

Paul R. LePage, Governor

Mary C. Mayhew, Commissioner

Department of Health and Human Services
Commissioner's Office
221 State Street
11 State House Station
Augusta, Maine 04333-0011
Tel.: (207) 287-3707; Fax (207) 287-3005
TTY Users: Dial 711 (Maine Relay)

April 7, 2017

Senator Eric L. Brakey, Chair
Representative Patricia Hymanson, Chair
Joint Standing Committee on Health and Human Services
100 State House Station
Augusta, Maine 04333-0100

Dear Senator Brakey, Representative Hymanson and members of the Joint Standing Committee on Health and Human Services:

Enclosed is the *Sentinel Events Annual Report for calendar year 2016*. The Sentinel Events Reporting statute (22 M.R.S.A. §8754) directs the Department of Health and Human Services to submit an annual report to the Legislature, healthcare facilities and the public that includes summary data of the number and types of sentinel events reported during each calendar year.

If you have any questions or would like further information, please feel free to contact Sheryl Peavey, Chief Operating Officer, Maine Center for Disease Control and Prevention.

Sincerely,

Mary C. Mayhew
Commissioner

MCM/klv

Enclosure

cc: Sheryl Peavey, Chief Operating Officer, Maine Center for Disease Control and Prevention

Sentinel Events

CY2016

Annual Report to the Maine State Legislature



*Maine Center for Disease
Control and Prevention*

*An Office of the
Department of Health and Human Services*

Paul R. LePage, Governor

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Sentinel Event Annual Report prepared by:
The Division of Licensing and Certification
Maine Center for Disease Control and Prevention
Department of Health and Human Services
41 Anthony Avenue
11 State House Station
Augusta, ME 04333-0011

For further information please contact:

Joseph Katchick, RN
Public Health Nurse Supervisor
(207) 287-9300 or joseph.katchick@maine.gov

Sarah Taylor, MBA, FACMPE
Director, Division of Licensing and Certification
(207) 287-9300 or sarah.taylor@maine.gov

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Executive Summary

Maine's Sentinel Event Program requires hospitals, ambulatory surgical centers (ASC), end stage renal disease facilities (ESRD) and intermediate care facilities for individuals with intellectual disabilities (ICF/IID) to report all sentinel events to the Sentinel Events Team (SET), with the goal of improving the quality of healthcare and increasing patient safety throughout the State. The Sentinel Event Program provides a structure by which facilities can gain an understanding of the causes that underlie the event and changes to systems and processes that will reduce the probability of future events. The SET, part of the Division of Licensing and Certification (DLC), is responsible for overseeing the Sentinel Event Program.

The SET collects data regarding sentinel events and near misses (events that did not rise to the level of a sentinel event, but might have if not discovered and prevented), the underlying causes and facility identified action plans, and stores this information in a secure database. While maintaining the confidentiality of facility-specific data, the SET uses aggregated and de-identified data in its outreach efforts. Facility-specific information is confidential and protected by statute; it is only shared with the original reporting facility.

Patient safety literature has identified the importance of taking a systems approach to safety, and sustaining a culture that supports patient safety efforts. Health care systems that embody these concepts are considered 'learning organizations'; organizations where leadership behavior supports learning and creates a supportive learning environment.¹ The level of importance that senior leaders place on patient safety is evident in an organization's response to sentinel events occurring in the facility. In recognition of this, the SET hosted a "Leadership in Patient Safety" conference in May, 2016, with a nationally recognized patient safety expert as the keynote speaker. Five senior leaders of healthcare facilities in Maine also made presentations, outlining their successes and challenges in developing an environment that supports patient safety and continuous learning.

The value and benefit of healthcare leaders and staff sharing their experiences with one another cannot be emphasized enough. In the collaborative programs that the SET has facilitated, the openness of the attendees and willingness to help one another has been inspirational. In 2016, the learning collaborative focused on patient falls prevention, one of the most frequently reported sentinel events.

The SET continued its on-site reviews to determine if facilities are in compliance with the Sentinel Event Program requirements. Thirteen on-site reviews were completed during 2016. Issues identified were predominantly related to policies/procedures, sentinel event orientation for new hires and education for providers and staff. Best practices were also identified during these on-site reviews which the SET identified for the facility and shared with others through the quarterly SE Newsletter.

¹ "An Organizational Framework for Patient Safety", Edwards, M., *American Journal of Medical Quality*, 2/25/16

How to Use this Report

The Maine Sentinel Event Annual Report is one of many sources of information available to the public related to health care quality and patient safety. It is designed to provide an overview of the Sentinel Event Program, including background information regarding the Program, review of SET activities, reporting of aggregated data and trends, and plans for the upcoming year.

The fact that health care providers are looking for potential adverse events and reporting them in order to learn and prevent harm to patients is a positive step in the work of improving patient safety. The sentinel event data listed in this report reflects organizational transparency in addressing patient safety issues. Consumers are discouraged from reaching conclusions about the safety of patient care in Maine healthcare facilities based only on the data included in this report. Consumers are encouraged to talk with their healthcare providers about patient safety questions or concerns, and to be active participants in their own health care.

The events listed in this report represent a very small fraction of all the healthcare services performed in Maine facilities. The number of reported events can fluctuate at a facility for a variety of reasons. The size of the facility, the volume of services, and the type and complexity of procedures will influence the number of events reported. The number of reported events will also be higher from facilities that are especially vigilant about identifying and reporting errors. This heightened vigilance helps foster an organizational culture where staff members feel comfortable reporting patient safety concerns without fear of reprisal. Healthcare facilities that embrace this safety-focused culture look at adverse events as opportunities to learn and improve.

Information regarding healthcare quality and safety is available from a number of organizations dedicated to promoting patient safety. A listing of some of these resources is provided in Appendix D of this report.

Background

Maine's Sentinel Event Program was established in 2002 with enactment of Public Law 2001, Chapter 678 to create a system for reporting all sentinel events, with the goal of improving the quality of healthcare and increasing patient safety throughout the State. Beginning in 2004, mandated reporting of sentinel events has been required of hospitals, ambulatory surgical centers (ASC), end-stage renal disease facilities (ESRD), and intermediate care facilities for individuals with intellectual disabilities (ICF/IID).

This report is submitted in accordance with Maine law (22 M.R.S.A. §§8751-8756) that requires that an annual report be provided 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. This report is designed to:

- Build awareness of Maine's sentinel event reporting requirements and the follow-up process used by facilities and the SET when events occur;
- Provide aggregated data and information about the number and nature of sentinel events reported;
- Identify patterns and make recommendations to improve the quality and safety of patient care;
- Describe efforts to address under-reporting;
- Review efforts to enhance the role of sentinel event reporting in improving patient safety; and
- Maintain best practice reporting by updating event criteria to current national standards.

Reporting systems are an important mechanism for generating knowledge about errors and their underlying causes. They help providers learn from experience; share lessons learned and monitor their progress over time.

Maine, along with all other New England states, make up some of the 28 states, including the District of Columbia, that have prioritized improvements in patient safety by implementing a mandatory sentinel event reporting program. As with the majority of reporting states, Maine uses state-identified sentinel event criteria as well as the National Quality Forum's (NQF) list of serious reportable events. Appendix A contains the Maine-specific and NQF definitions of mandatory reportable sentinel events. The Joint Commission, a healthcare accrediting agency for many hospitals, has been collecting sentinel event reports since 1995. This is a voluntary reporting program, however, so facilities are not compelled to report sentinel events.

There are other entities that collect information related to safety and quality of healthcare. One of these, the Leapfrog Group, is a voluntary program "aimed at mobilizing employer purchasing power to alert America's health industry that big leaps in health care safety, quality and customer value will be recognized and rewarded". [The Leapfrog Hospital Survey](#) compares hospitals' performance on the national standards of safety, quality, and efficiency that are

deemed most relevant to consumers and purchasers of care. The survey is the only nationally standardized and endorsed set of measures that captures hospital performance in patient safety, quality and resource utilization. Leapfrog's [Hospital Safety Score](#)[®] assigns A, B, C, D and F grades to more than 2,500 U.S. hospitals based on their ability to prevent errors, accidents, injuries and infections. The Hospital Safety Score is calculated by top patient safety experts, peer-reviewed, fully transparent, and free to the public.

Participation in the Leapfrog group surveys is not related to the Sentinel Event Program. It is, however, an indication of the importance hospitals place on patient safety and their willingness to be transparent regarding their performance. In 2016, all of Maine's acute and critical access hospitals submitted data to the Leapfrog Group. Eight Maine hospitals were included in the Leapfrog Top Hospitals lists (www.leapfroggroup.org/ratings-reports/top-hospitals), as announced in December. Hospitals recognized are as follows:

- Bridgton Hospital
- Charles A. Dean Memorial Hospital
- LincolnHealth
- Mayo Regional Hospital
- Pen Bay Medical Center
- Sebecook Valley Health
- Stephens Memorial Hospital
- St. Mary's Regional Medical Center of Maine

The Leapfrog Group has established criteria for hospitals, children's hospitals and rural hospitals. Criteria for inclusion in the Leapfrog Top Hospitals (hospitals and rural hospitals) include the following:

- A hospital must fully meet Leapfrog's standard for preventing medical errors (computerized physician order entry);
- A hospital must fully meet Leapfrog's standard for ICU physician staffing (does not apply to rural hospitals);
- A hospital must fully meet Leapfrog's standards for high-risk surgeries and procedures (does not apply to rural hospitals);
- A hospital must achieve a Value Score of 77 or better as calculated through Leapfrog's Hospital Recognition Program;
- Hospitals eligible for a Hospital Safety Score must receive an A on the letter grades publicly reported at the time of the Top Hospital public announcement; and
- Hospitals must satisfy the Top Hospital Selection Committee that in general the hospital embodies the highest standards of excellence worthy of the Leapfrog Top Hospital designation.

Children's Hospitals must achieve a Quality Score of 90 or better as calculated through Leapfrog's Hospital Recognition Program.

Reporting Requirements

The Maine Sentinel Event Program receives the authority to carry out its activities in Maine MRSA Title 22, Chapter 1684, §8754, *Division Duties*. This statute establishes a system for reporting sentinel events for the purpose of improving the quality of health care and increased patient safety.

Notification - facilities must notify the SET within one business day of discovering a possible sentinel event. Through a confidential telephone exchange of information, the SET determines whether the incident conforms to the statutory definition of a sentinel event. Upon confirmation by the SET that the event must be reported, the facility is required to submit a brief description of the incident to the SET. A copy of the notification form used by facilities can be found in Appendix A.

Root Cause Analysis - facilities are required to conduct a root cause analysis after every sentinel event. A root cause analysis is a systematic approach to problem solving that identifies the causal factors related to an adverse event. The SET does not dictate how facilities conduct or record root cause analyses. The Joint Commission and the Veterans Administration have developed root cause analysis forms and processes that are available for healthcare facilities to use, without charge. Additionally, the National Patient Safety Foundation released the RCA2 report. It was created with the intent to help health professionals standardize the process and improve the way they investigate medical errors, adverse events, and near misses.

To be acceptable to the SET, root cause analyses must be both thorough and credible. For purposes of the Sentinel Event Program, these terms are defined as follows:

A *thorough* root cause analysis includes at least the following information:

- An analysis of the underlying systems and processes to determine where redesign might reduce risk;
- An inquiry into all areas appropriate to the specific type of event;
- A determination of the human and other factors most directly associated with the sentinel event, and the processes and systems related to its occurrence;
- An identification of risk points and their potential contributions to the event;
- A determination of potential improvement in processes or systems that would tend to decrease the likelihood of such an event in the future or a determination, after analysis, that no such improvement opportunities exist;
- An action plan that identifies changes that can be implemented to reduce risks or formulates a rationale for not undertaking such changes; and,
- Where improvement actions are planned, an identification of who is responsible for implementation, when the action will be implemented and how the effectiveness of the action will be evaluated.

A *credible* root cause analysis meets the following criteria:

- It includes participation by the leadership of the healthcare facility and by the individuals most closely involved in the processes and systems under review;
- It is internally consistent (that is, it does not contradict itself or leave obvious questions unanswered);
- It provides an explanation for all findings, including those identified as “not applicable” or “no problem;” and,
- It includes the consideration of any relevant literature.

The root cause analysis report, including action plans, must be sent to the SET within 45 days of discovery of the sentinel event. The facility’s Chief Executive Officer (CEO) is required to sign this report to assure his/her active engagement in understanding factors leading to the event and plans for mitigating its recurrence.

Once received, the SET reviews the report to determine that a thorough and credible evaluation was performed, and that appropriate action plans were developed, with assigned responsibilities and timelines for their implementation. Reports that are incomplete are returned to the facility by the SET. The SET may provide technical assistance to facilities in discussing sentinel events, but it is the responsibility of the facility to conduct a thorough and credible root cause analysis. Once an acceptable report is received, the SET sends an acceptance letter to the facility’s CEO. A flow chart diagramming the sentinel event case review process can be found in Appendix B.

A facility that knowingly violates any provision of the notification and/or the reporting requirements is subject to a civil penalty of up to \$10,000.

The SET utilizes a confidential, secure database to gather and track information collected on reported events, their associated root causes and applicable action plans. This database provides a management system for tracking events and incoming reports, and is the primary source for the SET’s data and reports. The sentinel event management system helps the SET identify patterns or trends in the frequency of sentinel events and common factors associated with events. The management system continues to be refined by the SET to include more granular information that is helpful in identifying trends.

The SET provides facilities with facility-specific sentinel event data, which can be helpful in identifying ongoing issues. Aggregated data is made available in the Sentinel Event Annual Report. De-identified root causes and action plans may be used by the SET for educational purposes.

Not all events reported to the SET fit the definition of a sentinel event. The SET will notify a facility if the reported event does not constitute a sentinel event. Facilities are encouraged, although not required to report ‘near misses’. Conducting a root cause analysis of a ‘near miss’ can help identify systems’ issues that, if not addressed, could result in a sentinel event in the

future. The root cause and action plans from these 'near miss' reviews are entered into the database for educational purposes.

Annually, all covered facilities must provide the SET with a written attestation that contains an affirmative statement that it reported all sentinel events that occurred in the prior calendar year.

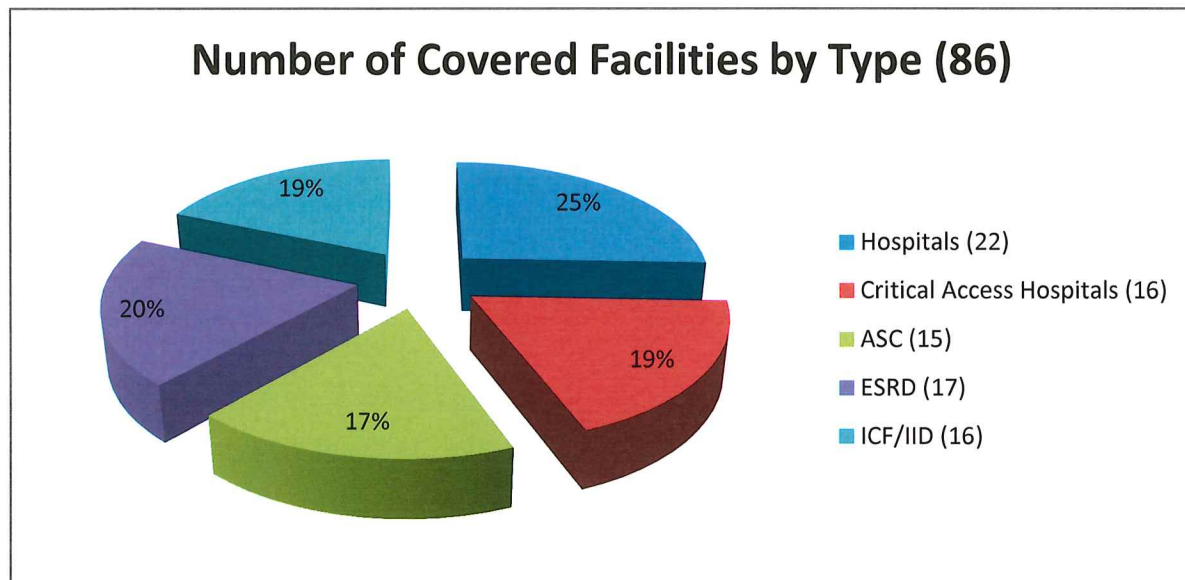
Confidentiality Provisions

By law, all sentinel event information submitted to the SET is considered privileged and confidential. No information about reporting facilities or providers is discoverable or made public. A firewall is maintained between the sentinel event program and the DLC licensing and certification unit. The only time that the SET is permitted to share information with DLC licensing and certification staff is when a reported sentinel event represents immediate jeopardy to the public. Immediate jeopardy is defined as a failure on the part of a healthcare facility/provider to comply with the Conditions of Participation for the Medicare and Medicaid certification program that has caused or is likely to cause serious injury, harm, impairment or death to a patient. Reporting of immediate jeopardy to the DLC licensing and certification unit ensures that there will be a timely investigation of the situation in order to avoid further harm to the public.

Covered Facilities

In 2016, Maine had 86 healthcare facilities that were responsible for reporting sentinel events.

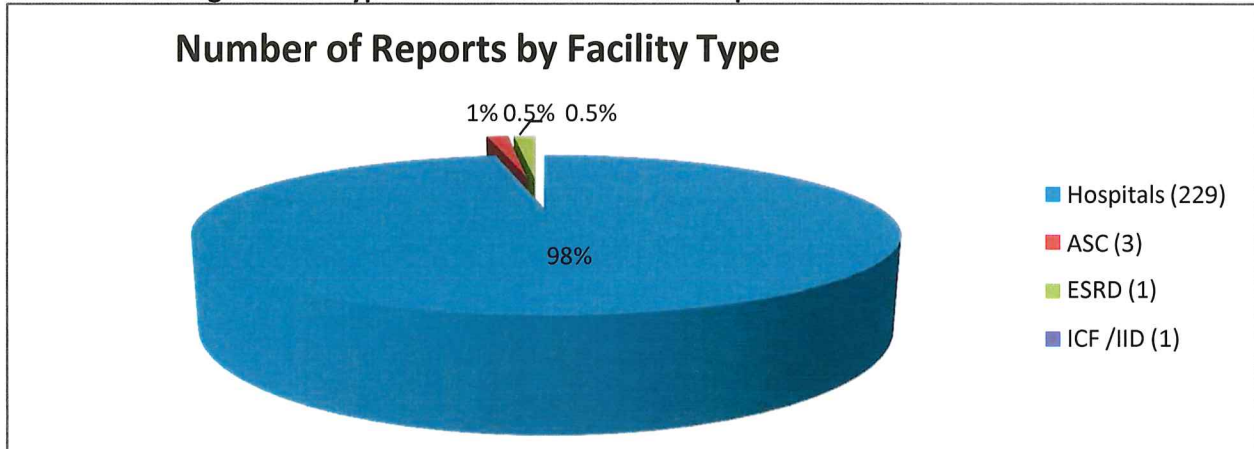
Table 1 Distribution of Covered Facilities



Percentage of Facilities Reporting by Type

Of the 86 facilities covered by the law, 40 (47%) reported sentinel events during 2016. Event reports were received from 97% (37) of all Maine hospitals. Reporting percentages for the other covered facilities were much lower. The larger percentage of hospitals reporting, as compared to other facilities, is not unexpected. Hospitals have higher volumes, a wider variety of and more complex services than the smaller facilities.

Table 2 Percentage of Each Type of Covered Facilities that Reported Events



Sentinel Events

A total of 1,443 sentinel events have been reported to the SET since 2004, when covered facilities began reporting. As illustrated in Table 3, few facilities reported sentinel events between 2004 and 2008. The SET engaged in outreach efforts to ensure that all facilities had a heightened awareness of the requirement to report, resulting in some increase in reporting, starting in 2008.

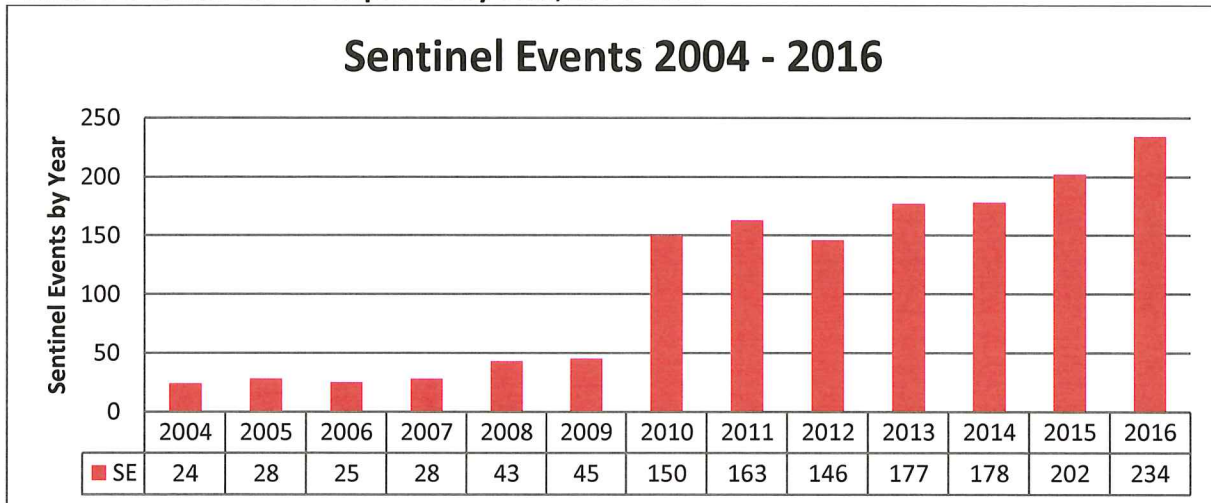
In 2010 the entire list of the NQF Serious Reportable Events¹ was formally adopted as part of statutory changes. Sometimes referred to as 'never events', because they represent situations that should *never* occur in healthcare facilities, the NQF Serious Reportable Events are structured around seven categories: surgical, product or device, patient protection, care management, environmental, radiologic and potential criminal. With an increase in the types of events required to be reported, the volume of reporting increased significantly in 2010, and, with the exception of 2012, has continued to grow.

The inclusion of the NQF list was significant in that Maine providers were then required to utilize nationally recognized reportable event definitions. The NQF is a consensus-driven private-public partnership aimed at developing common approaches to identification of events that are serious in nature and have been determined to be largely preventable. The NQF list increasingly has become the basis for states' mandatory reporting systems.² The list of NQF

Serious Reportable Events is intended to capture events that are clearly identifiable and measurable, largely preventable, and of interest to the public and other stakeholders.

Comparability of definitions enhances clarity about what must be reported and provides benchmarks for comparing experiences across states. The primary goals are to prevent harm and enhance public trust. In 2016, 68% of the sentinel events reported conformed with the NQF definitions and 32% were based on State definitions.

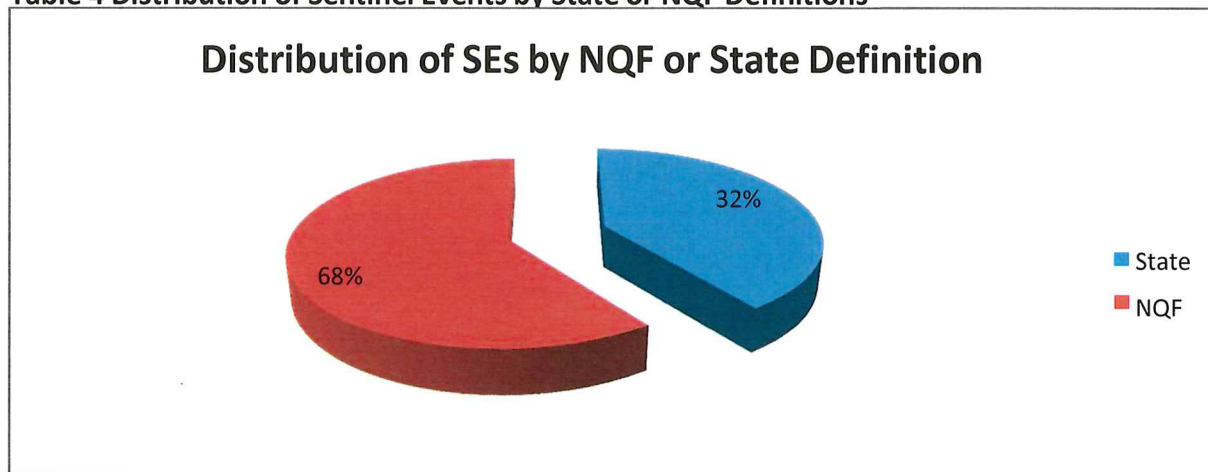
Table 3 Sentinel Events Reported by Year, 2004-2016



¹ National Quality Forum. (2002). *Serious reportable events in healthcare: A consensus report*. Washington, DC: The National Quality Forum.

² Rosenthal, J. & Takach, M. (December 2007). *2007 guide to state adverse event reporting systems*. (State Health Policy Survey Report, Vol. 1, No. 1). Portland, ME: National Academy for State Health Policy.

Table 4 Distribution of Sentinel Events by State or NQF Definitions



During the 13 years of reporting sentinel events, Maine hospitals have steadily increased participation in the Sentinel Event Program. In 2006, only 61% of all Maine hospitals had reported a sentinel event. By the end of 2010, 100% of the 41 acute care hospitals in Maine had

reported at least one sentinel event. Table 3 provides a graphic view of sentinel events reported from 2004 through 2016.

2016 Reported Events

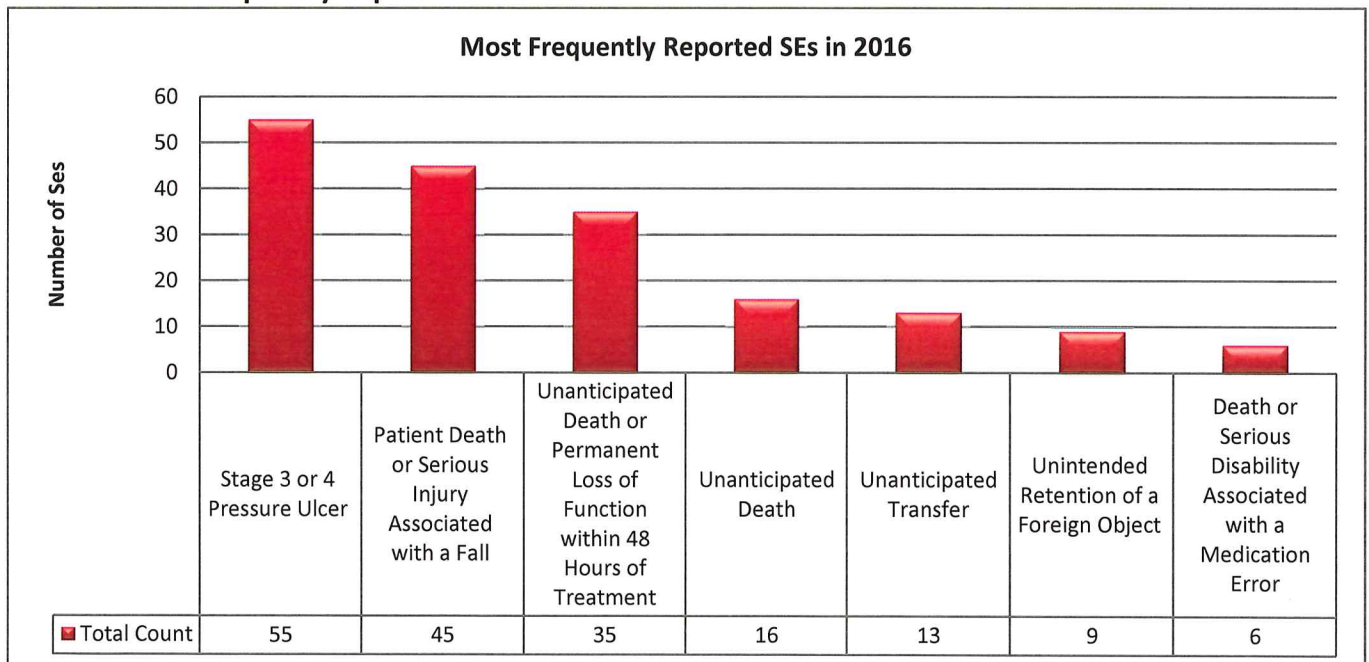
There were a total of 286 event notifications in 2016. Of those, 40 events did not meet the criteria of a sentinel event, and an additional 12 were determined to be ‘near misses’, bringing the total number of actual sentinel events to 234. This is a 15.8% increase in the reported sentinel events from 2015 to 2016. 19% of sentinel events occurred either on a holiday (3) or a weekend (41). The SET is encouraged by the increased reporting of events as it likely is indicative that surveillance has improved and more cases are being identified.

Types of Sentinel Events Reported

A listing of all sentinel events can be found in Appendix C. Of the 26 different categories of sentinel events in 2016, 6 categories made up 77% of the total sentinel event reported, as listed below:

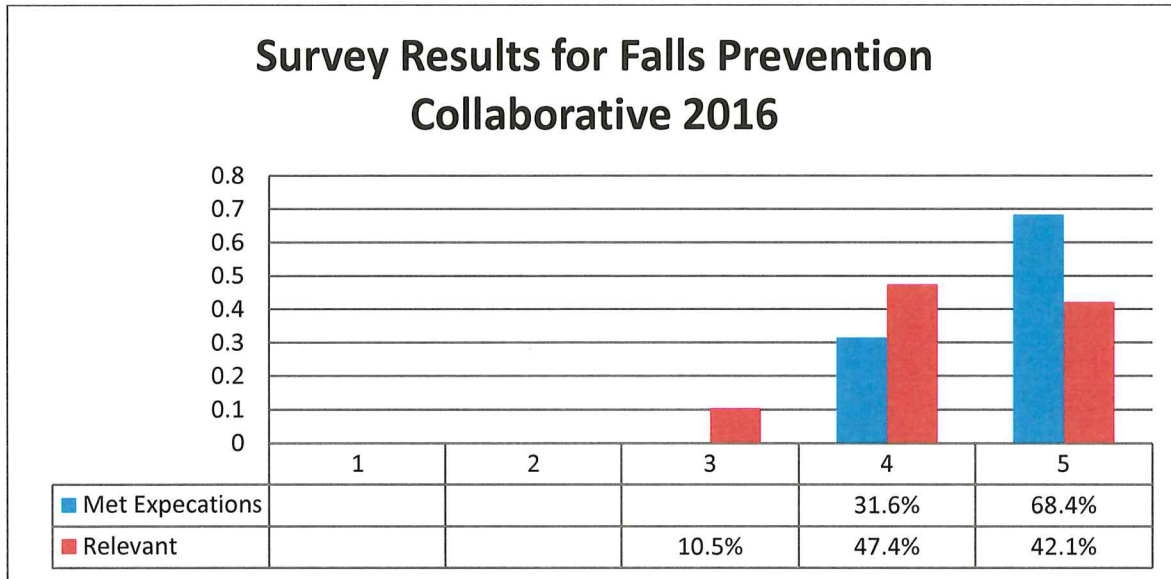
- Stage 3 or 4 and unstageable pressure ulcers at 55 (24%)
- Fall with serious injury at 45 (19%)
- Unanticipated death or permanent loss of function within 48 hours of treatment at 35 (15%)
- Wrong Site Surgery at 16 (7%)
- Unanticipated death at 16 (7%)
- Unanticipated transfer to another facility at 13 (6%)

Table 5 Most Frequently Reported Sentinel Events in 2016



Pressure ulcers have been in the top three most frequently reported sentinel events over the past six years. Falls with patient death or serious injury continue to remain the second most reported sentinel event. In order to assist facilities to reduce the number of patient falls, the SET held a falls collaborative work group. Representatives from four organizations presented material: Down East Community Hospital, ME Health, Maine Medical Center, and Mayo Regional Hospital. All facilities were invited to attend the collaborative and staff from twenty four facilities were in attendance.

Table 6. Survey Results from Falls Prevention Collaborative



Due to the increase in perinatal mortality and injury in 2014, the SET continues to monitor these events.

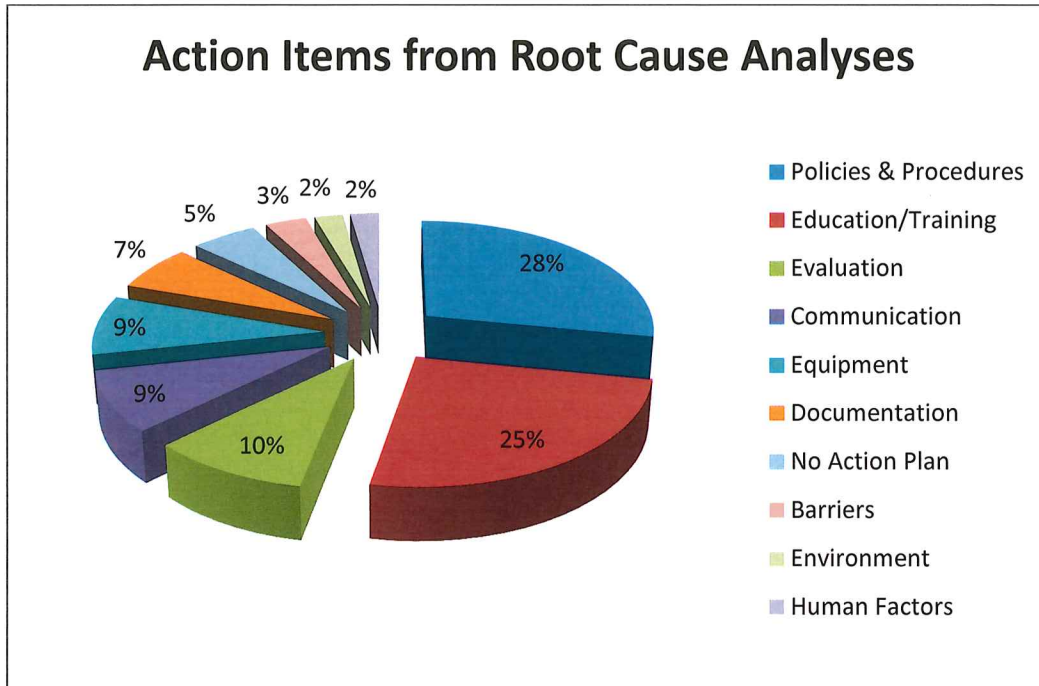
Table 7. Perinatal Death and Injury



Root Cause Analysis: Action Items

When an adverse event occurs, facilities are required to conduct a root cause analysis. Action items that were implemented as a result of root cause analyses are categorized by type. As can be seen in Table 8, the most common action item categories were: Education, Process, and Evaluation.

Table 8. Action Items Identified



On-Site Reviews

The SET conducted thirteen on-site reviews in 2016. Administrative and clinical requirements were evaluated to determine compliance with the program through review of policies, meeting minutes, and chart audits. Facilities were also encouraged to ask questions and seek clarification about the program during the on-site reviews.

Some areas that were identified as being best practice included: thorough staff education about the Maine SE program; discussion of events and RCA outcomes with all levels of staff in the organization; use of restraint logs/auditing; review of RCAs 3 weeks, 3 months and 12 months post-review to evaluate effectiveness of interventions; hand-off communication tools for both internal and outside transfers; an extensive review of falls data; use of a variance log to track patient safety events and follow up.

There were also some common areas identified with which many facilities were not in compliance.

These included failure to attach a copy of Sentinel Event Statute and Rules to a SE related policy; lack of procedures for preservation of evidence related to sentinel events; and sentinel event education programs lacking sufficient breadth. The facility responsibilities are located in the Sentinel Event Rules.

It has been noted, both through on-site reviews and also through general reporting of events, that many SEs are reported when discovered by the risk/quality staff, sometimes weeks or months after an event occurs. The SE Rules require each health care facility to include, in new employee orientation, and to all individuals with privileges, the facility's Sentinel Event Notification and Reporting System policies and procedures. Thus, all staff should be able to identify a sentinel event and should be compliant with reporting requirements. Reporting of sentinel events should not be delayed due to failure to identify an event when it occurs, or secondary to internal deliberations or pending autopsy/medical examiner results.

2016 was the first full year of on-site reviews. Throughout the year, the SET was able to enhance the review process. The SET will continue to utilize de-identified information from on-site reviews to educate others to improve the quality of healthcare and patient safety.

Progress on Goals

During 2016, the SET continued to work with covered facilities and other agencies to enhance understanding of the SE Program and the importance of patient safety. The following represents progress on the goals set for 2016:

- 1) Goal: Continue to provide technical assistance to facilities covered under the SE Rules and provide on-site visits and consultations as requested.
Actions: The SET completed 13 on-site visits to review the SE Program and provide technical assistance. The SET completed two on-site visits to meet new facility staff members and to assist them in understanding the requirements of the SE program.
- 2) Goal: Continue to assess facilities' compliance with MRSA Title 22, Chapter 1684, §8754, *Division Duties* by performing on-site reviews for covered facilities.
Actions: The SET utilized on-site review worksheets for administrative requirements (i.e., policies and procedures, staff education, reports, etc.) and clinical reviews. The clinical review is based on the individual facility's history of reported sentinel events, as well as most frequently reported sentinel events state-wide. The SET provides the facility with a report of any non-reported sentinel events and any unmet administrative requirements. Additionally, the SET includes 'best practices' identified during the on-site review.
- 3) Goal: Continue to enhance the SE database with relevant information, and analyze complaint data to identify trends in SEs being reported, track individual provider SEs and utilize data in the most effective manner.

Actions: The SET continues to encourage facilities to include the time/shift that sentinel events occurred to determine if there are any trends related to day of the week or time of day that sentinel events occur. The SE database tracks individual facility reporting history, and the SET is able to graphically display this data. The SET continues to work with USM Muskie to maintain and update the database.

- 4) Goal: Continue to produce the quarterly SE Newsletter focused on trends noted in Maine SE data and patient safety issues identified nationally.

Actions: Newsletters were distributed in March, June, September and December. Topics included: Diagnostic Errors; Improved Safety Culture, an End in Itself; Communication Failures; Call for Transparency/Identifying Medical Errors as a Cause of Death; End of the Road for Antibiotics; Including Patients in Patient Safety; High Reliability Organizations; Second Victims; Perioperative Pressure Ulcers; and The Strength of Action Items.

http://www.maine.gov/dhhs/dlrs/medical_facilities/sentinelevents/home.html

- 5) Goal: Continue to look at best practices in SE reporting systems.

Actions: The SET continues to communicate with other states regarding SE reporting. Based on information obtained from other states, the Maine SE program remains progressive in its program development and outreach activities.

- 6) Goal: Develop additional collaborative workgroups with interested providers to assist with the sharing of challenges and best practices related to SEs.

Actions: The SET coordinated a Falls Collaborative workgroup in September, 2016, with participation of 24 facilities.

- 7) Goal: Sponsor a Patient Safety Conference featuring a nationally recognized patient safety expert as the key note speaker to provide an opportunity for healthcare facilities to learn more about the importance of leadership in patient safety.

Actions: The SET held a Patient Safety Conference targeted at healthcare leaders. The theme was the important role leaders play in creating and maintaining an environment that supports patient safety. Keynote speaker, Dr. Alan Frankel discussed the framework for clinical and operational excellence, while emphasizing the importance of leadership in creating an environment that supports teamwork that identifies and acts upon defects, and that also supports a safety climate and resilience. Leaders from Central Maine Orthopedics, Maine Medical Center, Millinocket Regional Hospital, and Spring Harbor Hospital presented information related to leadership and its impact on patient safety. It was well attended with participants representing 30 hospitals, six ASCs, and eight ESRDs.

Program Goals 2017

In 2017, the SET will continue to enhance the SE program in the following areas:

- 1) Continue to provide technical assistance and consultations, as requested, to facilities covered under the SE Rules.
- 2) Continue to assess facilities' compliance with MRSA Title 22, Chapter 1684, §8754, *Division Duties* by performing on-site reviews for covered facilities.
- 3) Continue to enhance the SE database with relevant information, and analyze complaint data to identify trends in SEs being reported, track individual provider SEs, and utilize data in the most effective manner.
- 4) Continue to produce the quarterly SE newsletter focused on trends noted in Maine SE data and patient safety issues identified nationally.
- 5) Continue to research and implement best practices in SE reporting systems.
- 6) Continue to develop additional collaborative workgroups with interested providers to assist with the sharing of challenges and best practices related to SEs. Focus will be on RCAs and high reliability organizations.
- 7) Continue to monitor maternal and infant outcomes and resources in the State of Maine.
- 8) Collaborate with facilities to ensure compliance with notifying the SET of a SE within 1 business day of the event being discovered, and submission of RCA and associated requirements within 45 days of the SE being reported.

Conclusion

The goal of the Sentinel Event program continues to be maintaining a reporting system that supports Maine's healthcare facilities in improving patient safety while identifying adverse and preventable safety events. It is imperative that facilities encompass the Sentinel Event program by reporting events, and participating in the educational programs offered by the Maine SET and other patient safety related organizations. The Maine SET will continue to track and trend SE data with a focus on root cause analyses and implemented action items. Since the program's inception, the number of reported events has increased which likely indicates facilities are developing better ways to identify reportable events, and feel comfortable in reporting events. The SET looks forward to continuing to work with facilities in 2017 to deliver educational opportunities that are relevant and enhance patient safety efforts.

Appendix A Reporting Form

Maine Sentinel Event Notification and Near Miss Reporting Form

This form is required pursuant to 22 MRSA, Chapter 1684, and 10-44 CMR Chapter 114, Rules Governing the Reporting of Sentinel Events

1. What is being reported?
- Sentinel Event
 Near Miss
2. Today's Date: _____
Date of Discovery: _____
Date of Event: _____
Time of Event: _____ AM/PM
Date of Death (if applicable): _____

3. Patient Age: _____ M F Admitting Diagnosis: _____

4. Briefly describe the event including location: _____

5. What type of event is being reported?
- | | |
|--|---|
| <input type="checkbox"/> Unanticipated Death | <input type="checkbox"/> Major Permanent Loss of Function in perinatal infant |
| <input type="checkbox"/> Unanticipated Perinatal Death | <input type="checkbox"/> Major Permanent Loss of Function present at discharge |
| <input type="checkbox"/> Unanticipated Death within 48 Hrs. of Treatment | <input type="checkbox"/> Major Permanent Loss of Function within 48 Hrs. of Treatment |
| <input type="checkbox"/> Suicide within 48 Hrs. of Discharge | |

6. Unanticipated patient transfer to another facility? Y N

7. Does this event meet NQF criteria? Y N (If yes, continue on back – check all that apply)

Autopsy Requested	<input type="checkbox"/> Y <input type="checkbox"/> N	Autopsy Performed	<input type="checkbox"/> Y <input type="checkbox"/> N
Medical Examiner Called	<input type="checkbox"/> Y <input type="checkbox"/> N	Medical Examiner Accepted Case	<input type="checkbox"/> Y <input type="checkbox"/> N

9. Was equipment e.g., IV pump, medication vials, sequestered? N/A N Y Specify: _____

10. Facility _____ Name: _____
Reporter's _____ Name: _____
Title: _____
Telephone Number: _____ E-mail Address: _____

State notification of a Sentinel Event is required within one (1) business day of discovery.
Do not delay notification, for any reason, including pending autopsy or Medical Examiner results.

SENTINEL EVENT CONFIDENTIAL FAX (207) 287-3251

This information is protected from public disclosure

**NATIONAL CONSENSUS EVENTS
NATIONAL QUALITY FORUM SERIOUS REPORTABLE EVENTS**

Surgical or Invasive Events

- Surgery or other invasive procedure performed on the wrong site
- Surgery or other invasive procedure performed on the wrong patient
- Wrong surgical or other invasive procedure performed on a patient
- Unintended retention of a foreign object in a patient after surgery or other invasive procedure
- Intraoperative or immediately postoperative/post-procedure death in an American Society of Anesthesiologists Class I patient

Product or device events

- Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the healthcare setting
- Patient death or serious injury associated with the use or function of a device in patient care, in which the device is used for functions other than as intended
- Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in a healthcare setting

Patient Protection Events

- Discharge or release of a patient of any age, who is unable to make decisions, to other than an authorized person
- Patient death or serious injury associated with patient elopement (disappearance)
- Patient suicide, attempted suicide or self-harm resulting in serious injury, while being cared for in a healthcare setting

Care management events

- Patient death or serious injury associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration)
- Patient death or serious injury associated with unsafe administration of blood products
- Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare setting
- Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy
- Patient death or serious injury associated with a fall while being cared for in a healthcare setting
- Stage 3 or 4 pressure and unstageable pressure ulcers acquired after admission/presentation to a healthcare setting
- Artificial insemination with the wrong donor sperm or wrong egg
- Patient death or serious injury resulting from the irretrievable loss of an irreplaceable biological specimen
- Patient death or serious injury resulting from failure to follow up on or communicate laboratory, pathology or radiology test results

Environmental Events

- Patient or staff death or serious injury with an electric shock in the course of a patient care process in a healthcare setting
- Any incident in which systems designated for oxygen or other gas to be delivered to a patient contains no gas, the wrong gas or is contaminated by toxic substances
- Patient or staff death or serious injury associated with a burn incurred from any source while being cared for in a healthcare setting
- Patient death or serious injury associated with the use physical restraints or bedrails while being cared for in a healthcare setting

Radiologic Events

- Death or serious injury of a patient or staff associated with the introduction of a metal object into the MRI area

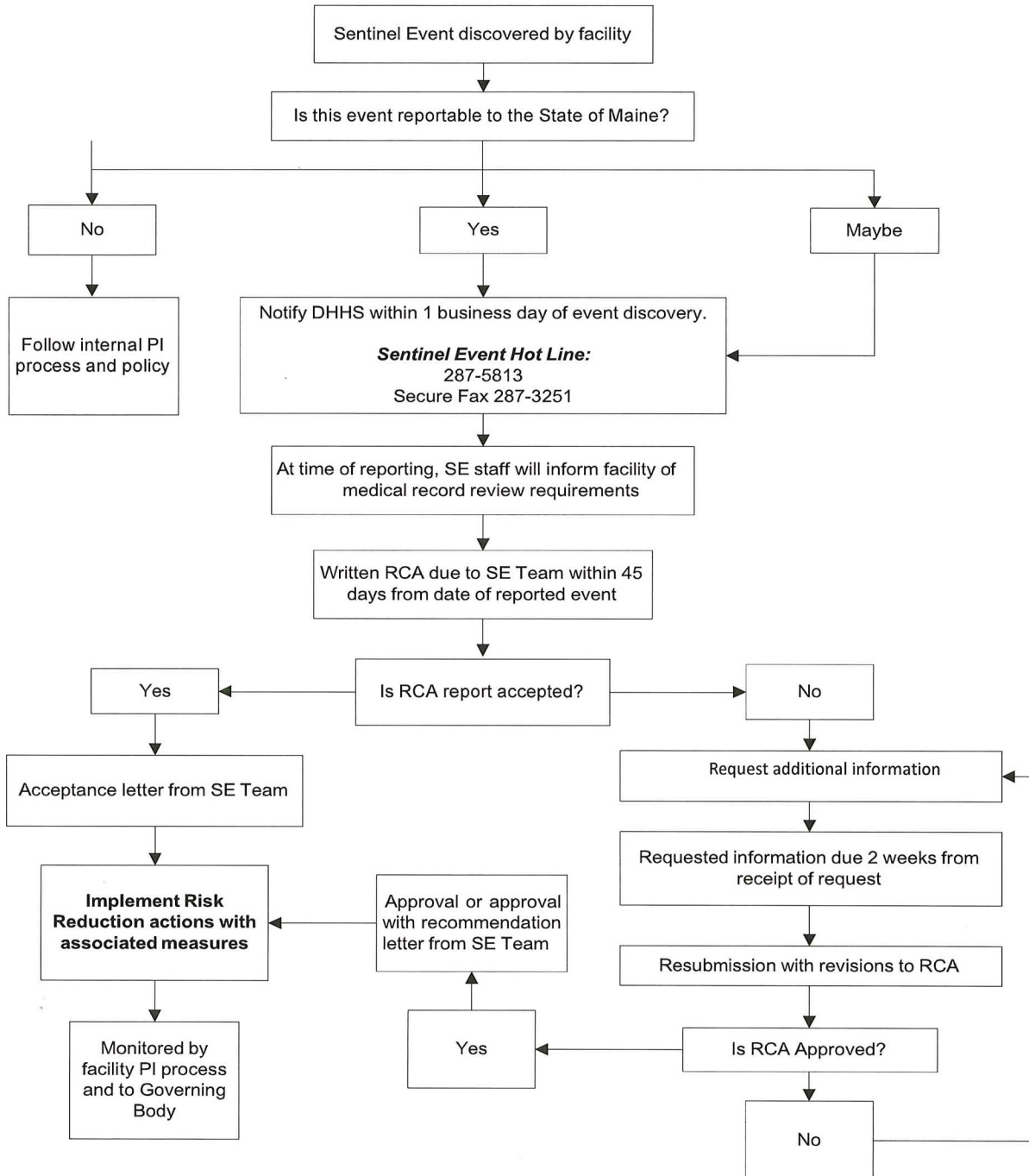
Potential Criminal Events

- Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider
- Abduction of a patient/resident of any age
- Sexual abuse/assault on a patient or staff member within or on the grounds of the healthcare setting
- Death or serious injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of the healthcare setting

Appendix B – Sentinel Event Process Flow

Sentinel Event Process Flow

State of Maine Department of Health and Human Services
 Division of Licensing and Regulatory Services



Appendix C – Sentinel Events Reported by Type

Table 2. Sentinel Events Reported by Event Type, 2016

Total Events	Category	Male	Female	Infant	<=18	19-64	65+	NQF or State
55	Stage 3 or 4 pressure ulcers acquired after admission to a health care facility	35	20	0	0	22	33	NQF
45	Patient death or serious disability associated with a fall while being cared for in a health care facility	17	28	1	0	15	29	NQF
35	Unanticipated Death or Permanent Loss of Function within 48 Hours of Treatment	25	10	3	0	25	7	State
16	Unanticipated Death	10	6	0	0	11	5	State
16	Surgery performed on the wrong body part	12	4	1	0	7	8	NQF
13	Unanticipated Patient Transfer to Another Facility	6	7	0	3	8	2	State
9	Unintended retention of a foreign object in a patient after surgery or other procedure	1	8	0	0	8	1	NQF
6	Patient death or serious disability associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration)	1	5	1	0	2	3	NQF
4	Death or significant injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the ground of the health care facility	3	1	0	0	3	1	NQF
4	Patient death or serious injury resulting from failure to follow up on or communicate laboratory, pathology or radiology test results.	2	2	0	0	2	2	NQF
4	Major Permanent Loss of Function in perinatal infant	2	2	4	0	0	0	State
4	Major Permanent Loss of Function present at discharge	2	2	0	1	3	0	State
3	Sexual assault on a patient within or on the grounds of the health care facility	3	0	0	2	1	0	NQF
2	Surgery performed on the wrong patient	1	1	0	0	0	2	NQF
2	Patient suicide or attempted suicide resulting in serious disability while being cared for in a health care facility	1	1	0	0	2	0	NQF
2	Suicide Within 48 Hours	1	1	0	0	2	0	State
2	Patient death or serious disability associated with the use or function of a device in patient care, in which the device is used for functions other than as intended	1	1	0	0	1	1	NQF
2	Discharge or release of a patient of any age, who is unable to make decisions, to other than an authorized person	1	1	0	0	2	0	NQF
2	Unanticipated Perinatal Death	0	1	2	0	0	0	State
2	Wrong surgical procedure performed on a patient	2	0	0	0	2	0	NQF
1	Patient death or serious disability associated with patient elopement(disappearance)	1	0	0	0	1	0	NQF

1	Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products	0	1	0	0	1	0	NQF
1	Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a health care facility	0	1	1	0	0	0	NQF
1	Patient death or serious injury resulting from the irretrievable loss of an irreplaceable biological specimen	0	1	0	0	1	0	NQF
1	Death or serious injury of a neonate associated with labor or delivery in a low risk pregnancy	0	1	1	0	0	0	NQF
1	Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a health care facility	1	0	0	0	0	1	NQF
234	Totals	128	105	14	6	119	95	

Appendix D Resources

The following represent additional resources from organizations that support healthcare quality and safety:

Maine Quality Counts – an independent, multi-stakeholder, regional healthcare collaborative dedicated to transforming health and healthcare in Maine: <http://www.mainequalitycounts.org/>

Hospital Safety Score - is a public service provided by The Leapfrog Group, a nonprofit organization committed to driving quality, safety, and transparency in the U.S. health system: www.hospitalsafetyscore.org

The Maine Health Management Coalition - is a charitable organization whose mission is to bring the people who get care, pay for care and provide care together in order to measure and improve the quality of health care services in Maine. By publicly reporting quality information on Maine doctors and hospitals, the MHMC hopes to empower the public to make informed decisions about the care they receive: www.getbettermaine.org

Maine Hospital Association - The Maine Hospital Association represents 36 community-governed hospitals in Maine. Formed in 1937, the Augusta-based non-profit Association is the primary advocate for hospitals in the Maine State Legislature, the U.S. Congress and state and federal regulatory agencies. It also provides educational services and serves as a clearinghouse for comprehensive information for its hospital members, lawmakers and the public. MHA is a leader in developing health care policy and works to stimulate public debate on important health care issues that affect all of Maine's citizens: <http://www.themha.org/>

WhyNotTheBest.org - was created by The Commonwealth Fund, and in January 2015, was transferred to **IPRO**, a national organization providing a full spectrum of healthcare assessment and improvement services. It is a free resource for health care professionals interested in tracking performance on various measures of health care quality. It enables organizations to compare their performance against that of peer organizations, against a range of benchmarks, and over time. Case studies and improvement tools spotlight successful improvement strategies of the nation's top performers. A regional map shows performance at the county, HRR, state, and national levels: www.whynotthebest.org

Maine Quality Forum - In 2003, the Maine Quality Forum was created as an independent division of Dirigo Health, to continue Maine's leadership in assuring high quality healthcare for its citizens. The Maine Quality Forum's mission is to advocate for high quality healthcare and help each Maine citizen make informed healthcare choices: www.mainequalityforum.gov

Maine Health Data Organization - is a state agency that collects health care data and makes those data available to researchers, policy makers, and the public while protecting individual privacy. The purpose of the organization is to create and maintain a useful, objective, reliable and comprehensive health information database that is used to improve the health of Maine citizens: <https://mhdo.maine.gov>

The Agency for Healthcare Research and Quality – AHRQ’s mission is to produce evidence to make health care safer, higher quality, more accessible, equitable, and affordable, and to work within the U.S. Department of Health and Human Services and with other partners to make sure that the evidence is understood and used: www.ahrq.gov

The National Academy for State Health Policy - is a non-profit that helps “states achieve excellence in health policy and practice” by working with each other. The organization is based in Portland, ME and Washington, DC, and they provide a “forum for constructive work across branches and agencies of state government on critical health issues.”: www.nashp.org

The Institute for Healthcare Improvement - is a nonprofit organization focused on motivating and building the will for change, partnering with patients and health care professionals to test new models of care, and ensuring the broadest adoption of best practices and effective innovations: www.ihl.org

The National Patient Safety Foundation – NPSF’s vision is to create a world where patients and those who care for them are free from harm. A central voice for patient safety since 1997, NPSF partners with patients and families, the health care community, and key stakeholders to advance patient safety and health care workforce safety and disseminate strategies to prevent harm. NPSF is an independent, not-for-profit 501(c) (3) organization: www.npsf.org

The VA National Center for Patient Safety - was established in 1999 to develop and nurture a culture of safety throughout the Veterans Health Administration. We are part of the VA Office of Quality, Safety and Value. Our goal is the nationwide reduction and prevention of inadvertent harm to patients as a result of their care: www.patientsafety.va.gov

The Pennsylvania Patient Safety Authority - is an independent state agency charged with taking steps to reduce and eliminate medical errors by identifying problems and recommending solutions that promote patient safety: <http://patientsafetyauthority.org/Pages/Default.aspx>

This Sentinel Event Annual Report may be found on the internet at:
http://www.maine.gov/dhhs/dlrs/medical_facilities/sentinelevents/home.html

The Maine Sentinel Event Reporting Statute may be found on the internet at:
<http://www.mainelegislature.org/legis/statutes/22/title22ch1684sec0.html>

The Rules Governing the Reporting of Sentinel Events may be found on the internet at:
<http://www.maine.gov/sos/cec/rules/10/144/144c114.doc>

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