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March 6, 2018

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

RE: Sentinel Events Annual Report, CY 2017

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 2017*.

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 Dr. Bruce Bates, Director, Maine Center for Disease Control and Prevention.

Sincerely,

Ricker Hamilton
Commissioner

RH/klv

cc: Dr. Bruce Bates, Director, Maine Center for Disease Control and Prevention

Enclosure

Sentinel Events

CY2017

Annual Report to the Maine State Legislature



*Department of Health
and Human Services*

*Maine People Living
Safe, Healthy and Productive Lives*

Paul R. LePage, Governor

Ricker Hamilton, Commissioner

Sentinel Event Annual Report prepared by:
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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.

Compliance with the Sentinel Event Program requires facilities to conduct root cause analyses (RCA) for all sentinel events. This investigative process identifies factors that contributed to the sentinel event. It is rare that only one 'root cause' is identified. More frequently, RCAs identify multiple process issues that lead to the event. To be effective, RCAs must include an understanding of the timeline related to the event, staff working in the area, the environment, staffing levels, whether equipment/technology was involved and human factors (fatigue, burn out, etc.). The SET coordinated two learning collaborative programs in 2017 that focused on RCAs and systems analysis. Participants were encouraged to discuss their challenges and successes related to surveillance, interviewing techniques, investigative processes and analysis of results. These two programs were well received by participating organizations, and additional programs of this nature have been requested.

The SET continued its on-site reviews to determine if facilities were in compliance with the Sentinel Event Program requirements. Ten on-site reviews were completed during 2017. Issues identified were predominantly related to administrative requirements, such as policies/procedures, sentinel event orientation for new hires and education for providers and staff. The SET also identified positive aspects of the facilities' patient safety programs. These observations were shared with the facilities and have also been incorporated into the quarterly SE Newsletter.

In 2017, the SET collaborated with other state partners, including the Maine Hospital Association, the Offices of Rural Health and Primary Care and the Maine Primary Care Association – Patient Safety Organization to provide patient safety related educational programs. Looking at patient safety across the continuum of care is essential to improving the quality and safety of healthcare in Maine. The SET looks forward to furthering these partnerships and others in 2018.

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. 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 2017, thirty-three of Maine's acute and critical access hospitals submitted data to the Leapfrog Group. Seven 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:

- Blue Hill
- Bridgton Hospital
- Down East Community Hospital
- Franklin Memorial Hospital
- Inland Hospital
- LincolnHealth
- The Aroostook Medical Center

The Centers for Medicare and Medicaid Services (CMS) has a consumer-oriented website that helps individuals learn about hospital quality and safety measures. There are fifty-seven quality measures used to generate an overall score or 'star rating'. In addition to patient satisfaction, these measures include information about patient safety, including complications and deaths and unplanned returns to the hospital. (<https://www.medicare.gov/hospitalcompare/About/What-Is-HOS.html>)

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. The SET determines whether the incident conforms to the statutory definition of a sentinel event. Upon confirmation by the SET that the event meets the sentinel event criteria, 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. The Joint Commission released an updated root cause analysis framework in 2017 that includes updated information, including a more detailed review of action item strength. Additionally, the National Patient Safety Foundation released the RCA2 report in 2016.

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 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

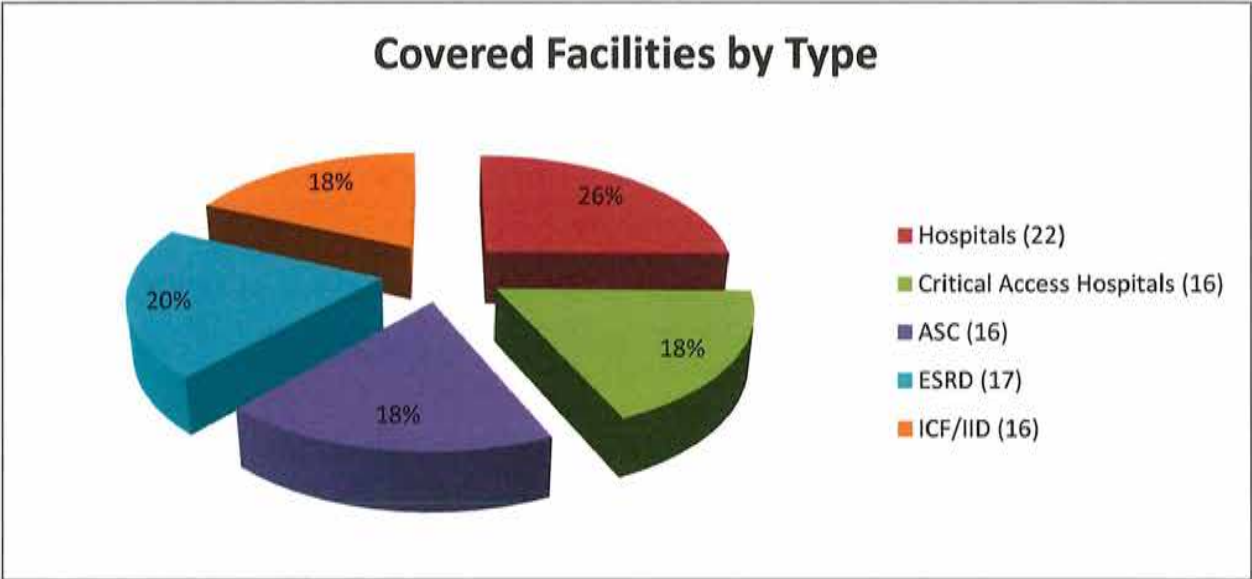
By law, all sentinel event information submitted to the SET is considered privileged and confidential. No information about reporting facilities or providers is discoverable or made public. A firewall is maintained between the sentinel event program and the DLC licensing and certification unit. The only 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 2017, Maine had 87 healthcare facilities that were responsible for reporting sentinel events. Table 1 shows the distribution of covered facilities by type.

Table 1 Distribution of Covered Facilities

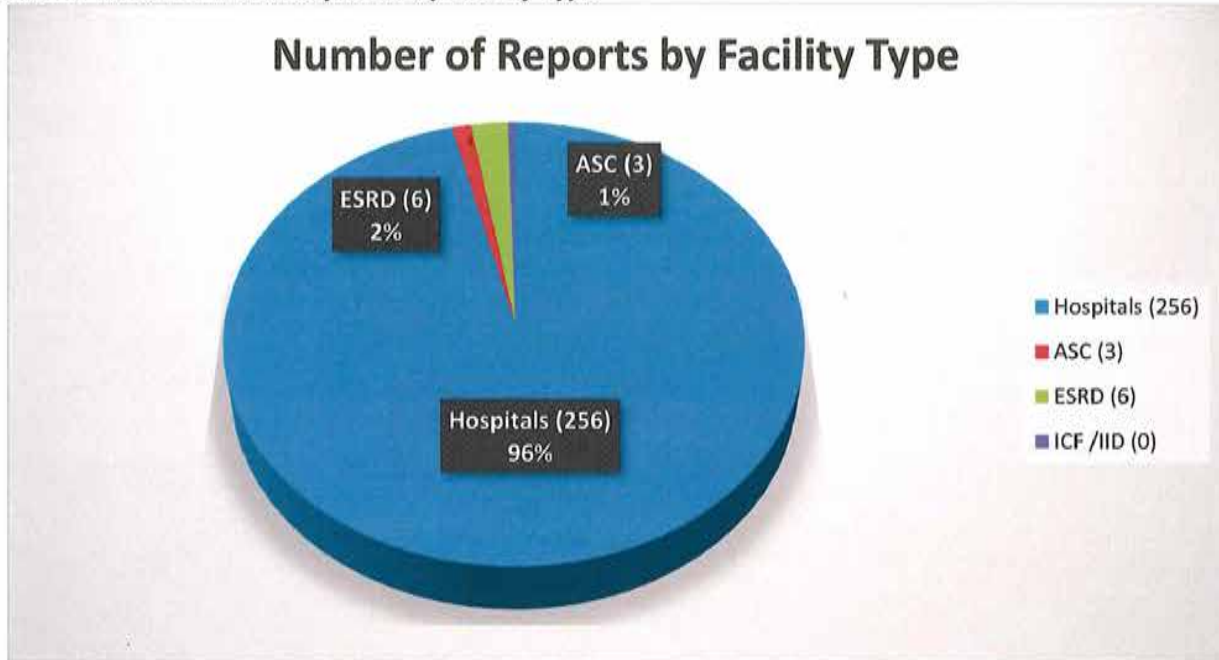


Reports by Facility Type

Of the 87 facilities covered by the law, 41 (47%) reported sentinel events during 2017. Event reports were received from 34 (89%) Maine hospitals. An additional eight facilities did report near miss and/or non-reportable cases. Including these reports, 56% of covered facilities reported activity to the SET in 2017.

There were 256 sentinel events reported by hospitals, 3 sentinel events reported by ASCs and 6 sentinel events reported by ESRDs. ICF/IID facilities did not report any sentinel events for 2017.

Table 2. Sentinel Events Reported by Facility Type



Sentinel Events

A total of 1,708 sentinel events have been reported to the SET since 2004, when covered facilities began reporting. As illustrated in Table 4, 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.

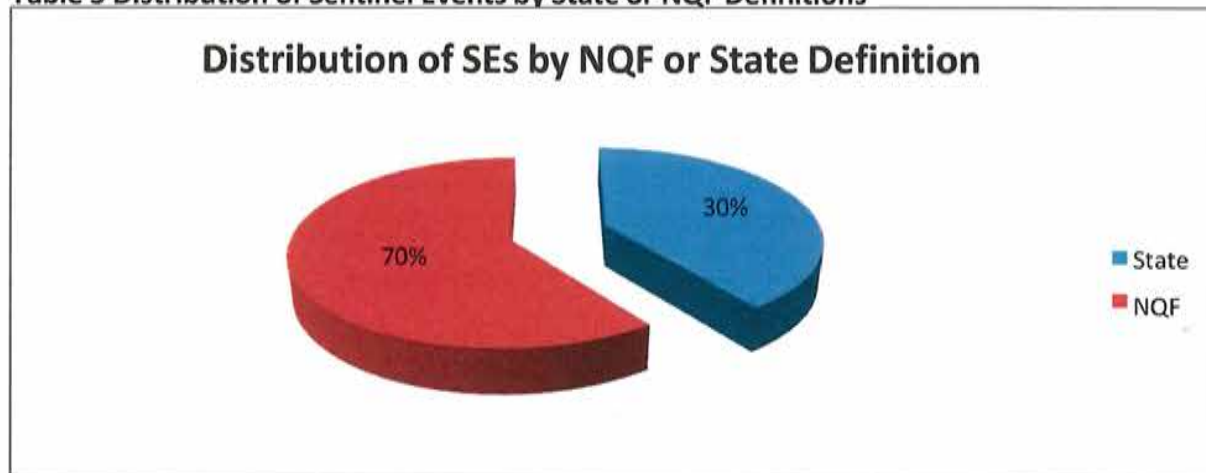
In 2010 the entire list of the NQF Serious Reportable Events was formally adopted as part of statutory changes. Sometimes referred to as 'never events', because they represent situations that should *never* occur in healthcare facilities, the NQF Serious Reportable Events are structured around seven 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. 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 2017, 70% of the sentinel events reported conformed with the NQF definitions and 30% were based on State definitions.

Table 3 Distribution of Sentinel Events by State or NQF Definitions



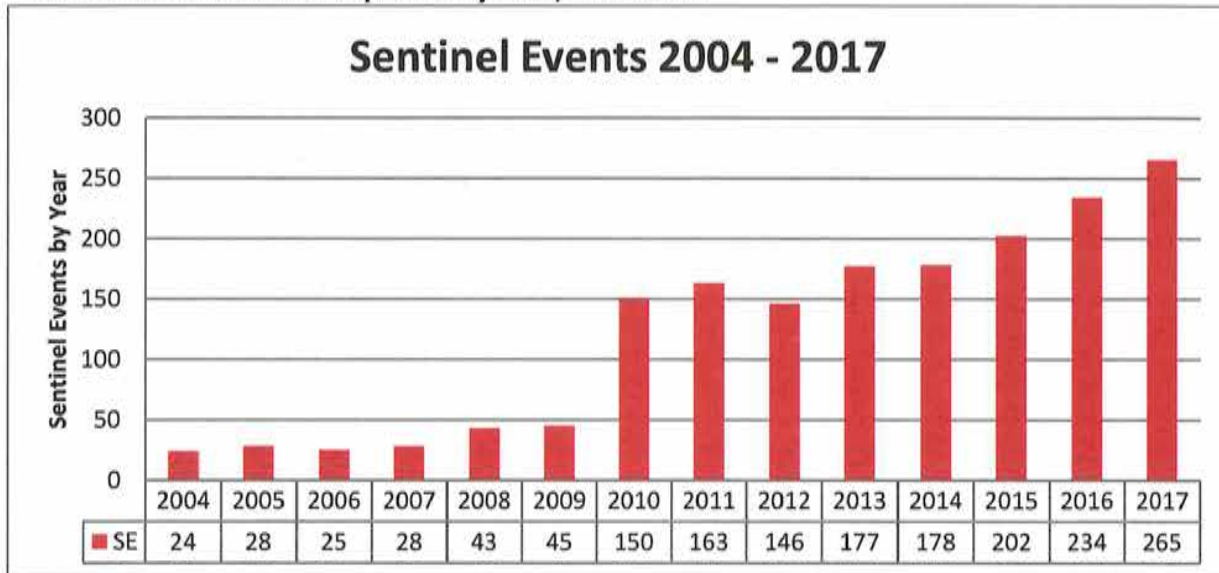
2017 Reported Events

There were 336 event notifications in 2017. Of those, 39 events did not meet the criteria of a sentinel event, and an additional 32 were determined to be 'near misses', bringing the total number of actual sentinel events to 265. This is a 13.2% increase in the reported sentinel events from 2016 to 2017. 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.

20% of sentinel events occurred either on a holiday (5) or a weekend (48). The SET encourages facilities to identify the day of the week, time of day and if the event occurred on a holiday as there is research that shows that more adverse events occur 'after hours'.

During the 14 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 4 provides a graphic view of sentinel events reported from 2004 through 2017.

Table 4 Sentinel Events Reported by Year, 2004-2017

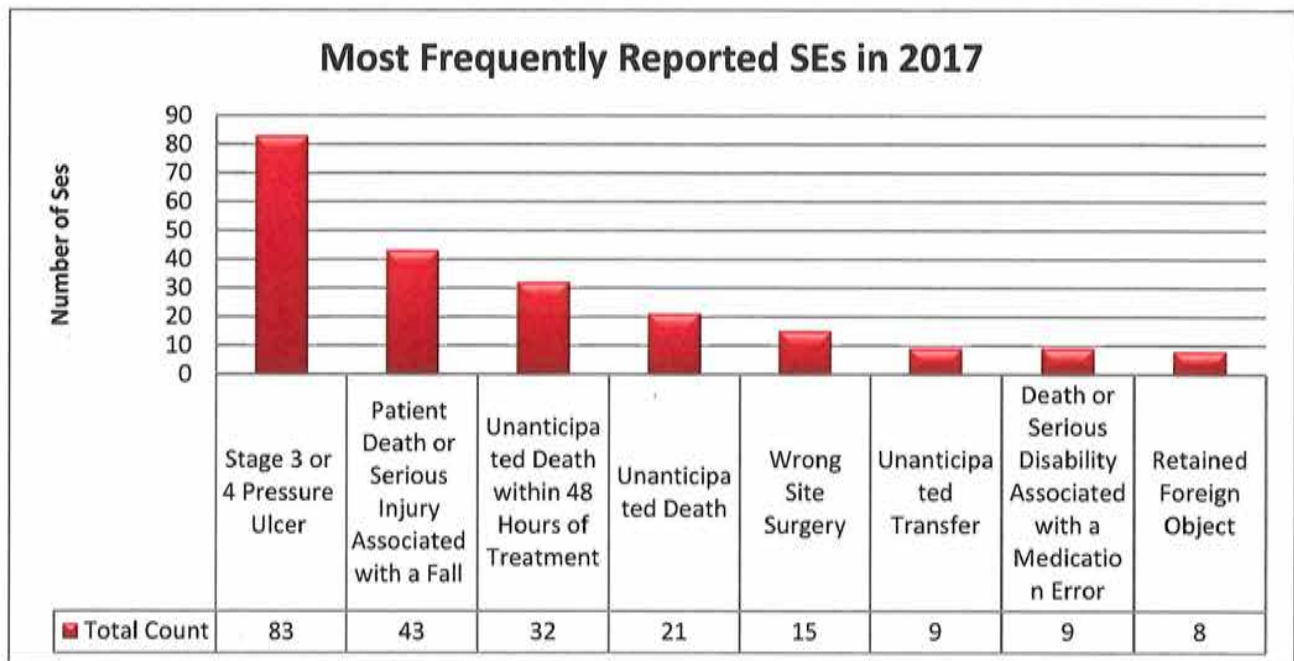


Types of Sentinel Events Reported

A listing of all sentinel events can be found in Appendix C. Of the 27 different categories of sentinel events in 2017, 8 categories made up 83% of the total sentinel events reported, as listed below:

- Stage 3 or 4 and unstageable pressure ulcers at 83 (31%);
- Fall with serious injury at 43 (16%);
- Unanticipated death within 48 hours of treatment at 32 (12%);
- Unanticipated death at 21 (8%)
- Wrong site surgery at 15 (6%)
- Unanticipated transfer to another facility at 9 (3%)
- Death or serious injury with medication error at 9 (3%)
- Unintended retention of foreign object at 8 (3%)

Table 5 Most Frequently Reported Sentinel Events in 2017

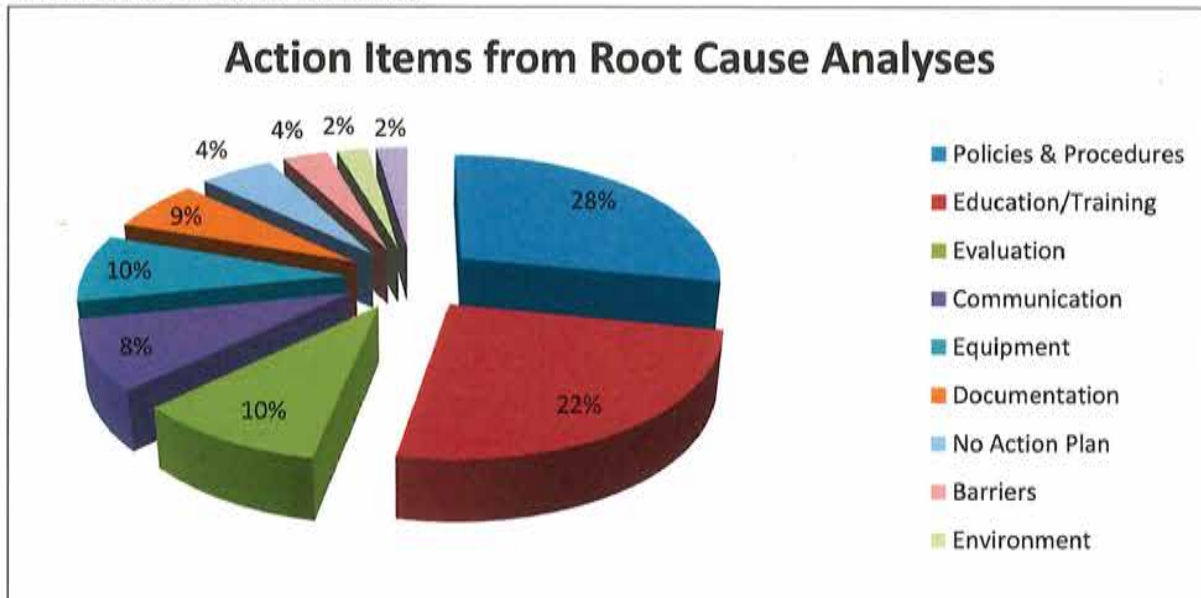


- Pressure ulcers have been in the top three most frequently reported sentinel events over the past seven years.
- Falls with patient death or serious injury continue to remain the second most reported sentinel event. Reported events show that falls frequently occur when the patient is getting up to use the bathroom.
- Wrong site surgical cases continue to remain elevated. While this type of sentinel event would seem to be more easily preventable (due to the nature of surgeries being planned and many tools available to help mitigate harm and risk), the SET continues to see issues, including failure of the timeout process to prevent adverse events. The SET questions if timeouts are being performed accurately and with the required attention.
- Unanticipated deaths and unanticipated death within 48 hours of treatment also remain elevated. While it is not clear that there is a pattern or trend related to these events, assessments and discharge planning are two areas that could be reviewed as areas for improvement. This category can be challenging for facilities as sometimes the cause of death is not known.

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 6, the most common action item categories were: Education, Process, and Evaluation.

Table 6. Action Items Identified



Opportunities for Improvement

The SET has identified the evaluation of the effectiveness of RCA action items as the most significant area of improvement for facilities. To be effective, action items must be evaluated to determine if the intended outcome has been achieved, and if not, possible modifications. Additionally, the SET continues to receive notification of events that have not been identified for weeks or months after they have occurred, indicating that there are insufficient surveillance mechanisms in place. The importance of identifying and reporting events cannot be stressed enough. The SET strongly encourages facilities to call if there are questions about whether an event meets the SE reporting criteria.

On-Site Reviews

The SET conducted ten on-site reviews in 2017. Administrative and clinical requirements were evaluated to determine compliance with the program through review of policies, meeting minutes, other reports and chart audits. Facilities were encouraged to ask questions and seek clarification about the program during the on-site reviews.

In addition to identifying areas of non-compliance, the SET also looks for ‘best practices’, and, with permission of the facility, shares these in the quarterly newsletters. Some ‘best practices are listed, below:

Education/training

- In addition to new hire orientation that includes sentinel event education, all employees receive similar annual training. In at least one facility, staff complete competency quizzes to assess the level of understanding related to sentinel events.

- New employees receive education about patient safety, including the importance of having a 'just culture', what to include in an incident report and the benefits of reporting near misses.
- Poster boards were created for annual skills day that explain what a sentinel event is, and include information about root cause analyses, sentinel event data, and lessons learned.
- Sharing of the SE newsletters with managers and directors.
- Dissemination of "lessons learned" from events to all staff, promoting transparency and ensuring that staff are informed of improvements to processes to prevent future sentinel events.

Analysis and tools

- Use of a Failure Mode and Effects Analysis to assess the possible consequences of implementing a high-risk process.
- Utilizing evidence-based practice to develop suicide risk tools.
- Development of a comprehensive restraint assessment form that is a resource for those staff members who are not frequently involved in restraint events.
- Identifying plans and measures to reduce patient falls by 25%.
- Use of the Institute for Healthcare Improvement tool for medication safety.
- Participating in the Leapfrog survey for computerized physician order entry.
- Assessing patient safety culture through use of the AHRQ patient safety culture survey.
- Instituting a quarterly 'Pressure Ulcer Prevalence' study to evaluate the effectiveness of skin care. The infection prevention nurse was noted to have targeted hand hygiene deficits and implemented action items for improvement.
- Use of the National Database for Nursing Quality indicators to report pressure ulcers and patient falls and access information to assist with quality improvement in those areas.
- Implementation of the 'Starting Hunger Screen' that is used to identify those in need of assistance with obtaining food.

Leadership Involvement:

- Leadership involvement as evidenced by the VP of Clinical Services/CNO presenting results of trends and analysis of sentinel events to the organization's quality committee, sharing root cause analyses for discussion and recommendations, and maintaining the root cause analysis on the committee's agenda until brought to a satisfactory conclusion by committee members.
- Distribution to all leaders of the facility of the '24-hour House Administrator Report' which captures relevant information, including adverse events.
- Comprehensive review of numerous topics related to patient safety by the quality committee, and relaying this information to the Board.
- Tracking information on a monthly restraint log such as duration of restraint and trends, and implementation of a 'Restraint Reduction Task Force' that evaluates the data and assesses ways to reduce restraint use.
- The 'Significant Event Team' evaluates action items from significant events on an on-going basis.

SE policy:

- Comprehensive sentinel event policy that includes a section on performance improvement tools, as well as information on root cause analysis.
- SE policy that addresses involved care givers (2nd victims), ensuring that they receive timely and systematic care to include treatment, respect, compassion, supportive medical care, and the opportunity to be fully involved in the investigation.

Progress on Goals

During 2017, 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 2017:

- 1) Goal: Continue to provide technical assistance and consultations, as requested, to facilities covered under the SE Rules.
Actions: The SET completed 10 on-site visits to review the SE Program and provide technical assistance. The SET completed one requested on-site visit 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 follow-up report that identifies any non-reported sentinel events found during the on-site review and any unmet administrative requirements. Additionally, the SET includes 'best practices' identified during the on-site review. With permission, the SET has published some of the identified best practices in the SE Newsletter.
- 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 complete (in entirety) the report form which can help determine trends. The SE database tracks individual facility reporting history, and the SET is able to graphically display this data. 2017 saw an increase in facility reporting of near miss and non-reportable cases. 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: Suicide Risk Screening Tools; Medication Errors; Organizational Transparency;

Preventable Health Care Harm as a Public Health Crisis; Cognitive Biases; Near Miss Identification; Surgical Errors; and Importance of Story Telling.

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

- 5) Goal: Continue to research and implement 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. The SET began to review the SE Rules with a focus on evaluating SE reporting categories and criteria specific to specialized environments.

- 6) Goal: 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.
Actions: The SET coordinated two Root Cause Analysis Collaborative workgroups in 2017, with participation of 44 facilities. The SET also presented information on systems, processes, and root cause analysis at the annual USM Patient Safety Academy. The Maine Hospital Association, with the Hospital Improvement Innovation Network and the SET, held a 2017 conference. The keynote speaker was Dr. Bruce Spurlock, President and CEO of Cynosure Health. Dr. Spurlock's presentation, "Building Safe Systems from the Middle: The Culture, the People and the Process" focused on ways middle managers can be effective in leading organizational change. Several facilities shared pertinent information on the discussion topics which lead to engaging dialogue between presenters and attendees.

- 7) Goal: Continue to monitor maternal and infant outcomes and resources in the State of Maine.
Actions: Maternal and infant outcomes continued to be monitored by the SET. The SET will continue to track reported cases related to maternal and infant serious injury or death and permanent loss of function. The trend in adverse events with infants has decreased from the spike in infant deaths seen in 2014.

- 8) Goal: 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.
Actions: Discussed with facilities at the time of on-site reviews and reminder included in SE newsletter.

Program Goals 2018

In 2018, 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. On-site reviews at all hospitals that have not yet been reviewed will be completed in 2018.
- 3) Continue to enhance the SE database with relevant information, and analyze complaint data to identify trends in SEs being reported, track individual facility 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 national patient safety issues.
- 5) Review and revise SE Rules to clarify reporting criteria and other modifications.
- 6) Continue to develop collaborative workgroups to assist with the sharing of challenges and best practices related to patient safety.
- 7) 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.
- 8) SET to begin to look at methods to review outpatient provider-based practices listed on facilities licenses, for compliance with program and reportable events.

Conclusion

The Sentinel Event program continues to work with balancing accountability with education, while supporting facilities in developing and continuing safer practices to enhance patient care in Maine. 2017 saw an increase in reported SEs, near misses and non-reportable events and this is attributed to increased facility surveillance and reporting. On-site reviews reveal that there are a number of facilities with best practices, and continued areas for improvements. The SET continues to focus on providing educational opportunities relevant to Maine and national trends.

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
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Revised August 19, 2015

**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

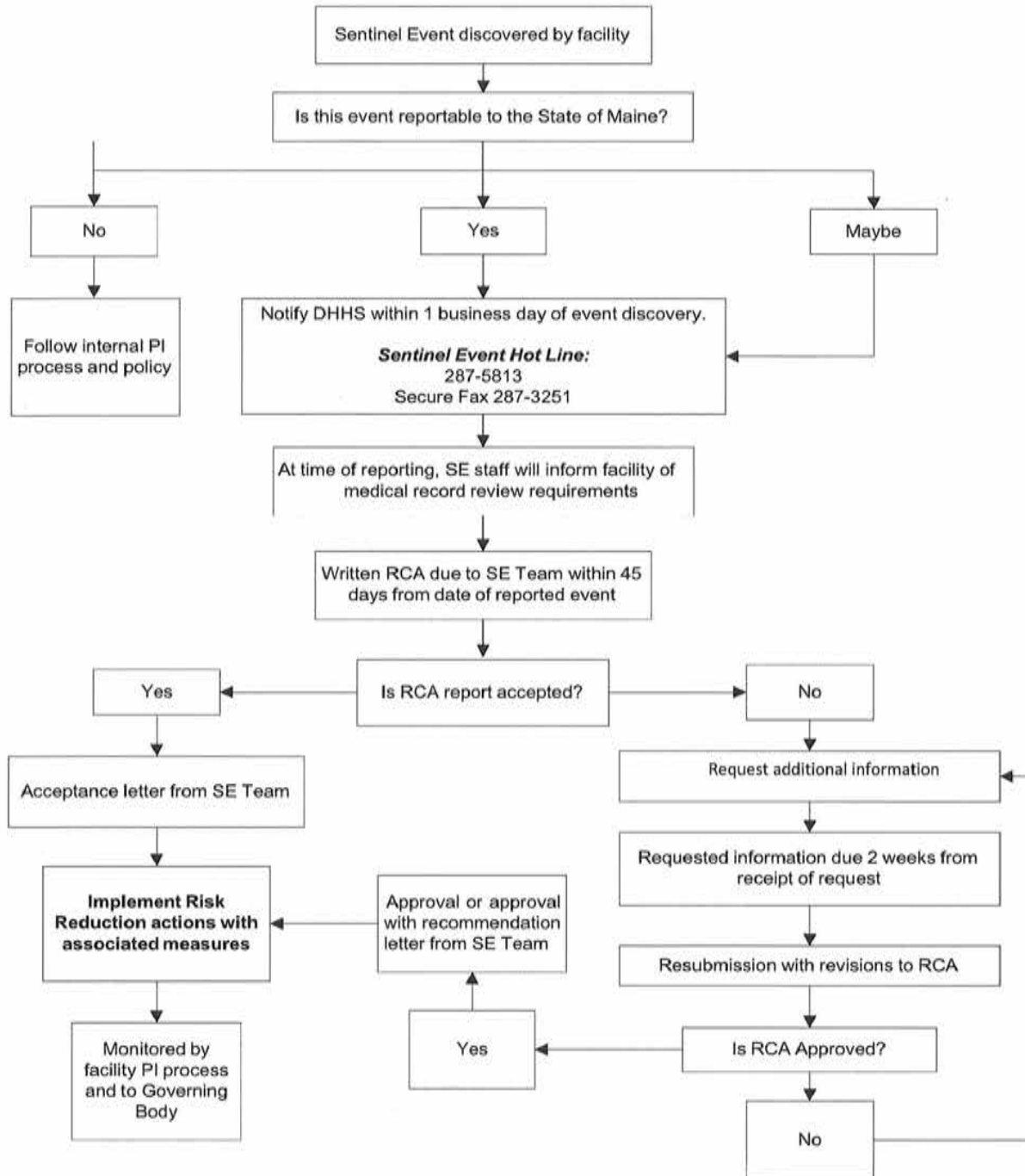
Potential Criminal Events

- 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, 2017

Total Events	Category	Male	Female	Infant	<=18	19-64	65+	NQF or State
83	Stage 3 or 4 pressure ulcers acquired after admission to a health care facility	54	29	1	0	34	48	NQF
43	Patient death or serious disability associated with a fall while being cared for in a health care facility	27	16	1	1	13	28	NQF
29	Unanticipated Death within 48 Hours of Treatment	19	10	0	0	12	17	State
22	Unanticipated Death	10	12	0	1	9	12	State
15	Surgery performed on the wrong body part	8	7	0	0	10	5	NQF
9	Unanticipated Patient Transfer to Another Facility	4	5	3	0	4	2	State
9	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)	6	3	1	1	4	3	NQF
8	Unintended retention of a foreign object in a patient after surgery or other procedure	4	4	0	0	5	3	NQF
6	Patient death or serious injury resulting from failure to follow up on or communicate laboratory, pathology or radiology test results.	4	2	1	0	2	3	NQF
5	Major Permanent Loss of Function in perinatal infant	3	2	5	0	0	0	State
5	Suicide Within 48 Hours	4	1	0	0	2	3	State
4	Wrong surgical procedure performed on a patient	2	2	0	0	1	3	NQF
4	Permanent loss of function within 48 hours of discharge	1	3	0	2	1	1	State
4	Patient suicide or attempted suicide resulting in serious disability while being cared for in a health care facility	2	2	0	1	3	0	NQF
3	Unanticipated death or permanent loss of function within 48 hours of treatment	1	2	0	0	2	1	State
2	Sexual assault on a patient within or on the grounds of the health care facility	2	0	0	0	2	0	NQF
2	Death or serious injury of a patient or staff member resulting from physical assault (i.e.: battery) that occurs within or on the ground of the health care facility	0	2	0	1	1	0	NQF
2	Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in a health care facility	2	0	0	0	0	2	NQF
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	2	0	0	0	1	1	NQF
1	Discharge or release of a patient of any age, who is unable to make decisions, to other than an authorized person	0	1	0	0	1	0	NQF

1	Patient death or serious injury associated with patient elopement (disappearance)	1	0	0	0	1	0	NQF
1	Major Permanent Loss of Function present at discharge	1	0	0	0	0	1	State
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	0	0	1	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	1	0	NQF
1	Patient death or serious injury associated with a burn incurred from any source while being cared for in a health care facility	1	0	0	0	1	0	NQF
1	Surgery performed on the wrong patient	1	0	0	0	0	1	NQF
1	Unanticipated Perinatal Death	1	0	0	0	0	0	State
265	Totals	161	104	14	7	110	134	

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 merged with the Institute for Healthcare Improvement in May 2017: 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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