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

Colleen Shannon
Chief Compliance and Privacy Officer

Structure of Duke Health

Duke University

Duke University Health System
- Duke University Hospital (Teaching Hospital with 957 beds)
- Duke Raleigh Hospital (186 beds)
- Duke Regional Hospital (369 beds)
- Duke Home & Hospice
- Duke Primary Care Physicians (Separate not-for-profit corporation)

School of Medicine

School of Nursing

Private Diagnostic Clinics
(SoM faculty clinicians)
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
    - Referrals
  - 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

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.

Revenue Cycle – Concurrent Surgery

Concurrent verses 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 – Hybrid/Affiliated Covered Entity

• 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
IT Security

- 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