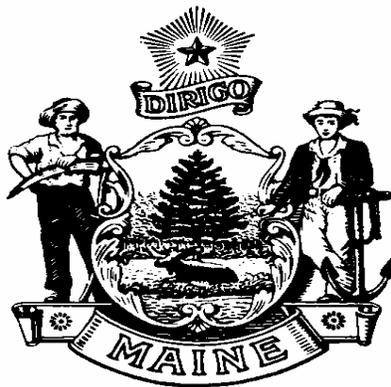


Rules Governing the Reporting of Sentinel Events

10-144 CMR Chapter 114
Effective Date



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

(207) 287-9300

1-800-791-4080

TDD 1-800-606-0215

Fax: 1-207-287-5815

DLRS.medfacilities@maine.gov

Table of Contents

Purpose	1-1
Section 1. Definitions	1-1
Section 2. Mandatory Reporting of Sentinel Events	2-1
Section 3. Sentinel Events Team (SET) Review Procedure of Sentinel Events	3-1
Section 4. Confidential and Privileged Information	4-1
Statutory Authority	A

Proposed

Purpose. The Regulations Governing the Reporting of Sentinel Events create a robust system for reporting all potential sentinel events to improve the quality of healthcare and increase patient safety. The reporting system focuses the attention of a health care facility on understanding the causes that underlie the event and on changing systems and processes to reduce the probability of future events.

Section 1. Definitions. As used in these rules, unless the context otherwise indicates, the following terms have the following meanings.

1.1 DLRS. “DLRS” means the Division of Licensing and Regulatory Services, Maine Department of Health and Human Services. The Sentinel Events Team (SET) is a unit of DLRS.

1.2 Health Care Facility. “Health care facility” or “facility” means the following:

1.2.1 State institutions including the Riverview Psychiatric Center and the Dorothea Dix Psychiatric Center (34-B M.R.S.A. Chapter 1);

1.2.2 All hospitals licensed pursuant to 22 M.R.S.A. Chapter 405, including all service locations as indicated on the hospital license application;

1.2.3 Ambulatory surgical facilities licensed pursuant to 22 M.R.S.A. Chapter 405;

1.2.4 Intermediate Care Facilities for Persons with Mental Retardation - Nursing (ICF/MR Nursing) licensed pursuant to 22 M.R.S.A. Chapters 1 and 405, and the Elizabeth Levinson Center (34-B M.R.S.A. Chapter 1); and

1.2.5 End-stage renal disease (ESRD) facilities licensed pursuant to 22 M.R.S.A. Chapter 412.

1.2.6 Health care facility does not include a facility licensed as a nursing facility pursuant to 22 M.R.S.A. Chapter 405, or assisted housing programs licensed pursuant to 22 M.R.S.A. Chapter 1664.

1.3 Major Permanent Loss of Function. “Major permanent loss of function” means sensory, motor, physiological or intellectual impairment that

1.3.1 requires continued treatment or

1.3.2 imposes persistent major restrictions in activities of daily living.

1.4 Root Cause Analysis. “Root cause analysis” (RCA) means a process for identifying the basic or causal factors that underlie variation in performance, including the occurrence or possible occurrence of a sentinel event. RCA focuses primarily on systems and processes, not on individual performance. RCA progresses from causes in clinical

processes to causes in organizational systems. Improvements are identified that would tend to decrease the likelihood of such events in the future.

1.5 Sentinel Event. A “sentinel event” means:

1.5.1 An unanticipated death that is determined:

1.5.1.1 to be unrelated to the natural course of the patient’s illness or underlying condition; or

1.5.1.2 to be unrelated to the proper treatment of the patient’s illness or underlying condition; or

1.5.1.3 to be the result of an elopement of a hospitalized inpatient who lacks the capacity to make decisions as defined in 18-A M.R.S.A. §5-801(c).

1.5.2 A major permanent loss of function, as defined in section 1.3, that is not present when the patient is admitted to the health care facility that is determined:

1.5.2.1 to be unrelated to the natural course of the patient’s illness or underlying condition; or

1.5.2.2 to be unrelated to the proper treatment of the patient’s illness or underlying condition; or

1.5.2.3 to be the result of an elopement of a hospitalized inpatient who lacks the capacity to make decisions as defined in 18-A M.R.S.A. §5-801(c).

1.5.3 Surgery on the wrong patient or wrong body part;

1.5.4 Hemolytic transfusion reaction involving the administration of blood or blood products having major blood group incompatibilities;

1.4.5 Suicide of a patient in a health care facility where the patient receives inpatient care;

1.5.6 Infant abduction or discharge to the wrong family; or

1.5.7 Rape of a patient. Rape, as a reportable sentinel event, is defined as unconsented sexual contact involving a patient and another patient, staff member, or other perpetrator while being treated or on the premises of the health care facility, including oral, vaginal or anal penetration or fondling of

the patient's sex organ(s) by another individual's hand, sex organ or object. One or more of the following must be present to determine reportability:

1.5.7.1 Any staff-witnessed sexual contact as described above.

1.5.7.2 Sufficient clinical evidence obtained by the health care facility to support allegations of unconsented sexual contact.

1.5.7.3 Admission by the perpetrator that sexual contact, as described above, occurred on the premises.

1.6 Sentinel Events Reporting System. "Sentinel events reporting system" means a system for reporting sentinel events for the purpose of improving the quality of health care and increasing patient safety.

Proposed

Section 2. Mandatory Reporting of Sentinel Events

- 2.1 Sentinel Events Team.** The Sentinel Events Team (SET), a unit of the Division of Licensing and Regulatory Services (DLRS), is assigned the responsibility to implement these rules.
- 2.2 Mandatory report.** A health care facility is mandated to notify the SET of a suspected sentinel event that occurs in the health care facility as defined in Section 1.2 of these rules. The SET shall determine whether a sentinel event is reportable.
- 2.3 Notification.** The health care facility must notify the SET of the suspected occurrence of a sentinel event by the next business day after the suspected sentinel event occurred. When a health care facility discovers that a suspected sentinel event may have occurred, it must notify the SET by the next business day after the date of discovery. The written notification must include the following information:
- 2.3.1** Name of the health care facility;
 - 2.3.2** Type of sentinel event as defined in Section 1.5 above;
 - 2.3.3** Date and time of the sentinel event; and
 - 2.3.4** Date and time of notification.
- 2.4 Written report.** A health care facility must file a written report with the SET no later than forty-five (45) days following the notification of the occurrence of a sentinel event. The written report must contain the following information:
- 2.4.1** The health care facility name and address;
 - 2.4.2** The name, title, telephone number, email address, and fax number of the contact person designated by the health care facility;
 - 2.4.3** The date and time of the sentinel event;
 - 2.4.4** The type of sentinel event, as defined in Section 1.5 above, and a brief description of the sentinel event;
 - 2.4.5** A copy of a thorough and credible RCA. See Section 1.4.
 - 2.4.6** Identification of changes that could be made to reduce the risk of the sentinel event occurring in the future;
 - 2.4.7** A description of any corrective action taken or planned as a result of the RCA;

Section 2. Mandatory Reporting of Sentinel Events

- 2.4.8** A description of any corrective action taken or planned for additional needed improvements discovered during the process; and
- 2.4.9** The signature of the chief executive officer of the health care facility.
- 2.5 SET acceptance of report.** The SET will determine if the written report is acceptable.
- 2.6 Immunity.** A person who in good faith reports a sentinel event in accordance with these rules is immune from any civil or criminal liability for the act of reporting or participating in the review by DLRS. “Good faith” does not include instances when a false report is made and the person reporting knows the report is false. These rules may not be construed to bar civil or criminal action regarding perjury or regarding the sentinel event that led to the report.
- 2.7 Annual notification.** By January 30 of each year, on a form provided by the SET, each health care facility must send the SET a written notice that contains an affirmative statement that it reported, in accordance with Section 2.2, all sentinel events that occurred in the prior calendar year.

Section 3. SET Review Procedure of Sentinel Events

- 3.1 Cooperation.** A health care facility that has filed a notification or a report of the occurrence of a sentinel event, as required by these rules, must cooperate with the SET as necessary for the SET to fulfill its duties.
- 3.2 Initial review.** Upon receipt of a notification or report of a sentinel event, the SET shall complete an initial review and may take other action that the SET determines is appropriate according to these rules.
- 3.3 On-site reviews.** The SET may conduct on-site reviews of medical records and may retain the services of consultants when determined necessary by the SET.
- 3.4 Annual SET Report.** On or before February first of each calendar year, the SET shall submit an annual sentinel events report to the Legislature, health care facilities, and the public. The report must include summary data of the number and types of sentinel events for the prior calendar year, including
- 3.4.1.** a compilation of data by type of health care facility;
 - 3.4.2.** a compilation of data by rates of change and other analyses; and
 - 3.4.3.** an outline of areas to be addressed during the next 12 months.
- 3.5 Civil Penalties.** A health care facility that knowingly violates any provision of the sentinel events reporting law or rules is subject to a civil penalty payable to the State of not more than \$5000 per unreported sentinel event to be recovered in a civil action. Funds collected pursuant to this rule must be deposited in a dedicated special revenue account to be used to support sentinel event reporting and education.

Section 4. Confidential and Privileged Information

- 4.1 Access.** The SET has access to all licensed facility records necessary to carry out the provisions of these rules. The records obtained by the SET are not available to the public except as allowed by law.
- 4.2 Federal law.** These rules do not affect the obligations of the department relating to Federal law.
- 4.3 Confidential and privileged information.** Notifications and reports of sentinel events filed pursuant to these rules and all information collected or developed as a result of the filing and proceedings pertaining to the filing, regardless of format, are confidential and privileged information and must be transmitted and handled as such.
- 4.3.1 Not subject to public access, discovery, or admissible as evidence.** Privileged and confidential information subject to these rules is not:
- 4.3.1.1** Subject to public access under 1 M.R.S.A. Chapter 13, except for data developed from the reports that do not identify or permit identification of the health care facility;
 - 4.3.1.2** Subject to discovery, subpoena or other means of legal compulsion for release to any person or entity; or
 - 4.3.1.3** Admissible as evidence in any civil, criminal, judicial or administrative proceeding.
- 4.3.2 Not a waiver of privilege.** The transfer of any information subject to these rules by a health care facility to the SET or to a national organization that accredits health care facilities may not be treated as a waiver of any privilege or protection established by these rules, the sentinel events reporting law, or other applicable Maine laws.
- 4.3.3 Other privileges.** These rules may not be construed to limit other privileges that are available under federal and state laws that provide for greater peer review or confidentiality protections than the peer review and confidentiality protections provided by the Sentinel Events Reporting statute.
- 4.3.4 Exclusions.** For the purposes of these rules, “privileged and confidential information” does not include:
- 4.3.4.1** Any final administrative action;
 - 4.3.4.2** Information independently received pursuant to a third party complaint investigation conducted pursuant to department rules; or

4.3.4.3 Information designated as confidential under rules and laws of this State.

4.3.5 Security of information. The SET shall take appropriate measures to protect the security of any information that is subject to these rules.

Proposed

Statutory Authority

22 M.R.S.A. Chapter 1684

22 M.R.S.A. §42

22-A M.R.S.A. §205

Regulatory History

Public Law 2001, chapter 678, established laws governing the reporting sentinel events and instructed the department to adopt rules to implement chapter 678.

ADOPTED

Adopted sentinel events reporting rules in the following:

- | | |
|-----------------------|--|
| 10-144 C.M.R. Ch. 112 | Regulations for the Licensure of General and Specialty Hospitals in the State of Maine. |
| 10-144 C.M.R. Ch. 118 | Regulations Governing the Licensing and Functioning of Intermediate Care Facilities for Persons with Mental Retardation. |
| 10-144 C.M.R. Ch. 125 | Regulations Governing the Licensing of Ambulatory Surgical Facilities. |
| 10-144 C.M.R. Ch. 126 | Regulations Governing the Licensing and Functioning of End Stage Renal Disease Units/Facilities. |

ADOPTED

[New] 10-144 C.M.R. Chapter 114, Rules Governing the Reporting of Sentinel Events, replaces the sentinel events reporting provisions in 10-144 C.M.R. Chapters 112, 118, 125, and 126. Effective date: