Navigating the Legal & Regulatory Landscape of AI in Healthcare – Presented by Stacey Klein

FEATURED ATTORNEY

Stacey P. Klein
Partner

Abrams Fensterman Partner Stacey P. Klein Presents to the Brooklyn Chamber of Commerce Life Sciences & Healthcare Committee

As artificial intelligence rapidly reshapes healthcare delivery, operations, and decision-making, **legal and regulatory risk has become inseparable from innovation**. Abrams Fensterman Healthcare Partner **Stacey P. Klein** recently delivered a highly regarded presentation, *Navigating the Legal & Regulatory Landscape of AI in Healthcare*, to the **Brooklyn Chamber of Commerce Life Sciences & Healthcare Committee**, offering practical, forward-looking guidance to healthcare leaders navigating this evolving terrain.

Her presentation positioned Abrams Fensterman at the **forefront of AI-driven healthcare compliance**, reinforcing the firm's reputation as a trusted advisor to hospitals, physician groups, life sciences companies, and healthcare-adjacent businesses implementing AI responsibly—*before* risk becomes liability.

AI in Healthcare: Opportunity Meets Accountability

AI is unlocking transformative opportunities across healthcare, including:

- Advanced diagnostics and imaging analysis
- Predictive analytics for patient outcomes and resource allocation
- Virtual health assistants and documentation automation
- Operational optimization and workflow efficiency
- Drug discovery and population health management\

But as Ms. Klein emphasized, **innovation without governance invites exposure**. Healthcare organizations remain fully accountable for outcomes—even when AI tools are embedded deep within clinical or administrative systems.

Where Legal Risk Emerges

Ms. Klein's presentation addressed the **real-world legal and operational risks** facing healthcare organizations deploying AI:

- Outdated regulatory frameworks not designed for AI technologies
- Algorithmic bias, black-box decision-making, and explainability concerns
- Privacy breaches and re-identification risks involving PHI
- Liability for AI-assisted clinical and billing decisions
- Over-reliance on "set-and-forget" automation
- Third-party vendor and cloud-based system vulnerabilities

Her message was clear: **AI does not shift responsibility away from providers—it heightens scrutiny.**

Key Legal Frameworks Impacted by AI

Corporate Practice of Medicine (CPOM)

AI may support clinicians—but it can never replace professional judgment. Ms. Klein outlined critical guardrails, including:

- Clinician control and override must always exist
- Vendors and MSOs cannot influence medical decision-making
- Contracts must preserve physician autonomy and CPOM compliance

Fraud & Abuse Laws (AKS, Stark, Fee-Splitting)

AI compensation and referral models can trigger serious exposure under federal and New York law, particularly when involving:

- Algorithm-driven patient routing
- Revenue-sharing or percentage-based compensation
- AI embedded in lab or radiology workflows
- Opaque or non-explainable referral logic

Violations may result in **substantial fines, exclusion from federal programs, or criminal liability**.

False Claims Act (FCA)

Ms. Klein highlighted heightened FCA risk tied to AI-assisted coding and documentation, noting recent enforcement actions involving automated upcoding logic. Key takeaways included:

- Providers remain responsible for every claim submitted
- AI errors do not excuse inaccurate documentation
- Human-in-the-loop review is essential

- DOJ and state AG scrutiny of AI vendors and providers is increasing

HIPAA & Data Privacy in the AI Era

AI systems significantly expand privacy and cybersecurity risk. Ms. Klein outlined critical compliance imperatives, including:

- Determining when AI vendors qualify as Business Associates
- Implementing robust BAAs and vendor due diligence
- Updating Notices of Privacy Practices to reflect AI workflows
- Safeguarding against re-identification of de-identified data
- Conducting AI-specific risk analyses and penetration testing
- Strengthening access controls, logging, encryption, and breach response planning

Building an AI-Ready Compliance Program

To mitigate risk while enabling innovation, Ms. Klein emphasized proactive strategies, including:

- Written agreements with fair market value compensation
- Prohibitions on referral-based or percentage-based payments
- AI governance committees and multidisciplinary oversight
- Continuous monitoring, auditing, and documentation
- Clear policies for AI validation, training, and override protocols
- Regular policy updates as AI technology evolves

She also highlighted how **AI itself can enhance compliance**, enabling faster data analysis and monitoring—while reinforcing that **patterns are not proof and human investigation remains essential**.

Thought Leadership That Moves Healthcare Forward

Ms. Klein's presentation sparked meaningful dialogue among healthcare executives, compliance leaders, and innovators—underscoring Abrams Fensterman's role as a **strategic legal partner for organizations adopting AI responsibly**.

As AI adoption accelerates across healthcare and adjacent industries, **early legal guidance is no longer optional—it is essential**.

Partner With Abrams Fensterman

Abrams Fensterman's Healthcare Practice advises providers, health systems, life sciences companies, and technology innovators on **AI governance, regulatory compliance, privacy, transactions, and risk mitigation**—helping organizations move forward with confidence in a rapidly evolving regulatory environment.

To learn more about AI in healthcare compliance or to speak with Stacey P. Klein, please contact us.

Our health law attorneys understand the demands of the market. We know how to take care of our clients' needs. For further information about our health law practice, please contact our law office on Long Island at 516-328-2300, in Brooklyn at 718-215-5300, White Plains at 914-607-7010, Rochester at 585-218-

9999 or Albany at 518-535-9477 to schedule an initial consultation.