Go Jump in a (Data) Lake

HALL RENDER
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HEALTH IT SEMINAR | INFORMATION TECHNOLOGY & DATA PRIVACY AND SECURITY

A SEMINAR FOR HOSPITAL AND HEALTH SYSTEM COUNSEL AND EXECUTIVES

Go Jump in a (Data) Lake

Managing Internal and External Requests for Big Data and Other Size PHI

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Agenda

- What is a Data Lake and what does Big Data mean?
- Legal Considerations
- Creating and Using a Data Access Group
- Licensing Data
- Case Scenario

Big Data

- Big Data
  - Large or complex data that is difficult to manage with traditional methods, software or hardware
- Data Lake
  - Storage repository that holds a vast amount of raw data in its native format, including structured, semi-structured, and unstructured data
- Big Data Analytics
  - Process of examining collected data to uncover hidden patterns, correlations and other useful information to predict outcomes, steer strategic decision-making, and improve core activities

Baiting the Hook

- Who are the legal entities? What types of entities are they?
- What is the relationship between the entities?
- ***What is the HIPAA status of the entities?***

HIPAA Status

- ***What is the HIPAA status of the entities?***
  - Health care provider covered entity
  - Health plan (health insurance company/HMO) covered entity
  - Employer-sponsored group health plan covered entity
  - Business associate
  - Affiliated covered entity (ACE)
  - Organized health care arrangements (OHCA)

Casting the Line

- ***What data do they want***?
  - Identifiable data (PHI, PII)
  - De-identified data
  - Limited data set
  - Competitively sensitive data
- ***What do they want to do with the data***?
  - Treatment, payment, health care operations
  - Research
  - Monetize (analyze, sell, develop)
- ***What rules apply to the data?***

What Rules Apply?

- ***What rules apply to the data***?
  - Privacy & Security
    - US laws – HIPAA, Part 2, Common Rule, GINA
    - State laws – sensitive information (HIV, mental health)
    - International laws – GDPR
  - Antitrust
  - Fraud and Abuse
  - Intellectual property

What Other Rules May Apply?

- 21st Century Cures Act
  - Interoperability and information blocking
- Special program rules
  - ACO / Medicare Advantage
- Private contractual restrictions
  - Conditions imposed by original source
- Other
  - Resource limitations and mission scope
  - Business and legal risks

Reeling It In

- What agreements will be in place?
- What safeguards will be required?
- How will the data be transferred or accessed?
- How will the data be maintained/returned/destroyed?

Data Access Group – Structure

- Combination of previously separate work groups
- Primary objective is the establishment of guidelines for the access and use of data throughout ProMedica
- Serves as final approval authority on data access
- Membership
  - IT; Compliance; Audit; Privacy; Legal; Research; HIM; Population Health

Data Access Group – Purpose

- Tasked with the following:
  - Establishing and revising policies and guidelines
  - Communicating guidelines throughout the system
  - Reviewing non-routine access requests
  - Reviewing strategic initiatives that involve data access or sharing and ensure appropriate access, use, and disclosure
  - Auditing pre-existing access rights for consistency with developed guidelines

Data Access Group – Lessons Learned

- Challenges

- Successes

Licensing Data – The Basics

- Define data
  - De-identified
- Use of data
  - Non-exclusive
  - Internal use only – restrict affiliate sharing
  - May not re-identify
- Pricing
  - What is fair market value?
  - Anti-Kickback Statute – no referrals required

Licensing Data – Other Concerns

- Intellectual property
  - Background IP
  - Collaborative IP
- Indemnification
  - Violation of use restrictions – re-identification
  - Excepted from any limitation on liability
- Media rights
  - Written approval
  - Right to refuse

Licensing Recommendations

- Consider nondisclosure agreement
- Identify business, legal concepts important to the organization
- Create a data licensing template, with a focus on the above
- Identify terms that are non-negotiable or require escalation
- Identify who can approve, who can sign, the process

Case Scenario – Baiting the Hook

- Players and HIPAA Status
  - Clinically Integrated Network (CIN) = OCHA
  - Multi-Specialty Physician Group = HCP CE
  - Virtual Care Scheduling Vendor (for CIN) = BA
  - EMR Vendor (for physician group) = BA

- Relationships
  - Physician Group is part of CIN/OHCA
  - Scheduling Vendor signed BAA with CIN
  - EMR Vendor signed BAA with parent of Physician Group

Case Scenario – Casting the Line

- Data and Purpose
  - EMR Vendor to upload PHI from Physician Group to Virtual Care Scheduling Vendor for CIN's treatment and health care operations purposes
- Legal considerations
  - HIPAA: BAAs in place to cover "affiliates"
  - HIPAA: Patients in common
  - Part 2: No Part 2 providers or SUD info
  - GDPR: No data controllers or data processors (yet)

Case Scenario – Reeling It In

- EMR vendor requires a signed “authorization and consent” form from Physician Group before agreeing to push PHI to Virtual Care Scheduling Vendor

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