Maine Department of Health and Human Services

Division of Licensing and Certification

Sentinel Event Reporting

Annual Report to the State Legislature
CY 2004

Maine Sentinel Events

ANNUAL REPORT
January 2005

BACKGROUND:

The Mandatory Sentinel Event Reporting statute was established under Section 1, 22 M.R.S.A., Chapter 1684, §8751-8756 (refer to Enclosure A). It became effective May 1, 2003 and provided a system for the reporting of sentinel events for the purpose of improving the quality of health care and increasing patient safety. Oversight for this reporting system lies with the Division of Licensing and Certification within the Department of Health and Human Services.

This program requires that Maine-licensed health care facilities, as defined under Title 34-B, Chapter 1 (includes all acute care hospitals, ambulatory surgical centers, end-stage renal disease facilities, intermediate care/mental retardation facilities and excludes nursing facilities or those facilities under chapter 1665), must report to the Division certain categories of patient injuries defined by statute as "sentinel events". Those incidents must be unrelated to the natural course of the patient's illness or underlying condition or proper treatment of that illness or underlying condition or that results from the elopement of a hospitalized inpatient who lacks capacity as defined in Title 18-A, section 5-801, paragraph C. They include unanticipated deaths; major permanent loss of function that is not present upon admission to the health care facility; surgery on the wrong body part or wrong patient; hemolytic transfusion reactions involving blood or blood components having major blood group incompatibilities; suicide in a facility where patient receives inpatient treatment; infant abduction or discharge to the wrong family; or rape of a patient.

The facility must also investigate the incident to identify systems or processes that may have impacted the event, recognize preventative risk reduction measures and institute corrective actions. In addition, within 45 (forty-five) days, the facility must submit a written report to the Division with their findings. *All information submitted to the Division is confidential, and no information about facilities or providers is discoverable or made public other than aggregate data.* This protection was instituted to encourage reporting of events and to foster a safe environment for open discussion and thorough analysis of these incidents. The Sentinel Event Reporting focus is on systems failures with a non-punitive posture, setting it apart from the other regulatory agencies.

The Division is mandated to review these sentinel events, take action as determined to be appropriate, collect data, and submit an annual report to the Legislature, health care facilities and the public with summary data, analyses, and future plans.

ACTIVITIES DURING 2004:

In December 2003, the first of two Health Services Consultants was hired to begin developing the process and procedures for the Sentinel Event Program. Reporting commenced in January 2004, leaving a single staff to design a system to accommodate the reporting process as well as perform reviews. By February 2004, the method for reporting and managing the incoming data was established with facilities submitting information via a designated, confidential fax line. A standardized form for submission was created and made available on the Department of Health and Human Services/Bureau of Medical Services website (www.maine.gov/bms/) for easy access for facilities. Information management was accomplished through the Health Services Consultant's secure/personal database with 128-byte encryption to protect confidentiality. This allowed a method of tracking events with basic facility information, setting time frames for follow up, and written report dates.

Rulemaking was completed for General/Specialty Hospitals and regulations became effective February 1, 2004; End Stage Renal Disease facilities on February 2, 2004; Ambulatory Surgical Centers on February 2, 2004. It was noted that Intermediate Care Facilities for Persons with Mental Retardation also fell under the reporting requirement. Rulemaking for those facilities was initiated in March 2004, with regulations effective July 1, 2004.

In February 2004 an educational presentation of the Sentinel Event Program and discussion session was held for the Maine Hospital Association. Suggestions from this presentation lead to the refinement of the standardized submission form and raised questions concerning the definition of "unanticipated death". A similar presentation was held for Licensing and Certification surveyor staff to acquaint them with the new statute, the policy/procedure for event review and how confidentiality is managed. This session also defined how events could potentially be reviewed under the sentinel event statute and concurrently at the complaint level, taking separate paths and protected confidentiality on the sentinel event side.

In July 2004, a second Health Services Consultant was hired to complete the Sentinel Event team.

In August 2004, the team recognized a potential need to provide similar information sessions to Ambulatory Surgical Centers, since they had no single organizational group. The team offered facility specific sessions for ASC staff that included nurses, doctors, and administrative personnel. At

facility request, the team provided this service. By mid November 2004, all facilities had responded, with half of all the licensed facilities requesting and receiving this additional education. These sessions promoted dialogue with the Department, opportunity for questions to the team and reinforced the goal of patient safety.

The Sentinel Event team carried out onsite visits for every event reported. Onsite activities included review of medical records, interviews with staff, consultation, and recommendations and follow-up. Conference calls with the Sentinel Event team and facility staff were made available for open discussion of incidents. Written reports from facilities were reviewed for completeness, presence of mandated components that included:

1. Identification of clinical or organizational systems or processes that may have contributed to the event;
2. Identification of changes that could reduce the risk of reoccurrence
3. Description of corrective actions and monitoring of actions.

Each event was examined for thoroughness of the internal investigation, appropriateness of actions taken with attention to systems improvements over a continuum.

A team goal was to provide consultation beyond the scope of event reporting and to foster a supportive and collaborative environment with the focus on improving patient safety.

FINDINGS 2004

There were a total of twenty-four reportable sentinel events (refer to Enclosure B) from January 2004 to December 2004. Twenty-three events occurred in the Hospital setting, and one event took place in an Ambulatory Surgical Center (refer to Enclosure C). Of those twenty-four, fifteen were deaths, five were loss of function and four were wrong surgery. With the limited data for this first year of reporting, no clear trends were identifiable (e.g., facility size, types of patients, ages, conditions). It was noted that the hospital size did not impact the quality of the report or depth of investigation and, in fact, some facilities with fewer staff/resources provided more in-depth, thorough reports utilizing consultants for additional opinions, than some of their larger counterparts.

Regulations for the Intermediate Care Facilities for People with Mental Retardation were not finalized until July 2004 and, the delay may have impacted reporting in that setting. Some Ambulatory Surgical Centers were also not aware of the reporting mandate until the last half of 2004. Department informational sessions have provided those facilities with

direction and may enhance the reporting process for any potential future events.

The team also consulted on twelve events, that after review, were subsequently determined to be non-reportable under the statute. Those events were addressed through the individual facility's internal policies.

All of the sentinel events were reported in a timely manner, with written reports within the mandated forty-five day window. No fines were levied for noncompliance with the statute.

Those facility-indicated areas or systems that impacted the reported events, were tracked to determine if common areas existed across the reported three-event types. Communication was cited in 54.55 percent of the reported events with Standards of Care at 50 percent, and Human Factors at 40.91 percent (refer to Enclosure D). The systems reported will be monitored in the future for any trending.

Risk reduction actions by health care facilities in response to events were also collected. These have been listed in relation to the system involved (refer to Enclosure E).

PLANS/RECOMMENDATIONS

The Department's goal is to collect and review the reported data impacting these events, along with the risk reduction strategies identified by the individual facilities. These strategies will be shared with all Maine facilities, with the intent of improving patient care systems. At the same time, the reporting process will foster quality assurance activities within the facilities.

Plans include:

1. The Department will continue to review written reports to assure that facilities have taken appropriate corrective action and have analyzed all possible components of the event. Recognizable trends will be identified, when sufficient analysis data has been compiled.

2. The Department will continue to provide sentinel event training to Hospitals; Ambulatory Surgical Centers (ASC); and expand services to include End Stage Renal Disease (ESRD) units; and Intermediate Care Facilities for People with Mental Retardation (ICF-MR). These consultative sessions serve to educate staff in the sentinel event reporting process, the role they play, as well as the role of the Department in the review.

3. The development of a sentinel event newsletter with pertinent articles, safety tips, best practice information is planned, but no target date has been established.

At the end of this first reportable year of the Sentinel Event program, the Department recommends the following:

1. Regulatory

   Presently all regulations promulgated as a result of 22 M.R.S.A., Chapter 1684, §8751-8756 mirror the statute. The regulations should be revised to clarify existing definitions, reporting requirements, facility internal review process, and what constitutes a thorough/acceptable report. The Department needs to define within the framework of the statute expectations regarding acceptable analysis methods, written reports, and action plan criteria. Maine should sample other states for direction and already established, commonly accepted approaches. All facilities must be working from the same template, as completeness of reports impact the data collected.

   Regulations need to specify that all Department requested information, findings, or actions surrounding the internal investigation is part of the reporting process and that all of the reported information is protected for confidentiality under the statute.

   There is no established procedure yet for the monitoring of mandated reporting, to determine whether fines are warranted. The regulations should provide language to allow a method of assuring compliance with the statute and to identify "missed events". This could be accomplished through examination of event logs, random audit of death records, etc.

2. Resources

   In order to remain current with standards and developments in patient safety, funding should be available for Health Services Consultants to attend trainings and conferences to facilitate dialogue with other reporting states, instate risk managers and quality assurance/improvement personnel. They should also have access to resource materials, books, journals and standards publications.

   The Department recommends future database evaluation to determine the potential for on-line capabilities for facilities, expanded networking with other states, technical data analysis, and provision of computer supports and upgrades as indicated.

Enclosure A

PUBLIC LAWS OF MAINE
Second Regular Session of the 120th

CHAPTER 678
S.P. 419 - L.D. 1363

An Act to Reduce Medical Errors and Improve Patient Health

Be it enacted by the People of the State of Maine as follows:

Sec. 1. 22 MRSA c. 1684 is enacted to read:

CHAPTER 1684
SENTINEL EVENTS REPORTING

§8751. Sentinel event reporting

There is established under this chapter a system for reporting sentinel events for the purpose of improving the quality of health care and increasing patient safety.

§8752. Definitions

As used in this chapter, unless the context otherwise indicates, the following terms have the following meanings.

1. Division. "Division" means the Division of Licensing and Certification within the Bureau of Medical Services.

2. Health care facility. "Health care facility" or "facility" means a state institution as defined under Title 34-B, chapter 1 or a health care facility licensed by the division, except that it does not include a facility licensed as a nursing facility or licensed under chapter 1665.

3. Major permanent loss of function. "Major permanent loss of function" means sensory, motor, physiological or intellectual impairment that requires continued treatment or imposes persistent major restrictions in activities of daily living.

4. Sentinel event. "Sentinel event" means:

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 or that results from the elopement of a hospitalized inpatient who lacks the capacity, as defined in Title 18-A, section 5-801, paragraph C, to make decisions:

(1) An unanticipated death; or

(2) A major permanent loss of function that is not present when the patient is admitted to the health care facility;

B. Surgery on the wrong patient or wrong body part;

C. Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities;

D. Suicide of a patient in a health care facility where the patient receives inpatient care;

E. Infant abduction or discharge to the wrong family; or

F. Rape of a patient.

§8753. Mandatory reporting of sentinel events

A health care facility shall report to the division a sentinel event that occurs to a patient while the patient is in the health care facility as provided in this section.

1. Notification. A health care facility shall notify the division of the occurrence of a sentinel event by the next business day after the sentinel event has occurred or the next business day after the facility determines that the event occurred. The notification must include the date and time of notification, the name of the health care facility and the type of sentinel event pursuant to section 8752, subsection 4.

2. Reporting. A health care facility shall file a written report no later than 45 days following the notification of the occurrence of a sentinel event pursuant to subsection 1. The written report must be signed by the chief executive officer of the facility and must contain the following information:

A. Facility name and address;

B. Name, title and phone number of the contact person for the facility;

C. The date and time of the sentinel event;

D. The type of sentinel event and a brief description of the sentinel event;

E. Identification of clinical and organizational systems or processes that may have contributed to the sentinel event;

F. Identification of changes that could be made that would reduce the risk of such a sentinel event occurring in the future; and

G. A brief description of any corrective action taken or planned.

3. Cooperation. A health care facility that has filed a notification or a report of the occurrence of a sentinel event under this section shall cooperate with the division as necessary for the division to fulfill its duties under section 8754.

4. Immunity. A person who in good faith reports a sentinel event pursuant to this chapter is immune from any civil or criminal liability for the act of reporting or participating in the review by the division. "Good faith" does not include instances when a false report is made and the person reporting knows the report is false. This subsection may not be construed to bar civil or criminal action regarding perjury or regarding the sentinel event that led to the report.

§8754. Division duties

The division has the following duties under this chapter.

1. Initial review; other action. Upon receipt of a notification or report of a sentinel event, the division shall complete an initial review and may take such other action as the division determines to be appropriate under applicable rules and within the jurisdiction of the division. The division may conduct on-site reviews of medical records and may retain the services of consultants when necessary to the division.

2. Procedures. The division shall adopt procedures for the reporting, reviewing and handling of information regarding sentinel events. The procedures must provide for electronic submission of notifications and reports.

3. Confidentiality. Notifications and reports of sentinel events filed pursuant to this chapter and all information collected or developed as a result of the filing and proceedings pertaining to the filing, regardless of format, are confidential and privileged information.

A. Privileged and confidential information under this subsection is not:

(1) Subject to public access under Title 1, chapter 13, except for data developed from the reports that do not identify or permit identification of the health care facility;

(2) Subject to discovery, subpoena or other means of legal compulsion for its release to any person or entity; or

(3) Admissible as evidence in any civil, criminal, judicial or administrative proceeding.

B. The transfer of any information to which this chapter applies by a health care facility to the division or to a national organization that accredits health care facilities may not be treated as a waiver of any privilege or protection established under this chapter or other laws of this State.

C. The division shall take appropriate measures to protect the security of any information to which this chapter applies.

D. This section may not be construed to limit other privileges that are available under federal law or other laws of this State that provide for greater peer review or confidentiality protections than the peer review and confidentiality protections provided for in this subsection.

E. For the purposes of this subsection, "privileged and confidential information" does not include:

(1) Any final administrative action;

(2) Information independently received pursuant to a 3rd-party complaint investigation conducted pursuant to department rules; or

(3) Information designated as confidential under rules and laws of this State.

This subsection does not affect the obligations of the department relating to federal law.

4. Report. The division shall develop an annual report to the Legislature, health care facilities and the public that includes summary data of the number and types of sentinel events of the prior calendar year by type of health care facility, rates of change and other analyses and an outline of areas to be addressed for the upcoming year. The report must be submitted by February 1st each year.

§8755. Compliance

A health care facility that knowingly violates any provision of this chapter or rules adopted pursuant to this chapter is subject to a civil penalty payable to the State of not more than $5,000 per unreported sentinel event to be recovered in a civil action. Funds collected pursuant to this section must be deposited in a dedicated special revenue account to be used to support sentinel event reporting and education.

§8756. Rulemaking

The department shall adopt rules to implement this chapter. Rules adopted pursuant to this section are routine technical rules as defined in Title 5, chapter 375, subchapter II-A.

Sec. 2. Appropriations and allocations. The following appropriations and allocations are made.

HUMAN SERVICES, DEPARTMENT OF

Bureau of Medical Services

Initiative: Effective May 1, 2003, adds 2 Health Services Consultant positions. Provides funding to establish a system for receiving, reviewing and reporting serious medical errors, referred to as "sentinel events."

General Fund	2001-02	2002-03
Positions - Legislative Count	(0.000)	(2.000)
Personal Services	$0	$14,526
All Other	0	25,333
Total	$0	$39,859

Sec. 3. Effective date. This Act takes effect May 1, 2003.

Effective May 1, 2003.

ENCLOSURE B

Sentinel Event Summary Data for Calendar Year 2004

2004	Reportable Incidents	Deaths	Loss of Function	Suicide	Blood Transfusions	Infant Abduction	DC to Wrong Family	Rape	Wrong Surgery or Body Part	Nonreportable Events	All Event Total
JAN	2	2								1	
FEB	2	2								3	
MAR	1	1								1	
APR	2	1	1							1	
MAY	4	2	1						1		
JUN										1	
JUL	5	3	1						1		
AUG	1	1								1	
SEP	4	1	2						1	2	
OCT										1	
NOV										1	
DEC	3	2							1		
Totals	24	15	5	0	0	0	0	0	4	12	36

ENCLOSURE C

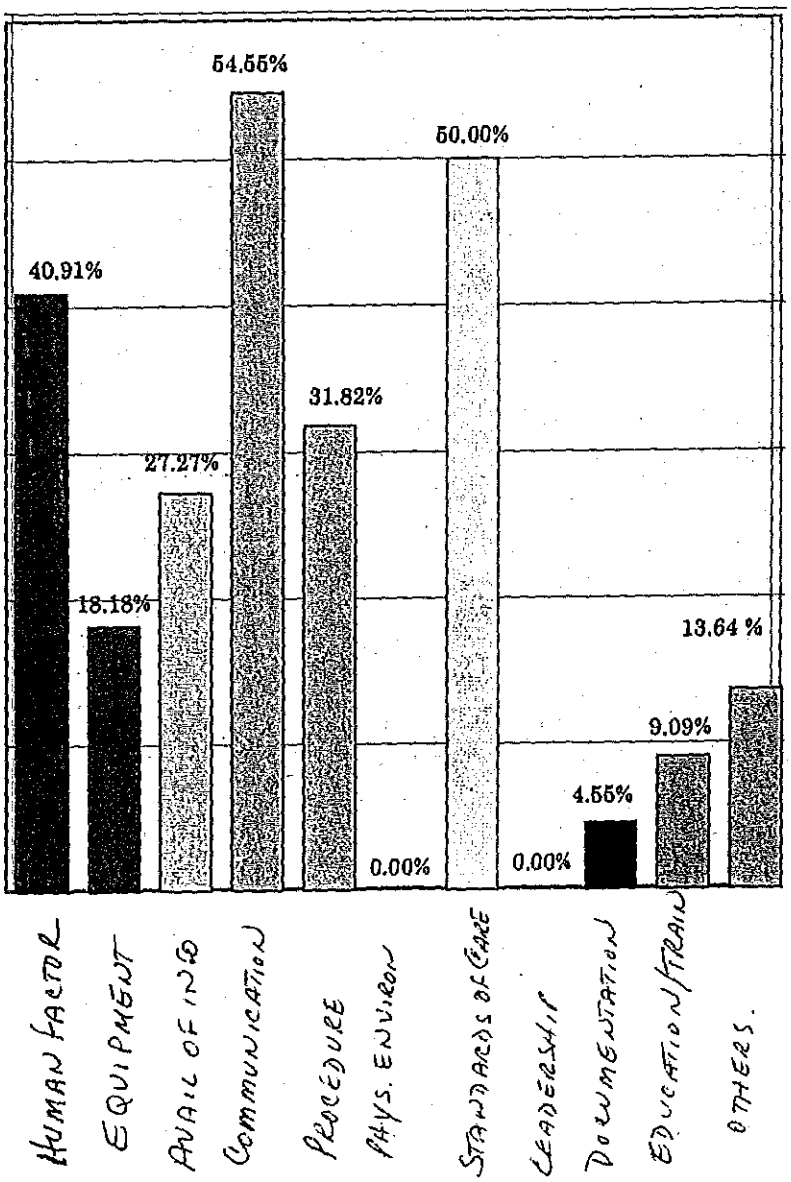
REPORTABLE SENTINEL EVENT SUMMARY DATA
CALENDAR YEAR 2004

Reportable Events by Facility Type

FACILITY TYPES	Deaths	Loss of Function	Suicide	Blood Reactions	Infant Abduction	DC to Wrong Family	Rape	Wrong Surgery or Body Part	Totals By Facility Type
ACUTE HOSPITALS	15	5						3	23
ASC								1	1
ESRD									0
ICF/MR									0

Enclosure D

Facility Systems Impacting Reported Events By Percentage



Human Factors

Equipment

Availability of Info

Communication

Procedure

Physical Environment

Leadership

Documentation

Education/Training

Others

Enclosure E

FACILITY SYSTEMS IMPACTED	RISK REDUCTION ACTIONS TAKEN BY FACILITIES IN RESPONSE TO EVENTS
HUMAN FACTORS/EDUCATION (Factors related to identification of adequate training/in-service to all pertinent staff)	Infection Control will: have open communication with the chiefs of staff for secondary clinical perspective if necessary; receive adequate training/orientation and continued education via attendance at national conferences; receive clinical support from certified Infection Control staff person from an affiliated hospital while in training, and have reference materials available Medical chiefs of staff and associated staff will review individual physician performance and make recommendations for further training/education/disciplinary action Mandatory clinical/clerical staff education to review patient care directives Staff reeducation with Assertive Communication Policy Facility specific pertinent policies added to staff competency requirements Addition of "dummy" medical emergency code carts for clinical practice and training

FACILITY SYSTEMS IMPACTED	RISK REDUCTION ACTIONS TAKEN BY FACILITIES IN RESPONSE TO EVENTS
	Development of competency skills and training for medical emergency (Code Blue) situations for clinical staff Clinical education/training and review of ventilation mask placement Surgical staff review of protocols for correct patient, site, procedure Clinical staff education for neuraxial anesthesia and the use of anticoagulant therapy Addition of electrolyte imbalance signs/symptoms/treatment to orientation curriculum for nurses Hospital wide in-service on electrolyte imbalance covering signs/symptoms and treatment In-service to clinical staff on signs/symptoms of alcohol withdrawal vs. differential medical diagnosis Mock emergency medical "Code" trainings for behavioral health clinical staff Nursing in-service for oxygen administration policy protocol In-service for understanding and following facility specific "chain of command policy" Proficiency training for use of earlobe and forehead oximetry monitors

FACILITY SYSTEMS IMPACTED	RISK REDUCTION ACTIONS TAKEN BY FACILITIES IN RESPONSE TO EVENTS
EQUIPMENT	Oral oxygen masks available in each patient room Initiation of use of earlobe and forehead oximeters Transition to computerized physician order entry system with safety nets for various medications Code cart check to include accuracy of defibrillator time/date settings Atomic (high accuracy) clocks for high risk areas
AVAILABILITY OF INFORMATION Factors related to the development of current policies/procedures, and availability of accurate systems/processes required to perform clinical duties and make accurate clinical decisions	Review/revise pre-registration procedure so History & Physical is available in operating room prior to the time of surgery Accurate telephone numbers for on-call staff posted on units to reduce delays in contact Old records present on charts for post operative reference Electronic medication alerts to providers regarding the risk of certain adverse reactions (Thymoglobulin) in patients with history of anaphylaxis or allergies to rabbit serum Inclusion in the History and Physical of a complete smoking history (question: "have you ever smoked?" not "do you smoke.")

FACILITY SYSTEMS IMPACTED	RISK REDUCTION ACTIONS TAKEN BY FACILITIES IN RESPONSE TO EVENTS
COMMUNICATION Issues related to the availability and flow of information between clinical staff/departments/management and proper interpretation of information to make clinical decisions	Review of facility communication standards with staff Nursing Education and orientation to include the standard of practice to communicate changes in patient status to physician Development of ancillary department policy identifying physician reportable results Update facility policy regarding conflict resolution to include physicians, nurses, rehab staff Provide consistency between Physician's plan of care and Physician's Assistant's orders Surgical verification process to include verbal responses from all team members to include (patient/procedure/correct site) Implement facility policy and procedure to include notification of Primary Care Physician (PCP) for any unusual clinical events occurring during a procedure Implementation of a medication verification system to notify pharmacy to contact physician if a medication dosage is outside designated normal range Review process of how and when to

FACILITY SYSTEMS IMPACTED	RISK REDUCTION ACTIONS TAKEN BY FACILITIES IN RESPONSE TO EVENTS
FACILITY POLICY/PROCEDURES	report potential events to Nurse Managers and Chiefs of Staff Revision of alcohol withdrawal protocol to include physician contact after initial "stat" medication for any Stage II symptoms Review of policy for consultation and need for direct communication between the ordering provider and the consultant Nursing in-service to address criteria for contacting physician and respiratory therapy based on patient's condition Nursing in-service for need to communicate patient condition/concerns to the proper provider (primary vs. consultant) Monitoring the timing of steroid administration per standing orders Development of a policy for Health Care Acquired infections Deep sedation clearly defined as no purposeful response to verbal commands and tactile stimulation (requiring a higher level of care) In moderate sedation, if deep sedation ensues, inform physician and suspend sedation If LOC (level of consciousness)

FACILITY SYSTEMS IMPACTED	RISK REDUCTION ACTIONS TAKEN BY FACILITIES IN RESPONSE TO EVENTS
	remains depressed in moderate sedation may suspend procedure Development of "When to Stop" (procedure) policy with in-servicing of staff and proficiency inclusion If monitoring (Oxygen saturation, B/P, etc.) is interrupted during moderate sedation physician is alerted If monitoring cannot be reestablished, joint assessment by nurse and provider for sedation level, respiratory and clinical status; action as indicated Staff review of admission policy and procedure for Labor and Delivery patients Revision of Electroconvulsive Therapy policy to include electrocardiogram for patients > 50 and ASA (American Association of Anesthetists Score) > 3 receiving maintenance therapy Implementation and revision of oral Potassium protocol to include signs and symptoms of under or over dosages Staff review of surgical consent policy Revision of policy for verification of surgical procedure/patient/site to include not only the correct patient and laterality but also the specific procedure Implementation of a flow sheet and

FACILITY SYSTEMS IMPACTED	RISK REDUCTION ACTIONS TAKEN BY FACILITIES IN RESPONSE TO EVENTS
STANDARDS OF CARE A benchmark that is accepted by recognized authorities and widely used	nursing plan of care for cervical trauma Review of a scheduling process for outpatient procedures done as inpatient Providers to review/revise their system for scheduling inpatient procedures Cardiac monitoring for Endoscopic Retrograde Cholangiopancreatography Written medication guidelines for moderate sedation Monitoring devices cannot substitute for educated assessments Review of OB/GYN high/low risk assessment guidelines to assure consistency with standards Vital signs and pulse oximetry repeated after inhaler medication administration. Provider to check results Development of trauma protocol Required consultation if no clinical improvement in infections by specified timeframes Continuous monitoring to include O2 sats, pulse for moderate sedation Vital signs at least every 5" and after

FACILITY SYSTEMS IMPACTED	RISK REDUCTION ACTIONS TAKEN BY FACILITIES IN RESPONSE TO EVENTS
	each medication administration during moderate sedation Prior to Electroconvulsive Therapy the provider will review most recent History & Physical, Electrocardiogram with tracing and labs Policy development for management of patients with epidurals and anticoagulation therapy Development of an emergency department flow sheet, policy and protocol addressing Cervical Spine injuries Review the limits of nursing orders Development of a protocol for Deep Venous Thrombosis
FACILITY DOCUMENTATION	Nursing education to address required documentation of patient acuity with accurate time sequence Medical staff to include the time when cosigning orders All communication between providers must be documented Nursing review of how to make corrections to medical records added to nursing competency Revision of emergency medical code sheets to reflect accurate timing

FACILITY SYSTEMS IMPACTED	RISK REDUCTION ACTIONS TAKEN BY FACILITIES IN RESPONSE TO EVENTS
	Emergency physicians instructed to document orders more specifically Admitting nurse assessment to document previous surgeries with dates Care plan to be part of the formal record to document any ECT (Electroconvulsive Therapy) treatment interventions MAR (Medication Administration Records) administrative notes reminder to review most recent labs on protocol meds (Potassium) Worksheet tool for HCA (Health Care Acquired) infection includes: CDC (Centers for Disease Control) definition; symptoms; tests, appropriate medication/s; other treatment/s; progress within timeframes; consultation/s; recommendations Infection Control to document evidence of clinical improvement of infections

INDEX TO ENCLOSURES