

## Miscellaneous Current Topics in Healthcare Professional Liability

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CLRS Session HC-2  
September 15, 2011

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September 15, 2011

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### Table of Contents

- Cyber Liability
- Clinical Trials
- Impact of Healthcare Reform



CLRS Session HC-2 2  
September 15, 2011

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**Cyber Liability**




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**Privacy Breach / Cyber Liability**  
**What is Privacy Breach / Cyber Liability?**

- Some actual examples of privacy breach:
  - UCLA – a hacker broke into a university database and stole up to 800,000 people's records (SSN, birth dates, addresses, etc.)
  - University of Utah Hospitals & Clinics – notified 2.2 million patients and payers that backup tapes containing billing information were stolen out of a storage company car
  - Johns Hopkins – more than 10,000 patients affected by a data breach. A hospital employee in patient registration used patient information in an identity theft scheme
  - Beth Israel Medical Center – a computer service vendor failed to restore proper security settings on a computer and it became infected with a virus that transmitted data files offsite
- Cyber Liability includes lawsuits arising from:
  - Dissemination of unauthorized private information, intellectual property infringement, libel, slander, invasion of privacy, system security failures that result in harm to third parties, etc.

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**Privacy Breach / Cyber Liability**  
**Laws and Regulations**

- Security Breach Notification Laws
  - Currently 46+ states have notification laws
  - Began with California Data Breach Disclosure Law (2003)
  - Most state laws require organizations to immediately disclose a data breach to customers (usually in writing)
  - A number of bills have been introduced in the U.S. Congress that would establish a national standard for security breach notification, but none have passed as of yet
- National PHI (Protected Health Information) Legislation
  - HIPAA – establishes regulations for the use and disclosure of PHI
  - HITECH – enacted in 2009 as an enhancement to HIPAA
    - » Establishes new, more severe penalties for non-compliance

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**Privacy Breach / Cyber Liability**  
**Cost of a Data Breach**

- The average cost of a data breach is in excess of \$200 per record and rising\*
- What is included in the cost of a data breach?
  - Forensics and Legal Analysis
  - Notification Costs
  - Call Center
  - Credit Monitoring
  - Replacement Cards (if applicable)
  - Lost Business
  - Reputational Risk

\* Source: Ponemon Institute / PGR Report 2009

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**Privacy Breach / Cyber Liability**  
**Coverage Considerations and Exposure Factors**

- Coverage Considerations
  - First Party Coverage Considerations – business interruption, loss due to theft of information assets, cyber extortion, crisis management, breach response, identity theft expenses, regulatory penalties
  - Third Party Coverage (Cyber Liability)
- Exposure Factors
  - Size (Revenue) and type-of-operation
  - System and laptop security policies
  - Third-party agreements (e.g. website, ASP, backup, etc.)
  - Disaster Recovery plans
  - Incident Response plans
  - Security Breach history

 CLRS Session HC-2  
September 15, 2011 7

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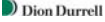
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**Malpractice Policy Considerations**

- Physicians
- Hospitals

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September 15, 2011 8

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**Clinical Trials**




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**Clinical Trials Liability**  
**What is Clinical Trials Liability?**

- Clinical Trials
  - Definition and Issues
- Entities with exposure:
  - Sponsoring Organizations
  - Physician Investigators
  - Hospitals where Equipment is Used
- Arising out of:
  - Clinical Research Services
  - Medical Services
  - Billing-Related Activities

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**Clinical Trials**  
**Impact on Medical Malpractice**

- Sponsors of Clinical Trials include:
  - Government agencies such as the National Institute of Health (NIH), the Department of Defense (DOD), and the Department of Veteran's Affairs (VA)
  - Pharmaceutical, biotechnology and medical devices companies
  - Individual researchers
  - Health care institutions such as academic medical centers and health maintenance organizations (HMOs)
- Medical Malpractice policies may or may not include coverage for liability arising out of clinical trials

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**Clinical Trials**  
**Examples of Claims**

- Suit against the hospital and manufacturer by the widow of an artificial heart recipient alleging that information they received prior to his implantation was insufficient to properly inform them of the ramifications of their decision to participate.
- Suit against research center from patients suffering from leukemia who died after participating in bone marrow transplant trials.
- Suit against university after death during a gene therapy trial, raising allegations that subjects were not provided with sufficient information regarding the risks of liver damage.



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**Clinical Trials Liability**  
**Exposure Factors**

- Exposure Factors
  - Number of Studies
  - Institutional Review Board ("IRB")
  - Informed Consent
  - Financial Incentives / Disclosure
  - Outsourced functions, e.g. patient recruitment
  - Experience level of Physician Investigators ("PI's")
  - Monitoring



CLRS Session HC-2 13  
September 15, 2011

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**Impact of  
Healthcare  
Reform**



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**Impact of Healthcare Reform**  
**Current Status**

- Patient Protection and Affordable Care Act (PPACA), signed March 23, 2010
- Health Care and Education Reconciliation Act of 2010 (H.R. 4872), which amended the PPACA and became law on March 30, 2010
- States and others have filed suits in federal court challenging the constitutionality of the PPACA
  - Appellate Courts split on constitutionality
  - Different rulings on individual mandate, and whether certain individuals provisions can be ruled unconstitutional without the entire Act being struck (severability)
  - Supreme Court expected to review

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**Impact of Healthcare Reform**  
**Some Potential Implications for Medical Malpractice**

- Creation of new entities:
  - Healthcare Exchanges
  - Accountable Care Organizations
- More patients in the system
- Government involvement in quality of care standards and measurement
- Changing economics of physician / hospital alignment
- Consolidation among hospitals, physicians and health insurers

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**Impact of Healthcare Reform**  
**Accountable Care Organizations (“ACO”s)**

- New model under PPACA organization for providing care for Medicare patients consisting of hospitals, physicians, etc. involving quality measures, Shared Savings Program
- Issues with professional liability/medical malpractice coverage:
  - ACO structure and organization
  - Risk Management structures within the ACO context
  - Concept of tying payment to outcomes
  - Vicarious liability issues

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**Impact of Healthcare Reform  
Possible System Changes**

- Malpractice Reform Provisions in the Act
  
- Other Tort Reform trends at the state and federal levels
  
- Organizational Liability and “no-fault” Systems



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