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Essential Checklist: 5 Critical Issues in Health Care AI Vendor Agreements

This reference checklist highlights emerging challenges that legal teams encounter specific to artificial intelligence (AI) vendor agreements in health care settings. Based on our experience developing AI vendor agreement playbooks for health care institutions, here are several of the key issues that require specialized attention beyond standard contract review. To learn more about Epstein Becker Green's AI capabilities, please click here.

1. AI OUTPUT WARRANTIES AND PERFORMANCE SPECIFICATIONS

- ☐ Standard software warranty language modified to reflect the probabilistic nature of AI
- ☐ Specific performance metrics replacing broad accuracy guarantees
- ☐ Clinical validation protocols and testing requirements explicitly defined
- ☐ Model card requirements with comprehensive documentation of algorithm development, training data, testing methodology, and performance metrics
- ☐ Remedies appropriate for health care AI deployment failures

Why This Matters:

Unlike traditional software contracts, most AI vendors explicitly disclaim warranties about output accuracy due to the unpredictable nature of generative AI, thus creating significant risks for clinical applications. Model cards provide standardized documentation of an AI model's performance, limitations, and training data, enabling hospital legal teams to make informed decisions about deployment risks.

2. DATA RIGHTS AND TRAINING RESTRICTIONS

- ☐ Clear restrictions on vendor use of hospital data for algorithm training
- ☐ Explicit prohibition of protected health information use for purposes outside direct service provision
- ☐ Technical requirements for data segregation and de-identification
- ☐ Data rights addressing both inputs and AI-generated outputs
- ☐ Post-termination data handling requirements (return, destruction, retention periods)
- ☐ Patient consent mechanisms for data use in algorithm

Why This Matters:

Many health AI startups are blindsided when learning how the Health Insurance Portability and Accountability Act and state privacy laws limit data use, creating barriers for such activities as machine learning and model training with patient data unless carefully negotiated. Standard confidentiality provisions rarely address algorithmic training adequately.

3. LIABILITY ALLOCATION AND INDEMNIFICATION

- ☐ Clear responsibility allocation between the provider's clinical judgment and AI recommendations
- ☐ Intellectual property indemnification addressing AI-generated content infringement risks
- ☐ Specific indemnification for data privacy and security violations
- ☐ Liability caps aligned with clinical risk profile rather than standard software terms
- ☐ Coverage for algorithmic bias and discrimination claims
- ☐ Defined incident investigation and remediation protocols

Why This Matters:

Emerging litigation risks linked to AI in health care raise complicated questions of accountability and concerns over data lineage and bias. Standard liability provisions often fail to address these unique challenges.

4. GOVERNANCE AND MONITORING REQUIREMENTS

- ☐ Access rights to model performance data and metrics
- ☐ Regular review cadence based on clinical risk tier
- ☐ Transparency requirements for model updates and retraining
- ☐ Performance degradation notification and remediation timelines
- ☐ Customer approval rights for significant algorithm changes
- ☐ Documentation requirements for regulatory compliance

Why This Matters:

The National Institute of Standards and Technology AI Risk Management Framework guides organizations in identifying and managing AI-related risks, offering a risk-tiering system that can be applied to evaluating health care AI products. Few agreements incorporate proper monitoring requirements aligned with this framework.

5. REGULATORY COMPLIANCE AND EVOLUTION

- ☐ Explicit vendor responsibility for maintaining regulatory compliance
- ☐ Clear allocation of responsibilities for Food and Drug Administration-regulated AI applications
- ☐ Compliance with state-specific AI health care regulations
- ☐ Documentation requirements for demonstrating compliance
- ☐ Change management process for addressing regulatory updates
- ☐ Audit rights for compliance verification

Why This Matters:

California enacted SB1120 in September 2024 (effective January 2025), regulating how AI-enabled automated decision tools can be used for processing health care claims, and several other states are considering similar regulations.