May 16, 2014

Senator Margaret M. Craven, Chair
Representative Richard R. Farnsworth, Chair
Members of the Joint Standing Committee on Health and Human Services
#100 State House Station
Augusta, ME 04333-0100

Dear Senator Craven, Representative Farnsworth, and Members of the Joint Standing Committee on Health and Human Services:

The Sentinel Events Reporting statute (22 M.R.S. §8754) directs the Department of Health and Human Services to submit an annual report to the Legislature, health care facilities and the public that includes summary data of the number and types of sentinel events of the prior calendar year.

Enclosed is the Sentinel Events Annual Report, calendar year 2013.

If you have any questions or would like further information, please feel free to contact Kenneth Albert, Director of the Division of Licensing and Regulatory Services at 287-6664.

Sincerely,

Mary C. Mayhew
Commissioner

MCM/klv

Enclosure
Sentinel Events

CY2013

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
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This report may be found on the internet at:

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
Executive Summary

In 2002 Maine enacted Public Law 2001, Chapter 678 establishing a mandatory sentinel event reporting system. Since 2004 Maine Hospitals, Ambulatory Surgical Centers (ASC), End-Stage Renal Disease Facilities (ESRD), and Intermediate Care Facilities for Individuals who are Intellectually Disabled (ICF/IID) have been required to report whenever a serious, unexpected and preventable event, or medical error, known as a Sentinel Event, occurs. These events include unanticipated patient deaths, falls with serious injury, serious medication errors, patient suicide, surgery on the wrong body part, or an error resulting in a major loss of function. In 2013, 177 such cases were reported to the Maine Division of Licensing and Regulatory Services.

The most important aspect of the reporting system is not the numbers themselves, but rather what is being learned from them. Counting events will not, by itself, make the system safer. But finding out why the events happen, and then working to prevent them from happening again, will lead to changes that increase safety for all patients. Aggregating adverse event data gathered from facilities is a powerful tool in identifying trends undermining safe and effective healthcare. Analysis of the information received can improve patient safety.

In 2009 the statute requiring sentinel event reporting was amended to include the adoption of the National Quality Forum list of Serious Reportable Events and enhancements to the sentinel event definition to reduce ambiguity. The “Rules Governing the Reporting of Sentinel Events” were updated in 2013 to reflect the changes in the list of Serious Reportable Events.

Every facility is required to conduct an in-depth analysis after every sentinel event. The facility gathers a Root Cause Analysis team and launches a review of why the event occurred, and what steps will be undertaken to prevent a recurrence. The Sentinel Event Team and facility staff will share findings to stimulate discussion in an effort to identify opportunities for system improvements. The final report is sent to the Division within 45 days of discovery of the sentinel event. The Sentinel Event Team analyzes all events for statewide trends and features. Results are then shared in the Sentinel Event Annual Report.

In 2013 the most prevalent type of event reported was Stage 3 or 4 and unstageable pressure ulcers acquired after admission to a healthcare setting. Falls resulting in significant injury or death, unanticipated transfers to another facility, unanticipated death and unanticipated death within 48 hours of treatment round out the top five most reported adverse events.

The Maine program has been enriched by our active participation in the National Quality Forum (NQF) and the Agency for Healthcare Research and Quality (AHRQ). The NQF and the AHRQ bring together the 27 states, including the District of Columbia, with mandatory sentinel event reporting requirements to collaborate in a national dialogue on priorities and goals to improve patient safety by preventing adverse events in healthcare.
Background

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

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

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.

Definition of Sentinel Event

Sentinel events are outcomes determined to be unrelated to the natural course of the patient’s illness or underlying condition, or proper treatment of that illness or underlying condition. The law further characterizes sentinel events as:

- Unanticipated death
- A major permanent loss of function that is not present when the patient is admitted to the health-care facility
- Surgery on the wrong patient or wrong body part
- Death or serious injury associated with unsafe administration of blood products
- Patient suicide or attempted suicide resulting in serious injury
- Patient abduction or discharge to an unauthorized person
- Sexual abuse/assault of a patient or staff member
- Unintended retention of a foreign object
- Patient death or serious injury associated with a fall
- Death or serious injury of a patient or a staff member resulting from a physical assault
In 2010 the entire list of the National Quality Forum (NQF) Serious Reportable Events was formally adopted as part of the statutory changes. This list was updated in 2013. NQF serious events are structured around seven categories: surgical, product or device, patient protection, care management, environmental, radiologic and potential criminal.

**National Quality Forum**

The National Quality Forum (NQF) is a national, 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. (National Quality Forum, 2002)\(^1\) Sometimes referred to as “never events,” the NQF list increasingly has become the basis for states’ mandatory reporting system. (Rosenthal, 2007)\(^2\) The list of NQF serious events is intended to capture events that are clearly identifiable and measurable, largely preventable, and of interest to the public and other stakeholders. 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.

**Reporting Requirements**

Facilities must notify the Division within one business day of discovering an event. Through a confidential telephone exchange of information, the Sentinel Event Team determines whether the incident conforms to the statutory definition of a sentinel event. Upon confirmation that the event must be reported, the facility is required to submit a brief description of the incident via a restricted fax to the Division. A facility that knowingly violates any provision of the requirements is subject to a civil penalty. A copy of the reporting form used by facilities can be found in Appendix A.

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

The Sentinel Event Team may conduct an onsite review at each facility reporting a sentinel event to assess the incident and to ensure that all relevant factors are considered in the development of an action plan. A case review occurs shortly after the incident is first reported so that findings can be incorporated into the facility’s action plan development.

The medical record of the patient is reviewed to identify contributing factors that may have gone unnoticed and have affected the outcome before, during and after an event. This process

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provides an independent assessment that augments the facility's own internal review of the incident.

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

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

In 2013 the Sentinel Event Team utilized the confidential Sentinel Event Database to gather and track information collected on reported events and their associated root causes and applicable action plans. This database provides an updated management system for incoming reports and data and is the primary source for identifying and generating aggregate statistics and trends. De-identified root causes and action plans will be available to share with facilities for educational purposes. It generates multi-level reporting, allowing identification of patterns of vulnerability or common factors that exist with relatively rare events or small numbers where trend analysis would be difficult.

A Near Miss is an event or situation that did not produce patient injury, but only because of chance, which may include, but is not limited to, robustness of the patient or a fortuitous, timely intervention. The reporting of near misses is voluntary and in 2013, 11 hospitals reported 39 such events. Near miss investigations identify and control safety and health hazards before they cause a more serious incident. They can signal a system weakness that may lead to problems if not corrected. The root cause and action plans from these reviews are entered into the database for educational purposes.

**Confidentiality Provisions**

By law, all sentinel event information submitted to the Division is considered privileged and confidential. No information about facilities or providers is discoverable or made public. A firewall is maintained between the sentinel event program and the survey unit that regulates facility licensing within the State. The Sentinel Event Team is responsible for reviewing the initial reported event, conducting on-site reviews, ensuring that all contributing factors to an event are identified, and that action plans are appropriate and implemented. The Sentinel Event Team is permitted to share information with the licensing team if it determines that a sentinel event represents
immediate jeopardy to the public. The information shared is limited to the Conditions of Participation for the Medicare and Medicaid certification program that was impacted by the event. This ensures that the immediate jeopardy can be investigated and separate corrections be made to avoid harm to the public.

**How to Use this Report**

This report is one of many sources of information available on health care quality and patient safety. It is designed to provide an overview of activities in the state and allow consumers to identify safety concerns. Other good sources of information on health care quality are listed below and in Appendix C.

The fact that health care providers are looking for potential adverse situations and reporting them in order to learn and prevent harm to patients is a positive step in patient safety. Rather than using this report to compare facilities based on incidence rates or to compare data from other years, consumers should use this report to identify situations of interest and then ask their provider what is being done in their facility to prevent these events from occurring. It is important to be aware that events listed in this report represent a very small fraction of all the admissions and procedures in Maine facilities. Patient awareness is an important tool in improving safety, but it is also important to keep these numbers in perspective.

The number of reported events can fluctuate at a facility for a variety of reasons. Examples would include the size of the facility, number and type of procedures conducted along with the type of patients seen. A higher number of reported events does not necessarily mean the facility is less safe. The number of reported events may be higher at facilities that are especially vigilant about identifying and reporting errors. This may foster a culture where staff feels more comfortable reporting potential situations without fear of reprisal. Higher numbers may also represent a trend to greater attention to adverse situations, their cause and prevention.

**Sources of Further Quality and Safety Information**

http://www.mainequalitycounts.org/
www.hospitalsafetyscore.org
www.getbettermaine.org
www.whynotthebest.org
www.mainequalityforum.gov
www.leapfroggroup.org
https://mhdo.maine.gov
Sentinel Events Historically Reported

A total of 828 sentinel events have been reported to the Division since the initiation of the program in 2004. Following focused efforts to ensure that all facilities had a heightened awareness and full understanding of the reporting requirements, reporting began to increase in 2008.

An increase in sentinel event reporting reflects a greater appreciation of the rules and changes in the statutory requirements. There is also a growing awareness of the benefit of increased transparency with an emphasis on establishing a ‘blame free’ culture and a focus on systems improvements and reduction of the likelihood of a recurrence.

Table 1. Sentinel Events Reported, by Year, 2009-2013

![Bar graph showing the total number of sentinel events by year from 2009 to 2013.]

Sentinel events reported during the period from 2004-2008 averaged approximately 30 sentinel events annually.

During the 10 years of reporting sentinel events, hospitals have steadily increased participation in the program. By 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. In 2013, 39 hospitals reported events including near miss or non-reportable cases.
Sentinel Events Reported in 2013

2013 Reported Events

There were 256 events reported in 2013. This caseload includes 117 female and 139 male patients. Of those, 40 events did not meet the criteria of a sentinel event, and an additional 39 were determined to be near misses, bringing the total number of actual sentinel events to 177. This is a slight increase over the 146 actual events in 2012. Six (6) events were associated with a holiday, while fifty-three (53) events occurred during a weekend.

Type of Sentinel Events Reported

Table 2 indicates sentinel events by category (20) in 2013. Stage 3 or 4 and unstageable pressure ulcers were reported in the majority of cases at 40 (23%). Fall with serious injury was the second leading event at 27 (15%) followed by unanticipated transfer the third leading event at 21 (12%).

Table 2. Sentinel Events Reported by Event Type, 2013

<table>
<thead>
<tr>
<th>Total Events</th>
<th>Category</th>
<th>Male</th>
<th>Female</th>
<th>Infant</th>
<th>&lt;18 years</th>
<th>19-64 years</th>
<th>65+ years</th>
</tr>
</thead>
<tbody>
<tr>
<td>40</td>
<td>Stage 3 or 4 and unstageable Pressure Ulcers acquired after admission to a healthcare setting</td>
<td>26</td>
<td>14</td>
<td>0</td>
<td>0</td>
<td>19</td>
<td>21</td>
</tr>
<tr>
<td>27</td>
<td>Patient death or serious injury associated with a fall while being cared for in a healthcare setting</td>
<td>11</td>
<td>16</td>
<td>0</td>
<td>1</td>
<td>7</td>
<td>19</td>
</tr>
<tr>
<td>21</td>
<td>Unanticipated transfer to another facility</td>
<td>15</td>
<td>6</td>
<td>4</td>
<td>0</td>
<td>8</td>
<td>9</td>
</tr>
<tr>
<td>19</td>
<td>Unanticipated death</td>
<td>12</td>
<td>7</td>
<td>0</td>
<td>0</td>
<td>9</td>
<td>10</td>
</tr>
<tr>
<td>19</td>
<td>Unanticipated death within 48 hours of treatment</td>
<td>12</td>
<td>7</td>
<td>1</td>
<td>0</td>
<td>13</td>
<td>5</td>
</tr>
<tr>
<td>10</td>
<td>Surgery or other invasive procedure performed on the wrong site</td>
<td>3</td>
<td>7</td>
<td>0</td>
<td>1</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>8</td>
<td>Unintended retention of a foreign object in a patient after surgery or other invasive procedure</td>
<td>5</td>
<td>3</td>
<td>1</td>
<td>1</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>8</td>
<td>Major permanent loss of function present at discharge</td>
<td>4</td>
<td>4</td>
<td>0</td>
<td>0</td>
<td>6</td>
<td>2</td>
</tr>
<tr>
<td>8</td>
<td>Suicide within 48 hours of discharge from a healthcare facility</td>
<td>6</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>7</td>
<td>1</td>
</tr>
<tr>
<td>3</td>
<td>Suicide or attempted suicide resulting in a serious injury while being cared for in a healthcare facility</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>3</td>
<td>Wrong surgical procedure performed on a patient</td>
<td>1</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>2</td>
<td>Patient death or serious injury associated with a burn incurred from any source while being cared for in a healthcare facility</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>Patient death or serious injury associated with a medication error</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>Patient death or serious injury associated with the use or function of a device in patient care in which the device is used or functions other than as</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>1</td>
<td>Patient death or serious injury associated with the use of contaminated drugs, devices or biologics provided by the healthcare facility</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>---</td>
<td>----------------------------------------------------------------------------------------------------------------------</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>1</td>
<td>Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>1</td>
<td>Death or serious injury of a patient or staff member resulting from a physical assault that occurs within or on the grounds of a healthcare setting</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>1</td>
<td>Sexual assault on a patient within or on the grounds of a healthcare facility</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>1</td>
<td>Surgery or other invasive procedure performed on the wrong patient</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>Major permanent loss of function in a perinatal infant</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

**Type of Facilities Reporting Events in 2013**

In 2013, general hospitals represented 70% of the facilities that reported to the sentinel event program. Critical Access Hospitals accounted for 26%, Psychiatric hospitals represented 2%, ESRD (dialysis) facilities 1%, Ambulatory Surgical Centers 0.5% and ICF/IID facilities 0.5% of cases.

Of the 93 facilities covered by the law, 36 (39%) reported sentinel events during 2013. This includes 32 hospitals, 2 ESRD, 1 ICF/IID and 1 ASC.

**Table 3. Sentinel Events Reported by Facility Type, 2013**

- Critical Access Hospital: 26%
- Psychiatric Hospital: 2%
- Other: 2%
- General Hospital: 70%
Determining Why: Root Cause Analysis

When an adverse event occurs, facilities are required to conduct a root cause analysis. This process involves convening a team to closely examine the factors that lead to the event. This process helps a facility determine what happened and why it happened. These findings are the key to preventing future events. Analyzing information from multiple RCA’s helps a facility identify trends or patterns of vulnerability within their organization.

<table>
<thead>
<tr>
<th>Identified Contributing Factor Categories</th>
</tr>
</thead>
<tbody>
<tr>
<td>Communication</td>
</tr>
<tr>
<td>Education</td>
</tr>
<tr>
<td>Environmental</td>
</tr>
<tr>
<td>Policies/Procedures</td>
</tr>
<tr>
<td>Documentation</td>
</tr>
<tr>
<td>Equipment</td>
</tr>
<tr>
<td>Human Factors</td>
</tr>
<tr>
<td>Process/System</td>
</tr>
</tbody>
</table>

Below is a summary of information provided by reporting facilities. The specifics of each event may differ, but it is possible to identify some commonalities in contributing causes across facilities.

Communication
- Between nursing staff
- Between physicians
- Between shifts
- Between departments
- Between patients and staff
- Between facilities

Documentation
- Incomplete/inconsistent
- Missing
- Shows needed change to established physician order sets
- Hybrid of electronic records and paper files
- Identified needed electronic medical record updates
Education
- To provide staff updates
- Expand topics in orientation
- On specialty equipment
- On staff competencies
- On pressure ulcer specifics such as warning signs, staging and current treatment options
- On electronic medical record fields
- On dementia training
- Include family education needs

Equipment
- Purchase new or updated
- Change products in use
- Limited availability
- Not used appropriately

Human Factors
- Patient refusing care
- Shortcuts
- Staff concerns
- Patient concerns
- Busy/Hurried
- Scheduling/Staffing with no backup
- Fatigue

Policy/Procedure
- Implement new
- Revise
- Not followed consistently
- Not in place
- Unclear to staff
- Varied interpretation between departments

Process/System
- Need to develop/implement new process
- Add new electronic alerts to capture certain events in the EMR
- Update process for the placement of verification images on permanent records
- Update “Time Out” to include all staff involved, prior to a procedure
- Develop a system to address staff fatigue and/or patient surge in numbers/backlog
• Revise the process to review small masses prior to surgery

**Environmental**
• Specialty room availability
• Hazardous/risks not identified
• Lack of signs posted
• Access to patient grab bars

**Conclusion**

Maine’s sentinel event reporting system focuses on identifying and deterring serious, preventable incidents. Mandatory reporting is the primary tool for the State to hold facilities accountable for disclosing that an event has occurred and that appropriate action has been taken to remedy the situation. The system was designed to learn from mistakes, not punish individual practitioners or providers.

To be effective, the system requires the participation of all reporting entities. Only by understanding the full scope of the problem can strategies be developed to improve patient safety throughout the State.

The increased amount of contact to the Division identifies a growing trend in more facilities accepting a culture of safety. The confidential and blame free aspects remain as crucial components heightening provider reporting and prevention.
Program Goals for 2014

During 2014, the sentinel events program will work closely with hospitals and others to strengthen the reliability of reporting. To achieve this, the sentinel events program will do the following:

- Work with the Maine Health Data Organization, the Maine Quality Forum and Maine hospitals to develop the analytical tools to identify reportable events that can reliably be detected through administrative data

- Continue to perform on-site visits with hospitals and other facilities. This may include a review of documents to determine compliance with the Rules Governing the Reporting of Sentinel Events

- Continue to assess the adequacy of a facility’s internal systems for detecting and reporting events

- Continue to analyze complaint data to determine if a situation reported as a complaint is a reportable sentinel event

- Implement and expand educational and technical assistance capabilities to include a semi-annual newsletter of changes or trends identified and share root cause factors and action plan topics.

To achieve its goals, the Sentinel Events Program will continue to maintain ongoing communications with Maine hospitals, other licensed facilities and stakeholders regarding reporting requirements and lessons that can be learned to prevent events from being repeated. The Sentinel Events Program is committed to maintaining a non-punitive environment that allows for a collaborative approach for identifying serious adverse events and working toward joint solutions for reducing their occurrence.

The predominant goal of the Sentinel Events Program is to have a reporting system that helps facilitate the improvement of quality health care for all Maine’s citizens.
Appendix A

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

Use this form to report a sentinel event or a near miss. Forward the completed form to the Sentinel Event Program confidential fax number (207) 287-3251.

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? Check all that apply
   ☐ Unanticipated Death
   ☐ Unanticipated Perinatal Death
   ☐ Suicide within 48 Hrs. of Discharge
   ☐ Major Permanent Loss of Function in perinatal infant
   ☐ Major Permanent Loss of Function present at discharge

6. Unanticipated Death or Major Permanent Loss of Function within 48 hours of treatment? ☐ Y ☐ N

7. Unanticipated patient transfer to another facility? ☐ Y ☐ N

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

9. Autopsy Requested ☐ Y ☐ N Medical Examiner Called ☐ Y ☐ N
   Autopsy Performed ☐ Y ☐ N Medical Examiner Accepted Case ☐ Y ☐ N

10. Was equipment e.g., IV pump, medication vials, sequestered? ☐ N/A ☐ N ☐ Y Specify: ________

11. Reporter’s Name: ____________________________ Title: ____________________________
    Telephone Number: ____________________________ E-mail Address: ______________________

Facility Name: ____________________________

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 HOTLINE (207) 287-5813
### Surgical or Invasive Events
- Surgery or other invasive procedure performed on the wrong site
- Surgery or other invasive procedure performed on the wrong patient
- Wrong surgical or other invasive procedure performed on a patient
- Unintended retention of a foreign object in a patient after surgery or other invasive procedure
- Intraoperative or immediately postoperative/post-procedure death in an American Society of Anesthesiologists Class I patient

### Product or Device Events
- Patient death or serious injury associated with the use or function of a device in patient care, in which the device is used for a function other than as intended
- Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in a healthcare setting

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

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

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

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

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

Sentinel Event Process Flow

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

Maybe

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

Yes

Is RCA report accepted?

No

Request for additional information

Requested information due 2 weeks from receipt of request

Re_submission with revisions to RCA

Is RCA Approved?

Yes

No

Acceptance letter from SE Team

Implement Risk Reduction actions with associated measures

Monitored by facility PI process and to Governing Body

Approval or approval with recommendation letter from SE Team

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Appendix C

Sources of Further Quality and Safety Information

http://www.mainequalitycounts.org/

www.hospitalsafetyscore.org

www.getbettermaine.org

www.whynotthebest.org

www.mainequalityforum.gov

www.leapfroggroup.org

https://mhdo.maine.gov
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