Sentinel EVENTS

CY 2011

Annual Report to the Maine State Legislature

Final Report June 2012

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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

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, End-Stage Renal Disease Facilities/Units, and Intermediate Care Facilities for Persons with Mental Retardation 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 significant injury, serious medication errors, patient suicide, surgery on the wrong body part, or an error resulting in a major loss of function. In 2011, 163 such cases were reported to the Maine Division of Licensing and Regulatory Services. The law further requires an annual report to the Legislature and public.

The number of cases reported, in and of itself, is not the most important information to focus on in this report. It is the lessons that are learned and the changes that are made as a result of these events that result in a safer environment for future patients.

In 2009 the statute requiring sentinel event reporting was amended to include new reporting requirements. Highlights of those changes include adoption of the National Quality Forum list of Serious Reportable Events and enhancements to the sentinel event definition to reduce ambiguity. Additionally, facilities are required to have standardized processes for the detection and reporting of all sentinel events.

In 2011 the most prevalent type of event reported was unanticipated death. Major loss of function and pressure ulcers came in as the second most reported event. Falls remain a high frequency event followed by retained foreign objects.

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.

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) which 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; and
- Describe efforts to address under-reporting and enhance the role of sentinel event reporting in improving patient safety.

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;
- Hemolytic transfusion reaction involving administration of blood or blood products having blood group incompatibilities;
- Patient suicide, or attempted suicide resulting in serious disability;
- Infant abduction or discharge to the wrong family;
- Rape of a patient
- Unintended retention of a foreign object;
- Patient death or serious disability associated with a fall; or
- Death or significant 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 List was formally adopted as part of the statutory changes. NQF serious events are structured around six categories: surgical, product or device, patient protection, care management, environmental 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.

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.

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 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. The on-site review occurs shortly after the incident is first reported so that findings can be incorporated into the facility's action plan. The facility's Chief Executive Officer (CEO) is briefed during this time by the Sentinel Event Team to assure his/her active engagement in understanding factors leading to the event and plans for mitigating its recurrence. The entire medical record of the patient is reviewed during the site visit to identify contributing factors that may have gone unnoticed and have affected the outcome before, during and after an event. This process provides an independent assessment that augments the facility's own internal review of the incident.

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

[2] 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. http://www.nashp.org/Files/shpsurveyreport_adverse2007.pdf

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 return to 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 A.

Information collected on sentinel events and their reviews are entered into a confidential database. This database is the primary source for identifying and generating aggregate statistics and trends through the Annual Report.

Confidentiality Provisions

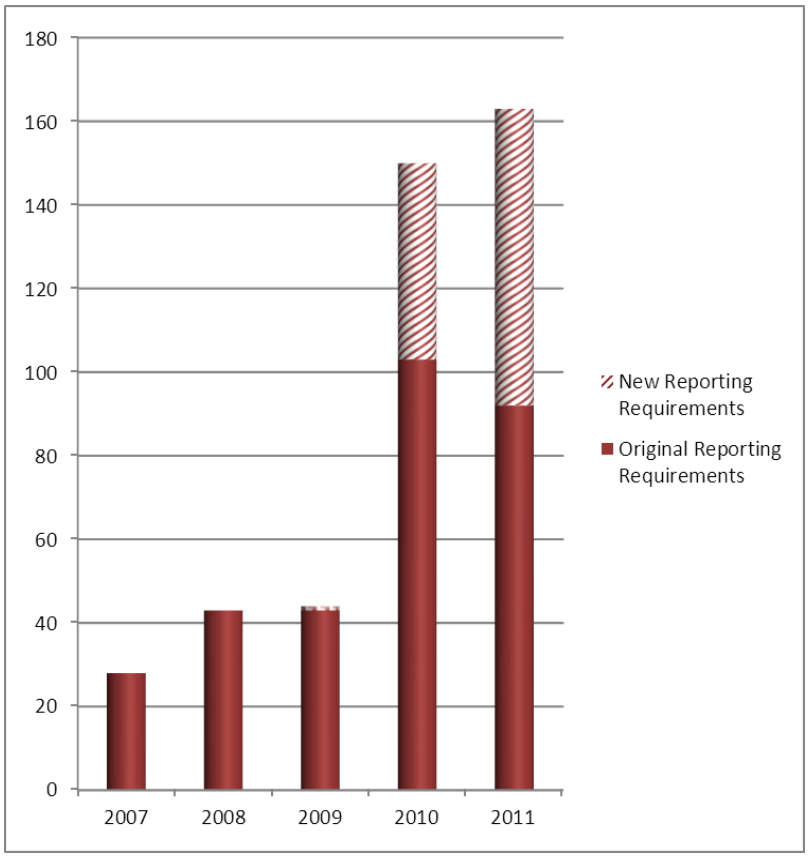
By law, all sentinel event information submitted to the Division is considered privileged and confidential. No information about facilities or providers is discoverable or made public. A firewall is maintained between the sentinel event program and the survey unit that regulates facility licensing within 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 and public corrections be made to avoid harm to the public.

Sentinel Events Historically Reported

A total of 505 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 through 2011.

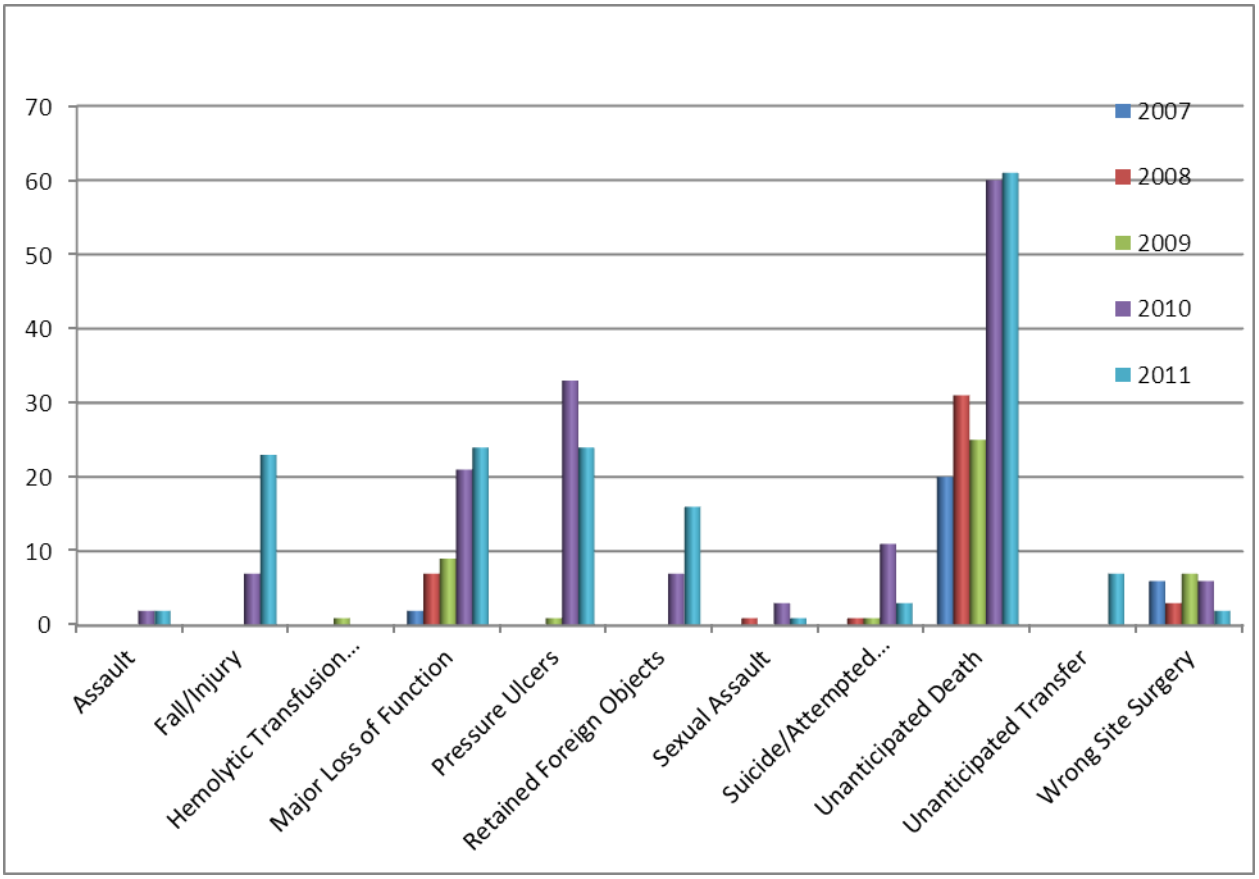
In 2010, a dramatic increase in sentinel event reporting occurred and continued through 2011. This spike in reports reflects a greater appreciation of the requirements and changes in the statutory requirements. There is also a growing awareness of the benefit of increased transparency with an emphasis 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, 2007-2011



Sentinel events reported during the period from 2004-2006 averaged approximately 25 sentinel events annually.

Table 2. Sentinel Events Reported, by Category, 2007-2011



	2007	2008	2009	2010	2011
Assault	0	0	0	2	2
Fall/Injury*	0	0	0	7	23
Hemolytic Transfusion Reaction	0	0	1	0	0
Major Loss of Function	2	7	9	21	24
Pressure Ulcers*	0	0	1	33	24
Retained Foreign Objects*	0	0	0	7	16
Sexual Assault	0	1	0	3	1
Suicide/Attempted Suicide	0	1	1	11	3
Unanticipated Death	20	31	25	60	61
Unanticipated Transfer	0	0	0	0	7
Wrong Site Surgery	6	3	7	6	2

*New reporting requirements in 2010

During the 8 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 2011, there was a slight decline in the number of reporting facilities.

Table 3. Reporting versus Non-Reporting Hospitals, 2007-2011

	2007		**2008**		**2009**		**2010**		**2011**	
	No.	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**
Reporting Hospitals	32	78%	33	80%	38	93%	41	100%	37	90%
Non-reporting Hospitals	9	22%	8	20%	3	7%	0	0%	4	10%
Total	**41**	**100%**	**41**	**100%**	**41**	**100%**	**41**	**100%**	**41**	**100%**

Sentinel Events Reported in 2011

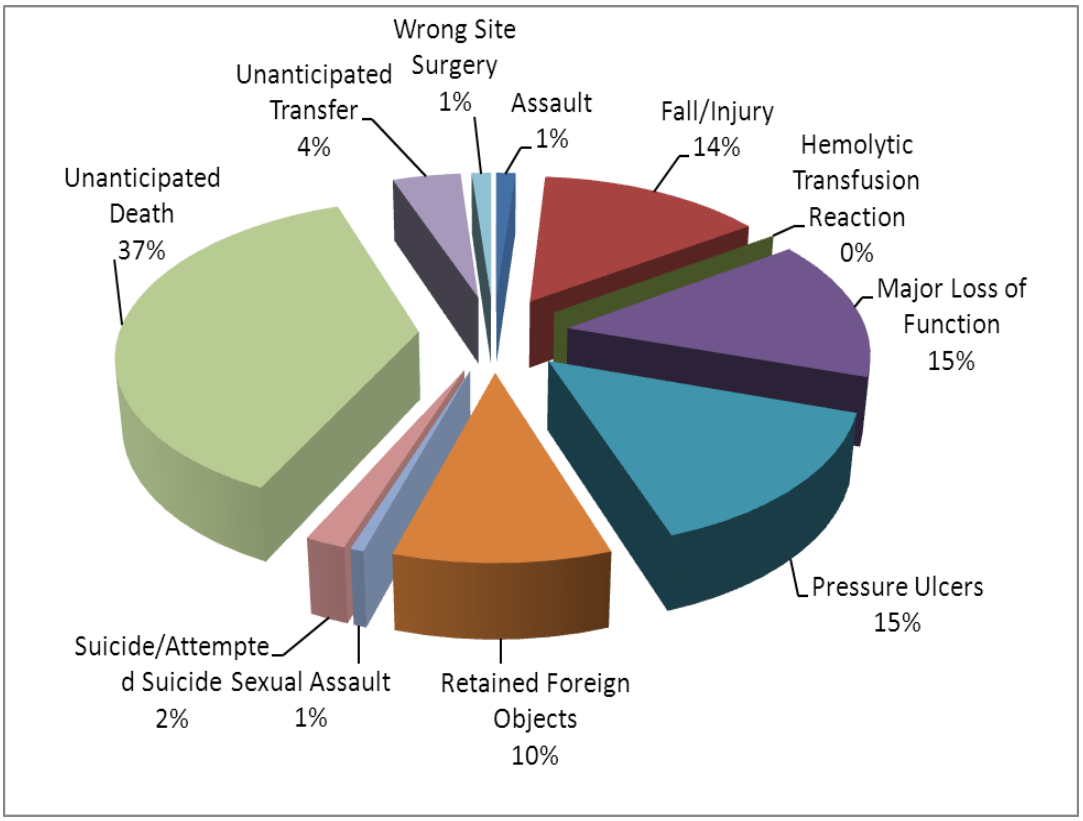
NUMBER OF SENTINEL EVENTS REPORTED IN 2011

There were 163 sentinel events reported in 2011. This is a slight increase over the 150 reported events in 2010.

CATEGORY OF SENTINEL EVENTS

Table 4 indicates sentinel events by category in 2011. Unanticipated deaths were reported in the majority of cases at 61 (37%). Pressure ulcers and major loss of function were the second leading events at 24 (15%) each.

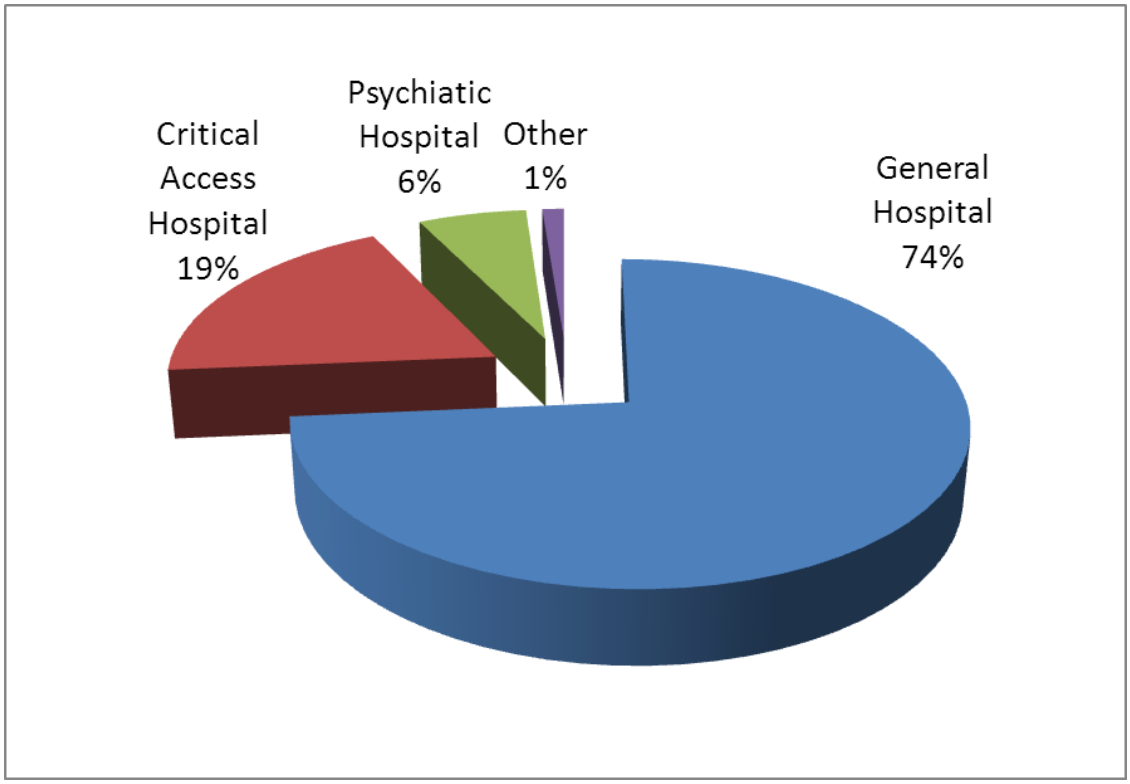
Table 4. Sentinel Events Reported, by Category of Event, 2011



TYPE OF FACILITIES REPORTING SENTINEL EVENTS IN 2011

In 2011, general hospitals represented 72.7% of the facilities that reported to the sentinel event program. Critical Access Hospitals accounted for 19.0 % and Psychiatric hospitals represented 6.1%, while ESRD (dialysis) facilities, Ambulatory Surgical Centers and ICF/MR facilities reported 1.2% of cases.

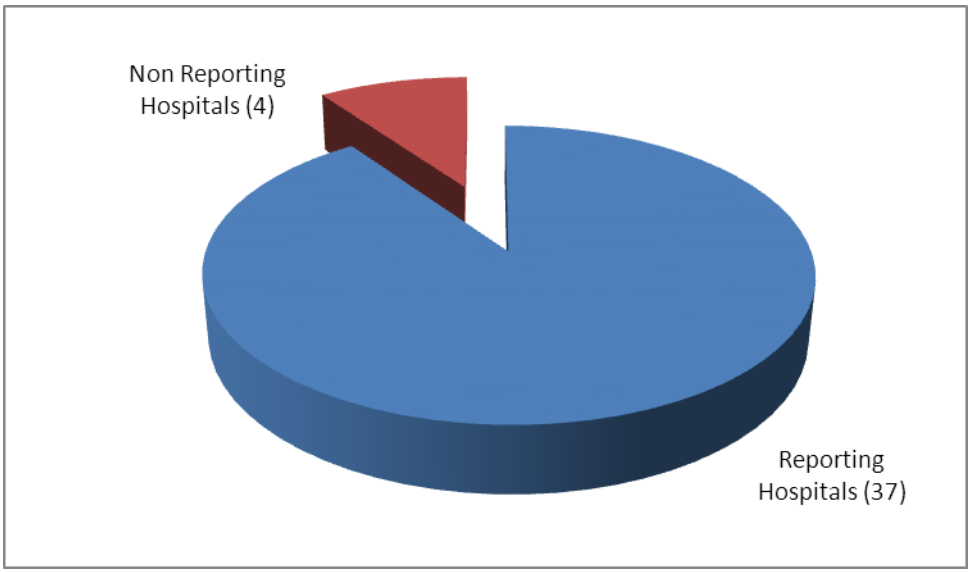
Table 5. Sentinel Events Reported, by Facility Type, 2011



REPORTING VERSUS NON-REPORTING HOSPITALS, 2011

As illustrated below, 90% of the 41 hospitals had reported a sentinel event to the Division for review in 2011.

Table 6. Reporting versus Non-Reporting Hospitals, 2011



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.

However, findings indicate that there is serious under-reporting in Maine.

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

Program Goals for 2012

During 2012, 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:

- Continue to utilize data from Maine's all-payer database to augment a review of events being reported.

- 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.

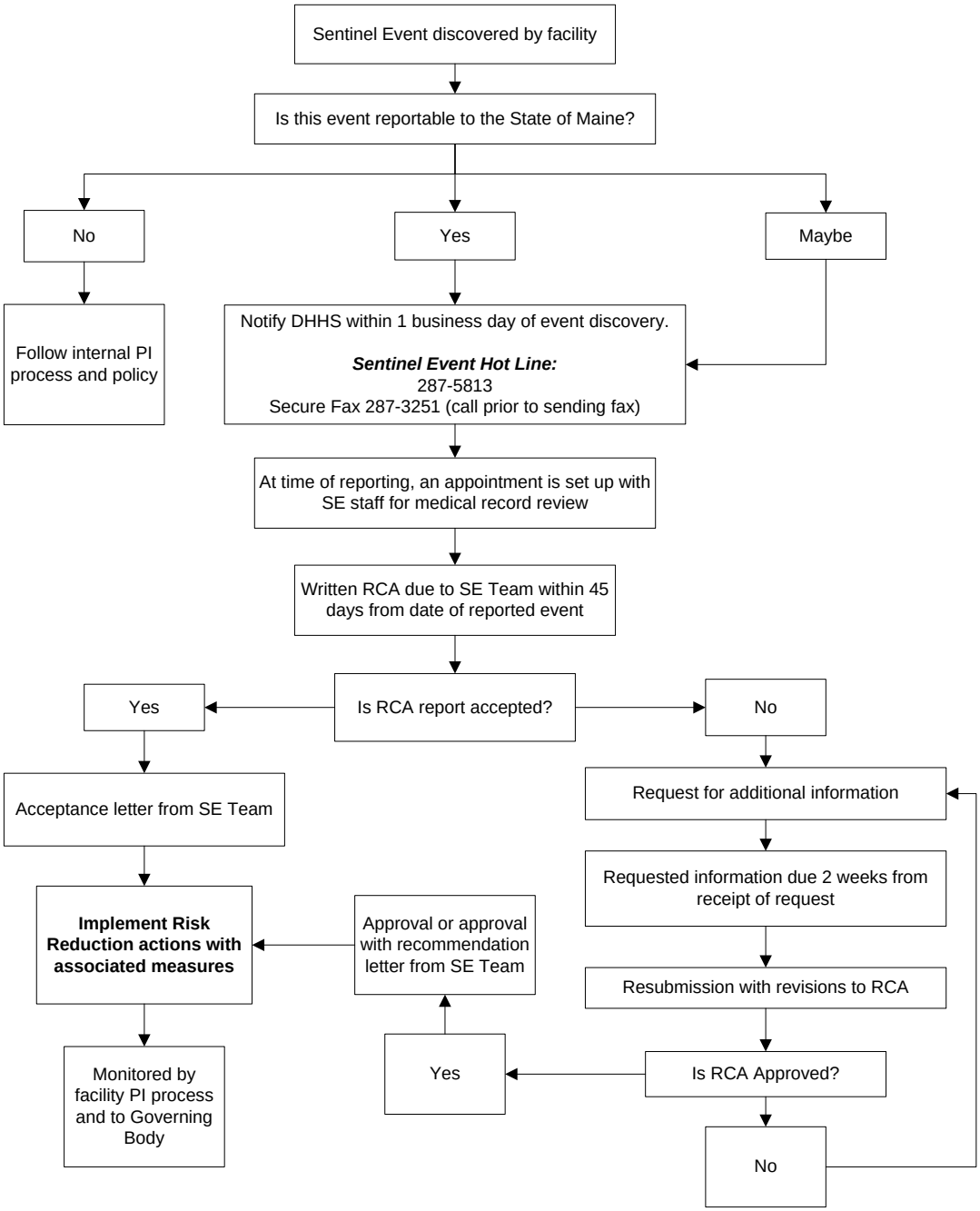
- Continue to analyze complaint data to determine if a situation reported as a complaint is a reportable sentinel event.

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

State of Maine
Department of Health and Human Services
Division of Licensing and Regulatory Services
Sentinel Event Process Flow



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