



Legal & Regulatory Considerations for HIT Patient Safety Framework Development

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Sources of Legal & Regulatory Authority

- Federal Patient Safety Initiatives
- State Patient Safety Initiatives
- Accrediting Organization Actions
- Fiduciary Duty of Healthcare Governing Boards
- HIT Vendor Contractual Limitations

Federal Patient Safety Initiatives

- 2003 – HIPAA Security Standards requiring appropriate administrative, technical and physical safeguards to ensure the confidentiality, integrity and availability of ePHI
- 2011 – *IOM Health IT and Patient Safety Report: Building Safer Systems for Better Care*, funded by HHS, examining how the use of HIT affects the safety of patient care

Federal Patient Safety Initiatives, Con't

- 2013 – *ONC HIT Safety Action and Surveillance Plan*, a joint HHS and AHRQ project, promoting the use of HIT: (i) to make care safer; and (ii) to continuously improve the safety of HIT itself
- 2014 – *ONC SAFER Guides* offer health care providers an interactive self-assessment tool to evaluate where their EHR is vulnerable to patient safety risks and then determine how to optimize safety

Federal Patient Safety Initiatives, Con't

- 2014 – *FDASIA Health IT Report*, joint FDA, ONC and FCC project, focuses on a risk-based framework for management of HIT functionalities:
 1. Promote the use of quality management principles;
 2. Identify, develop, and adopt standards and best practices;
 3. Leverage conformity assessment tools; and
 4. Create an environment of learning and continual improvement.

Federal Patient Safety Initiatives, Con't

- *FDASIA Health IT Report* also calls for ONC to create a Health IT Safety Center, in collaboration with FDA, FCC, and AHRQ, to develop a sustainable, integrated HIT learning system that avoids regulatory duplication and leverages and complements existing and ongoing efforts
- Focus on safety of EHRs also is in portions of the Stage 2 Meaningful Use requirements adopted for the Medicare and Medicaid Electronic Health Record Incentive Program¹

¹ 77 Fed. Reg. 53968

State Patient Safety Initiatives

- Hospital licensing regulations usually include a provision requiring licensees to comply with the Medicare Conditions of Participation
- Hospital mandatory reporting of Sentinel Events

Accrediting Organization Actions

- The Joint Commission (TJC) Sentinel Event Alert No. 42: *Safely Implementing Health Information and Converging Technologies* (Dec. 11, 2008)
- ONC has contracted to have TJC conduct at least 10 investigations to examine HIT events
 - 5 Hospitals and 5 Ambulatory Sites
 - Enhance use of TJC Sentinel Events Database

Fiduciary Duty of Healthcare Governing Boards

- Healthcare governing boards have a fiduciary obligation to oversee the quality of care and patient safety rendered within their institutions¹
- TJC Standards reinforce that a healthcare organization's "governing body is ultimately accountable for the safety and quality of care, treatment, and services"²
- Medicare Conditions of Participation³

¹ See *In re Caremark International Inc. Derivative Litigation*, 698 A. 2d 959 (Del. Ch. 1996).

² See The Joint Commission Hospital Accreditation Standards, Leadership (LD) Standards, LD.01.03.01, p. 101 (2009).

³ 42 C.F.R. § 482.21: Quality assessment and performance improvement program

Impact of Aforementioned Initiatives on the Standard of Care

- More studies and tools are needed to assist providers with evaluating and reporting HIT-related patient safety issues
- Instructions for SAFER Guides state that they are “for informational purposes only and not intended to be an exhaustive or definitive source”
- Plaintiff’s counsel now has more ammunition to argue that the standard of care has changed with respect to HIT-related errors

HIT Vendor Contractual Limitations

- “Hold harmless” clauses that require HIT purchasers to indemnify vendors for errors, injuries or malpractice claims arising from use of the product
- Limitations of liability which limit the total dollar amount of damages and exclude certain types of damages
- Non-disclosure provisions that prohibit HIT users' open disclosure of identified product defects, glitches or hazards

Consider Measures for a Shared Risk Environment

- Identification of HIT safety measures for ***both*** users and vendors
- Develop safety measures for vendors consistent with ISO/IEC Standard for Risk Management
- Include vendor performance standards based on HIT safety measures in software license and purchase agreements

Consider Measures for a Shared Risk Environment, Con't

- Vendors should notify users if they identify or become aware of software, hardware or other issues that materially affect patient safety
- Vendors should offer solutions to identified issues to all users (e.g., workflow guidance, features that should not be used, software updates)
- Whichever party can best mitigate the risk is the one who should bear that particular risk

Questions

