Apologies and Reporting
of Medical Errors

PRESENTER

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Topics Considered In This Presentation

- Scope of the Medical Error Problem
- State Apology Laws
- Federal and State Mandatory Reporting Statutes, Regulations and Regimes
- Voluntary Reporting under the PSQIA
- Compliance Considerations – Designing an Effective Compliance System

Scope of the Medical Error Problem

- 1999: “TO ERR IS HUMAN” Report of the National Institutes of Medicine on medical errors in acute care hospitals
  - 44,000-98,000 avoidable deaths per year

- 2006 – Institutes of Medicine report on Adverse Medication Errors ("AME’s")
  - 1.5 Million AME’s per year in the United States (in-patient and out-patient)
  - Each AME adds approximately $8,750 to cost of hospital stay
  - 400,000 AME’s occurring in U.S. Hospitals could cost as much as $3.5 Billion
Scope of the Malpractice Crisis

- Total malpractice payments jumped from:
  - $2.1 Billion in 1991
  - $4.1 Billion in 2004

- Malpractice insurance premiums rose by 15% between 2000 -2002:
  - Twice as fast as healthcare spending per person

  Source: Congressional Budget Office

Response to Medical Error Problem

- Federal Government initially left response largely to the states
- States responded in two primary ways
  - Mandatory Reporting Statues
  - Statutes Encouraging Apologies
- Federal Government now taking a lead role with the PSQIA and other quality measures
State Apology Laws

- “Apology Laws” generally provide that a medical provider’s expression of an “apology” to a patient following an adverse event cannot be used as evidence in a later malpractice lawsuit.

State Apology Laws

- Goal of “Apology Laws” is to:
  - Improve patient care by eliminating barriers to discussions about adverse events
  - Reduce the number of claims and lawsuits arising from unanticipated outcomes
State Apology Laws

- 35 States have “Apology Laws”
- Some are statutes, while others are contained within the state’s rules of evidence
- Bills pending in a number of states: PA
- Federal Bill possible:

State Apology Laws

- **Potential Impact:**
  - Can reduce malpractice actions
  - Can make settlement more likely
  - Can show employees and patients desire to recognize and learn from errors
- **Procedures for Making Apology:**
  - Plan ahead so that you known how and when to make the apology
State Apology Laws

- Statutes Differ in 5 Main Areas:
  - Type of covered conduct
  - Context of Expression
  - By Whom Apology Made
  - To Whom Apology Made
  - Type of Sentiment Covered

State Apology Laws

- Type of Communication Protected
  - Majority protect written and oral statement and conduct (“statements, affirmations, gestures, and conduct”)
  - Vermont does not protect written apologies
  - Utah does not protect unsworn statements
State Apology Laws

**Who Makes the Apology:**
- 21 States limit protections to apologies made by a healthcare provider
  - Most of these permit apology by employee/agent
- 15 States have no limit on who makes the apology

State Apology Laws

**Who Receives the Apology:**
- 29 States restrict protections to apologies made to the patient, patient’s family, and/or patient’s representative
- 2 States allow apologies to friends
- 2 States allow apologies to domestic partners
- Note: Definition of “family” and “representative” varies
State Apology Laws

**Sentiments Protected:**
- Most States protect expressions of “sympathy” “compassion” and discussions about future plan of care
- 19 States **Do Not** protect statements acknowledging fault or liability
- 5 States explicitly protect expressions of mistake, error and fault

**Context of the Apology:**
- 11 States require the apology relate to an unanticipated outcome of medical care
- 6 States permit apology related to any accident, whether medical or otherwise
- A number of states limit the amount of time during which an apology may be made
Federal And State Mandatory Reporting Rules - Overview

- Wide Range Of Mandatory Reporting Requirements For Hospitals and Providers - federal, State, Private Accreditation Organizations
- Wide Range Of Reportable Events - "medical errors," "adverse outcomes," "adverse events," "neglect," "abuse," "death" "central line infections"
- Wide Range Of Causation Or association-“suspected abuse,” “in connection with drug or device”
- Wide Range Of Regulatory Interest And Use Of Data

FEDERAL REPORTING REGIMES

- DEVICE USER FACILITY ADVERSE EVENTS-21 CFR 803.
- VACCINES HEALTH CARE PROVIDER REPORTS-42 USC 300aa-25
- BLOOD PRODUCTS-7 CFR 606.
- GOOD TISSUE PRACTICES
- RESTRAINTS (Medicare Conditions of Participation)
State Mandatory Reporting Statutes

- 25 + States currently have some form of mandatory reporting statute
- Statutes vary widely:
  - Different definitions of “Adverse Events”
  - Different time frame for reporting
  - Different information required to be reported
  - Different consequences for failure to report (criminal, civil, administrative)
  - Different “confidentiality” provisions

State Mandatory Reporting Statutes

- “Adverse Events” Defined in 3 Ways:
  - **Specific List**: Based on National Quality Forum’s List of 27 Serious Reportable Events (CT, IL, MN)
  - **Broad Definitions**: Can even include “near misses” (CA, PA, NJ, TN)
  - **Narrow Definitions**: Applies to specific types of facilities (OH)
Consequences For Failure To Report Errors

- Civil Monetary Penalties
- Criminal Penalties
- State Licensing Problems (Institution and Providers)
- Failure to Report as Evidence of Intent in False Claims Act Case

PATIENT SAFETY AND QUALITY IMPROVEMENT ACT OF 2005
(42 U.S.C. § 299C-21 et seq.)

- Voluntary Reporting System
- Provides protection for reporting to Patient Safety Organization ("PSO") certified by HHS
- HHS regulations took effect Jan. 2009
- Strong Federal Confidentiality Protections for certain reports to PSO’s
Federal Reporting
PSQIA Regulations

- Patient Safety Organizations (PSO’s):
  - Mission and Duty designed to improve patient safety and quality of healthcare
  - Appropriately qualified staff
  - Has Bona-fide contracts with more than one provider for reviewing work product
  - Not a component of a health insurer
  - If part of another entity, work product must be kept separate
  - PSO collects work product in a standardized manner
  - Approved by HHS for 3 year periods

Federal Reporting
PSQIA Regulations

- Patient Safety Work Product:
  - Information (oral/written) that may improve patient safety, health care quality/outcomes
  - Must be gathered for reporting to a PSO, or developed by a PSO for patient safety activities
  - Items not protected: patient medical records, billing/discharge information, “original patient or provider information,” other information collected, maintained or developed separately from patient safety evaluation system
Federal Reporting
PSQIA Regulations

- **Confidentiality/Privilege of Work Product:**
  - PSWP not subject to civil subpoena, discovery in civil, criminal or administrative cases, FOIA, with 10 exceptions – 73 Fed. Reg. 70806
  - Civil monetary penalty of up to $10,000 per violation for knowingly or recklessly divulging PSWP.
  - Employer responsible for violations of employees and agents.

Federal Reporting
PSQIA Regulations

- PSQIA Does **Not** Preempt Federal and State Mandatory Reporting Rules
- Broad Whistleblower Protection for Reporting to PSO
- HHS Anticipates 45% of Hospitals Will Participate in PSQIA by 2012
- HHS anticipates costs will reach $186.5 Million by 2012
Federal Reporting
PSQIA - Whistleblower protection

- "A provider may not take an adverse employment action. . .against an individual. . .Based upon good faith reported information. . .To the provider. . .Or to a patient safety organization.
- "Adverse employment action" includes credentialing and certification. See generally (Burlington Northern & Santa Fe Ry. v. White, 2006 U.S. LEXIS 4895 (2006))
- Equitable relief authorized "for any aggrieved individual" to enjoin any violation or for reinstatement and back pay

Apology – Reporting
Compliance Considerations

- Best practice is to develop and implement comprehensive step-by-step policy for dealing with adverse events (both for reporting and apology)
- Make sure all interested parties know duties and limits of reporting rules and apology protections
- Train all interested parties on the policy
Pathway for Disclosure

Discovery of Adverse Outcome

Mitigate Harm to Patient

Notify Treating & Attending Physician, Nurse Manager, Risk Manager and Others
Investigate Causes and Circumstances
Complete Occurrence Report or PEERS Report
Offer Spiritual Care and Employee Assistance Program

T Treating Physician, Risk Manager, Nurse Manager Agree on Time, Manner, Who Will Disclose or Whether to Disclose

No

Refer to Ethics Team

Ethics Team Makes Recommendation To Hospital Administration

Hospital Administration & Ethics Consult Team Representative Jointly Develop Decision About Disclosure

Hospital Administration Notifies Treating & Attending Physicians, Risk Manager & Nurse Manager of Action to Be Taken

Yes

Notify Attending Physician Prior to Disclosure and Offer Opportunity to Participate

Provide Apology, Disclosure, Further Need For Medical Attention, Second Opinion and Spiritual Care Consultation

Disclose Recommended

Document Elements of Disclosure in Medical Record

Disclosure Not Recommended

Identity & Advise Stakeholders of Rationale

IMPLEMENTATION CONSIDERATIONS OF A DISCLOSURE/ APOLOGY PROCESS

- Responding Justly to Adverse Outcomes Toolkit
  - Template policy
  - Frequently Asked Questions
  - White Paper: Disclosure Skills and Liability Issues
  - White Paper: Physician Insurance Company Positions
  - Scenario-based coaching tools
  - Audience-specific training
    - Governance
    - Physicians
    - Managers and Leadership
    - Associates
Apology Program Resources

- National VA Disclosure Policy
- University of Mich. Full Disclosure Policy
  www.med.umich.edu/patientsafetytoolkit/disclosure/disclosure.doc

Conclusion

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