Transforming Care Strategies -- Integration of AI in Healthcare: Summary of Legal/Regulatory Issues

New England Health Executives Network
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How Is AI Being Used for Healthcare Applications?

- UMass Memorial Health:
  - partnership with Google Cloud
  - to use artificial intelligence to identify good candidates for advanced drug therapies
  - for heart disease and diabetes, including GLP-1 agonists like Ozempic and Mounjaro.

Boston Business Journal, March 7, 2024, available at https://www.bizjournals.com/boston/news/2024/03/07/umass-memorial-google-cloud-partner-on-new-tool.html?utm_source=st&utm_medium=en&utm_campaign=ae&utm_content=BO&j=34604218&senddate=2024-03-07&empos=p7

- Amazon:
  - training an AI chatbot
  - to handle incoming patient messages and
  - address administrative queries for One Medical.

Becker's Health IT, March 1, 2024 available at https://www.beckershospitalreview.com/disruptors/amazon-training-chatbot-for-healthcare-report.html?origin=CIOE&utm_source=CIOE&utm_medium=email&utm_content=newsletter&oly_enc_id=1905F7435578H3V

- Nebraska Medicine:
  - using AI at two of its primary care clinics
  - to detect diabetic retinopathy in patients.

Modern Healthcare, March 4, 2024, available at https://www.modernhealthcare.com/digital-health/nebraska-medicine-ai-artificial-intelligence-diabetic-retinopathy?utm_source=modern-healthcare-alert&utm_medium=email&utm_campaign=20240304&utm_content=hero-headline

How Is AI Being Used for Healthcare Applications? (cont)

- GE HealthCare ‘actively pursuing’ AI for all products
  - GE HealthCare is among a growing number of radiology companies embracing AI. The company is developing its App Orchestrator, a technology that it said would help providers manage imaging software from different technology vendors. The company said it plans to invest in AI technologies tied to physical devices and others that are cloud-based software. Last month, the company announced plans to acquire medical imaging AI company MIM Software for an undisclosed amount. It intends to fold MIM’s imaging analytics and digital workflow capabilities into its precision medicine offerings. In February 2023, it acquired Caption Health, a software company focused on AI-assisted ultrasound scans. The company plans to use Caption Health’s AI to integrate real-time guidance into ultrasound systems for clinicians and non-expert users to capture better quality images of the heart.
- Hims & Hers says AI can help retain customers
  - Telehealth company Hims & Hers announced in November it was testing an AI and machine learning clinical decision support feature that could suggest treatments for some mental health conditions. The company's AI-driven MedMatch technology can recommend clinicians prescribe certain medications and doses, could contribute to customer retention.
- Insurers using AI to improve customer service
  - Insurers are removing repetitive tasks from workflows by using AI to help with responses to consumer inquiries, updating provider directories and summarizing interactions with customers and patients.
  - An insurer has used AI and machine learning to improve the rate in which member questions are resolved when someone reaches out to their customer service team.
  - UnitedHealth and Cigna have been separately accused of using automated tools to deny some claims.
- R1 RCM examines AI for denials and eligibility
  - R1 RCM, a tech company that handles providers’ billing and claims management services, has developed AI models that can help clinicians identify a patient’s insurance eligibility more efficiently. They also help health systems streamline writing an appeal for a complex clinical denial.
  - R1 RMC sees autonomous coding as an opportunity for generative AI use cases.

Modern Healthcare, March 1, 2024, available at https://www.modernhealthcare.com/digital-health/ge-healthcare-unitedhealth-hims-hers-ai-uses?utm_source=modern-healthcare-alert&utm_medium=email&utm_campaign=20240301&utm_content=hero-readmore

What Laws Apply to the Intersection of Healthcare and AI?

- PRIVACY AND DATA SECURITY:
  - Health Insurance Portability and Accountability Act (HIPAA): HIPAA sets standards for the protection of sensitive patient health information, known as protected health information (PHI). Any AI applications or systems used in healthcare must comply with HIPAA regulations to ensure the privacy and security of patient data.
  - FTC on non-HIPAA health information and separately regulating AI
  - State laws on non-HIPAA health information and separately regulating AI
  - General Data Protection Regulation (GDPR): In regions covered by GDPR, such as the European Union, strict regulations govern the collection, processing, and storage of personal data, including health data. AI applications in healthcare must comply with GDPR requirements to protect patient privacy and obtain appropriate consent for data usage.
- MEDICAL DEVICE REGULATION:
  - President Biden signed an executive order on October 30, 2023 and invoked the Defense Production Act to establish the first set of standards on the use of artificial intelligence in healthcare and other industries.
  - FDA: In the United States, the Food and Drug Administration (FDA) regulates medical devices and software used in healthcare, including AI-based technologies. Depending on the intended use and risk level, AI applications may need to undergo FDA approval or clearance processes to ensure safety and effectiveness.
    - The process involves the FDA reviewing clinical data to ensure the AI-enabled device or software product is safe, effective and only does what it's marketed to do.
    - Between 1995 and October, the FDA approved, designated or cleared 692 AI-enabled devices.
  - Other Medical Device Regulations: AI-based medical devices may be subject to specific regulations governing their design, development, manufacturing, and post-market surveillance. Compliance with medical device regulations, such as ISO 13485 and IEC 62304, is essential to ensure the quality and safety of AI-enabled healthcare products.
  - Health AI companies that do business in Europe have to comply with the European Union’s Artificial Intelligence Act, which took effect in February. The law categorizes AI into different categories of risk. It requires certain health AI developers to register their models into a database and be transparent with the data that informs their models.

What Laws Apply to the Intersection of Healthcare and AI? (cont.)

- REIMBURSEMENT/FRAUD AND ABUSE:
  - Some regulatory guidance from the Centers for Medicare and Medicaid Services has come in response to the alleged use of AI for prior authorization and claim denials.
  - Major insurers UnitedHealth Group, Humana and Cigna are fighting lawsuits alleging they use AI and other automated tools to routinely decline coverage for post-acute care and other services. The insurers have denied the allegations and Humana filed a motion to dismiss the lawsuit.
  - In February, CMS issued guidance to clarify how Medicare Advantage insurers could use AI to assess coverage decisions. CMS said insurers can't use AI tools to override benefits rules and medical necessity standards.
  - The Department of Justice has begun subpoenaing pharmaceuticals and digital health companies to learn more about the role artificial intelligence may play in facilitating anti-kickback and false claims violations.
- QUALITY OF CARE AND TRANSPARENCY:
  - A White House executive order instructed the Department of Health and Human Services to develop new AI-specific regulatory strategies addressing equity, safety, privacy, and quality for AI in health care before April 27, 2024.
  - The Office of the National Coordinator for Health Information Technology finalized a rule in December that set transparency standards for the development of AI in health IT software.
  - Republican Utah Gov. Spencer Cox signed the Artificial Intelligence Policy Act earlier this month. Under the law, regulated occupations, which the state says include many professions within healthcare, must disclose any time they have generative AI, such as a chatbot, interact with a consumer.
  - Republican Georgia Gov. Brian Kemp signed a law in May that permits the use of AI for eye assessments to generate a prescription for contact lenses or glasses. Some state legislators in Georgia proposed a bill in January that would limit how clinicians could use of AI within healthcare.

What New Laws Under Consideration Might Apply to the Intersection of Healthcare and AI?

- The EU already has a draft law, the EU AI Act: https://artificialintelligenceact.eu/the-act/
- Congress is circling healthcare and AI warily:
  - On February 1, 2024, Reps. Troy Balderson (R-Ohio) and Robin Kelly (D-Ill.) launched the bipartisan Congressional Digital Health Caucus at a Capitol Hill event focused on AI.
    - Representatives from Amazon, Google, Microsoft, Hippocratic AI and the Consumer Technology Association participated in the briefing.
- There are 14 bills pending in Congress that include the terms "health" and "artificial intelligence.“
- Sen. Mike Rounds (R-S.D.) proposed that the Senate Finance Committee look at using Medicare and Medicaid programs to fund AI innovations in health care, as part of a new framework that Senate leaders on AI are creating for Congress.
- The FDA and ONC have backed the idea of AI assurance labs, which could validate and monitor AI in healthcare.

What Other Concerns Exist to the Intersection of Healthcare and AI?

- Bias/Data Quality
  - Algorithms already in common use have been found to disproportionately deny care to Black patients.
    - Dr. Ziad Obermeyer, a University of California, Berkeley School of Public Health professor who found in 2019 that a biased algorithm affected 150 million patients, told the Finance Committee that the tool is still in wide use, despite fixes being available.
- Ethical:
  - Various organizations, such as the American Medical Association (AMA) and the World Medical Association (WMA), have established ethical guidelines for the use of AI in healthcare.
    - The Coalition for Health AI is moving forward with new guidelines to ensure that artificial intelligence is safe and effective in health care
    - These guidelines often emphasize principles such as transparency, fairness, accountability, and the primacy of patient welfare.
  - In January, the World Health Organization said governments should either assign an existing regulatory agency or create an agency to assess and approve AI applications and models intended for use in healthcare.
  - Should you form your own internal AI advisory board?
- Professional Standards/Training:
  - Healthcare professionals, including physicians, nurses, and other practitioners, are bound by professional standards of conduct and care.
  - AI applications used in healthcare must align with these standards and support clinicians in delivering high-quality, evidence-based care to patients.

What Activities at the Intersection of Healthcare and AI Are *Not* Being Regulated?

- Large language models (LLMs) that summarize clinical notes, medications, and other forms of patient data are in advanced development and could soon reach patients without FDA oversight or approval.
  - Summarization is a complex activity, and variation in LLM-generated summaries could exert as yet unknown effects on clinician decision-making.
- Liability: who should be held responsible when things go wrong?
  - An HHS proposal from 2022 would largely leave health care providers on the hook for verifying that AI tools work and don't lead to discriminatory outcomes.
  - Physicians vehemently oppose the proposal, and would like Congress to step in.
- Insurance
  - It’s not required.

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- Practice focused on health care and compliance issues, often involving intersection of those two subjects in investigations, administrative proceedings, or litigation
- Work has particular emphasis on compliance issues related to life sciences, pharmaceutical and medical device companies, laboratories, hospitals, health care providers, and provider organizations
- Compliance work includes helping clients establish and maintain effective compliance programs
- Defends clients in disputes alleging kickbacks, overpayments, and billing and coding problems, and represents clients before state health care licensing and regulatory entities
- Counsels health care, life science, technology and consumer-facing clients on issues involving information privacy and security (including HIPAA and other federal and state data privacy and security laws, EU/GDPR privacy and security issues, AI, and data breach response)
- Co-founded firm's Data Security and Privacy Practice Group and regularly contributes to "Security, Privacy and the Law" blog
- Practice covers work on health care transactional matters, including data licensing, M&A, joint ventures, creation of new entities, drafting and negotiation of management service and employment contracts, creation of patient assistance programs, and negotiating data use and clinical trial agreements