August 3, 2016

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

RE: Sentinel Events Annual Report, CY 2015

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

Enclosed is the Sentinel Events Annual Report for calendar year 2015. 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.

This report is posted on the Department’s publicly accessible webpage at: http://www.maine.gov/dhhs/dlrs/medical_facilities/sentinelevents/home.html

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

Sincerely,

Mary C. Mayhew
Commissioner

MCM/klv

Enclosure

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

CY2015

Annual Report to the Maine State Legislature

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

Maine People Living Safe, Healthy and Productive Lives
Sentinel Event Annual Report prepared by:
The Division of Licensing and Regulatory Services
Maine Center for Disease Control and Prevention
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Executive Summary

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). The reporting of sentinel events by healthcare facilities 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 Sentinel Event Team (SET), part of the Division of Licensing and Regulatory Services (DLRS), is responsible for overseeing the Sentinel Event Program.

The success of the Sentinel Event Program can only be achieved with cooperation and support of the healthcare facilities it covers. While reporting of sentinel events is mandated by statute, the learning that can be achieved through event investigation occurs at the facility level. Healthcare is provided to individual patients within a highly complex system involving healthcare professionals, clinical and support staff, and ever-changing technologies. An adverse event that occurs in a particular department may have its origin in a completely different area. For example, a surgical procedure performed on the wrong side of the body may have resulted from a miscommunication regarding the surgical referral from the primary care provider office. While in the past, individuals closest to an adverse event were often blamed and punished, healthcare leaders are coming to understand that most adverse events are related to system issues as opposed to individual incompetence. The sentinel event program, through its requirement of conducting thorough and credible analysis of the root causes of the event, promotes this ‘system-thinking’.

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. However, the information and understanding that comes from event investigation cannot be optimized by simply keeping it in a database. To that end, the SET in CY 2015 began its first collaborative workgroup related to pressure ulcer\(^1\) prevention, in collaboration with the Maine Hospital Association. 20 hospitals participated, and five hospitals presented in-depth information regarding the successes and challenges they experienced in addressing pressure ulcers. These presentations were inspirational, and demonstrate the commitment Maine facilities have to improving safe, quality care for their patients.

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\(^1\) Pressure ulcer – also known as bed sore or decubitus ulcer, it is a localized injury to the skin and/or underlying tissue, usually over a bony prominence, as a result of pressure or pressure in combination with shear (National Pressure Ulcer Advisory Panel).
The SET has continued its outreach efforts to engage facilities with on-site visits, telephonic communications, and the publishing of a quarterly newsletter, focusing on patient safety issues identified within Maine and nationally. The SET has also made formal presentations at various forums, including the Patient Safety Academy sponsored by the USM Muskie School, the University of New England and the Maine Primary Care Association.

In 2015, the SET began its on-site review of facilities, in accordance with MRSA Title 22, Chapter 1684, §8754, *Division Duties* to determine facilities’ compliance with requirements outlined in that chapter. Three on-site reviews of hospitals were conducted in CY 2015. No significant issues were identified, and the SET observed a number of ‘best practices’, including routine use of root cause analysis for investigating all adverse events, regardless of level of harm; multi-disciplinary rounding for ICU patients; and a pressure ulcer prevention program that resulted in a significant decrease in pressure ulcers throughout the facility.

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

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

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 directly related to the Sentinel Events Program. It is, however, an indication of the importance hospitals place on patient safety and their willingness to be transparent regarding their performance. In 2015, all of Maine’s acute and critical access hospitals submitted data to the Leapfrog Group. Six Maine hospitals were included in the Leapfrog Top Rural Hospitals list (www.leapfroggroup.org/ratings-reports/top-hospitals), as announced in December. Hospitals recognized are as follows:

- Blue Hill Memorial Hospital
- Cary Medical Center
- Houlton Regional Hospital
- Inland Hospital
- LincolnHealth
- Sebasticook Valley Health

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

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

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

**Reporting Requirements**

The Maine Sentinel Event Program receives the authority to carry out its activities in Maine MRSA Title 22, Chapter 1684, §8754, Division Duties. This statute establishes a system for reporting sentinel events for the purpose of improving the quality of health care and increased patient safety.
Facilities must notify the SET within one business day of discovering a possible sentinel event. Through a confidential telephone exchange of information, the SET determines whether the incident conforms to the statutory definition of a sentinel event. Upon confirmation by the SET that the event must be reported, the facility is required to submit a brief description of the incident to the SET. A facility that knowingly violates any provision of the reporting requirements is subject to a civil penalty of up to $10,000. A copy of the reporting form used by facilities can be found in Appendix A.

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 root cause analyses, or what forms facilities use to 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.

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, is 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.

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 gathering of data and generating reports. The sentinel event management system helps the SET identify patterns or trends in the frequency of sentinel events and common factors associated with events. The management system continues to be refined by the SET to include more granular information that is helpful in identifying trends.

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

Not all events reported to the SET fit the definition of a sentinel event. The SET will notify a facility if the reported event does not constitute a sentinel event. Facilities are encouraged, although not required to report ‘near misses’. Conducting a root cause analysis of a ‘near miss’ can help identify systems’ issues that, if not addressed, could result in a sentinel event in the future. The root cause and action plans from these ‘near miss’ reviews are entered into the database for educational purposes.

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

By law, all sentinel event information submitted to the SET is considered privileged and confidential. No information about reporting facilities or providers is discoverable or made public. A firewall is maintained between the sentinel event program and the DLRS licensing and certification unit. The only time that the SET is permitted to share information with DLRS licensing and certification staff is if the 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 DLRS licensing and certification unit ensures that there will be a timely investigation of the situation in order to avoid further harm to the public.

Sentinel Events

A total of 1,209 sentinel events have been reported to the SET since 2004, when covered facilities began reporting. As illustrated in Table 2, 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

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and enhance public trust. The Sentinel Event Rules were updated in 2013 to reflect a change in the NQF's listing of Serious Reportable Events. In 2015, 60% of the sentinel events reported conformed with the NQF definitions and 40% were based on State definitions.

Table 1 Distribution of Sentinel Events by State or NQF Definitions

<table>
<thead>
<tr>
<th>Distribution of SEs by NQF or State Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Pie chart showing 60% State and 40% NQF]</td>
</tr>
</tbody>
</table>

During the 12 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 2 provides a graphic view of sentinel events reported from 2004 through 2015.

Table 2 Sentinel Events Reported by Year, 2004-2015

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of SE Reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>2004</td>
<td>24</td>
</tr>
<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>
</tbody>
</table>
2015 Reported Events

There were a total of 230 event notifications in 2015. Of those, 20 events did not meet the criteria of a sentinel event, and an additional 8 were determined to be ‘near misses’, bringing the total number of actual sentinel events to 202. This is a 13.4% increase in the reported sentinel events from 2014 to 2015.

26% of sentinel events occurred either on a holiday (8) or a weekend (45). A phenomenon, sometimes called the ‘weekend effect’ has gained attention in patient safety literature. In a 2015 article in the British Medical Journal\(^4\), a study of admissions between 2002 and 2010 showed that 19% of admissions occurred on weekends, and patients admitted on weekends were 20% more likely to sustain a hospital acquired condition (trauma due to fall, pressure ulcers and catheter acquired urinary tract infections) than patients admitted Monday through Friday. Factors that may contribute to the increased risks to patients receiving hospital care outside of the regular work hours include, without limitation: reduced staffing, less experienced staff, decreased availability of services, lack of access to information from other providers, communication delays and coverage by on-call physicians unfamiliar with patients. The SET is encouraging facilities to consistently report dates and times when sentinel events occur, with particular attention to off-shifts, weekends and holidays, and to take this into consideration when identifying causal factors of the sentinel event.

Types of Sentinel Events Reported

Of the 18 different categories of sentinel events in 2015, 7 categories made up 80% of the total sentinel event reported, as listed below:

- Stage 3 or 4 and unstageable pressure ulcers at 45 (22%);
- Fall with serious injury at 40 (20%);
- Unanticipated death or permanent loss of function within 48 hours of treatment at 32 (16%);
- Unanticipated transfer to another facility 15 (7%);
- Unanticipated death 12 (6%); and
- Retention of a Foreign Object 10 (5%)
- Suicide within 48 hours 9 (4%)

A listing of all sentinel events can be found in Appendix C.

\(^4\) Incidence of “never events” among weekend admissions versus weekday admissions to US hospitals: national analysis (F. Attenalo, et al, April 15, 2015)
Pressure ulcers have been in the top three most frequently reported sentinel events over the past five years. Many facilities struggle with pressure ulcer prevention. In 2015, the SET, in conjunction with the Maine Hospital Association, held a pressure ulcer collaborative work group. All hospitals were invited to attend, and 20 hospitals sent staff. The SET presented aggregated data related to pressure ulcer sentinel event reports, and also shared some of the de-identified action plans that were part of the root cause analyses. Representatives from five hospitals made formal presentations: Maine Medical Center, The Aroostook Medical Center, Southern Maine Health Center, Bridgton and Rumford Hospitals. These facilities shared data, the challenges that they face in dealing with pressure ulcers, and successes with their respective programs. A survey was sent out after the collaborative workgroup to assess attendees' satisfaction. The following graph indicates the response to questions about content of the program, how helpful was the information shared, and the benefit of future collaborative workgroups. Scores were on a scale from 1 – 5, where 1 is the lowest score and 5 is the highest score. Table 4 provides the frequency distribution of responses across this scale.
Perinatal mortality and injury gained SET attention in 2014. (The perinatal period is measured from the 28th week of gestation through the 28th day after birth) Although not rising to the most frequently reported sentinel events, unanticipated perinatal death and major permanent loss of function in a perinatal infant were significantly higher in 2014 than in previous years. No common factors were noted in reviewing these events. The SET is continuing to monitor perinatal deaths and injuries.
Covered Facilities in 2015

Due to closures and/or mergers, Maine had 87 covered healthcare facilities in 2014. See Table 5 for a breakdown of covered facilities by type for 2015.

Table 5 Covered Facilities by Type in 2015

<table>
<thead>
<tr>
<th>Type</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospitals</td>
<td>27%</td>
</tr>
<tr>
<td>Critical Access Hospitals</td>
<td>18%</td>
</tr>
<tr>
<td>ASC</td>
<td>20%</td>
</tr>
<tr>
<td>ESRD</td>
<td>17%</td>
</tr>
<tr>
<td>ICF/IID</td>
<td>18%</td>
</tr>
</tbody>
</table>

Percentage of Facilities Reporting by Type

Of the 87 facilities covered by the law, 40 (43%) reported sentinel events during 2015. Event reports were received from 89.7% (35) of all Maine hospitals. Reporting percentages for the other covered facilities were much lower. The larger percentage of hospitals reporting, as compared to other facilities, is not unexpected. Hospitals have higher volumes, a wider variety of and more complex services than the smaller facilities.

Table 6 Percentage of Each Type of Covered Facilities that Reported Events

<table>
<thead>
<tr>
<th>Type</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospitals</td>
<td>97%</td>
</tr>
<tr>
<td>ASC</td>
<td>2%</td>
</tr>
<tr>
<td>ESRD</td>
<td>1%</td>
</tr>
<tr>
<td>ICF/IID</td>
<td>0%</td>
</tr>
</tbody>
</table>

15
Determining Why: Root Cause Analysis

When an adverse event occurs, facilities are required to conduct a root cause analysis. Contributing factors are categorized by type. As can be seen in Table 7, the most common contributing factors were: Policies & Procedures, Education/Training and Equipment.

Table 7 Causal Factors from Root Cause Analyses

<table>
<thead>
<tr>
<th>Causal Factors from Root Cause Analyses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policies &amp; Procedures: 33%</td>
</tr>
<tr>
<td>Education/Training: 27%</td>
</tr>
<tr>
<td>Equipment: 13%</td>
</tr>
<tr>
<td>Documentation: 10%</td>
</tr>
<tr>
<td>Communication: 9%</td>
</tr>
<tr>
<td>Barriers: 3%</td>
</tr>
<tr>
<td>Environment: 3%</td>
</tr>
<tr>
<td>Human Factors: 2%</td>
</tr>
</tbody>
</table>

Progress on Goals

During 2015, 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 2015:

1) **Goal:** Continue to provide technical assistance to facilities covered under the SE Rules and provide on-site visits and consultations as requested.
   **Actions:** The SET completed 12 on-site visits to review the SE Program and provide technical assistance. The SET completed two on-site visits to meet new facility staff members and to assist them in understanding the requirements of the SE program.

2) **Goal:** Implement an on-site review process, in accordance with MRSA Title 22, Chapter 1684, §8754, Division Duties that addresses the SET responsibilities for determining compliance of covered facilities with the SE Rules.
   **Actions:** The SET developed 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 completed three on-site visits during the last four months of the year.

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 is actively encouraging facilities to include time/shift that sentinel events occurred to determine if there are any trends related to day of the week or time of day that sentinel events occur. The SE database tracks individual facility reporting history, and the SET is able to graphically display this data. The SET continues to work with USM Muskie to maintain and update 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: Fatigue and Its Effect on Patient Safety; Safety Culture; Perinatal/Neonatal Mortality; Healthcare ‘After Hours’; Using Root Cause Analysis; Leadership’s Role in Safety Culture; CDC Advisory and Life in the ‘Post-Antibiotic Era’; Ambulatory Surgery and VTE (venous thromboembolism); Safety Culture in ESRDs; Falls; and Learning from Failure. All SE Newsletters may be accessed on the Sentinel Events home page: [http://www.maine.gov/dhhs/dlrs/medical_facilities/sentinel-events/home.html](http://www.maine.gov/dhhs/dlrs/medical_facilities/sentinel-events/home.html)

5) **Goal:** Continue to look at best practices in SE reporting systems.
   **Actions:** The SET continues to communicate with other states regarding SE reporting. Based on information obtained from other states, the Maine SE program is ahead of many other states in its program development and outreach activities.

6) **Goal:** Enhance collaborative workgroups with interested providers to assist with the sharing of challenges and best practices related to SEs.
   **Actions:** The SET coordinated, in conjunction with the Maine Hospital Association, a Pressure Ulcer Collaborative workgroup in December, 2015, with participation of 20 hospitals.

In addition to progress on the goals outlined in the 2014 Sentinel Event Annual Report, the SET participated in the following activities:

- **Revision of the Sentinel Event Rules:** These were approved and went into effect January 1, 2015.
- **Outreach efforts:** The SET presented at the Patient Safety Academy regarding Fatigue and its Impact on Patient Safety; met with Maine CDC and the Perinatal Leadership Coalition to review perinatal mortality; presented at the Maine Health Quality meeting; presented to the Critical Access Hospital nursing group.
- **Educational activities:** The SET subscribed to the IHI membership in order to access various educational opportunities, including webinars and on-line
training. Some of the educational topics the SET reviewed were: reduction of diagnostic errors and delays; impacting patient safety and outcomes with healthcare technology/EHR; EHR documentation and IT safety; Patient Safety Organizations, benefits/success stories from hospitals; life cycle of a QI project and teamwork and communications.

Program Goals 2016

In 2016, the SET will continue to enhance the SE program in the following areas:

1) Continue to provide technical assistance to facilities covered under the SE Rules and provide on-site visits and consultations as requested.
2) Continue to assess facilities’ compliance with MRSA Title 22, Chapter 1684, §8754, Division Duties by performing on-site reviews for covered facilities.
3) Continue to enhance the SE database with relevant information, and analyze complaint data to identify trends in SEs being reported, track individual provider SEs, and utilize data in the most effective manner.
4) Continue to produce the quarterly SE newsletter focused on trends noted in Maine SE data and patient safety issues identified nationally.
5) Continue to look for best practices in SE reporting systems.
6) Develop additional collaborative workgroups with interested providers to assist with the sharing of challenges and best practices related to SEs.
7) Sponsor a Patient Safety Conference featuring a nationally recognized patient safety expert as the keynote speaker to provide an opportunity for healthcare facilities to learn more about the importance of leadership in patient safety.

Conclusion

While the predominant goal of the Sentinel Events Program is to have a reporting system that focuses on identifying and deterring serious, preventable incidents, and supporting Maine’s healthcare facilities to improve patient safety, the effectiveness of this system is dependent upon the level of participation of covered entities. To that end the Maine SET has conducted outreach and educational activities to enhance the understanding of the Sentinel Event Program, the value of root cause analysis, and patient safety issues state-wide and nationally. The Maine SET utilizes data to track and trend sentinel events, contributing causes and facilities’ plans to address the underlying contributing factors to sentinel events. The SET’s accessibility to facility staff and outreach efforts have resulted in enhancing trust by healthcare facility staff of the SET, and increasing participation in the Sentinel Events Program.
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.

SENTINEL EVENT CONFIDENTIAL FAX (207) 287-3251
This information is protected from public disclosure
Page 1 of 2

Revised August 19, 2015
### 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 of 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>

Sentinel Events Notification Form Page 2 of 2
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 (call prior to sending fax)

At time of reporting, an appointment is set up with
SE staff for medical record review

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 for additional information

Requested information due 2 weeks from
receipt of request

Resubmission with revisions to RCA

Is RCA Approved?

Yes

No
# Appendix C – Sentinel Events Reported by Type

## Table 2. Sentinel Events Reported by Event Type, 2015

<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></th>
</tr>
</thead>
<tbody>
<tr>
<td>45</td>
<td>Stage 3 or 4 Pressure Ulcer Acquired After Admission to a Health Care Facility</td>
<td>32</td>
<td>13</td>
<td>1</td>
<td>0</td>
<td>17</td>
<td>27</td>
<td>NQF</td>
</tr>
<tr>
<td>40</td>
<td>Patient Death or Serious Disability Associated with a Fall While Being Cared for in a Health Care Facility</td>
<td>14</td>
<td>26</td>
<td>1</td>
<td>0</td>
<td>12</td>
<td>27</td>
<td>NQF</td>
</tr>
<tr>
<td>32</td>
<td>Unanticipated Death or Permanent Loss of Function within 48 Hours of Treatment</td>
<td>15</td>
<td>17</td>
<td>0</td>
<td>1</td>
<td>14</td>
<td>17</td>
<td>State</td>
</tr>
<tr>
<td>15</td>
<td>Unanticipated Transfer to Another Facility</td>
<td>5</td>
<td>10</td>
<td>0</td>
<td>0</td>
<td>9</td>
<td>6</td>
<td>State</td>
</tr>
<tr>
<td>12</td>
<td>Unanticipated Death</td>
<td>7</td>
<td>5</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>9</td>
<td>State</td>
</tr>
<tr>
<td>10</td>
<td>Unintended Retention of a Foreign Object in a Patient after Surgery or Other Procedure</td>
<td>4</td>
<td>6</td>
<td>0</td>
<td>1</td>
<td>7</td>
<td>2</td>
<td>NQF</td>
</tr>
<tr>
<td>9</td>
<td>Suicide Within 48 Hours</td>
<td>9</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>9</td>
<td>0</td>
<td>State</td>
</tr>
<tr>
<td>7</td>
<td>Death or Significant Injury of a Patient or Staff Member Resulting from a Physical Assault (i.e. battery) that occurs within or on the ground of the health care facility</td>
<td>5</td>
<td>2</td>
<td>0</td>
<td>3</td>
<td>4</td>
<td>0</td>
<td>NQF</td>
</tr>
<tr>
<td>6</td>
<td>Major Permanent Loss of Function in Perinatal Infant</td>
<td>3</td>
<td>3</td>
<td>6</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>State</td>
</tr>
<tr>
<td>6</td>
<td>Wrong surgical procedure performed on a patient</td>
<td>2</td>
<td>4</td>
<td>0</td>
<td>1</td>
<td>3</td>
<td>2</td>
<td>NQF</td>
</tr>
<tr>
<td>5</td>
<td>Major Permanent Loss of Function Present at Discharge</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>4</td>
<td>State</td>
</tr>
<tr>
<td>5</td>
<td>Surgery Performed on the Wrong Body Part</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>4</td>
<td>NQF</td>
</tr>
<tr>
<td>3</td>
<td>Unanticipated Perinatal Death</td>
<td>3</td>
<td>0</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>State</td>
</tr>
<tr>
<td>2</td>
<td>Patient Suicide or Attempted Suicide Resulting in Serious Disability While Being Cared for in a Health Care Facility</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>NQF</td>
</tr>
<tr>
<td>2</td>
<td>Sexual Assault on a Patient Within or on the Grounds of 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>1</td>
<td>Patient Death or Serious Disability Associated with a Medication Error (e.g. errors involving wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation or wrong route of administrations)</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>NQF</td>
</tr>
<tr>
<td>1</td>
<td>Patient Death or Serious Disability Associated with Intravascular Air Embolism that Occurs While Being Cared For in a Health Care Facility</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>NQF</td>
</tr>
<tr>
<td>1</td>
<td>Patient Death or Serious Injury Resulting from Failure to Follow Up on or Communicate Laboratory, Pathology, or Radiology Test Results</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>NQF</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>109</td>
<td>93</td>
<td>13</td>
<td>7</td>
<td>84</td>
<td>98</td>
<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/](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](http://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](http://www.getbettermaine.org)

**WhyNotTheBest.org** - was created by The Commonwealth Fund and in January 2015, was transferred to [IPRO](http://ipro.org), 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](http://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](http://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](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](http://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](http://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.ihi.org](http://www.ihi.org)

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

This Sentinel Event Annual Report may be found on the internet at: [http://www.maine.gov/dhhs/dhrs/medical_facilities/sentinelevents/home.html](http://www.maine.gov/dhhs/dhrs/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](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](http://www.maine.gov/sos/cec/rules/10/144/144c114.doc)
Non-Discrimination Notice

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