Sentinel Events

CY2018

Annual Report to the Maine State Legislature
Sentinel Event Annual Report prepared by:
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**Executive Summary**

In 1999, the Institute of Medicine published *To Err is Human*, a report that brought attention to the prevalence of medical errors and underscored the important of patient safety. In the years since then, there have been many important changes, including patient safety research, and hospital programs focused on measurement and accreditation.\(^1\) Maine has taken an active role in the promotion of patient safety through its requirement for mandatory reporting of sentinel events (22 M.R.S.A. §§ 8751-8756) for hospitals, ambulatory surgical centers (ASC), end stage renal disease facilities (ESRD) and intermediate care facilities for individuals with intellectual disabilities (ICF/IID). Since 2004, these facilities have been required 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 that promotes understanding of the causes that underlie sentinel events which can lead to system and process changes 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 Sentinel Event Statute and Rules have a number of requirements, including the collection of data regarding sentinel events and sharing aggregated data with the Legislature and the public. This annual report provides information related to the number and types of sentinel events that were reported in 2018, as well as the actions taken by facilities to prevent future occurrences and to mitigate the harm caused by similar events. However, the work of the SET goes well beyond these data collection and reporting requirements. The SET provides extensive technical assistance to covered facilities in terms of understanding sentinel events and identifying their root causes. The SET has established relationships with covered facilities that promotes communication and interactions related to serious adverse events. A key feature of the SE Program is the confidentiality outlined by statute, which protects sentinel event information from discovery, allowing covered facilities to do the system investigations necessary to truly understand the causal factors of these sentinel events.

In an effort to ensure that facilities are in compliance with the SE requirements, the SET conducted ten on-site reviews in 2018. Issues identified were predominantly related to the administrative requirements of the Sentinel Event Statute and Rules, such as policies and procedures, orientation and training. During these on-site reviews, the SET also identified positive aspects of facilities’ patient safety programs, which are highlighted in this report.

The SET continues to publish a quarterly newsletter that focuses on key patient safety issues identified by covered facilities in the state, as well as those issues that have been identified nationally. The newsletters include information and links to tools that are available to facilities as a means of assisting in the promotion of their patient safety programs.

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\(^1\) Two Decades Since To Err is Human: An Assessment of Progress and Emerging Priorities in Patient Safety, Bates and Singh, Health Affairs, November 2018
In order to truly make a difference in improving patient safety throughout the state, facilities must be able to share their experiences – their challenges and successes – with one another. In support of this, the SET has conducted learning collaborative programs that are open to all covered facilities. In 2018, the learning collaborative focused on the challenges of caring for behavioral health patients in emergency departments and outpatient settings. Over 70 attendees from 35 facilities participated in the program, with presentations by five hospitals from Maine and New Hampshire. The program was well received, and requests have been made for a follow up program. This learning collaborative was done in association with the Offices of Rural Health and Primary Care. This partnership is beneficial to healthcare facilities in rural areas that have challenges that may be very different from those of their urban colleagues. In 2019, the SET plans to expand its work with the Offices of Rural Health and Primary Care to explore the challenges of coordinating care across the healthcare continuum.

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 2018, 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 Memorial Hospital
- Bridgton Hospital
- Rumford Hospital
- Northern Light Sebastian Valley Hospital
- Waldo County General Hospital
- LincolnHealth
- Northern Maine 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 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 2018, Maine had 88 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 in 2018

<table>
<thead>
<tr>
<th>Covered Facilities by Type 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospitals (22)</td>
</tr>
<tr>
<td>Critical Access Hospitals (16)</td>
</tr>
<tr>
<td>ASC (16)</td>
</tr>
<tr>
<td>ESRD (18)</td>
</tr>
<tr>
<td>ICF/IID (16)</td>
</tr>
</tbody>
</table>

Reports by Facility Type

Of the 88 facilities covered by the law, 41 (46%) reported sentinel events during 2018. Event reports were received from 35 (92%) Maine hospitals. An additional seven facilities did report near miss and/or non-reportable cases. Including these reports, 48% of all covered facilities reported activity to the SET in 2018.

There were 245 sentinel events reported in 2018. 239 were reported by hospitals, 2 were reported by ASCs and 2 were reported by ESRDs. ICF/IID facilities reported 2 sentinel events for 2018.

Table 2. Sentinel Events Reported by Facility Type 2018
**Sentinel Events**

A total of 1,947 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.

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 2018, 73% of the sentinel events reported conformed with the NQF definitions and 27% were based on State definitions.

**Table 3. NQF or State Definition Distribution 2018**

<table>
<thead>
<tr>
<th>Distribution of SEs by NQF or State Definition</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>State</td>
<td>73%</td>
</tr>
<tr>
<td>NQF</td>
<td>27%</td>
</tr>
</tbody>
</table>

**2018 Reported Events**

There were 335 event notifications in 2018. Of those, 61 events did not meet the criteria of a sentinel event, and an additional 29 were determined to be ‘near misses’, bringing the total number of actual sentinel events to 245.
Twenty percent of sentinel events occurred either on a holiday (4) or a weekend (45). 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’.

Table 4 Sentinel Events Reported by Year, 2005-2018

<table>
<thead>
<tr>
<th>Year</th>
<th>SE</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td>28</td>
</tr>
<tr>
<td>2006</td>
<td>25</td>
</tr>
<tr>
<td>2007</td>
<td>28</td>
</tr>
<tr>
<td>2008</td>
<td>43</td>
</tr>
<tr>
<td>2009</td>
<td>45</td>
</tr>
<tr>
<td>2010</td>
<td>150</td>
</tr>
<tr>
<td>2011</td>
<td>163</td>
</tr>
<tr>
<td>2012</td>
<td>146</td>
</tr>
<tr>
<td>2013</td>
<td>177</td>
</tr>
<tr>
<td>2014</td>
<td>178</td>
</tr>
<tr>
<td>2015</td>
<td>202</td>
</tr>
<tr>
<td>2016</td>
<td>234</td>
</tr>
<tr>
<td>2017</td>
<td>265</td>
</tr>
<tr>
<td>2018</td>
<td>245</td>
</tr>
</tbody>
</table>

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 2018, 8 categories made up 87% of the total sentinel events reported, as listed below:

- Stage 3 or 4 and unstageable pressure ulcers at 75 (31%);
- Fall with serious injury at 47 (19%);
- Unanticipated death within 48 hours of treatment at 24 (10%);
- Unanticipated death at 23 (9%)
- Physical assault of a patient or staff member at 10 (4%)
- Wrong site surgery at 9 (4%)
- Unanticipated transfer to another facility at 9 (4%)
- Unintended retention of foreign object at 9 (4%)

Table 5 Most Frequently Reported Sentinel Events in 2018

<table>
<thead>
<tr>
<th>Event</th>
<th>Number of SEs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stage 3 or 4 Pressure Ulcer</td>
<td>75</td>
</tr>
<tr>
<td>Patient Death or Serious Injury</td>
<td>47</td>
</tr>
<tr>
<td>Unanticipated Death within 48 hours</td>
<td>24</td>
</tr>
<tr>
<td>Unanticipated Death</td>
<td>23</td>
</tr>
<tr>
<td>Physical Assault of a patient or staff member</td>
<td>10</td>
</tr>
<tr>
<td>Wrong site surgery</td>
<td>9</td>
</tr>
<tr>
<td>Unanticipated transfer</td>
<td>9</td>
</tr>
<tr>
<td>Retained Foreign Object</td>
<td>9</td>
</tr>
</tbody>
</table>

Total Count | 12 |
• Pressure ulcers have been in the top three most frequently reported sentinel events over the past eight 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.
• Surgical related cases continue to be identified. While these type of sentinel events 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. This includes wrong site surgery, retained foreign objects, wrong surgical procedures and surgery performed on the wrong patient.
• 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 2018**

<table>
<thead>
<tr>
<th>Action Items from Root Cause Analyses 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policies &amp; Procedures</td>
</tr>
<tr>
<td>31%</td>
</tr>
</tbody>
</table>

**Opportunities for Improvement**

The SET notes that the evaluation of the effectiveness of RCA action items continues to be the biggest challenge 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 sentinel event reporting criteria.
On-Site Reviews

The SET conducted ten on-site reviews in 2018. 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.
- Sentinel event educational content that is shared with staff, directors and board members.
- Sharing of the sentinel event newsletters with managers and directors.
- Risk Management report that shares sentinel events and improvement ideas from the RCAs.
- “Tracer Notes” sent out to keep quality/safety topics circulating among staff.

Analysis and tools
- Assessing patient safety culture through use of the AHRQ patient safety culture survey.
- Pharmacy & Therapeutics Committee approach to medication reconciliation audits, fall risks and educational sessions.
- Checklists and prompts for “Thorough & Credible RCA”.
- TelePsych utilized to decrease patient wait times for placement from the ED.
- Various mechanisms in place to work on reduction of “ligature risks”.
- Annual Mitigation of Risk Report with a quiz and competency report.
- ‘Speak Up for Safety’ and ‘Great Catch’ programs in place.
- Patient Safety & Quality newsletter which shares patient safety information.

Leadership Involvement:
- Comprehensive review of numerous topics related to patient safety by the quality/safety/risk committees, and relaying this information to the Board.
- Leadership’s use of the five principles of high reliability organizations to keep momentum on safety projects.
- Task Force created with a designated Safety Officer.
- Process for the disclosure of unanticipated outcomes and involving the family in the information gathering portion of an RCA.
- Nurse Educator position that serves as a resource and provides follow-up for new staff.
Sentinel event policy:

- Comprehensive sentinel event policy that includes a section on performance improvement tools, as well as information on root cause analysis.
- Sentinel event policy that clearly addresses the requirements of the Maine Sentinel Event Program, provides direction to staff and is carried over to orientation for staff.

Progress on Goals

During 2018, the SET continued to work with covered facilities and other agencies to enhance understanding of the Sentinel Event Program and the importance of patient safety. The following represents progress on the goals set for 2018:

1) **Goal:** Continue to provide technical assistance and consultations, as requested, to facilities covered under the sentinel event rules.
   **Actions:** The SET completed 4 requested on-site visits to provide technical assistance in understanding the requirements of the Sentinel Event Program. The SET also continues to receive phone calls from facilities seeking clarification on topics.

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 completed ten on-site reviews which are based on the individual facility’s history of reported sentinel events, as well as most frequently reported sentinel events statewide. 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 sentinel event newsletter.

3) **Goal:** Continue to enhance the sentinel event database with relevant information, and analyze complaint data to identify trends in sentinel events being reported, track individual provider sentinel events and utilize data in the most effective manner.
   **Actions:** The SET continues to encourage facilities to complete (in its entirety) the report form which can help determine trends. The sentinel event database tracks individual facility reporting history, and the SET is able to graphically display this data. 2018 saw an increase in 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 sentinel event data and patient safety issues identified nationally.
   **Actions:** Newsletters were distributed in March, June, September and December. Topics included: Clinician Burnout, Facility Culture and Patient Safety, Diagnostic Accuracy, Violence Affecting Healthcare Workers, Competition in Patient Safety, Improvement in Wrong Site Surgery and Patient Experience in Patient Safety.
5) **Goal:** Review and revise the sentinel event rules to clarify reporting criteria and other modifications.
   **Actions:** The SET continues to evaluate the sentinel event rules with a focus on sentinel event reporting categories and criteria specific to specialized environments. The SET remains in contact with other states regarding sentinel event reporting. Based on information obtained from other states, reporting facilities, healthcare systems and other agencies, the SET is preparing a revision packet for approval.

6) **Goal:** Continue to develop collaborative workgroups with interested providers to assist with the sharing of challenges and best practices related to patient safety issues.
   **Actions:** The SET collaborated with the Offices of Rural Health and Primary Care to provide an educational session on “Treating Behavioral Health Patients in the ED or Outpatient Settings: Challenges and Strategies”. Over 35 facilities participated. The SET continues to share ideas and resources, as available, to enhance patient safety.

7) **Goal:** Collaborate with facilities to ensure compliance with notifying the SET of a sentinel event within 1 business day of the event being discovered, and submission of RCA and associated requirements within 45 days of the sentinel event being reported.
   **Actions:** Continue to remind facilities during on-site visits and on all phone interactions.

8) **Goal:** SET to begin to look at methods to review outpatient provider – based practices listed on facilities’ licenses, for compliance with our program and reportable events.
   **Actions:** We have discussed this on facility visits, have provided information on this to clinics and employee health and occupational medicine staff.

**Program Goals 2019**

In 2019, the SET will continue to enhance the Sentinel Event Program in the following areas:

1) Continue to provide technical assistance and consultations, as requested, to facilities covered under the sentinel event 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 will focus on facilities that have not previously received an on-site review, including ambulatory surgical centers, and dialysis centers.
3) Will conduct on-site revisits for facilities at which there were previous deficiencies noted.
4) Identify resources for outpatient providers related to those sentinel events that are most prevalent in the outpatient setting.
5) Continue to produce the quarterly SE newsletter focused on trends noted in Maine sentinel event data and national patient safety issues.
6) Review and revise sentinel event rules to clarify reporting criteria and other modifications.
7) In collaboration with the Maine Offices of Rural Health and Primary Care, develop collaborative education programs with a focus on the challenges for rural healthcare providers.
Conclusion

The Sentinel Event Program provides valuable oversight of and technical support to hospitals, ambulatory surgical centers, dialysis centers and ICF/IIDs. The Sentinel Event Program continues to balance accountability with education, while supporting facilities in developing and continuing safer practices to enhance patient care in Maine. 2018 saw an increase in communication about events that did not meet sentinel event criteria, indicating the facility surveillance is identifying potential sentinel events. 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?
   - Unanticipated Death
   - Unanticipated Perinatal Death
   - Unanticipated Death within 48 Hrs. of Treatment
   - Suicide within 48 Hrs. of Discharge
   - Major Permanent Loss of Function in perinatal infant
   - Major Permanent Loss of Function present at discharge
   - Major Permanent Loss of Function within 48 Hrs. of Treatment

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)

8. Autopsy Requested  Y  N  Autopsy Performed  Y  N
   Medical Examiner Called  Y  N  Medical Examiner Accepted Case  Y  N

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

10. Facility Name: __________
    Reporter’s Name: __________
    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.

SENTEINEL EVENT CONFIDENTIAL FAX (207) 287-3251
This information is protected from public disclosure
Page 1 of 2
**NATIONAL CONSENSUS EVENTS**  
NATIONAL QUALITY FORUM SERIOUS REPORTABLE EVENTS

<table>
<thead>
<tr>
<th>Surgical or Invasive Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Surgery or other invasive procedure performed on the wrong site</td>
</tr>
<tr>
<td>☐ Surgery or other invasive procedure performed on the wrong patient</td>
</tr>
<tr>
<td>☐ Wrong surgical or other invasive procedure performed on a patient</td>
</tr>
<tr>
<td>☐ Unintended retention of a foreign object in a patient after surgery or other invasive procedure</td>
</tr>
<tr>
<td>☐ Intraoperative or immediately postoperative/post-procedure death in an American Society of Anesthesiologists Class I patient</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product or device events</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the healthcare setting</td>
</tr>
<tr>
<td>☐ 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</td>
</tr>
<tr>
<td>☐ Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in a healthcare setting</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patient Protection Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Discharge or release of a patient of any age, who is unable to make decisions, to other than an authorized person</td>
</tr>
<tr>
<td>☐ Patient death or serious injury associated with patient elopement (disappearance)</td>
</tr>
<tr>
<td>☐ Patient suicide, attempted suicide or self-harm resulting in serious injury, while being cared for in a healthcare setting</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Care management events</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ 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)</td>
</tr>
<tr>
<td>☐ Patient death or serious injury associated with unsafe administration of blood products</td>
</tr>
<tr>
<td>☐ Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare setting</td>
</tr>
<tr>
<td>☐ Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy</td>
</tr>
<tr>
<td>☐ Patient death or serious injury associated with a fall while being cared for in a healthcare setting</td>
</tr>
<tr>
<td>☐ Stage 3 or 4 pressure and unstageable pressure ulcers acquired after admission/presentation to a healthcare setting</td>
</tr>
<tr>
<td>☐ Artificial insemination with the wrong donor sperm or wrong egg</td>
</tr>
<tr>
<td>☐ Patient death or serious injury resulting from the irretrievable loss of an irreplaceable biological specimen</td>
</tr>
<tr>
<td>☐ Patient death or serious injury resulting from failure to follow up on or communicate laboratory, pathology or radiology test results</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Environmental Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Patient or staff death or serious injury with an electric shock in the course of a patient care process in a healthcare setting</td>
</tr>
<tr>
<td>☐ 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</td>
</tr>
<tr>
<td>☐ Patient or staff death or serious injury associated with a burn incurred from any source while being cared for in a healthcare setting</td>
</tr>
<tr>
<td>☐ Patient death or serious injury associated with the use physical restraints or bedrails while being cared for in a healthcare setting</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Radiologic Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Death or serious injury of a patient or staff associated with the introduction of a metal object into the MRI area</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Potential Criminal Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider</td>
</tr>
<tr>
<td>☐ Abduction of a patient/resident of any age</td>
</tr>
<tr>
<td>☐ Sexual abuse/assault on a patient or staff member within or on the grounds of the healthcare setting</td>
</tr>
<tr>
<td>☐ 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</td>
</tr>
</tbody>
</table>

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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

Sentinel Event discovered by facility

Is this event reportable to the State of Maine?

No

Follow internal PI process and policy

Yes

Notify DHHS within 1 business day of event discovery.

Sentinel Event Hot Line:
287-5813
Secure Fax 287-3251

At time of reporting, SE staff will inform facility of medical record review requirements

Written RCA due to SE Team within 45 days from date of reported event

Is RCA report accepted?

Yes

Acceptance letter from SE Team

Implement Risk Reduction actions with associated measures

Monitored by facility PI process and to Governing Body

No

Request additional information

Requested information due 2 weeks from receipt of request

Resubmission with revisions to RCA

Is RCA Approved?

Yes

No
## Table 2. Sentinel Events Reported by Event Type, 2018

<table>
<thead>
<tr>
<th>Total Events</th>
<th>Category</th>
<th>Male</th>
<th>Female</th>
<th>Infant</th>
<th>&lt;=18</th>
<th>19-64</th>
<th>65+</th>
<th>NQF or State</th>
</tr>
</thead>
<tbody>
<tr>
<td>75</td>
<td>Stage 3 or 4 pressure ulcers acquired after admission to a health care facility</td>
<td>37</td>
<td>38</td>
<td>0</td>
<td>1</td>
<td>32</td>
<td>42</td>
<td>NQF</td>
</tr>
<tr>
<td>47</td>
<td>Patient death or serious disability associated with a fall while being cared for in a health care facility</td>
<td>20</td>
<td>27</td>
<td>0</td>
<td>0</td>
<td>17</td>
<td>30</td>
<td>NQF</td>
</tr>
<tr>
<td>24</td>
<td>Unanticipated Death within 48 Hours of Treatment</td>
<td>10</td>
<td>14</td>
<td>0</td>
<td>0</td>
<td>12</td>
<td>12</td>
<td>State</td>
</tr>
<tr>
<td>23</td>
<td>Unanticipated Death</td>
<td>15</td>
<td>8</td>
<td>0</td>
<td>0</td>
<td>10</td>
<td>13</td>
<td>State</td>
</tr>
<tr>
<td>10</td>
<td>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</td>
<td>7</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>10</td>
<td>0</td>
<td>NQF</td>
</tr>
<tr>
<td>9</td>
<td>Surgery performed on the wrong body part</td>
<td>4</td>
<td>5</td>
<td>0</td>
<td>0</td>
<td>4</td>
<td>5</td>
<td>NQF</td>
</tr>
<tr>
<td>9</td>
<td>Unintended retention of a foreign object in a patient after surgery or other procedure</td>
<td>5</td>
<td>4</td>
<td>0</td>
<td>0</td>
<td>7</td>
<td>2</td>
<td>NQF</td>
</tr>
<tr>
<td>9</td>
<td>Unanticipated Patient Transfer to Another Facility</td>
<td>3</td>
<td>6</td>
<td>1</td>
<td>0</td>
<td>6</td>
<td>2</td>
<td>State</td>
</tr>
<tr>
<td>7</td>
<td>Wrong Surgical Procedure performed on a patient</td>
<td>5</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>5</td>
<td>NQF</td>
</tr>
<tr>
<td>5</td>
<td>Major Permanent Loss of Function present at Discharge</td>
<td>4</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>4</td>
<td>1</td>
<td>State</td>
</tr>
<tr>
<td>4</td>
<td>Patient death or serious injury associated with a burn incurred from any source while being cared for in a health care facility</td>
<td>4</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>1</td>
<td>NQF</td>
</tr>
<tr>
<td>4</td>
<td>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)</td>
<td>3</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>2</td>
<td>NQF</td>
</tr>
<tr>
<td>3</td>
<td>Suicide within 48 hours of Discharge</td>
<td>1</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>0</td>
<td>State</td>
</tr>
<tr>
<td>3</td>
<td>Patient suicide or attempted suicide resulting in serious disability while being cared for in a health care facility</td>
<td>0</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>0</td>
<td>NQF</td>
</tr>
<tr>
<td>3</td>
<td>Surgery performed on the wrong patient</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>NQF</td>
</tr>
<tr>
<td>2</td>
<td>Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a health care facility</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>NQF</td>
</tr>
<tr>
<td>2</td>
<td>Patient death or serious injury resulting from failure to follow up on or communicate laboratory, pathology or radiology test results</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>NQF</td>
</tr>
<tr>
<td>1</td>
<td>Major Permanent Loss of Function in perinatal infant</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>State</td>
</tr>
<tr>
<td>1</td>
<td>Death or Serious Injury of a neonate associated with labor or delivery in a low risk pregnancy</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>NQF</td>
</tr>
<tr>
<td>1</td>
<td>Discharge or release of a patient of any age, who is unable to make decisions, to other than an authorized person</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>NQF</td>
</tr>
<tr>
<td>1</td>
<td>Death or Serious Injury of a patient or staff associated with the introduction of a metal object into the MRI area</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>NQF</td>
</tr>
<tr>
<td>1</td>
<td>Major Permanent Loss of Function within 48 hours of Treatment</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>State</td>
</tr>
<tr>
<td>1</td>
<td>Unanticipated Perinatal Death</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>State</td>
</tr>
<tr>
<td>245</td>
<td>Totals</td>
<td>125</td>
<td>120</td>
<td>5</td>
<td>1</td>
<td>120</td>
<td>119</td>
<td></td>
</tr>
<tr>
<td>-----</td>
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<td></td>
</tr>
</tbody>
</table>

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.hospitalsafety.score.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: https://mhdo.maine.gov/mqf.html

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 National Patient Safety Foundation – Institute of Healthcare Improvement – NPSF-IHI’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: https://www.maine.gov/dhhs/dlc/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
Non-Discrimination Notice

The Department of Health and Human Services (DHHS) does not discriminate on the basis of disability, race, color, creed, gender, sexual orientation, age, or national origin, in admission to, access to, or operations of its programs, services, or activities, or its hiring or employment practices. This notice is provided as required by Title II of the Americans with Disabilities Act of 1990 and in accordance with the Civil Rights Act of 1964 as amended, Section 504 of the Rehabilitation Act of 1973, as amended, the Age Discrimination Act of 1975, Title IX of the Education Amendments of 1972, the Maine Human Rights Act and Executive Order Regarding State of Maine Contracts for Services. Questions, concerns, complaints or requests for additional information regarding the ADA may be forwarded to the DHHS ADA Compliance/EEO Coordinators, #11 State House Station, Augusta, Maine 04333, 207-287-4289 (V), or 287-3488 (V)1-888-577-6690 (TTY). Individuals who need auxiliary aids for effective communication in program and services of DHHS are invited to make their needs and preferences known to one of the ADA Compliance/EEO Coordinators. This notice is available in alternate formats, upon request.