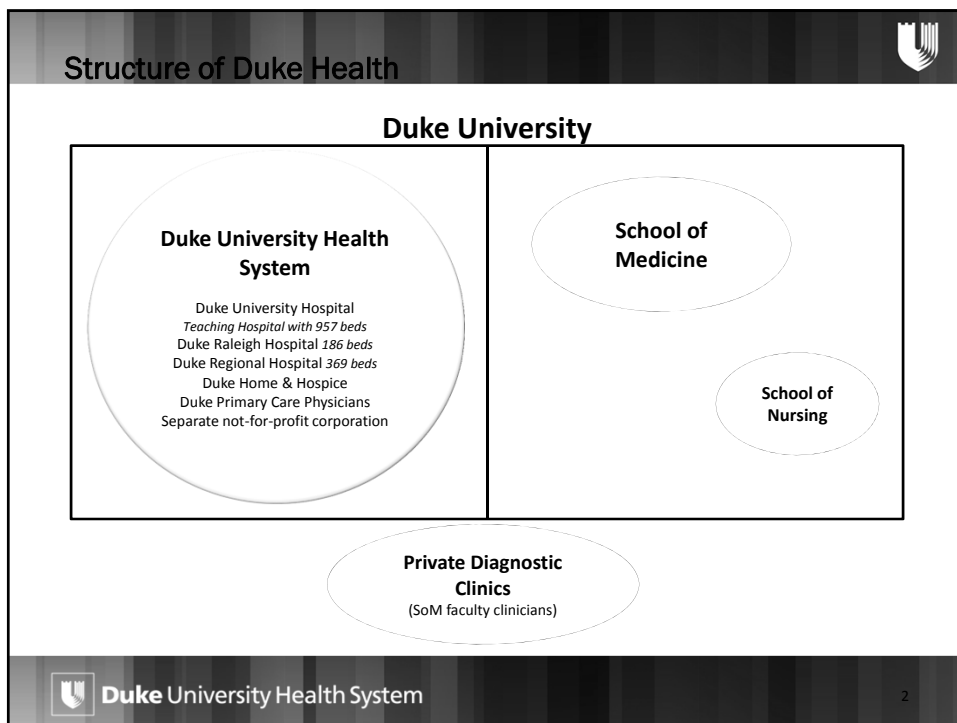# Academic Medical Center Compliance: Tips, Traps, and Emerging Best Practices

Colleen Shannon
Chief Compliance and Privacy Officer

Duke University Health System

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)

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Compliance Effectiveness

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

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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

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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

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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

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2/24/2017

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

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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

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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.

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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

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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

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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

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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

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Privacy – Hybrid/Affiliated Covered Entity

- 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

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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

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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

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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

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Privacy – Access to Clinical Data

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

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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

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