Rule** establishes first of its kind transparency requirements for AI and other predictive algorithms that are part of certified health IT.

AI Litigation / Enforcement Risk

AI Litigation Risk

Use of AI to Anticipate Patients' Future Healthcare



Dinerstein v. Google (Class Action), 73 F.4th 502 (7th Cir. 2023)

- Google, U of Chicago, U of Chicago Medical Center: Used AI to create software to anticipate patients' future healthcare needs; University delivered anonymized patient medical records to Google.
- Former hospital inpatient sued under privacy, unjust enrichment, patient confidentiality, tortious interference w/contract theories; District Ct. (N.D. Ill.) rejected on procedural grounds, 7th Circuit aff'd.
 - District Ct (N.D. Ill. 2020): Dismissed consumer fraud claim on standing, rest on failure to state a claim
 - 7th Circuit (July 2023): aff'd all on lack of standing, held Plaintiff failed to establish injury in fact traceable to Defendant's conduct

AI Litigation Risk

Software Influencing Prescribing Patterns



- In January 2020, the Department of Justice announced a settlement Electronic Health Records vendor (a San Francisco-based health information technology developer) to Pay \$145 Million to Resolve Criminal & Civil Investigations in Kickback Scheme
- DOJ alleged receipt of kickbacks from a major opioid company in exchange for using EHR software to influence physicians prescribing opioid pain medications—first ever criminal action against EHR vendor
- Alleged caused users to submit false claims for federal payments by misrepresenting EHR software capabilities
- DOJ: “Prescription decisions should be based on accurate data regarding a patient’s medical needs[.]”

AI Enforcement Risk

Medicare Advantage and Algorithms



- Health insurers often use tech to review claims/assess patient medical records for evidence of certain diagnoses have already been subject to enforcement
- In 2021 DOJ intervened in 6 FCA complaints alleging health insurer submitted inaccurate diagnosis codes for Medicare Advantage Plan enrollees in order to receive higher reimbursements
- Some of the allegations relate to the use of algorithms/applications without appropriate human involvement

AI Enforcement Risk

Principal Deputy Asst. AG Brian M. Boynton: FCA's "Wide Reach"



Federal Bar Association's Qui Tam Conference, February 22, 2024:

- "One reason why the False Claims Act has been so successful is its wide reach. It covers those who submit false claims and those who cause such claims to be submitted. It is no defense that an individual or entity did not sign or transmit the specific claim at issue if their conduct played a significant and foreseeable role in advancing the scheme."
- "In the past few years...we have also seen other ways that third parties can influence the type and frequency of claims that are submitted."
- "For example, we have seen how common technology, like electronic health record software, can be corrupted to bias certain types of medical decisions."

Leveraging AI in the Health Care Industry

Leveraging AI in the Health Care Industry



Providers:

- How AI Is Improving Diagnostics, Decision-Making, and Care
- AI Outperformed Standard Risk Model for Predicting Breast Cancer



Payors:

- How algorithms are being used to deny health insurance claims in bulk
- Generative AI brings great potential—and risks—to payor space

Leveraging AI in the Health Care Industry



Patients:

- ChatGPT for Self-Diagnosis: AI Is Changing the Way We Answer Our Own Health Questions
- US patients believe generative AI can improve healthcare access, affordability, survey finds



Policymakers

- HHS CIO Mathias says tree-based AI models helping to combat Medicare fraud



What Keeps You Up at Night?

Some AI Best Practices

Monitoring and Managing Use of AI



Adopt the 7 Elements of the OIG's Compliance Program Guidance

1. Implement written policies, procedures, and standards of conduct.
2. Designate a compliance officer and compliance committee.
3. Conduct effective training and education.
4. Develop effective lines of communication.
5. Conduct internal and external monitoring and auditing.
6. Enforce standards through well-publicized disciplinary guidelines for failure to comply.
7. Respond promptly to detected offenses and undertaking corrective action.

Monitoring and Managing Use of AI



How to Get Started:

- Choose stakeholders within the organization.
- Establish an AI Compliance Committee.
- Take an inventory of existing and/or desired uses of AI tools within the organization.
- Educate committee members.
- Determine enterprise risk.
- Draft policies, procedures, and standards of conduct.
- Develop the auditing/monitoring plan.
- Incorporate the concept of AI tools in overall compliance training materials.

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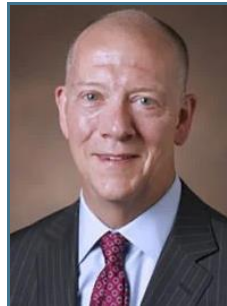
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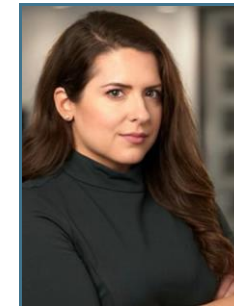
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