
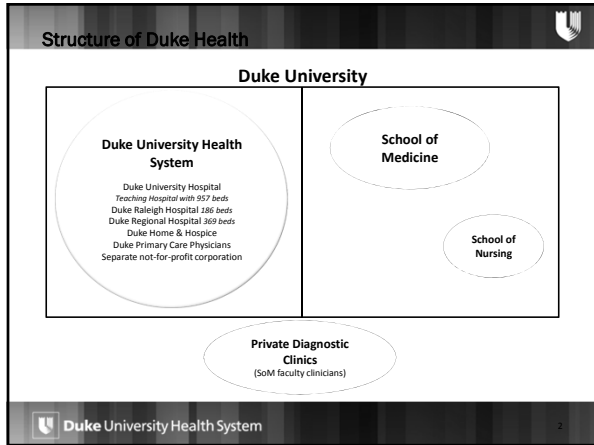


Academic Medical Center Compliance: Tips, Traps, and Emerging Best Practices


Colleen Shannon
Chief Compliance and Privacy Officer





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

Duke University Health System

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

Duke University Health System

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

Duke University Health System

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

Duke University Health System

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

Duke University Health System

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.

Duke University Health System

Revenue Cycle – Concurrent Surgery

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

Duke University Health System

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

Duke University Health System

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

Duke University Health System

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

Duke University Health System

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

Duke University Health System

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

Duke University Health System

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

Duke University Health System 16

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


Duke University Health System 17

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

Duke University Health System 18

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

 Duke University Health System 19
