HCCA's 12TH ANNUAL COMPLIANCE INSTITUTE

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MANDATORY REPORTING OF ADVERSE EVENTS, NEAR MISSES, AND MISTAKES FOR ACUTE CARE HOSPITALS

HCCA HEALTH CARE COMPLIANCE ASSOCIATION

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TOPICS CONSIDERED IN THIS PRESENTATION

- Scope of the Adverse Event / Non-Reporting Problem
- Federal and State Mandatory Reporting Statutes, Regulations and Regimes
- Consequences for Failing to Report
- Legal Protections Given to Reporting
- Compliance Considerations – Designing an Effective Compliance System

SCOPE OF THE ADVERSE EVENT / NON-REPORTING 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
  - Lucien Leape analysis-systemic problems, not individual failures, are responsible for most errors
  - First step in addressing system problems-accurate and complete data

SCOPE OF THE PROBLEM – MEDICATION ERRORS

- 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

HOW SIGNIFICANT IS THE ADVERSE EVENT PROBLEM

- HealthGrades, a for-profit evaluator of hospitals for consumers (Healthgrades.com) does annual study: "Patient Safety in American Hospitals"(2006)
- of 304,702 deaths among patients with one or more "patient safety incidents" 250,246 were "potentially preventable"
- 1.24 million patient safety incidents in 40 million Medicare hospitalizations over three years-$9.3 billion in excess costs
- Walter Reed Outpatient Failures of Care

SCOPE OF THE PROBLEM - EXAMPLES OF THE ERRORS

- "Failure to Rescue"-patient does not recover from a hospital-based complication (e.g., pneumonia)
- Hospital acquired central line infections
- "Post-operative infection"
- Medication errors
- Washington Post reporter Gilbert Gaul series-July 2005- "Inefficient Spending Plagues Medicare" (discussion of Florida hospital infection issues, failure of JCAHO oversight)

HOW SERIOUS IS THE NON-REPORTING PROBLEM?

- Baltimore Sun, September 30, 2005:
- "There needs to be a cultural change at hospitals." Carol Benner, former Director of Maryland's Office of Health Care Quality. "Some hospitals still want to sweep things under the rug.
- In Maryland, 10 hospitals out of 69 reported half the adverse events. 27 hospitals reported no adverse events.
- At present, underreporting is the norm.
- Dr. Steven Miles, U of Minnesota- 2002 "Concealed Nursing Home Deaths"-nearly half of nursing home reported causes of death are inaccurate-destroyed or altered records, warnings to employees not to report

SCOPE OF THE PROBLEM – RESPONSES

- "To Err is Human" recommended mandatory reporting of medical errors, accidents, and near misses-builds on aviation safety model
- Congress' response-start with state mandatory reporting systems, see if national program needed
- 2007-30 states have mandatory reporting systems for at least some events for acute care hospitals (See, Chapter in 2007 Health Law Handbook (Gosfield, ed ;National Academy for State Health Policy website www.NASHP.org)

SCOPE OF THE PROBLEM – RESPONSES

- Most acute hospital mandatory reporting statutes and regulations are new
- Case law on failure of mandatory reporting developed mostly in FDA cases (e.g., Section 303 of the Food, Drug and Cosmetic Act) and the Nursing Home Reform Act(42 U.S.C. §§ 1395i-3(a)-(h), 1396r(a)-(h)) with longstanding mandatory reporting requirements.
- Increasing scrutiny of reporting failures by journalists, regulators, whistleblowers
- Catastrophic events-angels of death, killer bugs, impaired or incompetent surgeons
- Raising the bar-Institute for Healthcare Improvement ("100,000 lives campaign") Medicare reporting, JCAHO standards, state reporting (Pennsylvania as model)

FEDERAL AND STATE MANDATORY REPORTING RULES

- WIDE RANGE OF MANDATORY REPORTING REQUIREMENTS FOR ACUTE CARE HOSPITALS-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.
- RESTRAINTS (Medicare Conditions of Participation)

Physician Quality Reporting Initiative of 2007

- CMS Program
- Voluntary Reporting of 74 specified quality measures
- Financial Incentive of up to 1.5% of total allowed charges, subject to cap, for physicians who participate
- 2008 Program similar in many respects to 2007 Program

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 Reporting Statutes (PA)

- Act 13 of 2002, 40 P.S.A. 1303. – requires mandatory reporting to the Patient Safety Authority and the Department of Health by hospitals of “serious events” and “incidents” starting June 2004 (14,000 events in 2004)
- Requires designation of patient safety officer and patient safety committee, patient safety plan, reporting scheme
- Prohibits retaliation against employee for reporting serious event or incident
- Requires written notice to patients of certain events

STATE REPORTING STATUTES (Missouri, Ill., NY, & other states)

- Missouri Healthcare Associated Infection Reporting System (MHIRS)
- dhss.mo.gov/MHIRS
- Mandatory reporting from hospitals and ambulatory surgery centers about central line and surgical site infections
- NY had original system; Illinois new in 2006

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

- Provides protection for reporting to Patient Safety Organization ("PSO") certified by HHS
- Requires HHS Regulations – Not Yet Issued
- Strong Confidentiality Protections for certain reports to PSO's

FEDERAL REPORTING STATUTE – 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

CONSEQUENCES FOR FAILURE TO REPORT MEDICAL ERRORS – EXCLUSION

- American Healthcare Management v. InspectorGeneral(www.hhs.gov/dab/decisionsCR1278) (February 15, 2005)
- Misdemeanor conviction of parent company of a skilled nursing facility for failure to report elder abuse is a conviction which relates to" neglect or abuse of patients in connection with delivery of a healthcare item or service."
- 5 year exclusion upheld

CONSEQUENCES FOR FAILURE TO REPORT MEDICAL ERRORS – CRIMINAL PENALTIES

- "If the circumstances give rise to an objective basis for suspecting that abuse occurred, the reporting is mandatory. The duty to investigate and authority to determine whether abuse actually did occur are vested in outside agencies." People v. Davis, 25 Cal. Rptr. 3d 92,97(Court of Appeal 2005) (no need to prove in criminal case the state of mind of mandated reporter)
- This is a "public welfare offense. . . Primary purpose of statute is regulation rather than punishment. . . And wrongful intent is not required in the interest of enforcement." Id. at 104
- This was a nursing home case, but same theory applies to acute care hospitals

CONSEQUENCES – MEDICAL ERRORS AS CRIMINAL CASES

- US v. Martha Bell and Atrium I (W.D.Pa. 2005) Bell (nursing home administrator) convicted of health fraud and Atrium convicted of making false statements arising out of false records of care
- Juror interviewed after trial in Pittsburgh paper- "an administrator knows what is going on in her home."

CONSEQUENCES – MEDICAL ERRORS AS CRIMINAL CASES

- "Worthless Services" U.S. v. Wachter, 2006 WL 2460790(E.D.Mo. 8/23/06)
- Indictment alleged that providers are prohibited from submitting claims that are "of a quality which fails to meet professionally recognized standards of health care" citing 42 U.S.C. 1320c-5 (Obligations of health care . . . Providers)
- Court upheld indictment; guilty plea by defendants to federal health care offenses.

OTHER CONSEQUENCES FOR FAILURE TO REPORT ERRORS

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

LEGAL PROTECTIONS FOR REPORTING MEDICAL ERRORS

- PROTECTION FOR ENTITIES PROVIDING MANDATORY REPORTS
  - No common law federal medical peer review privilege-In re Administrative Subpoena Blue Cross Blue Shield of Massachusetts 400 F. Supp 2d 386(D. Mass. November 2005)(at least where it would inhibit a federal investigation); In Re Baptist Memorial Hospital, 2004 WL 2905391(W.D. Tenn. Jun. 22, 2004)
  - State law privilege does not protect materials from disclosure where federal common or federal statutory law applies. If state law supplies rule of decision in federal court case (e.g., malpractice) state privilege law applies. Federal Rule of Evidence 501.

LEGAL PROTECTIONS FOR REPORTING MEDICAL ERRORS

- PROTECTION FOR INDIVIDUALS PROVIDING MANDATORY REPORTS (beyond the federal and state statutes)
  - DEVELOPING RULE-individuals submitting mandatory reports (where law imposes affirmative obligation to report) have cause of action for retaliatory discharge, even if not explicitly provided by statute.
  - Hausman v. St. Croix Medical Center, 57l NW2d 393(Wisconsin 1997)
  - Wendeln v. Beatrice Manor, 712 NW 2d 226(Nebraska 2005)
    - Reasonable cause required; good faith not required
  - Bachtel v. Miller County Nursing Home District, 110 SW 3d 799(Mo. 2003)

COMPLIANCE CONSIDERATIONS FOR MANDATORY REPORTING

- FOR EACH REPORTING REQUIREMENT, INSTITUTION MUST CONSIDER:
  - What events (deaths, serious injuries, near misses, suspected abuse or neglect) must be reported
  - What causation or association must be reported (drug, device, clinical trial, tissue or blood transfer, error, intentional conduct)
  - Who must report events (institution, individual)
  - To whom events must be reported (government agency, JCAHO, patient and family, IRB (QIO? Patient Safety Committee?)
  - Format of reports
  - Timing of reports (how soon after events, triggers for reports)

COMPLIANCE CONSIDERATIONS (compliance officer and counsel)

Record integrity and retention relating to reports

Availability of reports to third parties (patients, media, plaintiff's attorneys)

Availability, preservation of privileges related to reports

Legal consequences of failures to report

Use of reports

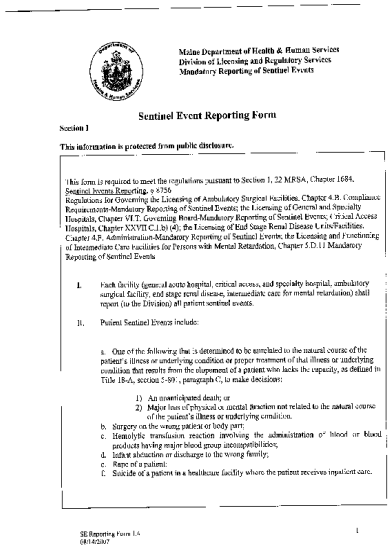
Personal exposure of attorneys, managers participating in reporting decisions

COMPLIANCE CONSIDERATIONS FOR MANDATORY REPORTING

- Whose practical responsibility is reporting?
  - Counsel
  - Patient Safety Officer
  - Compliance Officer
  - Risk Manager
  - Medical Staff Organization
  - Attending Physician
  - Board, CEO, CFO

Mandatory Reporting Hypothetical

- Hospital in Maine
- Surgery on wrong part of body occurs
- Report due next business day, written report due in 45 days
- Who will be in charge of gathering information, completing initial and written reports and developing and implementing corrective action plan?



Maine Department of Health & Human Services
Division of Licensing and Regulatory Services
Mandatory Reporting of Sentinel Events

Sentinel Event Reporting Form

Section I

This information is protected from public disclosure.

This form is required to meet the regulations pursuant to Section 1, 22 MRSA, Chapter 1684, Sentinel Events Reporting, § 8756 Regulations for Governing the Licensing of Ambulatory Surgical Facilities, Chapter 4.R. Compliance Requirements-Mandatory Reporting of Sentinel Events; the Licensing of General and Specialty Hospitals, Chapter VI.T. Governing Board-Mandatory Reporting of Sentinel Events; Critical Access Hospitals, Chapter XXVII.C.1.b)-d); the Licensing of End Stage Renal Disease Units/Facilities, Chapter 4.P. Administration-Mandatory Reporting of Sentinel Events; the Licensing and Functioning of Intermediate Care Facilities for Persons with Mental Retardation, Chapter 5.D.11 Mandatory Reporting of Sentinel Events

I. Each facility (general acute hospital, critical access, and specialty hospital, ambulatory surgical facility, end stage renal disease, intermediate care for mental retardation) shall report (to the Division) all patient sentinel events.

II. Patient Sentinel Events include:

a. One of the following that is determined to be unrelated to the natural course of the patient's illness or underlying condition or proper treatment of that illness or underlying condition that results from the elopement of a patient who lacks the capacity, as defined in Title 18-A, section 5-309-, paragraph C, to make decisions:

1) An unanticipated death; or
2) Major loss of physical or mental function not related to the natural course of the patient's illness or underlying condition.

b. Surgery on the wrong patient or body part;
c. Hemolytic transfusion reaction involving the administration of blood or blood products having major blood group incompatibilities;
d. Infant abduction or discharge to the wrong family;
e. Rape of a patient;
f. Suicide of a patient in a healthcare facility where the patient receives inpatient care.

SE Reporting Form I.A
08/14/2007

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Section II

Part I: To be submitted or called in to the Division by the next business day after the sentinel event occurred or the next business day after the hospital determines that an event occurred.

Name of facility	
Type of Sentinel Event	
Date of Event	
Time of Event	
Date of detection (date event identified by facility)	
Date event reported to State	
Physical location of patient when SE occurred	
How was event discovered?	
Describe any immediate corrective action taken?	
Patient's Age	
Patient's Gender	
Admitting Diagnosis	
Admitting ICD-9 Codes	
Discharge ICD-9 Codes	
Name, title and contact information of person submitting report (Phone and confidential e-mail)	

SE Reporting Form 1-4
08/14/2007

Part II: Narrative Report To be submitted in writing forty-five (45) days from the date the event was reported to the Division. (May include attachments if all information is provided.)

Name of facility and address	
Name, title and contact information of person submitting report (phone and *confidential e-mail)	
Date and time of event	
Type of event	
Detailed Narrative Report to include:	1. Description of event 2. Clinical or organizational systems or processes that may have contributed to the sentinel event 3. Identification of changes to reduce the risk of reoccurrence, and all corrective actions taken or planned 4. Identifies who will be responsible to implement and measure/monitor effectiveness of risk reduction measures 5. Identifies when the proposed actions begin, and how frequently will they be assessed 6. Describes how corrective actions will be communicated to all levels of facility quality improvement process 7. Includes documentation of a relevant literature search related to system/process improvement 8. Includes signature of the Chief Executive Officer/Administrator of the hospital

SE Reporting Form 1-4
08/14/2007

Part III: Detailed Narrative Report

Please submit via fax to 207 287-3251, e-mail (carole.kennelly@maine.gov, or anne.flanagan@maine.gov), or mail (suggest Return Requested)

Confidential to Carole Kennelly, RN, Health Services Consultant or Anne Flanagan, MS, RN, Health Services Consultant

Maine Department of Health & Human Services
Division of Licensing and Regulatory Services
11 State House Station
41 Anthony Ave
Augusta, Maine 04333-0011

SE Reporting Form 1.4
04/14/2007

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Mandatory Reporting Hypothetical

- Action Team comprised of CMO and Compliance Officer (or legal counsel) best able to address medical and reporting aspects
- Compliance Officer gathers information and completes reports to State
- CMO coordinates investigation and development of corrective action plan

Mandatory Reporting Hypothetical

- CMO and CO must have clearly defined roles given deadlines for reporting
- CMO and CO must have backing of CEO and Board to investigate and report
- Mandatory Reporting Rules and Action Plan part of compliance training
- Demonstrates commitment to quality and commitment to learn from errors

COMPLIANCE CONSIDERATIONS
Hospital Boards

- "Getting the Board on Board: Engaging Patient Boards in Quality and Patient Safety" in 32 Joint Commission Journal on Quality and Patient Safety 179-187 (April 2006)
- Interviews conducted with CEOs and Board Chairs at 30 hospitals in 14 states
- "The level of knowledge of landmark IOM quality reports among CEOs and board chairs was remarkably low."

COMPLIANCE CONSIDERATIONS
Hospital Boards

- Increasing education on quality-part of orientation and reporting (errors, outcomes)
- Recruiting one or more board members with expertise on quality
- Frame an agenda for quality
- Cooperation between board and medical staff
- Governance responsibility for quality-measures and goals
- JCAHO -2007 Ongoing Professional Practice Evaluation requirements
- Sept. 2007 OIG/AHLA Report – Urges Board to take active role in quality of care

CONCLUSION

- MULTIPLE FEDERAL AND STATE REPORTING STANDARDS
- MUST DEVELOP PLAN OF ACTION AHEAD OF TIME – CAN'T BE REACTIVE
- FRAME AN AGENDA OF QUALITY AT ALL LEVELS

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