

SHARING CLINICAL DATA: Legal and Privacy Issues

Health Information Technology
Summit
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Legal Issues Overview

- Data Privacy (and Security)
- Fraud and Abuse
- Anti-Trust
- Medical Malpractice

Data Privacy in a Hub and Spoke Model

For Each Participant Determine HIPAA Status

- Covered Entity
- Business Associate

- Most Participating Institutions and Organizations are Covered Entities
- Most Hub Organizations are not Covered Entities
 - Clearinghouse exception

Is Hub a Business Associate?

■ Factors to Consider:

- Managing data on behalf of participants
- Data access rights for any purpose
- Merely a conduit (like the phone company)

Usually, participants that exchange data through the Hub are not business associates of each other.

Legal Obligations

Business Associate Agreement (can be included in master contract)

Covered Entity ...

- Is liable for actions of business associate only if the Covered Entity has knowledge of a breach and fails to act.
- Is required by contract to notify business associate of breach.
- Should have procedure for escalation and remediation.

Privacy and Security Oversight of the Hub

- Business judgment
- Sensitivity of data and reputational harm that can result from breaches suggests some diligence is appropriate, even if not required by law.
- Third party can monitor or certify compliance with standards.
- Audit requirement is two-edged sword.

Privacy Policies

Policies Should Increase in Specificity as Sub-Unit Grows Smaller

- NHIN
- SNO
- Participant

Policies Needed For:

- Notice to Consumer
- Uses and Disclosures of Health Information
- Information Subject to Special Protection (HIV, substance abuse, mental health)
- Minimum Necessary
- Role-Based Access
- Amendment of Data
- Requests for Restrictions
- Mitigation
- Limited Data Sets/De-identification

Patient Control of Records

What HIPAA Requires

- Treatment
- Payment
- Health Care Operations
- Public Health
- Research

Should Institutions Go Beyond HIPAA?

- Notice and Opt-Out
- Prior Consent

Other Legal Issues

Stark and Anti-Kickback

- Structure and Financing of RHIO ~ SNO
- Outfitting physicians with HIT (community-wide health technology exception inadequate)
- Current exceptions inadequate

Anti-trust

- Does RHIO ~ SNO advantage some providers over others?
- To the extent the benefits can be shown to outweigh anti-competitive impact, they are not likely to violate federal anti-trust laws.

Medical Malpractice

Concern among physicians that availability of information will increase potential liability. In the end, the net effect of EMR will likely be to improve care and lower liability risks. At this point, the liability question is unanswered and the cause of significant anxiety among some physicians.