

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 providers expression of an "apology" to a patient following an adverse event can not 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 know 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

State Apology Laws

- 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

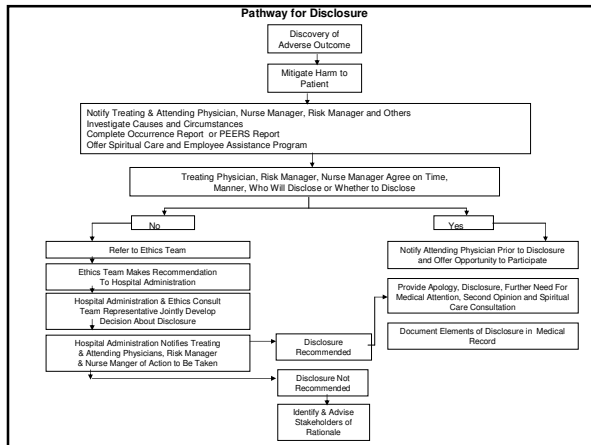
- PSQIA Does **Not** Preempt Federal and State Mandatory Reporting Rules
- Broad Whistleblower Protection for Reporting to PSO
- HHS Anticipates 45% of Hospitals Will Participate in PSQIA by 2012
- HHS anticipates costs will reach \$186.5 Million by 2012

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



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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