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Sentinel EVENTS

CY 2007

Annual Report to the Maine State Legislature



Department of Health
and Human Services

Maine People Living
Safe, Healthy and Productive Lives

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Sentinel EVENTS

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Annual Report to the Maine State Legislature

■ Executive Summary

In 2002, Governor Angus S. King, Jr. enacted Public Law 2001, Chapter 678 establishing a mandatory sentinel event reporting system in Maine. The law requires licensed General and Specialty Hospitals, Ambulatory Surgical Centers, End-Stage Renal Disease Facilities/Units, and Intermediate Care Facilities for Persons with Mental Retardation to report certain serious events, referred to as sentinel events, to the State. The Law further requires an annual report to the Legislature and public.

Key Findings

- Maine significantly under-reports sentinel events compared to estimates from national studies.
- Changes to the statutory language are needed to reduce ambiguities about what must be reported.
- Maintaining a commitment to a collaborative approach among all stakeholders for identifying and reporting sentinel events offers the best opportunity for preventing recurrences.

Goal of Reporting System

Maine's sentinel event reporting system was designed to encourage reporting, yet under-reporting persists. The confidentiality of reports, the public disclosure of only aggregate reports without hospital identifiers, and the separation of reporting from the hospital licensure process were embedded in the system as ways to promote reporting, collaboration and shared learning. Understanding that it is not possible to solve problems that are not identified, Maine's sentinel event reporting system was intended to look beyond blame and promote patient safety through collaboration and shared responsibility. An important precept of the system has been to provide a non-punitive environment for reporting so that others can learn from mistakes and prevent their recurrence. Essential to the success of the program is confidence that full reporting is taking place.

Definition of Sentinel Event

Sentinel events are defined to include outcomes 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 capacity. The law further characterizes sentinel events as:

- Unanticipated death;
- A major permanent loss of function that is not present when the patient is admitted to the health-care facility;
- Surgery on the wrong patient or wrong body part;
- Hemolytic transfusion reaction involving administration of blood or blood products having blood group incompatibilities;
- Suicide of a patient in a healthcare facility where the patient receives inpatient care;
- Infant abduction or discharge to the wrong family; and
- Rape of a patient.

State Review

The Maine Sentinel Event Team conducts an onsite review at each facility reporting a sentinel event to analyze the incident and to ensure that all relevant factors are considered in the development of an action plan. This process provides an independent assessment that augments the facility's own internal review of the incident.

Confidentiality Provisions

By law, all sentinel event information submitted to the Division is considered privileged and confidential. No information about facilities or providers is discoverable or made public. A firewall is maintained between the sentinel event program and the survey unit that regulates facility licensing within the State.

Relationship of Mandatory Reporting to Other Hospital Initiatives

In 2007, the Maine State Legislature authorized the Division to accept Joint Commission accreditation as also satisfying State licensing requirements for hospitals. The effect of this legislation means that regular onsite visits of accredited hospitals are no longer conducted by the State as part of its licensing function.¹

The Joint Commission accreditation program includes the voluntary reporting of specified reviewable sentinel events, many of which are similar to reportable events in Maine. There are stark contrasts between the Joint Commission and Maine sentinel event reporting systems. The Joint

Commission system is voluntary, does not include the validation that all events are reported, and does not conduct an onsite review following each reported event.

In an environment where the State now has a radically reduced presence in some hospitals, mandatory reporting provides an important window into the quality and patient safety issues of Maine hospitals.

Sentinel Events Reported in 2007

Twenty-eight sentinel events were reported to the Division in 2007. All of these events were reported by licensed hospitals. Slightly over three-fourths (78 percent) of Maine hospitals have reported at least one sentinel event since the inception of the program. Nine hospitals have not reported a single event since 2004 when the program began.

- Of the 28 reported events, 20 were unanticipated deaths. Four of the unanticipated deaths were related to fetal death.
- Of the remaining eight cases, two were wrong surgeries, four wrong site surgeries, and two cases resulted in permanent loss of function.
- There were no reports of infant abduction or discharge to the wrong family, rape of a patient, suicide, or hemolytic transfusion reaction.

Statewide Trends and Observations

The overwhelming majority of cases (24 of 28) were the result of mistakes, or cognitive errors, suggesting the need for training or educational programs. Twenty-two events related to non-clinical circumstances, including hand-off, chain of command, weekend/holidays, new practitioners and bias. Aspects of 23 reported events focused on the clinical management of a patient. There is a wide range of contributing factors in these cases including misdiagnosis and failure to rescue.

Facilities reported that communication and education were each a contributing factor in 21 of the 28 reported events. Documentation, and policies and procedures were each cited as factors influencing 19 sentinel events. Human factors and standards of care explained 18 events, followed by the availability of information (16 events).

The National Quality Forum (NQF)

The NQF is a national, consensus-driven private-public partnership aimed at developing common approaches to quality improvement, including identification of events that are serious in nature and have been determined to be largely preventable. Increasingly, states are using the NQF list of serious

events as the basis of their mandatory reporting systems. Comparability of definitions enhances clarity about what must be reported and provides benchmarks for comparing experiences across states.

The Maine Quality Forum commissioned a review of the impact if Maine was to adopt the NQF list of serious reportable events in lieu of its current list. The study found a major distinction between Maine's reportable events and those of the NQF. NQF events are known to be primarily preventable and/or serious in nature and therefore, *a priori*, must be reported. According to Maine law, events must be reported when the facility determines them to be unrelated to the natural course of the patient's illness or underlying condition or proper treatment of that illness or underlying condition.² The 'proper treatment clause' enables facilities to review sentinel events and determine whether they are the result of proper treatment. This discretion may lead to under-reporting.

Context for Reviewing Maine's Sentinel Events

There are many reasons why differences in the rate of adverse events may exist, only some of which are indicative of variations in quality. Studies of other state mandatory reporting systems show that hospital systems for identifying and reporting events improve over time, yet the number of reported events in Maine has remained notably static. The report compares the number of reported events to estimates based on national studies. The magnitude of the discrepancy suggests serious under-reporting in Maine.

Sentinel Event Program Highlights

The sentinel event program, in partnership with Maine Medical Center, was accepted into the national Patient Safety Improvement Corps (PSIC). Co-sponsored by the Agency for Health Care Quality (AHRQ) and the Veterans Administration (VA), the PSIC is a unique collaborative of public and private entities to reduce medical errors and improve patient safety.

In an effort to improve awareness of the State's sentinel event system and to strengthen reporting, onsite visits were made to every hospital that had not reported a sentinel event since the program's inception. Sentinel Event Team members focused these visits on reporting requirements, their relationship to the facility's own risk management program, and the reporting process. Following an established protocol, the Sentinel Event Team also assessed a facility's readiness to detect and report events. Findings from these visits indicate that serious events have gone significantly unreported.

Conclusions and Recommendations

Maine's sentinel event reporting system focuses on identifying and deterring serious, preventable incidents. Due to the serious nature of these events, the State has a vested interest and responsibility for assuring that everything possible is done to address sentinel events when they happen, and that practices to prevent their recurrence are widely understood and adopted. Mandatory reporting is the primary tool for the State to hold facilities accountable for disclosing that an event has occurred and that appropriate action has been taken to remedy the situation.

In the coming year, the sentinel event program will work closely with hospitals and others to strengthen the reliability of reporting.

- The State will assess the feasibility of using Maine's all payer database to isolate potential reportable sentinel events and validate that all events are being reported.
- Protocols for conducting audits within hospitals will be developed to validate that all sentinel events have been reported.
- The Sentinel Event Team will continue to assess the adequacy of hospitals' internal systems for detecting and reporting events and to explore why some hospitals have not reported.
- Complaint data will continue to serve as a cross-check on the reporting system for those incidents that rise to the level of a reportable event.

A second major initiative will focus on the sentinel event statute. Working with the Maine Quality Forum, key stakeholders and subject matter experts, the program will examine how statutory language and specifications can be improved to reduce ambiguities about what must be reported and enhance the review process.

Finally, the program will continue to maintain ongoing communications with Maine hospitals and stakeholders about reporting requirements and lessons that can be learned to prevent events from being repeated. The State is committed to maintaining a collaborative approach for identifying serious adverse events and finding joint solutions for reducing their occurrence. However, the overarching goal of the reporting system is to improve the quality of hospital care and to honor our pledge to the Maine people that the State is a credible overseer of the quality of care in Maine.

Endnotes

¹ Exceptions include cases of a complaint investigation or if the hospital is selected by the Medicare program for a survey to validate Joint Commission findings.

² Me. Rev. Stat. Ann. tit. 22, § 8753 (2003). Definitions at <http://janus.state.me.us/legis/statutes/22/title22sec8752.html>

Introduction

This report is submitted in accordance with Maine law (22 M.R.S.A. §§8751-8756) which requires the Division of Licensing and Regulatory Services (the Division) to annually report to the Legislature, health care facilities and the public on the aggregate number and type of sentinel events for the prior calendar year, rates of change, causative factors, and activities to strengthen patient safety in Maine (see Appendix A for details of the law). This report is designed to:

- Build awareness of Maine’s sentinel event reporting requirements and the follow-up process used by facilities and the State when events occur;
- Provide aggregate information on the number and nature of sentinel events reported;
- Identify patterns and make recommendations to improve the quality and safety of patient care; and
- Describe efforts to address under-reporting and enhance the role of sentinel event reporting in improving patient safety.

The report begins with a summary of Maine’s sentinel event reporting requirements and the process used for reviewing reported events. This is followed by a brief description of how the system fits within other hospital oversight activities and national patient safety initiatives. A summary of sentinel events reported in 2007 is presented, followed by an analysis of statewide trends and observations. The report concludes with a context for assessing reporting levels under Maine’s sentinel event reporting system, major program highlights during 2007, and recommendations for enhancing the sentinel event reporting system going forward.

Maine Sentinel Event Reporting and Review Process

The Institute of Medicine (IOM) report, *To Err is Human: Building a Safer Health System* (Kohn et al, 1999) heightened awareness of the serious injuries and deaths that occur every year from preventable medical errors. The IOM report proposed a combination of strategies to reverse these trends, among them:

- The establishment of state-based mandatory reporting systems, tied to systems of accountability, for the most serious medical errors that may cause harm and death.

- The encouragement of voluntary reporting systems for the broad spectrum of errors and near misses to better understand why and how events happen and what can be done to prevent their recurrence.
- The promotion of non-punitive systems within hospitals that encourage reporting at all levels and develop system solutions for their prevention.
- The promulgation of national efforts to standardize reporting, study patient safety trends, and disseminate best practices for reducing medical errors.

In 2002, Governor King enacted Public Law 2001, Chapter 678 establishing a mandatory sentinel event reporting system in Maine. As implemented in subsequent regulations, the law requires licensed General and Specialty Hospitals, Ambulatory Surgical Centers, End-Stage Renal Disease Facilities/ Units, and Intermediate Care Facilities for Persons with Mental Retardation to report certain serious events, referred to as sentinel events, to the State. Requirements for mandatory reporting are embedded in the licensing regulations governing each reporting entity (Appendix A).

Definition of Sentinel Event

Under Maine law, sentinel events are defined to include outcomes 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 capacity. The law further characterizes sentinel events as:

- Unanticipated death;
- A major permanent loss of function that is not present when the patient is admitted to the health-care facility;
- Surgery on the wrong patient or wrong body part;
- Hemolytic transfusion reaction involving administration of blood or blood products having blood group incompatibilities;
- Suicide of a patient in a healthcare facility where the patient receives inpatient care;
- Infant abduction or discharge to the wrong family; and
- Rape of a patient.

Reporting Requirements

Facilities must notify the Division within one business day of discovering an event. Through a confidential telephone exchange of information, the

Sentinel Event Team determines whether the incident conforms to the statutory definition of a sentinel event. Upon confirmation that the event must be reported, the facility is required to submit a brief description of the incident via a restricted fax to the Division. A facility that knowingly violates any provision of the requirements is subject to a civil penalty.

Within 45 days of discovering a reportable event, the facility is required to share a written report with the State and the facility's quality improvement committee describing key elements of the event, the circumstances surrounding its occurrence, the actions taken or proposed to prevent its recurrence, methods for communicating the event, and planned risk reduction actions.

The Sentinel Event Team conducts an onsite review at each facility reporting a sentinel event to assess the incident and to ensure that all relevant factors are considered in the development of an action plan. The on-site review occurs shortly after the incident is first reported so that findings can be incorporated into the facility's action plan. The facility's Chief Executive Officer (CEO) is briefed during this time by the Sentinel Event Team to assure his/her active engagement in understanding factors leading to the event and plans for mitigating its recurrence. The entire medical record of the patient is reviewed during the site visit to identify contributing factors that may have affected the outcome before, during and after an event. This process provides an independent assessment that augments the facility's own internal review of the incident.

Throughout their review of a sentinel event, the Sentinel Event Team studies relevant standards of care and evidence-based research to help inform their review of the facility's response to an event. Depending on the nature of the event, content experts may also be consulted to expand understanding of the possible system failures or other factors that may have contributed to a sentinel event.

Upon receipt of the facility's full written report, the Sentinel Event Team confirms that direct causal factors have been examined by the facility and that corrective actions are appropriate, comprehensive, and implemented. If the report is accepted, a letter is sent to the facility's CEO. Should more information be required, a letter requesting specific details is sent to the Risk Manager with a copy to the CEO. When this report is complete, a final approval letter is sent to the facility. Should it be necessary, the Sentinel Event Team may return to the facility to follow-up on the implementation of the action plan. A flow chart diagramming the sentinel event case review process can be found in Appendix B.

Information collected on sentinel events and their reviews are entered into a confidential database. This database is the primary source for sharing aggregate statistics and trends through the Annual Report.

Confidentiality Provisions

By law, all sentinel event information submitted to the Division is considered privileged and confidential. No information about facilities or providers is discoverable or made public. A firewall is maintained between the sentinel event program and the survey unit that regulates facility licensing within the State. The Sentinel Event Team is responsible for reviewing the initial reported event, conducting on-site reviews, ensuring that all contributing factors to an event are identified, and that action plans are appropriate and implemented.

Relationship of Mandatory Reporting to Other Hospital Initiatives

Maine's mandatory sentinel event reporting system fits within a broader system of oversight of patient safety within hospitals. This section focuses on oversight of hospitals since the vast majority of sentinel events nationally occur within hospitals and hospitals were the source of all reported events in Maine during 2007.

Hospitals, their staff, and providers serve as the initial safeguard against adverse events through their credentialing processes, risk management programs, and quality improvement systems. These internal systems are essential underpinnings to early detection and resolution of quality problems. The State is responsible for licensing healthcare providers to assure that their internal procedures and systems of care meet public expectations of quality. The State survey team conducts on-site visits to monitor compliance with licensure requirements and to investigate complaints.

In its role as healthcare payer through the Medicare program, the Federal government also has a stake in the quality of Maine hospitals. The Medicare program relies on two types of external reviews to assure that hospitals are providing quality care: accreditation by the Joint Commission and certification by state agencies for those hospitals not accredited.

The Joint Commission is a voluntary program that accredits a hospital based on an evaluation of its performance compared to operational standards associated with a quality performing facility. In 2007, the Maine State Legislature authorized the Division to accept Joint Commission accreditation

as also satisfying State licensing requirements for hospitals (see Appendix C for 22 M.R.S.A. §1816). The purpose of the legislation was to reduce duplication and burden in that many of the standards are equivalent between State hospital licensing and the Joint Commission. Nothing in this new statute eliminates the legal duty of Maine hospitals to report sentinel events to the State. The effect of this legislation, however, means that regular on-site visits of accredited hospitals are no longer conducted by the State as part of its licensing function.¹ Currently, 24 of Maine's 41 hospitals are Joint Commission accredited and thus exempt from routine State licensing oversight. Findings of the Joint Commission review of a hospital currently are not made available to the Division.

The Joint Commission accreditation program includes the voluntary reporting of specified reviewable sentinel events, many of which are similar to reportable events in Maine. Although the definition of reportable events is similar, there are stark contrasts between the Joint Commission and Maine sentinel event reporting systems in other respects.

First, the Joint Commission reporting system is voluntary while the Maine system is mandatory. Between 1995 and 2006, the Joint Commission's website indicates that a total of 11 reviewable events were submitted by Maine hospitals (Joint Commission, 2007). This compares to the over 100 events reported under Maine's mandatory system since it began in 2004.

Second, the Joint Commission does not validate that events are being reported. The Joint Commission's website specifically states that "surveyors are instructed not to seek out specific sentinel events beyond those already known to the Joint Commission" (Joint Commission, 2007, July).

As will be discussed later in this report, Maine's Sentinel Event Team has actively worked with hospitals with a history of no reporting to assure that internal systems are in place to detect quality issues. More will be done by the Sentinel Event Team in the coming year to target potential areas of under-reporting.

Third, the two systems are distinguished by the extent of follow-up to a reported event. No on-site review is conducted by the Joint Commission to assure an examination of all causative factors. In contrast, Maine's Sentinel Event Team visits each reporting facility and actively works with them to make certain that action plans adequately address the root causes and are implemented to prevent a recurrence.

The purpose of this section was to underscore the heightened significance of Maine's sentinel event reporting system. In an environment where the State now has a radically reduced presence in some hospitals, mandatory reporting

provides an important window into the quality and patient safety issues of Maine hospitals.

Sentinel Events Reported in 2007

Twenty-eight sentinel events were reported to the Division in 2007. All of these events were reported by licensed hospitals. The Sentinel Event Team also reviewed over 250 public complaints to determine whether they met the statutory definition of a sentinel event. None of them did.

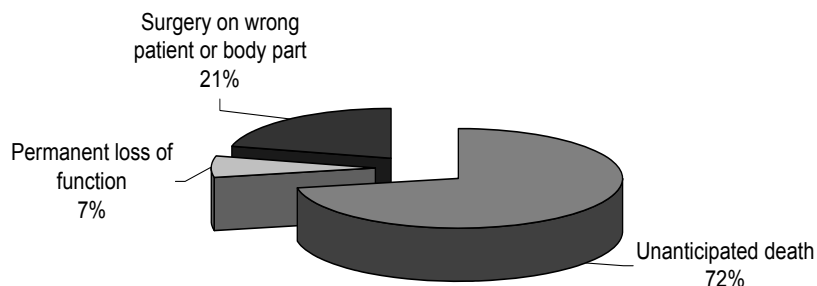
As shown in Table 1, slightly over three-fourths (78 percent) of Maine hospitals have reported at least one sentinel event since the inception of the program. Nine hospitals have not reported a single event since 2004. Other states report that the number of reporting hospitals generally increases when facilities see the relevance of reporting to improving patient safety within their own institutions and the state (Rosenthal et al, 2001). Whereas the number of reporting hospitals has continuously increased in Maine, the number of events has remained fairly static.

Table 1: Reporting versus Non-Reporting Hospitals

	2004		2005		2006		2007	
	No.	%	No.	%	No.	%	No.	%
Reporting hospitals	28	67%	22	54%	25	61%	32	78%
Non-reporting hospitals	13	33%	19	46%	16	39%	9	22%
Total	41	100%	41	100%	41	100%	41	100%

Of the 28 reported events, 20, or 72 percent, were unanticipated deaths (e.g., falls, hemorrhage, fetal deaths).

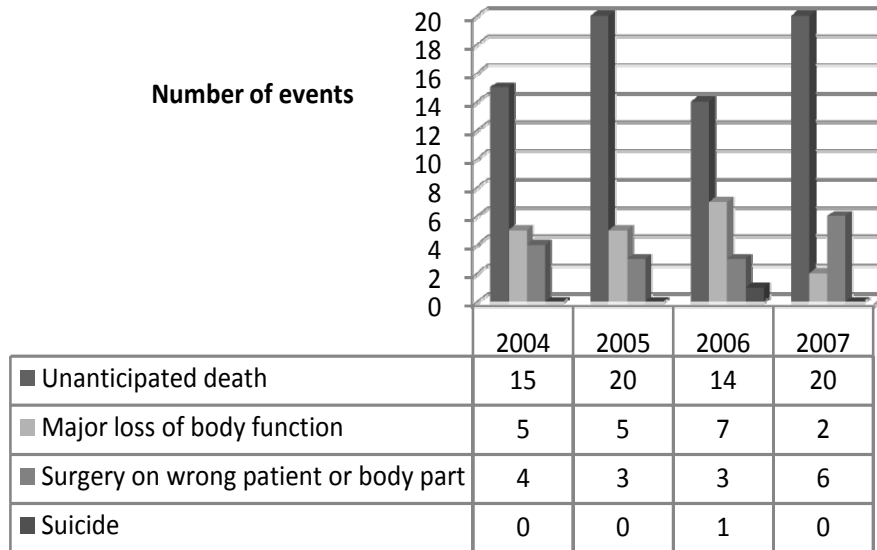
Table 2. Sentinel Events by Category, 2007



Of the remaining eight cases, two were wrong surgeries, four wrong site surgeries, and two cases resulted in permanent loss of function. Confidentiality provisions restrict the State from disclosing further information about these events given the small numbers and the potential to trace events to individual patients or hospitals. There were no reports of infant abduction or discharge to the wrong family, rape of a patient, suicide, or hemolytic transfusion reaction.

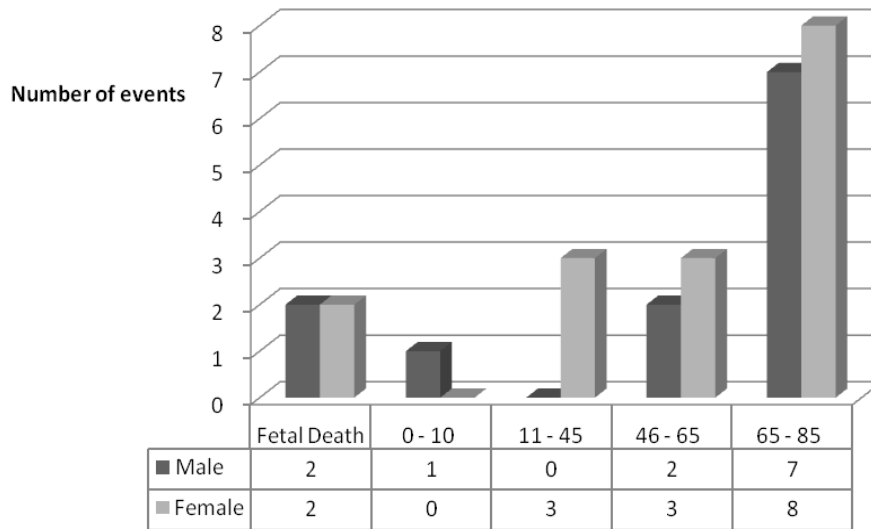
Table 3 indicates the number and types of reported events for each year since the inception of the program.

Table 3. Sentinel Events by Category, 2004-2007



The majority of the 28 sentinel events (57 percent) involved females and patients between the ages of 65-85 years (54 percent). A total of four reported were related to fetal death.

Table 4. Sentinel Events by Age and Gender, 2007



Statewide Trends and Observations

In this section, we probe deeper to understand common themes across events that can help us identify opportunities for reducing their occurrence. These observations are based on the on-site reviews conducted by the Sentinel Event Team following each reported event; the documentation provided by facilities in their analyses of circumstances surrounding an event; and a review of patient safety literature. In this analysis, we looked to identify contributing factors throughout the entire episode of care and did not limit ourselves to the primary cause of an event.

There are many ways to cluster findings, each of which offers its own insights into possible remedies. For purposes of this report, we review the findings with respect to:

- Cognitive versus non-cognitive trends
- Non-clinical trends
- Clinical trends
- Facility-reported root causes and action plans

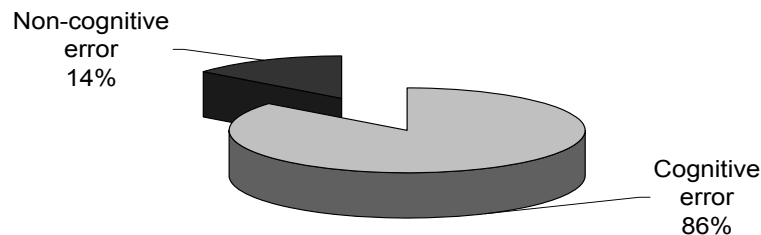
■ Cognitive versus Non-Cognitive Trends

Sentinel events are considered preventable and occur as the result of error. Errors can fall into two distinct groups: Cognitive errors or ‘mistakes’, and non-cognitive errors or ‘slips or lapses’. Mistakes reflect incorrect judgments or choices. Mistakes typically involve insufficient knowledge, or failure to correctly interpret available information. For example, choosing the wrong diagnostic test or ordering a suboptimal medication represent mistakes.

A non-cognitive error, or ‘slip’, on the other hand, involves forgetting. An example would be failure to check a patient’s identification prior to administering the medication (Croskerry, 2003).

As shown in Table 5, the overwhelming majority of cases (86 percent) reported in 2007 were the result of mistakes, or cognitive errors, suggesting the need for training or educational programs. Later we describe specific areas of training that may be appropriate based on our review of the events.

Table 5. Cognitive versus Non-Cognitive Events



■ Non-Clinical Trends

Twenty-two of the reported events can be understood within the context of situations that leave patients and practitioners vulnerable to exercising poor choices. Each of these is described and potential remedies identified from our research and understanding of patient safety practices.

HAND-OFF

Hand-off involves the period of time during which there is a transfer of rights, duties and obligations for a patient from one person or team to another. Hand-off issues include cross coverage/on call, nursing shift change/break relief, and transfer to another facility (e.g., tertiary center, long term care facility). Ineffective hand-off can lead to wrong treatment, delay in diagnosis, and serious adverse events.

Nine of the 28 sentinel events reported in 2007 reflected problems in the transfer of knowledge from shift-to-shift report, or from physician-to-physician transfer of on-call responsibilities. In several instances, the information included critical laboratory or radiology tests ordered by one provider, and results going undetected by the incoming covering physician. Other examples of hand-off issues included incomplete or erroneous information relayed from the outpatient setting to the inpatient facility prior to a scheduled procedure.

Patients who are transferred to a higher level of care, a tertiary or secondary setting, are vulnerable to communication failures. Despite efforts to the contrary, there may be a breach in continuity of care in the process of transfer following discharge, or after the patient's return to the community (Wachter, 2004). Often there is no process in place to communicate back to the sending institution regarding results of treatment or issues surrounding the patient's care. This failure can contribute to error, and challenge the ability of the hospital to identify areas for improvement (Leonard, 2004).

In a number of cases, a sentinel event occurred and resulted in the need to transfer to a tertiary center. A technicality in the State's definition of a sentinel event does not place responsibility on the facility to report an event if the individual dies in another facility. The accountability for the patient's outcome and the reportability of the event thus may become ambiguous.

Potential Remedies:

1. Implement a standardized approach to 'hand-off' communications, including an opportunity to ask and respond to questions (Joint Commission, 2008). The practice of using a standardized form coupled with verbal handover demonstrated the highest rate of accurate transfer of information (Solet, 2005).
2. Learn from hand-off strategies used in high-risk settings such as nuclear power plants and NASA (Patterson, 2004; Naik, 2006).
3. Develop methods for follow-up communication after transfer.
4. Amend Maine's statute to eliminate ambiguities about reporting responsibilities for a sentinel event in the case of a patient death following transfer.

CHAIN OF COMMAND

Sometimes steps are not taken in a timely manner to assure that the right person(s) is brought in to mediate a situation or to direct a proper course of action. This was a factor in 17 sentinel events reported in 2007. In several cases, a reluctance to involve the physician/provider resulted in a delay in treatment. Some of these situations occurred late at night or on the weekend when the provider was not available on-site.

Studies show that nurses are sometimes reluctant to activate the chain of command (Dougherty, 2007). Nationally, facilities are using evidence-based teamwork building systems, such as TeamSTEPPS™, to improve communication and teamwork skills among healthcare professionals (Agency for Healthcare Research and Quality, 2007 November). The goal of these programs is to create an atmosphere where people communicate without hierarchical barriers or fear of reprisal. The Hospital Survey on Patient Safety Culture, developed by the Agency for Healthcare Research and Quality (AHRQ), assesses how well an environment or culture encourages health professionals to communicate about problems or share information about actions that can be taken to make care safer (Agency for Healthcare Research and Quality, 2007 April).

Potential Remedies:

1. Promote team-based training to improve communication skills across teams and in one-on-one communication.
2. Encourage the administration of patient safety culture surveys in all Maine hospitals to help identify staff perceptions about barriers and opportunities for more effective communication and other strategies around patient safety issues.

WEEKEND/HOLIDAYS

Weekends and holidays present many of the same issues described under hand-off and chain of command. A total of nine events, or 33 percent, occurred at times when there was a transition to weekend coverage, during the weekend, or on a holiday. In most of these cases, staffing was not cited as a causative factor. Similarly, fatigue was not cited as a contributing factor. Research on weekend events generally has focused on higher mortality rates for patients admitted on a weekend day versus weekday (Bell, 2001; Kostis, 2007). This was not a factor in any of the nine reported events. We will continue to monitor the effect of weekends and holidays as a risk factor for adverse events.

Potential Remedies:

1. Based on the literature and the observations of these events it is recommended that the 'weekend factor' be considered in the treatment plan of high risk cases (Bendavid, 2007).
2. When undertaking review of adverse events, or near miss cases, the 'weekend factor' should be considered (Becker, 2007).

NEW PRACTITIONERS

Three events reported in 2007 involved practitioners that were new to the facility, new to their role, or new to both the facility and their role. Two of these cases were related to wrong site surgery. Additional reported events may have involved new practitioners but that fact was not necessarily identified in the case review. In some cases, locum tenen (temporary) practitioners were involved in the event.

Potential Remedy:

Institute standardized orientation to the clinical setting for all new staff. Include safety practices and communication tools.

BIAS

A bias is an inclination to prejudge a situation without fully reviewing the facts (Groopman, 2007). Six sentinel events reported in 2007 involved patients who were well known to the reporting facility because of a history of frequent emergency room visits or admissions. In these cases, familiarity with the patient seemed to be associated with a false sense of confidence or overconfidence that the problem was not new and that interventions applied in the past should be used.

Another form of bias is 'hindsight bias' which can cause us to remember facts differently than how they actually occurred. For example, a person may make a judgment or choice and later be asked to recall the judgment. If, in the interim, the person is told what the correct judgment should have been, his/her memory of their own judgment may become biased toward the new information (Croskerry, 2003). Reviews of facilities' analyses of events found that hindsight bias often undermined the ability to look objectively at a situation when trying to determine all relevant causative factors of an event.

Potential Remedies:

1. Incorporate concepts of bias in facility staff and sentinel event team training.
2. Provide increased supervision for new staff and create an atmosphere that encourages questions.

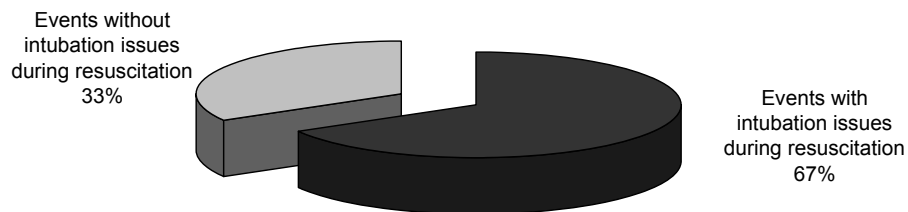
■ Clinical Trends

Aspects of 23 of the 28 reported events focused on the clinical management of a patient. The trends listed below were not identified by the facility as the primary or only cause of a sentinel event. However, they all are thought to have contributed to the complexity of the situation and/or are important to understanding opportunities for future training and improvement.

TRACHEAL INTUBATION

Of the 28 reported cases, nine involved issues with tracheal intubation during resuscitation. None of these cases were reported as sentinel events for this reason; all were reported under the “unanticipated death” category.

Table 6. Sentinel Events Involving Intubation Issues during Resuscitation



Problems identified during tracheal intubation included:

- Misplacement of the tube, including esophageal intubation as well as tube placement in the right bronchus. In some cases, the incorrect placement of the tube was not immediately assessed or detected.
- Difficulty visualizing the vocal cords was cited following aspiration.
- Equipment availability, in particular specific blade or endotracheal tube sizes.
- Equipment malfunction.

- Lack of familiarity with intubation equipment was cited as an issue during the resuscitation attempt.

Potential Remedies:

1. Ensure standardized intubation equipment on all code carts.
Inspect code carts for equipment availability and proper function
2. Consider use of fiberoptic scope to ensure proper tube placement
3. Initiate systematic review of all codes with attention to possible complications of intubation (Caplan, 1990).
4. Inspect code carts.

OBSTETRICS

Four of the reported events related to obstetrical care. Common themes among these cases included; communication between providers, delay in notifying the physician, 'failure to rescue', and coordination of care.

In, July 2004, the Joint Commission issued a Sentinel Event Alert, *Preventing Infant Death and Injury during C-Section Delivery* (Joint Commission, 2004). The Alert notes 77 percent of the cases reported to the Joint Commission involve non-reassuring fetal status as an identified complication. This is similar to the Maine experience in which three of the four fetal deaths were related to fetal heart detection and monitoring. There is a considerable amount of literature and research available on this subject (Downs, 2007; Lindsey, 2006; Sweet, 2006; Simpson, 2005, Simpson, 2006).

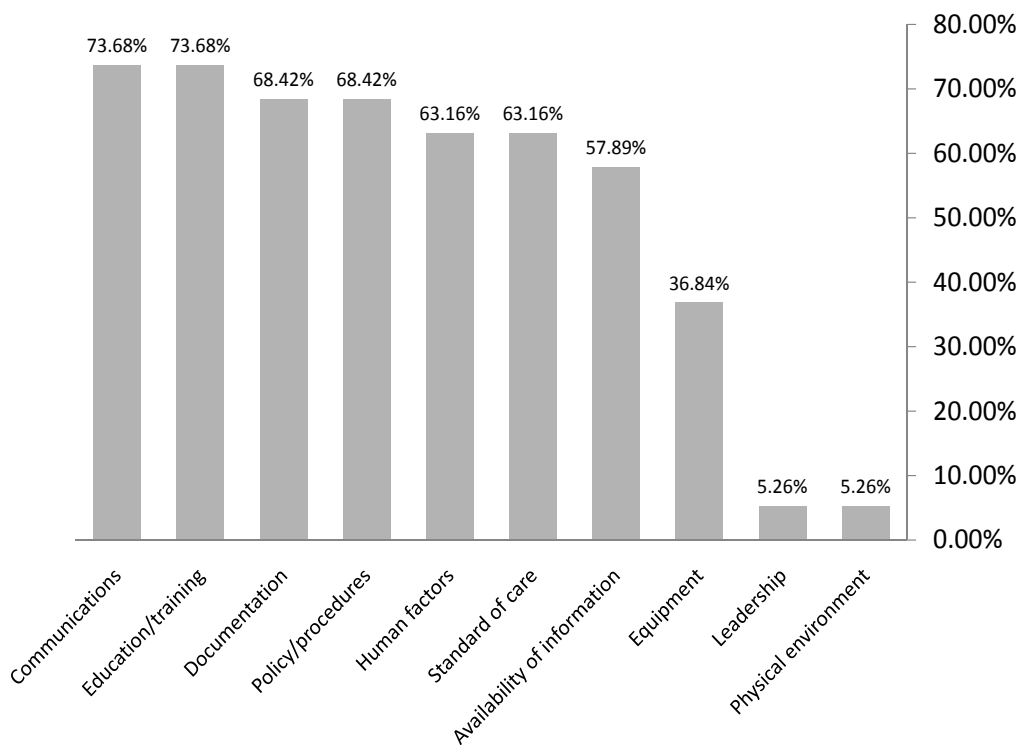
Potential Remedies:

1. Consider including the risk reduction strategies recommended in the Sentinel Event Alert (Joint Commission, 2004).
2. Consider the Joint Commission recommendations regarding organizational culture and communication among caregivers in Sentinel Event Alert (Joint Commission, 2004).

■ Facility-Reported Root Causes and Action Plans

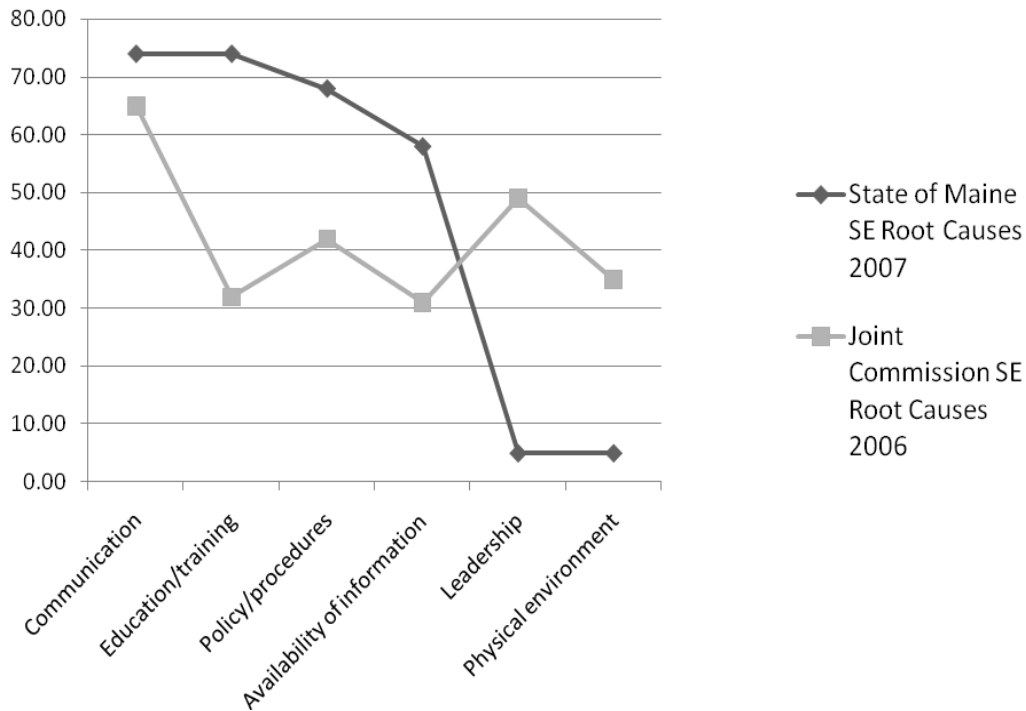
After reporting an event, the facility is required to complete an analysis of root causes and a plan to prevent their recurrence. Communication and Education were each reported as a contributing factor in nearly three-fourths of all sentinel events. Documentation and Policy and Procedures were each cited as factors influencing over 68 percent of sentinel events. Human Factors and Standards of Care each accounted for slightly over 63 percent of explanations as to why an event occurred, followed by the Availability of Information (58 percent).

Table 7. Facility-Reported Root Causes for Closed Sentinel Events, 2007



Findings in Table 7 closely parallel our analysis that the vast majority of reported events constitute cognitive errors (see Table 5). In Table 8, we compare root causes reported in Maine to those of the Joint Commission. Maine exceeds the Joint Commission average of events related to communication, education, policies and availability of information. A smaller percentage of Maine events are reported as being related to facility leadership or physical environment compared to those of the Joint Commission.

Table 8. Comparison of Reported Root Causes in Maine to those of Joint Commission



Appendix D summarizes the specific nature of root causes reported by facilities under each major category. Appendix E presents the remedies proposed by reporting facilities in their action plans.

Maine Sentinel Events by National Quality Forum (NQF) Criteria

At the request of the Maine Quality Forum, each year the Sentinel Event Team reports Maine’s events by categories of adverse events adopted by the NQF. The NQF is a national, consensus-driven private-public partnership aimed at developing common approaches to defining and measuring health care quality. A major initiative of the NQF was the identification of events that are serious in nature and have been determined to be largely preventable (National Quality Forum, 2002).² Sometimes referred to as “never events”, the NQF list increasingly has become the basis for states’ mandatory reporting system (Rosenthal, 2007). The list of NQF serious events is intended to capture events that are clearly identifiable and measurable, largely

preventable, and of interest to the public and other stakeholders. Increasingly states are using the NQF list of serious events as the basis of their mandatory reporting systems. Comparability of definitions enhances clarity about what must be reported and provides benchmarks for comparing experiences across states.

NQF serious events are structured around six categories: surgical, product or device, patient protection, care management, and environmental. Table 9 shows an increase in the number and proportion of Maine sentinel events that meet the NQF definition of an adverse event.

Table 9. State of Maine Sentinel Events Captured by NQF Criteria

Year	2005		2006		2007	
	No.	%	No.	%	No.	%
Yes	7	25%	8	32%	11	39%
No	21	75%	17	68%	17	61%
Total	28	100%	25	100%	28	100%

Note: Maine data was not compiled into NQF categories in 2004.

Of Maine’s 28 reported events, 11, or 39 percent, met NQF criteria. The remaining 17, or 61 percent, did not meet NQF criteria and would not have resulted in a report if NQF definitions alone were applied (National Quality Forum, 2002).

The Maine Quality Forum commissioned a review of the impact if Maine was to adopt the NQF list of serious reportable events in lieu of its current list (Booth et al, 2005). The use of a nationally accepted standardized list of events generally was seen as offering greater specification on what constitutes a reportable event as well as the opportunity to compare Maine’s experience with that of other states. Currently, half of the 26 state mandatory reporting systems use the NQF list or a close approximation (National Academy for State Health Policy, 2007). The study concluded that use of the NQF list would lead to the reporting of some events that are not currently or explicitly included in the Maine sentinel event list (e.g, State retention of a foreign object in a patient after surgery or other procedure unless it causes death or permanent injury). In other cases, there are events that Maine currently collects that would not be required under the NQF definition of sentinel event (e.g. NQF list is quite specific in defining which types of unanticipated deaths are reportable; Maine requires the reporting of all unanticipated deaths, subject to the ‘proper treatment’ clause).

The study found another major distinction between Maine’s reportable events and those of the NQF. National Quality Forum events are known to be primarily preventable and/or serious in nature and therefore, *a priori*, must be reported. According to Maine law, events must be reported when the facility determines them to be unrelated to the natural course of the patient’s illness or underlying condition or proper treatment of that illness or underlying condition.³ The ‘proper treatment clause’ enables facilities to review sentinel events and determine whether they are the result of proper treatment before determining whether they are reportable. The study concluded that this discretion creates an irony by allowing poor judgment that may have led to event to also affect the decision about whether an event gets reported and reviewed by the State.

Context for Reviewing Maine’s Sentinel Events

A common response when reviewing findings from a state’s adverse event reporting system is to question whether the numbers are good or bad, complete or incomplete, and how they compare to benchmarks. These are reasonable questions that cannot be easily or definitively answered. At best we are able to show how Maine’s 28 reported events fit within a range of estimated adverse events to assess our relative standing. Even then, we are not able to determine the nature of any variation or why it exists.

There are many reasons why differences in the rate of adverse events may exist, only some of which are indicative of variations in quality.

- Adverse events are defined differently across states and within the research community. Thus, in the aggregate, rates of adverse events will differ. Even within a single category of event (e.g., unanticipated death) interpretations of what must be reported may vary thus leading to a different number of reported events.
- The number and type of adverse events are affected by the mix of hospital size, volume and patient acuity – factors that vary within and across states.
- Low numbers of adverse events should not automatically be interpreted as improved performance. In cases of a hospital that rarely reports or persistently reports no events, failure to report may indicate the lack of an effective internal system for detecting problems or learning from mistakes.

- Similarly, high numbers of adverse events are not necessarily indicative of poor care. State reporting systems generally have low rates of adverse event reporting when first implemented. The number of adverse events typically increases within hospitals as their systems for identifying and reporting events improve and they better understand the requirements for what constitutes a reportable event (Rosenthal et al, 2001). Contrary to these national trends, reporting levels have remained fairly static in Maine since the program began in 2004.

Maine's sentinel event reporting system was designed to encourage reporting. The confidentiality of reports, the public disclosure of only aggregate reports without hospital identifiers, and the separation of reporting from the hospital licensure process were embedded in the system as ways to promote reporting, collaboration and shared learning. Understanding that it is not possible to solve problems that are not identified, Maine's sentinel event reporting system was intended to look beyond blame and promote patient safety through collaboration and shared responsibility. An important precept of the system has been to provide a non-punitive environment for reporting so that others can learn from mistakes and prevent their recurrence.

With these goals in mind, Maine has looked for ways to determine how well the State is doing in identifying and reporting events and thus learning from the mistakes that are occurring. The following two tables estimate the potential upper and lower bounds for the number of adverse events that may be occurring in Maine's hospitals based on national studies. There is wide variation in findings among the studies, given how each study defined a "reportable event". Some studies captured a broad net of events, including near misses or all adverse events, not just those defined as serious adverse events under Maine's reporting system.

The purpose of Table 10 is to illustrate the range of events that may be occurring in Maine hospitals. A total of 28 adverse events were reported under the sentinel event reporting system in 2007. Table 10 should not be used to determine how well Maine's reporting system is capturing reportable events given variations in how an adverse event is defined by the studies compared to reporting requirements in Maine. However, the magnitude of the discrepancy suggests serious under-reporting in Maine.

Table 10. The Expected Rate of Events in Maine Using Estimates Derived from National Studies

Study	Rate of Adverse Events	Maine 2006 * Expected Number **
Sari et al (2007). Random sample of 1006 hospital admissions in 2004 in a large national health service hospital in England. Focus was on the full range of adverse events.	8.7 per 100 admissions	12,915
Nuckols et al (2007). Review of 16,575 randomly selected patients from an academic and community hospital in the US in 2001. Focus was on the full range of adverse incidents occurring in hospitals.	17 per 1000 patient days	11,437
Baker et al, (2004). Review of incidence of adverse events among 1 teaching, 1 large community and 2 small community hospitals in each of 5 Canadian provinces in 2000. Focus was on the full range of adverse incidents occurring in hospitals.	7.5 per 100 admissions	11,133
Davis et al (2002). Review of 6579 records in 13 public hospitals with 100 beds or more in New Zealand, 1998. Focus was on preventable adverse events.	6.3 per 100 admissions	9,352
Brennan et al (1991). Harvard Medical Practice Study. Review of 30,124 randomly selected records from 51 randomly selected acute care, non-psychiatric hospitals in NY in 1984. Focus was on injuries caused by medical management.	3.7 per 100 hospital discharges	5,492
Thomas et al (2002). Review of 15,000 medical records from 28 hospitals in Utah and Colorado in 1992. Focus on injury caused by medical management that results in prolonged hospital stay or disability at discharge.	2.9 per 100 admissions	4,305

* Data provided by the Maine Health Data Organization (MHDO) for the CY 2006, the most recent full year of data available.

** Estimates derived by applying the rate of adverse events found in each study to applicable Maine data for CY 2006. Note that discharges and discharge days were used in place of admissions and patient days. Discharges and discharge days do not include codes related to mental illness and disorders, alcohol and drug abuse.

Table 11 looks at only the subset of adverse events related to deaths. Each of the identified studies focused on identifying deaths that were caused by medical management and could have been prevented. Definitions used in these studies for “probably preventable” approximate the reportable event under Maine’s reporting system known as “unanticipated death”.

Table 11: The Expected Rate of Unanticipated Deaths in Maine Hospitals Using Estimates Derived from National Studies

Study	Rate of Adverse Events	Maine 2006 * Expected Number **
Dubois and Brook (1988). Reviewed 182 deaths from 12 hospitals to assess those that were preventable	27% of deaths might be preventable; 14% probably preventable	1026 deaths might be preventable; 532 deaths probably preventable
Hayward and Hofer (2001). Reviewed records on 111 hospital deaths at 7 VA Centers, 1995-96.	22.7% of deaths might be preventable; 6.0% probably preventable	1008 deaths might be preventable; 224 deaths probably preventable

* Data provided by the Maine Health Data Organization (MHDO) for the CY 2006, the most recent full year of data available.

** Estimates derived by applying the rate of deaths in each study to total number of deaths occurring in Maine hospitals for CY 2006.

The actual number of unanticipated deaths reported in Maine was 14 in 2006 and 20 in 2007. Tables 10 and 11 help put Maine’s sentinel event reporting system within a broader context and raise questions about whether the current system is effective in identifying all serious events. Later we discuss plans for the coming year to strengthen the program and to work more closely with hospitals to improve the detection and disclosure of reportable events.

Sentinel Event Program Highlights

The sentinel event program serves a broader goal than documenting and following-up on reported events. The program is the focal point within State government for promoting patient safety in Maine’s hospitals and other licensed facilities. Following is a summary of major program activities in 2007.

Patient Safety Improvement Corps

The sentinel event program, in partnership with Maine Medical Center, was accepted into the national Patient Safety Improvement Corps (PSIC). Cosponsored by the Agency for Health Care Quality (AHRQ) and the Veterans Administration (VA), the PSIC is a unique collaborative of public and private entities to reduce medical errors and improve patient safety.

Over the course of the two-year initiative, teams from the Sentinel Event Program and Maine Medical Center will be joining other states and their partners in intensive skill-building training to better understand why adverse events occur, to design effective and sustainable interventions, and to evaluate the effectiveness of improvement efforts. As part of its participation, Maine has committed to two projects to advance patient safety within the State: (1) build awareness in Maine hospitals of the TeamSTEPPS™ program as a way to strengthen communication across practitioners, and (2) work with hospital risk managers and quality improvement staff on using a root cause analysis (RCA) approach when identifying factors contributing to the occurrence of an event. A statewide conference is planned in Fall, 2008, at which time experts on the subject of patient safety will present to Maine hospital leaders.

Outreach Activities

In an effort to build awareness of the State's sentinel event system and to strengthen reporting, on-site visits were made to every hospital that had not reported a sentinel event since the program's inception. Sentinel Event Team members focused these visits on reporting requirements, their relationship to the facility's own risk management program, and the reporting process. Following an established protocol, the Sentinel Event Team also assessed a facility's readiness to detect and report events. This included a review of areas where serious cases are documented or discussed, such as various committee minutes, incident reports, medication error review, and code reviews

Visits were also an opportunity to hear directly from facilities about their perceptions of the sentinel event reporting system and its relevance to improving the patient safety of Maine hospitals. At the conclusion of a visit, the team shared their observations on the 'readiness' of the facility to report an event and made recommendations for strengthening the facility's patient safety efforts.

Findings from these visits indicate that sentinel events have gone unreported. These on-site visits, which concluded in December 2007, raise important observations about factors affecting sentinel event reporting:

- There is a strong sentiment that reporting a sentinel event is construed as a negative mark against the facility. CEOs were

less likely to see reporting as indication of an effective quality management system or a culture of safety that is open to revealing problems.

- Statutory language referring to an event as being “unrelated to the natural course of the patient’s illness or underlying condition or proper treatment of that illness or underlying condition”, can lead to different conclusions as to whether an event must be reported. Some facilities rely on the advice of standing committees. Others make their determinations based on criteria provided by the facility’s insurance carrier. Other facilities are simply unclear.
- Individuals new to the patient safety and risk reduction processes expressed a need for education and training in reporting requirements and the analysis of weak points in their systems that may lead to events.
- Key elements were seen by the Sentinel Event Team as contributing to the ‘readiness’ of a facility to report sentinel events and a presence of a culture of safety. These included:
 - ❑ a history of documenting problems and their likely causes
 - ❑ staff knowledgeable of patient safety principles and Maine’s sentinel event reporting requirements
 - ❑ evidence of patient safety initiatives
 - ❑ policies and procedures governing when and how events get reported
 - ❑ specific identifiable person or entity responsible for reviewing and reporting events
 - ❑ criteria for determining when indepth analyses should be conducted to determine root cause
 - ❑ database for tracking occurrences/incidents or medication errors
 - ❑ conflict resolution and chain of command policies adopted and understood by staff.

At the close of each on-site visit, the Sentinel Event Team provided specific recommendations on how the facility could enhance its patient safety efforts. The Sentinel Event Team provided feedback on best practices and shared available tools and techniques to identify, address and report adverse events. The Team also reinforced its availability to assist and consult on issues or events that are identified. Recommendations to facilities based on these reviews are presented in Appendix F.

Conclusions and Recommendations

Maine's sentinel event reporting system focuses on identifying and deterring serious, preventable incidents. Due to the critical nature of these events, the State has a vested interest and responsibility for assuring that everything possible is done to address sentinel events when they happen, and that practices to prevent their recurrence are widely understood and adopted. Mandatory reporting is the primary tool for the State to hold facilities accountable for disclosing that an event has occurred and that appropriate action has been taken to remedy the situation. The system was designed to learn from mistakes, not punish individual practitioners or providers. To be effective, the system requires the participation of all hospitals and other reporting entities. Only by understanding the full scope of the problem can strategies be developed to improve patient safety throughout the State. However, findings suggest that there is serious under-reporting in Maine. In the coming year, the sentinel event program will work closely with hospitals and others to strengthen the reliability of reporting.

- The State will assess the feasibility of using Maine's all payer database to validate whether all events are being reported. The State will work with the Maine Health Data Organization, the Maine Quality Forum and Maine hospitals to identify reportable events that can reliably be detected through administrative data and to develop the specifications for doing so. Results from this analysis will be used for case finding.
- Protocols for conducting audits within hospitals will be developed to validate that all sentinel events have been reported.
- The Sentinel Event Team will continue to assess the adequacy of hospitals' internal systems for detecting and reporting events and to explore why some hospitals have not reported.
- Complaint data will continue to serve as a cross-check on the reporting system for those incidents that rise to the level of a reportable event.

A second major initiative will focus on the sentinel event statute. Working with the Maine Quality Forum, the program will examine how statutory language and specifications can be improved to reduce ambiguities about what must be reported.

Finally, the program will continue to maintain ongoing communications with Maine hospitals, other licensed facilities and stakeholders regarding reporting requirements and lessons that can be learned to prevent events from being repeated. The State is committed to maintaining a collaborative approach for identifying serious adverse events and working toward joint solutions for reducing their occurrence in a non-punitive environment. However, the overarching goal of the reporting system is to improve the quality of health care and to honor our pledge to the Maine people that the State is a credible overseer of the quality of care in Maine.

Endnotes

¹ Exceptions include cases of a complaint investigation or if the hospital is selected by the Medicare program for a survey to validate Joint Commission findings.

² Since the original publication of the NQF list of serious reportable events, additional events have been added.

³ Me. Rev. Stat. Ann. tit. 22, § 8753 (2003). Definitions at <http://janus.state.me.us/legis/statutes/22/title22sec8752.html>

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Appendix A

Chapter 1684: SENTINEL EVENTS REPORTING (HEADING: PL 2001, c. 678, §1 (new))

§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. [2001, c. 678, §1 (new); §3 (aff).]

PL 2001, Ch. 678, §1 (NEW).

PL 2001, Ch. 678, §3 (AFF).

§8752. Definitions

As used in this chapter, unless the context otherwise indicates, the following terms have the following meanings. [2001, c. 678, §1 (new); §3 (aff).]

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

[2001, c. 678, §1 (new); §3 (aff).]

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.

[2001, c. 678, §1 (new); §3 (aff).]

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.

[2001, c. 678, §1 (new); §3 (aff).]

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, subsection (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;

[RR 2001, c. 2, Pt. A, §37 (cor); §38 (aff).]

B. Surgery on the wrong patient or wrong body part; [2001, c. 678, §1 (new); §3 (aff).]

C. Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities; [2001, c. 678, §1 (new); §3 (aff).]

D. Suicide of a patient in a health care facility where the patient receives inpatient care; [2001, c. 678, §1 (new); §3 (aff).]

Text current through December 31, 2006, document created 2006-11-01, page 1.

E. Infant abduction or discharge to the wrong family; or [2001, c. 678, §1 (new); §3 (aff).]

F. Rape of a patient. [2001, c. 678, §1 (new); §3 (aff).]

[RR 2001, c. 2, Pt. A, §37 (cor); §38 (aff).]

PL 2001, Ch. 678, §1 (NEW).

PL 2001, Ch. 678, §3 (AFF).

RR 2001, Ch. 2, §A37 (COR).

RR 2001, Ch. 2, §A38 (AFF).

§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. [2001, c. 678, §1 (new); §3 (aff).]

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.

[2001, c. 678, §1 (new); §3 (aff).]

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; [2001, c. 678, §1 (new); §3 (aff).]

B. Name, title and phone number of the contact person for the facility; [2001, c. 678, §1 (new); §3 (aff).]

C. The date and time of the sentinel event; [2001, c. 678, §1 (new); §3 (aff).]

D. The type of sentinel event and a brief description of the sentinel event; [2001, c. 678, §1 (new); §3 (aff).]

E. Identification of clinical and organizational systems or processes that may have contributed to the sentinel event; [2001, c. 678, §1 (new); §3 (aff).]

F. Identification of changes that could be made that would reduce the risk of such a sentinel event occurring in the future; and [2001, c. 678, §1 (new); §3 (aff).]

G. A brief description of any corrective action taken or planned. [2001, c. 678, §1 (new); §3 (aff).]

[2001, c. 678, §1 (new); §3 (aff).]

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.

[2001, c. 678, §1 (new); §3 (aff).]

Text current through December 31, 2006, document created 2006-11-01, page 2.

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.

[2001, c. 678, §1 (new); §3 (aff).]
PL 2001, Ch. 678, §1 (NEW).
PL 2001, Ch. 678, §3 (AFF).

§8754. Division duties

The division has the following duties under this chapter. [2001, c. 678, §1 (new); §3 (aff).]

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.

[2001, c. 678, §1 (new); §3 (aff).]

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.

[2001, c. 678, §1 (new); §3 (aff).]

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.

[2001, c. 678, §1 (new); §3 (aff).]

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. [2001, c. 678, §1 (new); §3 (aff).]

C. The division shall take appropriate measures to protect the security of any information to which this chapter applies. [2001, c. 678, §1 (new); §3 (aff).]

Text current through December 31, 2006, document created 2006-11-01, page 3.

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. [2001, c. 678, §1 (new); §3 (aff) .]

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.

[2001, c. 678, §1 (new); §3 (aff) .]

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

[2001, c. 678, §1 (new); §3 (aff) .]

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.

[2001, c. 678, §1 (new); §3 (aff) .]

PL 2001, Ch. 678, §1 (NEW) .

PL 2001, Ch. 678, §3 (AFF) .

§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. [2001, c. 678, §1 (new); §3 (aff) .]

PL 2001, Ch. 678, §1 (NEW) .

PL 2001, Ch. 678, §3 (AFF) .

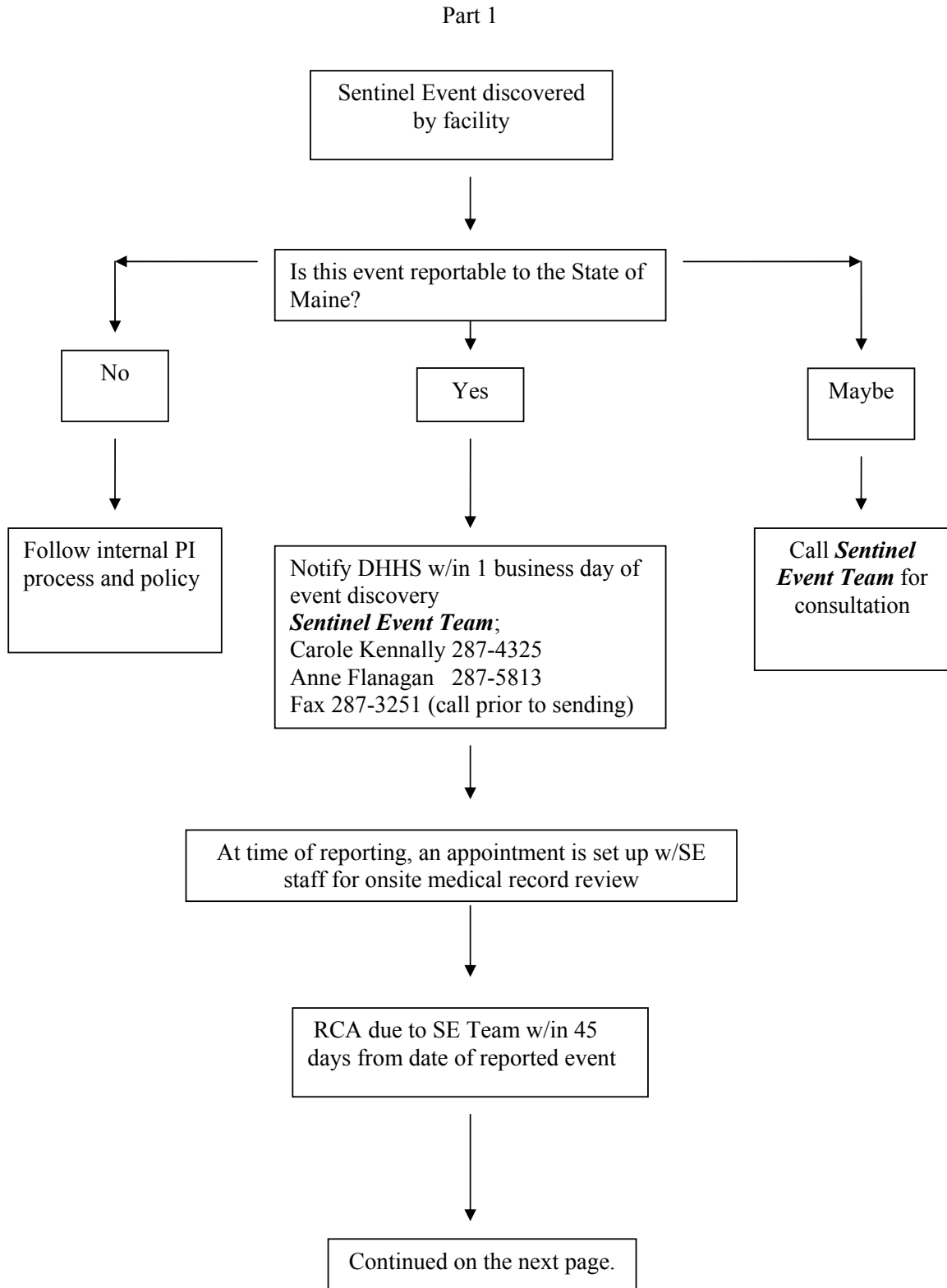
§8756. Rulemaking

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. [2001, c. 678, §1 (new); §3 (aff) .]

PL 2001, Ch. 678, §1 (NEW) .

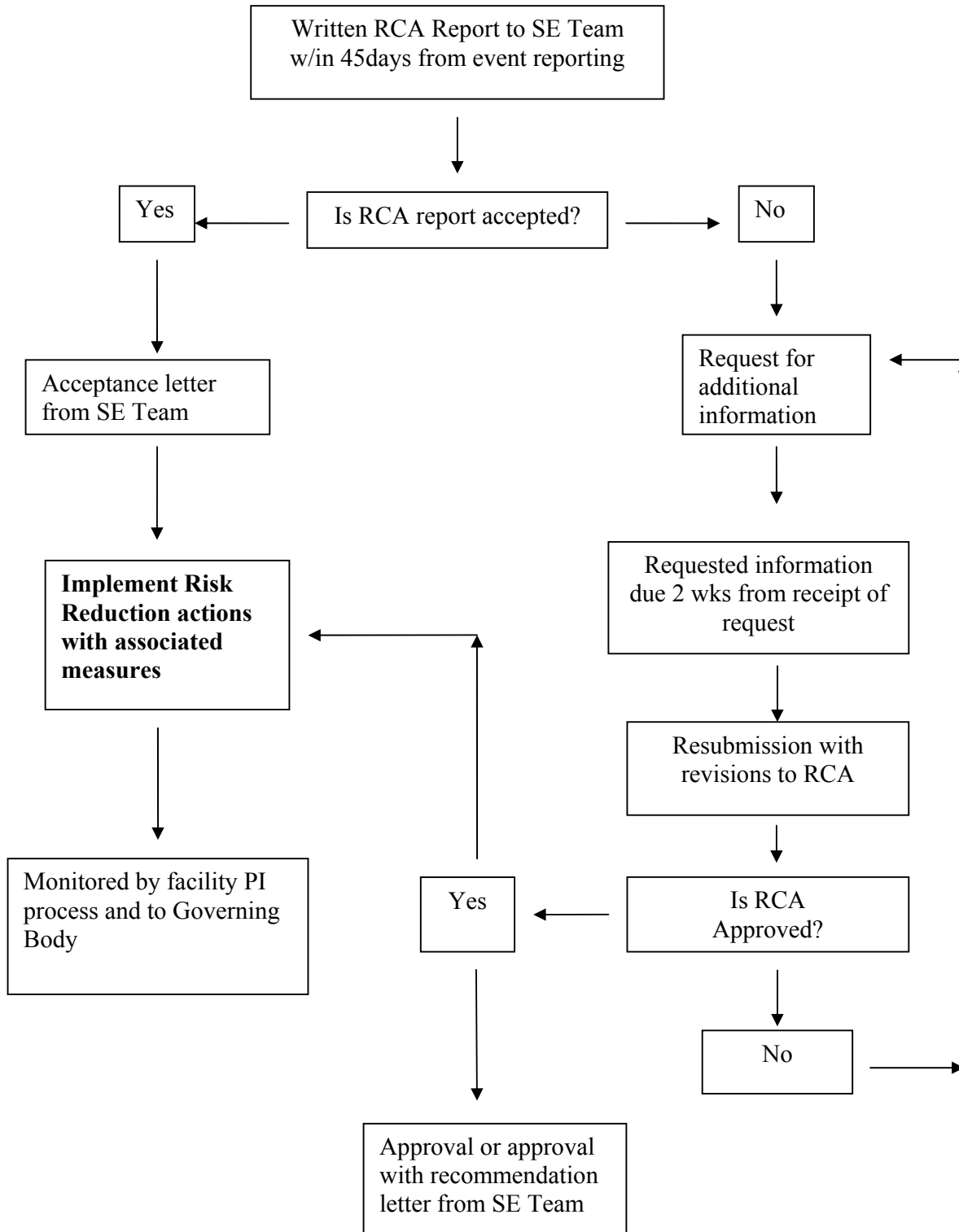
PL 2001, Ch. 678, §3 (AFF) .

Appendix B



Sentinel Event Process Flow

Part 2



Appendix C

PUBLIC Law, Chapter 314, 123rd Maine State Legislature
An Act To Prevent Duplication in Certification of Hospitals

An Act To Prevent Duplication in Certification of Hospitals

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

Sec. 1. 22 MRSA §1816, as amended by PL 1997, c. 488, §2, is further amended by adding at the end a new paragraph to read:

A hospital licensed under this chapter is exempt from department inspection requirements under this chapter if the hospital is certified by the Centers for Medicare and Medicaid Services for participation in the federal Medicare program and holds full accreditation status by a health care facility accrediting organization recognized by the Centers for Medicare and Medicaid Services. If a hospital is certified to participate in the federal Medicare program and not accredited by a health care facility accrediting organization recognized by the Centers for Medicare and Medicaid Services, the department shall inspect the hospital every 3 years for compliance with the Centers for Medicare and Medicaid Services' conditions of participation. The provisions of this paragraph do not exempt a hospital from an inspection by the department in response to a complaint or suspected violation of this chapter or of the Centers for Medicare and Medicaid Services' conditions of participation or an inspection by another state agency or municipality for building code, fire code, life safety code or other purposes unrelated to health care facility licensing or accreditation. For purposes of this paragraph, "Centers for Medicare and Medicaid Services" means the United States Department of Health and Human Services, Centers for Medicare and Medicaid Services.

Sec. 2. Effective date. This Act takes effect July 1, 2008.

Appendix D

FACILITY-REPORTED ROOT CAUSES

Most Frequently Cited Root Causes
Communication (number of events =14)
<ul style="list-style-type: none"> • One-on-one communication/conflict • Failure to utilize the chain of command policy when issues arise • Failure to communicate change in clinical status • Delay in notifying physician due to time of day/day of week • Failure to communicate clinical information at change of shift
Education/Training (number of events = 14)
<ul style="list-style-type: none"> • Resuscitation issues: errors in intubation; procedures and assessment, lack of familiarity with use of defibrillator paddles and pacemaker • New personnel; unfamiliar with procedures and staff • Variable level of knowledge regarding the operative procedure
Policy and Procedures (number of events = 12)
<ul style="list-style-type: none"> • Universal protocol for timeout (validation) procedures not followed • Process for obtaining Informed consent; timing, process for including family • Fall prevention program: criteria for requesting one-on-one observation
Documentation (number of events = 12)
<ul style="list-style-type: none"> • Incomplete forms and tools • Surgery scheduled without laterality identified
Human Factors (number of events = 12)
<ul style="list-style-type: none"> • Individual reluctance to activate the chain of command • Reluctance to ask for additional assistance when needed • Documentation between physicians • Surgeon beginning procedure before the equipment is ready
Standard of Care (number of events = 12)
<ul style="list-style-type: none"> • INR/anticoagulants heparin procedures/policies • Need for timely intervention when patient status changed • Interpreter services not readily available
Availability of Information (number of events = 11)
<ul style="list-style-type: none"> • Out patient medical record and history not available • Information following transfer not available
Equipment (number of events = 11)
<ul style="list-style-type: none"> • Improper endotracheal tube placement • Need for rapid blood transfusion and defibrillator paddles • Incompatible with defibrillator

Appendix E

FACILITY REPORTED ACTION PLANS (Page 1 of 2)

Communication (number of events =14)
<ul style="list-style-type: none"> • Request additional assistance as patients' status changes. • Provide TeamSTEPPS™ training • Communicate change in patient status to physician and entire team • Communicate to team when decision is made to advance case to more invasive procedure
Education/Training (number of events = 14)
<ul style="list-style-type: none"> • Institute medication reconciliation • Expand training on use of ultrasound to determine fetal heart • Educate new, less assertive staff regarding chain of command • Enhance code skills, e.g. defibrillation, pacemaker, intubation • Provide additional training for fetal heart monitoring
Policy and Procedures (number of events = 12)
<ul style="list-style-type: none"> • Improve timeout process in the operating room: no noise, no music during time out procedure, increase involvement in timeout procedure, require all surgery to include laterality at the time of booking, clarify process for viewing radiology images in the operating room, ensure patient identification bracelet does not interfere with markings, require adherence to timeout in all operative settings, scalpel blade will not be loaded until timeout completed • Adhere to universal timeout procedure • Add an Interdisciplinary guidelines checklist • Fall prevention program criteria addresses one-to-one staffing, sitter duties, hourly patient checks • Update Chain of Command policy • Institute Methadone Maintenance Protocol • Develop policy to include 2nd pathologist read • Develop process for sequestering records • Site verification prior top starting IV
Documentation (number of events = 12)
<ul style="list-style-type: none"> • Revise fall scoring tool to include related factors such as obesity • Create pre-printed heparin order sheets • Revise Code form to capture times and events • Require timely documentation of change in patient status • Ensure prenatal information is available in patient medical record • Include discharge information in all transfer documents

■ Appendix F

Recommendations from Sentinel Event Team to Non-Reporting Hospitals

Policy and Procedures
<ol style="list-style-type: none"> 1. Update sentinel event policies and procedures to reflect regulatory language, including Division contact information, and the current Sentinel Event Reporting Form: <ol style="list-style-type: none"> a. Identify the person(s) responsible to initiate contact with the Division; b. Clarify and separate sentinel event definitions based on State regulatory language, and the Joint Commission. Also indicate that notification to the Division takes priority; c. Provide consistent language defining sentinel events, serious adverse events, and near-misses and close calls.
<ol style="list-style-type: none"> 2. Develop policy regarding Conflict Resolution to include communication between all levels of staff.
<ol style="list-style-type: none"> 3. Develop policy explaining use of Chain of Command.
Tracking/Trending Data
<ol style="list-style-type: none"> 1. Develop a process to track incidents and other high risk events.
<ol style="list-style-type: none"> 2. Create a mechanism to grade the gravity of the event, with a “trigger” for risk reduction review.
<ol style="list-style-type: none"> 3. Review cases that meet the ‘trigger’ designation, including ‘near misses’ and ‘close calls’, for possible Root Cause Analysis or Healthcare Failure Mode Effect Analysis activity.
Patient Transfer
<p>Develop a mechanism to track and trend high risk patient transfer activity to identify opportunities to improve.</p>
Post Discharge Follow-Up
<p>Develop a system to monitor post-discharge follow up calls for possible complications or untoward outcomes.</p>
Case Review and Committee Activity
<p>Documentation from committees reviewing cases should provide sufficient evidence to support conclusions that appropriate care was provided.</p>