Academic Medical Center Compliance: Tips, Traps, and Emerging Best Practices

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Structure of Duke Health

Duke University

Duke University Health System
- Duke University Hospital
- Duke Regional Hospital at Durham
- Duke Regional Hospital at Morehead
- Duke Regional Hospital at Warrenton
- Duke Regional Hospital at Smithfield

School of Medicine

School of Nursing

Private Diagnostic Clinics

Separate from for profit corporation

Compliance Effectiveness

- Open communication
- Collaboration among management, operational and compliance in evaluation of activity
- Create processes to develop compliant operations with compliance controls
Conflict of Interest

• Evaluate Financial Relationships with Industry
• Benefits of Industry and Academic Medical Centers/Physicians working together
• Risk of creating bias that may affect results/interpretations
• Risk of appearance of referral arrangements
• Evaluation of Research, Clinical and Institutional activities
• COI may affect research, faculty technology development, clinical care, purchasing and fundraising
• Compliance Control
• Policy and management plan
  – Research, Purchasing, Clinical
  – Patient Awareness/Communication

Conflict of Interest Scenario

• Surgeons’ creation of clinical app and considers commercialization
• Considerations
  – Research vs. Quality Improvement
  – FDA regulated
  – App meet regulatory and risk management requirements
  – Faculty owned app becomes vendor
  – Use in clinical care, efficacy
  – Patient Awareness

Conflict of Interest Scenario

• Considerations
  – Self interest versus Medical Center activity
  – Use of Institutional assets
  – Is Faculty a Vendor?
    • Designation of Representative to interact with facility/physicians
    • Contract
    • Indemnification and Insurance
  – Patient data
  – IT Security
  – Privacy – Privacy Policy/Terms and Conditions
  – Evaluation within facility
  – Patient Awareness
Clinical Care Conflict of Interest

- Clinicians’ activities:
  - Speaker Bureau/Promotional Speaker
  - Consultants for Device/Drug Companies
  - Development/Test new product

- Considerations:
  - Anti-kickback considerations
    - Fair Market Value
    - Services provided
  - Internal Gift policy

Clinical Care Conflict of Interest

Compliance Controls

- Prohibit Speaker Bureau/non-CME approved Participation
  - Faculty independent material required
  - Content Expert

- Evaluation of Product Process

- Anti-kickback Settlements
  - Device/Pharmaceutical Companies

- Internal Gift policy
  - No payment for Advisory Board participation (evaluate purchasing involvement)
  - No payment for review of new product
  - No meals on or off campus

Warner Chilcott Settlement

- Warner Chilcott resolved kickback investigation paying $125 million and receiving permanent exclusion from Medicare and Medicaid participation for illegal marketing of 7 brand name drugs.

- In addition to corporate resolution, individual settlements

- Allegations that President instructed sales force to provide free expensive dinners and questionable speaker fees in exchange for prescriptions.
Concurrent versus Overlapping Surgery

- **Concurrent surgery**
  - Surgeries where critical or key portions performed simultaneously
- **Overlapping surgery**
  - Surgeries where non-critical or non-key portions performed simultaneously
  - Critical or key portions of 1st surgery complete before becoming involved in second surgery
    - Documentation of presence during critical or key portions

**Revenue Cycle – Concurrent Surgery**

- Compliance Controls
  - Policy
    - 2nd surgeon immediately available if Attending involved in 2nd surgery
    - Patient consent of overlapping procedure
    - Definition of "Immediately Available," e.g., same surgical platform
    - Documentation of participation in critical or key portions
  - Daily scheduling review meeting
  - Documentation and Time audits

**Revenue Cycle – Clinical Research**

- National Coverage Analysis
  - Involvement of PI and Office of Clinical Research
  - Initiation Meeting – PI, clinical research team, Revenue Cycle, Compliance, and Office of Clinical Research
    - Review of protocol
    - Billing grid build – charge assignment
    - Review of Medical necessity/coverage determinations
    - Review of CPT codes
- Use of Epic for research billing
  - Charge assignment review built into system
  - Continue 100% pre-bill review
Privacy – Hybrid/Affiliated Covered Entity

- Duke Health Enterprise (Covered Entity/Components)
  - Duke University Health System
  - Duke Primary Care Physicians
  - Duke Home Care & Hospice
  - Duke School of Medicine
  - Duke School of Nursing
  - Other supporting departments
  - Administrative Services, e.g., IT, Procurement, Legal
- Established policies & procedures for sharing PHI with university components (non-covered entity)
- Established review for PHI requests

Privacy Rule permits creation of ACE/Hybrid entity
- Segregate care and non-care components of university
- Segregate components that provide covered functions (business associate functions)
- Covered component restricted to sharing PHI with non-covered component
  - Comply with Privacy Rule for disclosures
  - Business Associate Agreement for potential non-routine access

Privacy Rule Requirements
- Designated status in writing
- Inventory of entities/services lines/administrative services
- Comply with HIPAA Policies & Procedures
- Orientation and Annual training
- Risk Analysis

Compliance Controls
- ACE Policies & Procedures
- Reevaluation with new entities and entity changes on a routine basis, with minimum of annually
- Train staff of PHI restriction; not mere paper policy
- Monitor as Big Data/Population Health activities grow
Privacy – Hybrid/Affiliated Covered Entity

University of Massachusetts Amherst Settlement

Resolution Agreement describes:
• Language, Speech and Hearing Center, not included in health care component, workstation infected with malware
  – Center not held to HIPAA policies and procedures
  – Center not implement technical security measures
• U Mass had not conducted thorough Risk Analysis

Privacy – Access to Clinical Data

Governance of Clinical Data
• Activities – Population Health, Quality/Outcome Improvement, Research
• EHR seen as treasure trove
  – Internal use
  – Non-covered care component staff
    • Services to Health Care Component, e.g., statistician
    • Research
    • Desire to develop predictive analytics
  – External
    • County Health Department
    • Registries

Compliance Controls:
• Governance of Clinical Data
• Covered Entity review process
• Considerations:
  – Population Health
    • De-identified information
    • Limited data set
  – Research – Health Care IRB approval
  – Quality Improvement – Health Care approval
• Created database within Secure Environment
• Creation of clinical database; not direct access to EHR
• User Provisioning Categories
  – De-identified information access
  – Limited data set access
  – PHI access
• Access Approval
  – Research – IRB
  – Quality – Internal staff
    – Departmental approval
  – External – Privacy Office
• Data Analytics Oversight – implementation of data stewards