Department of Health and Human Services
Maine People Living
Safe, Healthy and Productive Lives

Paul R. LePage, Governor Mary C. Mayhew, Commissioner

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

May 13, 2015

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 2014

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 2014.* 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 Kenneth Albert, RN, Esq., Director and Chief Operating Officer, Maine Center for Disease Control and Prevention.

Sincerely,

Mary C. Mayhew
Commissioner

MCM/klv

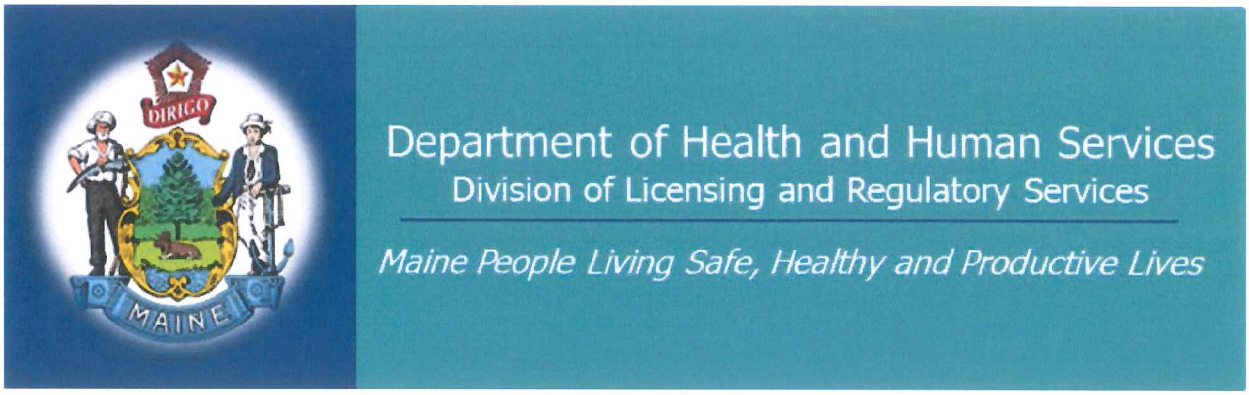
Enclosure

cc: Kenneth Albert, RN, Esq., Director and Chief Operating Officer, Maine Center for Disease Control and Prevention

Sentinel Events

CY2014

Annual Report to the Maine State Legislature



Sentinel Event Annual Report prepared by:

The Division of Licensing and Regulatory Services
Department of Health and Human Services
41 Anthony Avenue
11 State House Station
Augusta, ME 04333-0011

For further information please contact:

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

Sarah Taylor, MBA, FACMPE
Assistant Director Medical Facilities
(207) 287-9300 or sarah.taylor@maine.gov

Kenneth J. Albert RN, Esq.
Director, Division of Licensing and Regulatory Services
(207) 287- 9300 or kenneth.albert@maine.gov

TABLE OF CONTENTS

EXECUTIVE SUMMARY 4

HOW TO USE THIS REPORT 5

BACKGROUND 5

Reporting Requirements 7

Confidentiality Provisions 8

SENTINEL EVENTS 8

2014 Reported Events 10

Types of Sentinel Events Reported 11

Percentage of Facilities Reporting by Type 13

Determining Why: Root Cause Analysis 13

PROGRESS ON GOALS 14

PROGRAM GOALS FOR 2015 16

CONCLUSION 16

APPENDIX A 17

APPENDIX B 19

APPENDIX C 20

APPENDIX D RESOURCES 21

Executive Summary

The overarching aim of the Maine Department of Health and Human Services (DHHS) is to promote safe, healthy and independent lives for all, while ensuring efficient and effective use of resources for Maine's most vulnerable residents. Maine's Sentinel Event Program supports this mission by improving the safe care of patients throughout the state. Maine's Sentinel Event Program was established in 2002 with enactment of Public Law 2001, Chapter 678. 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 Sentinel Event Team (SET), part of the Division of Licensing and Regulatory Services (DLRS), is responsible for overseeing the Sentinel Event program.

Since the inception of the Sentinel Event Program, over 1000 sentinel events have been reported to Maine's SET. Participation by covered providers has increased over time. In 2006, only 61% of all Maine hospitals had reported a sentinel event; this increased to 95% of hospitals reporting events in 2014. Increased reporting of sentinel events should not be misconstrued as worsening patient safety. Rather, it signifies the commitment of Maine's hospitals and other covered healthcare providers to greater transparency in reporting of, and learning from significant patient safety issues. A 2013 article in the "Journal of Patient Safety" estimates that premature deaths in the United States, as a result of preventable medical errors, could be upwards of 400,000 per year[1], making medical errors the third leading cause of death in the United States, behind heart disease and cancer. John James, PhD, author of this article emphasizes the importance of transparent accountability for harm and intentional correction of root causes of harm as essential in addressing what he calls "the epidemic of patient harm in hospitals".

The SET supports Maine's healthcare facilities in their efforts to learn from sentinel events and near misses (events that do not rise to the level of a sentinel event, but might have if not discovered and prevented) through their investigation and identification of the root causes of those events. Sentinel event data provided to the SET from healthcare facilities is entered into a secure database. This data is tracked and trended. Facility-specific data is shared during on-site visits by the SET. These visits afford facilities the opportunity to receive technical assistance and updates regarding the Sentinel Event Program. Aggregated data is published in the Sentinel Event Annual Report. In its continuous efforts to add value for healthcare providers, in 2014 the SET initiated a quarterly newsletter that provides information regarding state trends in event occurrence, as well as national patient safety information. In the coming year, the SET will conduct on-site audits of covered facilities, in accordance with MRSA Title 22, Chapter 1684, §8754, Division Duties that requires SET to determine compliance with requirements outlined in that chapter.

---

[1] *A New, Evidence-based Estimate of Patient Harm Associated with Hospital Care*; James, J.T.; Journal of Patient Safety; September 2013, Vol. 9, Issue 3, p 122-128

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 situations 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 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 the DLRS 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 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.

The Maine Sentinel Event Program has been enriched by its active participation with the National Quality Forum (NQF) and the Agency for Healthcare Research and Quality (AHRQ). The NQF and the AHRQ bring together the states 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. Maine aligns itself with the majority of reporting states in using a state identified list of criteria. The other states utilize the list of serious reportable events as published by NQF or a modified NQF list. Appendix A contains the Maine-specific and NQF definitions of mandatory reportable sentinel events.

Maine, along with all New England states, make up some of the 27 states, including the District of Columbia that have prioritized improvements in patient safety by implementing a mandatory sentinel event reporting program. Texas plans to initiate mandatory reporting of sentinel events in 2015. 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.

In 2014, the National Academy for Health System Policy (NASHP) surveyed all 50 states and the District of Columbia to develop insight into the nation's monitoring, regulation and promotion of patient safety, with a focus on adverse event reporting systems. Key Findings of the NASHP report include:

- The number of adverse event reporting systems has not changed since 2007, with 27 systems still in place. One new system has been implemented and one system ended. One additional system will be active beginning in January 2015, which will bring the total number of systems to 28.
- There continues to be wide variation in the types of individual events reported to states. As of 2014, 15 states have adopted or adapted the NQF's list—a slight increase from 2007.
- Reporting systems are now more technologically advanced than in 2007. 22 systems are now partially or fully electronic, compared to 9 in 2007.
- Communication of findings to providers and the public continues to be common, with 22 systems publicly reporting data and 20 sharing system data with facilities. 8 states have increased the frequency of public reporting since 2007.
- Formal evaluations of reporting systems are rare (3 states), however officials from most (23) state systems have anecdotal, survey or other sources indicating an impact on communication among facilities, provider education, internal agency tracking or trending, and/or implementation of facility processes to address quality

of care. 9 states report increased levels of provider and facility transparency and awareness of patient safety as a result of their reporting systems.

- System officials partner with provider, patient safety, and state agency representatives to carry out patient safety initiatives.

This report is available on the NASHP website: http://www.nashp.org/2014-guide-state-adverse-event-reporting-systems/

Reporting Requirements

The Maine Sentinel Event Program receives the authority to carry out its activities in Maine Revised Statute Title 22, Chapter 1684: Sentinel Events Reporting 22 §8751-Sentinel Event Reporting. 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 via a restricted fax 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 their 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.

Facilities are encouraged to conduct the root cause analysis using a multidisciplinary team that includes those individuals involved with the event. This helps to ensure that all contributing factors are considered, and that a timeline of the event may be reconstructed. The complexity of the healthcare environment often contributes to systems breakdowns that result in multiple causal factors. Once the team is comfortable that all root causes have been identified, action plans are developed to address each root cause, in an effort to prevent future recurrences. 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 their own sentinel event histories, 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.

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 1007 sentinel events has been reported to the SET since 2004 when covered facilities began reporting. As illustrated in Table 1, 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[2] 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 system.[3] 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. The Sentinel Event Rules were updated in 2013 to reflect changes in NQF's listing of Serious Reportable Events.

Continued growth in the reporting of sentinel events also reflects a growing awareness of the importance of patient safety. Over the last decade and a half there has been increasing concern regarding the state of U.S. Healthcare. The Institute of Medicine (IOM) published its first report on patient safety in 1999. The report, *To Err is Human: Building a Safer Health System* brought the spotlight on healthcare with its attribution of 98,000 deaths per year to preventable medical error. The IOM's follow up report in 2001, *Crossing the Quality Chasm: Building a Health System for the* 21st Century brought further attention in its call for fundamental change to close the quality gap and a redesign of the American health care system. As previously noted in this report, the estimated premature death rate due to preventable medical errors in hospitals now is estimated at up to 400,000 deaths per year. Significant work has been done in patient safety by the Institute of Healthcare Improvement (IHI), the Agency for Healthcare Research and Quality (ARHQ), the National Patient Safety Foundation (NPSF) and many other organizations. Value Based Purchasing efforts at the federal and state level are tying payments to safety and quality indicators. With both "carrots and sticks" the results of Value Based Purchasing incentives and disincentives can significantly impact hospital reimbursement from Medicare and Medicaid. Recognizing that healthcare costs drive up the cost of doing business, The Leapfrog Group, an employer-based coalition advocating for improved transparency, quality and safety in hospitals, conducts a

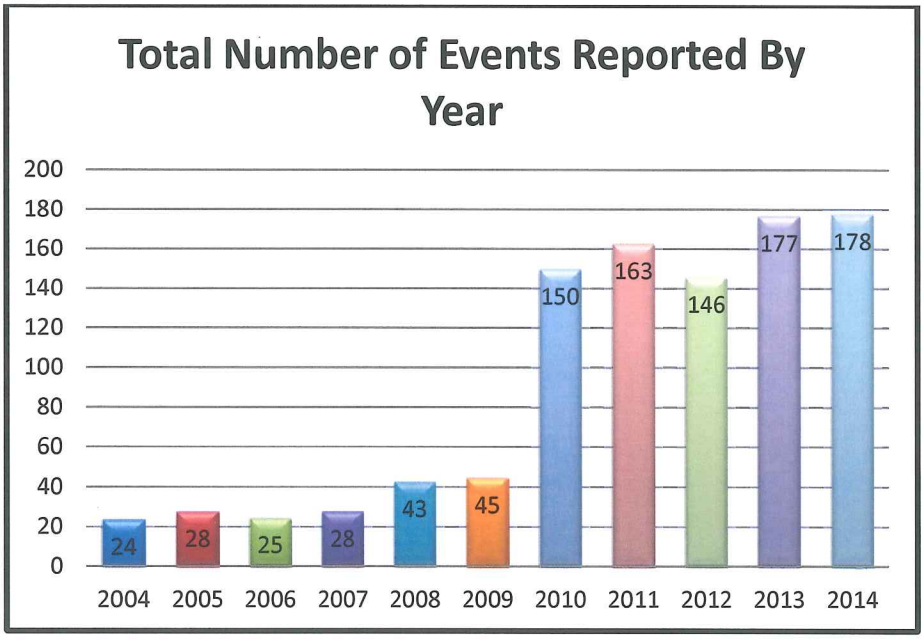
[2] National Quality Forum. (2002). *Serious reportable events in healthcare: A consensus report.* Washington, DC: The National Quality Forum.

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

voluntary survey of hospitals, and publishes the results on its website. Members of the public can search for survey results by city/state, zip code or hospital.[4] Survey results are categorized into 5 areas: general information, maternity care, high risk surgeries, hospital acquired conditions and resource use. In a recent Leapfrog report, Maine was one of only four states where more than half of the graded hospitals received an "A" (*Washington Post*, October 2014)

During the 11 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. In 2014, 37 of the 39 hospitals reported events including near miss or non-reportable cases. Table 1 provides a graphic review of sentinel events reported from 2004 through 2014. The number of events reported by year is shown in Table 1.

Table 1 Sentinel Events Reported by Year, 2004-2014



2014 Reported Events

There were a total of 228 events reported in 2014. Of those, 23 events did not meet the criteria of a sentinel event, and an additional 27 were determined to be 'near misses', bringing the total number of actual sentinel events to 178. This is a negligible increase over the 177 actual events in 2013. 30% of sentinel events occurred either on a holiday (4) or a weekend (50). The SET is encouraging facilities to consistently report dates and times when sentinel events occur, with

[4] Maine hospital results can be found at: http://www.leapfroggroup.org/cp?fr,bmd=cp_listings&find_by=state&city=&state=ME

particular attention to off-shifts, weekends and holidays, when staffing levels may vary. A listing of all sentinel events can be found in Appendix C.

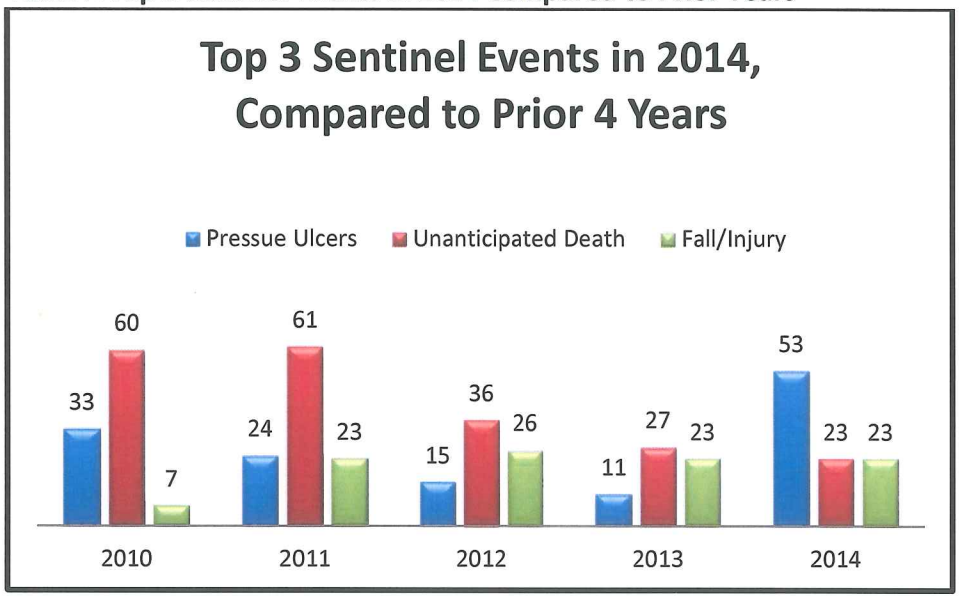
Types of Sentinel Events Reported

Of the 22 different categories of sentinel events in 2014, the top three were:

- Stage 3 or 4 and unstageable pressure ulcers at 53 (29.8%);
- Unanticipated death at 23 (12.9%); and
- Fall with serious injury at 23 (12.9%).

From 2010 – 2014, Unanticipated Death was in the top three types of sentinel events, and Pressure Ulcers and Falls with Serious Injury were in the top four. The Joint Commission reported the most frequent sentinel events during the first half of 2014 as: Retention of Foreign Body, Other Unanticipated Events and Falls with Serious Injury.

Table 2 Top 3 Sentinel Events in 2014 Compared to Prior Years



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 (9) and major permanent loss of function in a perinatal infant (3) are significantly higher in 2014 than in previous years, see Table 3.

No common factors were noted in reviewing these events. Of the perinatal deaths:

- 1 infant was early preterm (<34 weeks gestation);
- 1 infant was associated with preterm (34 – 36 weeks);
- 6 infants were not preterm (delivered at 37 weeks or more).

1 former premature infant was 28 days old at the time of death. The injuries were fractures (2 clavicles and 1 humerus). 2 injuries were related to shoulder dystocia (the baby's shoulders fail to deliver very shortly after the head). There were no complications and no manipulation during delivery for the third injury.The SET is continuing to monitor perinatal deaths and injuries.

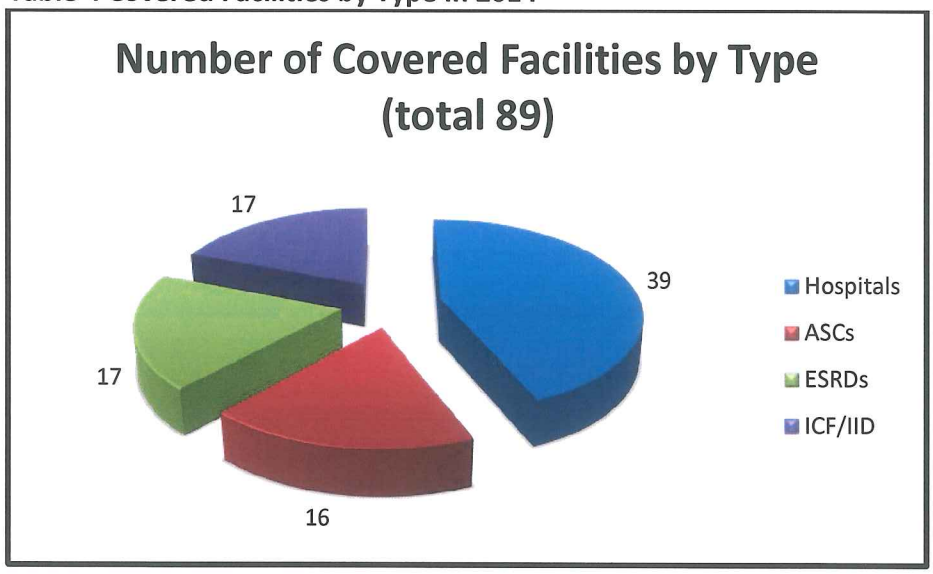
Table 3 Unanticipated Perinatal Death & Major Permanent Loss of Function

	2010	2011	2012	2013	2014
Perinatal Death	1	1	0	0	9
Perinatal Injury	0	1	2	1	3

Covered Facilities in 2014

Due to closures and/or mergers, Maine had 89 covered healthcare facilities in 2014. See Table 4 for a breakdown of covered facilities by type for 2014.

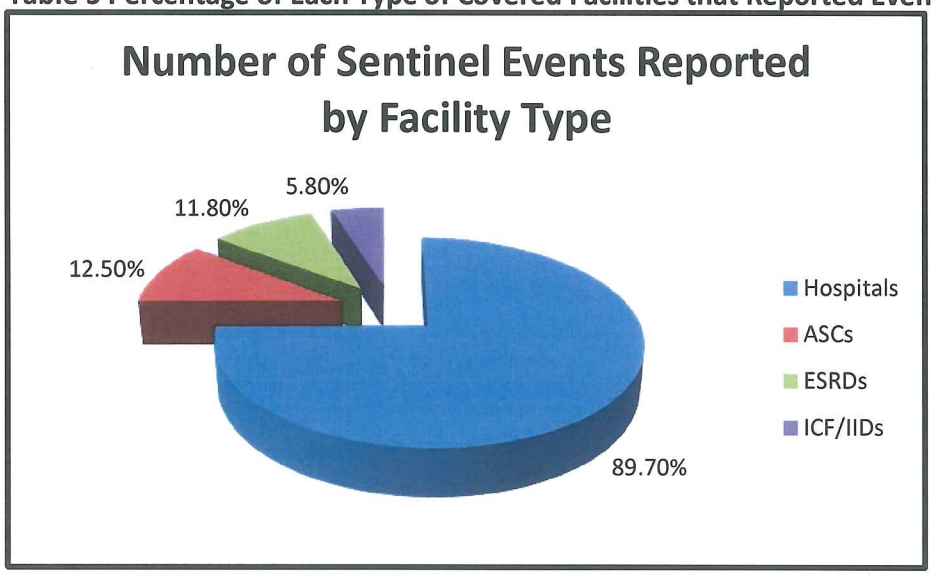
Table 4 Covered Facilities by Type in 2014



Percentage of Facilities Reporting by Type

Of the 89 facilities covered by the law, 40 (43%) reported sentinel events during 2014. 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 5 Percentage of Each Type of Covered Facilities that Reported Events



Determining Why: Root Cause Analysis

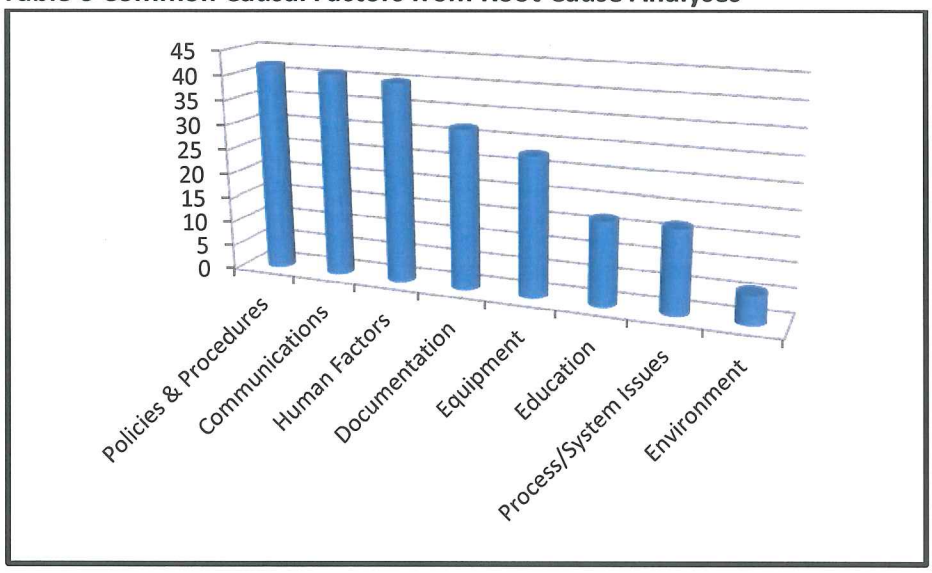
When an adverse event occurs, facilities are required to conduct a root cause analysis. Contributing factors are categorized by type. As can be seen in Table 6, the most common contributing factors were: Policies & Procedures, Communications, and Human Factors.

The science of human factors, while used commonly in industries such as aviation, is a relatively new concept in the study of patient safety. Human Factors can be defined as the study of the relationship between humans, the tools and equipment they use in the workplace, and the environment in which they work.[5] The term, human factors, is not as directly about humans as the name would imply; it is about understanding human limitations and designing the workplace

[5] *To Err is Human: Building a Safer Health System*, Kohn LT, Corrigan JM, Donaldson MS. Washington, DC, Committee on Quality of Health Care in America, Institute of Medicine, National Academy Press, 1999

and the equipment to allow for variability in humans and human performance.[6] Healthcare is a complex environment, where healthcare workers are interacting with sophisticated technology, utilizing complex equipment, in a variety of settings, all the while focusing on direct care of patients. Gaining a better understanding of human factors will assist healthcare organizations in their efforts to improve patient safety.

Table 6 Common Causal Factors from Root Cause Analyses



Progress on Goals

During 2014, the SE program worked closely with facilities and others to strengthen the reliability of reporting. The following represents progress on the goals set for 2014:

1) Goal: 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.
   Actions: The SET focused on working with Maine hospitals and the Muskie School related to tools and reliability of data. In addition, the SET reached out to other states that have SE reporting requirements in an effort to identify best practices. Maine participated in the National Academy for State Health Policy's Guide to State Adverse Event Reporting. A copy of this report is available at: http://www.nashp.org/publication/2014-guide-state-adverse-event-reporting-systems.

2) Goal: Continue to perform on-site visits with hospitals and other facilities. This may

[6] *Topic 2: What is human factors and why is it important to patient safety?* World Health Organization Patient Safety Guide for Medical Schools, World Health Organization, 2009

include a review of documents to determine compliance with the Rules Governing the Reporting of Events.
Actions: The SET visited 19 hospitals, and conducted a group meeting of ASC and ESRD staff during 2014. Onsite visits provided technical assistance and education surrounding the sentinel event program and current rules. Facility specific data related to the reporting of sentinel events was shared. Presentations were also made to ICF/IID administrator meetings, quality conferences and other healthcare associates.

3) Goal: Continue to assess the adequacy of a facility's internal systems for detecting and reporting events.
Actions: The SET deferred conducting on-site audits until 2015 in order to be able to visit with facilities, either individually or in groups to provide technical assistance and an overview of the program. Actual on-site auditing will begin in 2015, and will include review of all requirements as outlined in the Sentinel Event Rules.

4) Goal: Continue to analyze complaint data to determine if a situation reported as a complaint is a reportable sentinel event.
Actions: During 2014 the database was refined, and the SET began capturing more information regarding time of day, day of week, shifts and holidays when SEs occurred.

5) Goal: 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.
Actions: The SET implemented the SE Newsletter, the first issue was sent in June, 2014. These newsletters are being developed and distributed on a quarterly basis. Subjects are chosen based on types of SEs being reported in Maine, as well as patient safety issues identified nationally. Some of the topics explored in the SE Newsletter included: pressure ulcers, wrong site surgery, suicide, and patient safety culture. Newsletters are available on the Sentinel Event Website:
www.maine.gov/dhhs/dlrs/medical_facilities/sentinelevents/home.html

In addition to progress on the goals outlined in the 2013 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;
- Developed standard operating procedures to ensure reliable and accurate maintenance of the Sentinel Event program;
- Education – the SET acknowledges the importance of continually improving knowledge of sentinel events and patient safety initiatives, to the end the SET joined as an IHI (Institute for HealthCare Improvement) member, and have access to IHI online classes; and
- Attended the 2014 Patient Safety Academy.

Program Goals for 2015

In 2015, 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) Implement an auditing program, in accordance with MRSA Title 22, Chapter 1684, §8754, Division Duties that requires SET to determine compliance with requirements outlined in that chapter.
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 collaborative workgroups with interested providers to assist with the sharing of challenges and best practices related to SEs.

Conclusion

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. Maine's sentinel event reporting system focuses on identifying and deterring serious, preventable incidents, and supporting Maine's healthcare facilities to improve patient safety. 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. Data gleaned from sentinel event reports and root cause analyses provide a rich source of information that can assist Maine's healthcare facilities improve patient safety.

To be effective, the system requires the participation of all reporting entities. The SET is committed to working with covered facilities to enhance their understanding of the Sentinel Event Program, to increase their skills in root cause analysis and process improvement, to collect, analyze and share data to identify trends, to promote sharing of best practices and to continuously learn from sentinel events.

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.

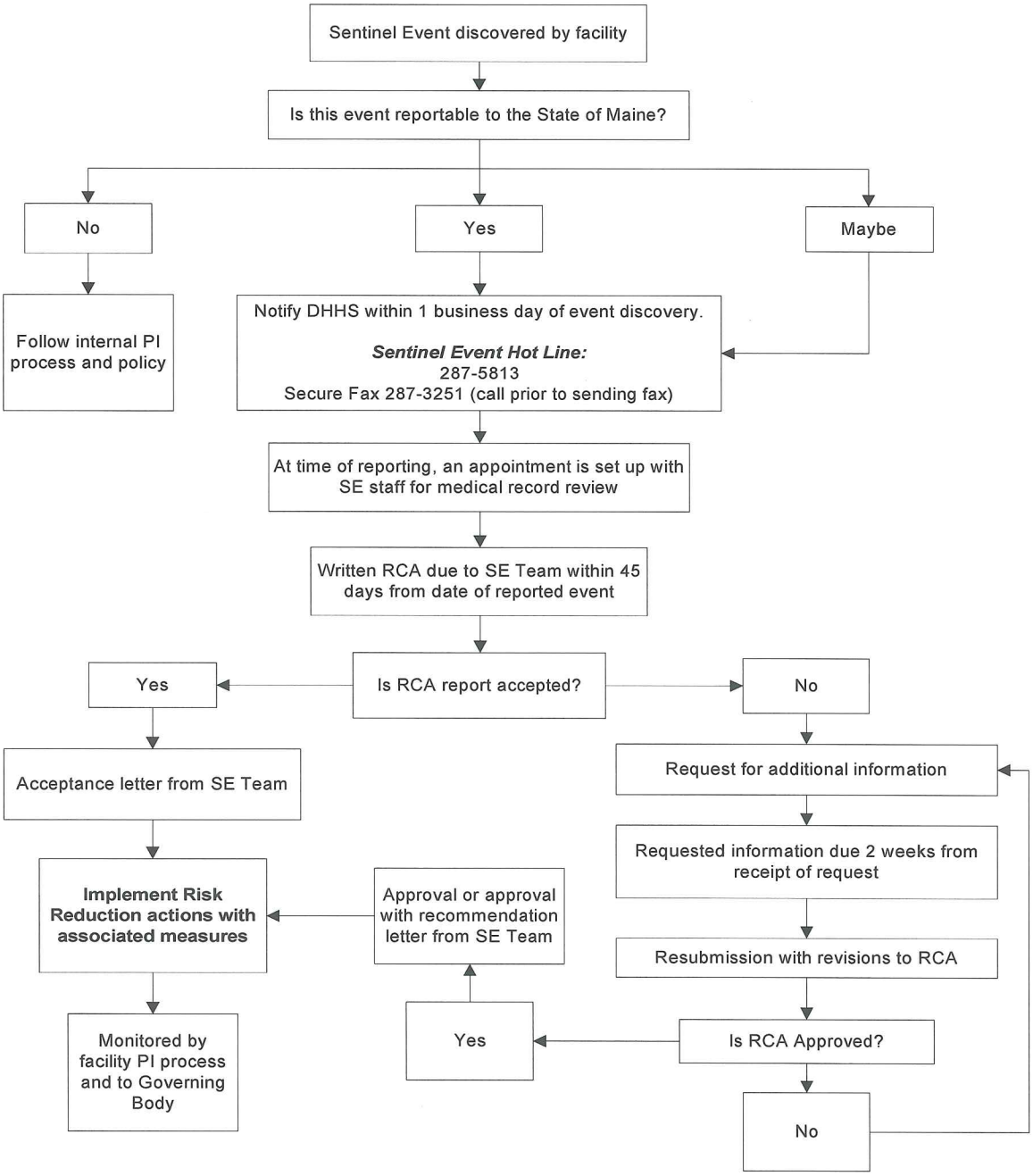
SENTINEL EVENT HOTLINE (207) 287-5813

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 of contaminated drugs, devices, or biologics provided by the healthcare setting
☐ Patient death or serious injury associated with the use or function of a device in patient care, in which the device is used for functions other than as intended
☐ Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in a healthcare setting
Patient Protection Events
☐ Discharge or release of a patient of any age, who is unable to make decisions, to other than an authorized person
☐ Patient death or serious injury associated with patient elopement (disappearance)
☐ Patient suicide, attempted suicide or self-harm resulting in serious injury, while being cared for in a healthcare setting
Care management events
☐ Patient death or serious injury associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration)
☐ Patient death or serious injury associated with unsafe administration of blood products
☐ Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare setting
☐ Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy
☐ Patient death or serious injury associated with a fall while being cared for in a healthcare setting
☐ Stage 3 or 4 pressure and unstageable pressure ulcers acquired after admission/presentation to a healthcare setting
☐ Artificial insemination with the wrong donor sperm or wrong egg
☐ Patient death or serious injury resulting from the irretrievable loss of an irreplaceable biological specimen
☐ Patient death or serious injury resulting from failure to follow up on or communicate laboratory, pathology or radiology test results
Environmental Events
☐ Patient or staff death or serious injury with an electric shock in the course of a patient care process in a healthcare setting
☐ Any incident in which systems designated for oxygen or other gas to be delivered to a patient contains no gas, the wrong gas or is contaminated by toxic substances
☐ Patient or staff death or serious injury associated with a burn incurred from any source while being cared for in a healthcare setting
☐ Patient death or serious injury associated with the use physical restraints or bedrails while being cared for in a healthcare setting
Radiologic Events
☐ Death or serious injury of a patient or staff associated with the introduction of a metal object into the MRI area
Potential Criminal Events
☐ Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider
☐ Abduction of a patient/resident of any age
☐ Sexual abuse/assault on a patient or staff member within or on the grounds of the healthcare setting
☐ Death or serious injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of the healthcare setting

Appendix B

Sentinel Event Process Flow

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



Appendix C

Table 2. Sentinel Events Reported by Event Type, 2014

Total Events	Category	Male	Female	Infant	<18 years	19-64 years	65+ years
53	Stage 3 or 4 and unstageable Pressure Ulcers acquired after admission to a healthcare setting	36	17	1	0	31	21
23	Unanticipated Death	12	11	0	0	11	12
23	Patient death or serious injury associated with a fall while being cared for in a healthcare setting	10	13	0	0	4	19
20	Unanticipated death or permanent loss of function within 48 hours of treatment	14	6	0	0	12	8
9	Unanticipated Perinatal Death	4	5	9	0	0	0
8	Unanticipated patient transfer to another facility	2	6	1	0	5	2
7	Surgery or other invasive procedure performed on the wrong site	5	2	0	0	4	3
5	Wrong Surgical Procedure performed on a patient	0	5	0	0	3	2
4	Suicide within 48 hours of discharge from a healthcare facility	3	1	0	0	2	2
4	Death or serious injury of a patient or staff member resulting from a physical assault that occurs within or on the grounds of the healthcare setting	3	1	0	3	1	0
4	Major Permanent Loss of Function present at discharge	2	2	0	0	1	3
3	Major Permanent Loss of Function in a perinatal infant	3	0	3	0	0	0
3	Patient death or serious injury associated with patient elopement (disappearance)	2	1	0	0	2	1
3	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	2	1	0	1	2	0
2	Sexual assault on a patient within or on the grounds of the healthcare setting	1	1	0	0	2	0
2	Patient death or serious injury resulting from failure to follow up on or communicate laboratory, pathology or radiology test results	0	2	0	0	0	2
1	Patient suicide, attempted suicide or self-harm resulting in serious injury, while being cared for in a healthcare setting	0	1	0	0	1	0
1	Unintended retention of a foreign object in a patient after surgery or other invasive procedure	1	0	0	0	1	0
1	Patient death or serious injury associated with the use of physical restraints or bedrails while being cared for in a healthcare setting	1	0	0	1	0	0
1	Patient death or serious injury associated with a medication error	0	1	0	0	1	0
1	Patient death or serious injury associated with a burn incurred from any source while being cared for in a healthcare setting	0	1	0	0	1	0

Appendix D Resources

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

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

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

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

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

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

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

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

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

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 report may be found on the internet at:
http://www.maine.gov/dhhs/dlrs/medical_facilities/sentinelevents/home.html

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

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

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.