



Department of Health  
and Human Services

Maine People Living  
Safe, Healthy and Productive Lives

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**Division of Licensing and Regulatory Services  
RESPONSE TO COMMENTS  
on Proposed Rules  
5 MRSA § 8052**

**Rules Governing the Reporting of Sentinel Events  
10-144 C.M.R. Ch. 114**

After a timely published notice and a mailing to interested parties, the Division of Licensing and Regulatory Services (the Division) accepted written comments through January 30, 2010 at 5:00 p.m. (no public hearing was held). The following is the Division's response to comments on the proposed rules. The Division thanks the commenter for participating in the rulemaking process.

**List of commenters**

1. Ms. Sandra L. Parker, Maine Hospital Association

**Comments and Responses**

**Section 1.4 Definition of "discovered."**

**Comment:** Commenter recommends that the definition of "discovered" in Section 1.4 be amended, as follows, because a "sentinel event" is a defined term, and "an occurrence" is not. In addition, the mandatory actions under these rules are triggered by the detection of a sentinel event.

**Discovered.** For the purposes of these rules, "discovered" means the point at which one becomes aware of ~~an occurrence~~ sentinel event that triggers an action under these rules.

**Division Response:** The Division agrees to the change suggested by the commenter. **The section is changed to read as follows:**

**1.4 Discovered.** For the purposes of these rules, "discovered" means the point at which one becomes aware of a sentinel event.

**Section 1.13 Major Life Activities.**

**Comment:** Commenter appreciates the Division's use of federal and/or nationally accepted definitions of terms whenever appropriate for consistency and availability of additional guidance. Accordingly, just as Section 1.3's definition of "disability" references the Americans with

Disabilities Act, we recommend amending the definition of “major life activities” to reference the Americans with Disabilities Act.

**Division Response.** The Division agrees to amend Section 1.13 by adding the following language at the end of the definition: “(see the federal Americans with Disabilities Act).” **The section is changed to read as follows:**

**1.13 Major Life Activities.** For the purposes of these rules, “major life activities” means functions, including but not limited to, caring for oneself, performing manual tasks, seeing, hearing, eating, sleeping, walking, standing, lifting, bending, speaking, breathing, learning, reading, concentrating, thinking, communicating, working and the operation of a major bodily function. Major bodily functions include but are not limited to functions of the immune system, normal cell growth, digestive, bowel, bladder, neurological, brain, respiratory, circulatory, endocrine, and reproductive functions. (see the federal Americans with Disabilities Act).

**Section 1.23 Definition of “Sentinel Events Team.”**

**Comment.** In the interest of mutual transparency, to simply record how the Division has orally described its process and consistent with the confidentiality provisions of the statute, the commenter recommends the following amendment to the definition of the “sentinel event team:”

**Sentinel Events Team.** The Sentinel Events Team (SET), is a segregated unit of the Division of Licensing and Regulatory Services (DLRS) that maintains separate and confidential communications and records to assure that all notifications and reports of sentinel events filed pursuant to this chapter and all information collected or developed as a result of the filing and proceedings pertaining to the filing, regardless of format, are confidential and not disclosed, except as permitted under Section 7.4. The SET is assigned the responsibility to implement these rules.

**Division Response.** It is not necessary to describe how the Division will carry out its functions unless it is necessary to guide the regulated industry. In this case, the suggested revision provides no guidance to those who are required to follow these rules and has no value added. **No change is made to the definition of Sentinel Events Team.**

**Section 2.1 Notification and Reporting System.**

**Comment.** In lieu of creating a new sentinel event notification, reporting and staff education set of requirements, the commenter recommends adopting the existing and well-accepted national standardized set of requirements for same. The Joint Commission surveys facilities for their compliance with these standards so the state SET team should also be able to easily ascertain hospital compliance with these requirements for a patient safety program that includes requirements specific to sentinel event discovery, notification, reporting and staff education.

Adopting the Joint Commission standards also would address a number of specific concerns the commenter has about the proposed language:

- he proposed language of Section 2.1.1 uses the inapplicable term “Serious Adverse Event.” This rule governs “sentinel events” (a defined term) and “near misses” (a defined term), and also provides separate definitions for “serious” and “adverse” and “event”.
- Section 2.2.1 requires policies and procedures detailing a systematic process for identifying “near misses”. While hospitals have such mechanisms in place, the enabling statute only authorizes voluntary reporting of near misses, so requiring a process for identification is outside of other statutory authority for the mandatory sentinel event reporting program.
- Section 2.1.1.5 requires a review of death logs and transfer logs, among other records. While hospitals have mechanisms in place to identify unexpected deaths or harm, those mechanisms do not necessarily require review of every individual patient who died or was transferred. For example, one of our tertiary care centers had about 700 deaths and 6,000 transfers last year. To review everyone of those records would not be productive and would require hiring a dedicated staff person to document and review records of thousands of appropriate transfers in/out of their hospital as well as reviewing records of patients who died of natural causes.
- Section 2.3 requires documenting annual proscriptive educational programs for all staff and individuals with privileges. Hospitals have other staff educational requirements by law, but the depth and breadth of the requirements in this proposed section is inappropriate for all levels of personnel. Additionally, providing and documenting such annual education in a tertiary care center with over 4,000 employees and over 1,000 active medical staff would be simply impossible. Staff education, both generally and specifically around sentinel events, is ongoing and the design of educational programming around adverse events is the responsibility of the hospital according to the federal CMS Conditions of Participation (page 3437)

After monitoring, tracking, and assessing performance in all areas of hospital service and operations, the hospital has the flexibility to design a program to address its specific needs. We also believe giving the hospital flexibility to design its own program provides the hospital with the flexibility to adopt its own best practices in specific areas, (for example, hospital staff education, record reviews, and information technology.)

Therefore, the commenter strongly urges incorporating the applicable Joint Commission standards in place of proposed Sec. 2.1, 2.2 and 2.3, as follows:

**2.1 Notification and Reporting System.** A healthcare facility must have a Sentinel Event Notification and Reporting System that includes but is not limited to:

~~2.1.1 — Discovery Policy. A Discovery System with policies and procedures that detail a systematic process for identifying specific categories of cases including but not limited to Near Miss Events (Section 1.15), Serious Adverse Events, and events that resulted in a sentinel event (Section 1.22). The written policies and procedures must include but are not limited to the following:~~

~~2.1.1.1 — Copy of the current Sentinel Events Reporting law, 22 M.R.S.A. Chapter 1684.~~

- ~~2.1.1.2~~ Copy of the current Rules Governing the Reporting of Sentinel Events, 10-144 C.M.R. Ch. 114.
- ~~2.1.1.3~~ Preservation of evidence procedures, including but not limited to the following:
  - ~~2.1.1.3.1~~ Procedure for sequestering equipment involved in the event.
  - ~~2.1.1.3.2~~ Procedure for sequestering other evidence including but not limited to medication vials and intravenous (IV) administration bags.
- ~~2.1.1.4~~ Procedure for identifying clinical indications for requesting an autopsy.
- ~~2.1.1.5~~ Procedure for review of death logs, transfer logs, patient complaints, patient records submitted for case review, and resuscitation reviews.
- ~~2.1.2~~ Notification Policy. Facility sentinel event notification policies and procedures that include but are not limited to the following:
  - ~~2.1.2.1~~ Facility procedure for notifying the SET.
  - ~~2.1.2.2~~ Facility procedure that identifies the person responsible in the facility for the notification of the SET and, in the absence of that person, the identification of the alternate person responsible for the notification of the SET.
- ~~2.1.3~~ Investigation and Reporting Policies. Facility investigation and reporting policies and procedures including but not limited to the following:
  - ~~2.1.3.1~~ Facility procedure for conducting a RCA.
  - ~~2.1.3.2~~ Facility procedure that ensures corrective actions are implemented and evaluated for effectiveness.
- ~~2.2~~ **Staff Education.** Maintain documentation of education during new employee orientation and annually to staff, and individuals with privileges, at all levels regarding:
  - ~~2.2.1~~ The facility's Sentinel Event Notification and Reporting System.
  - ~~2.2.2~~ Maine rules regarding mandatory reporting of sentinel events, the voluntary reporting of near miss events, and the standardized procedures for notification and reporting.
  - ~~2.2.3~~ Facility internal processes for notifying leadership.
  - ~~2.2.4~~ Facility responsibility to implement action plans.
  - ~~2.2.5~~ Facility responsibility to annually attest that all sentinel events were reported to the SET.
- 2.1.1 The hospital implements a hospital-wide patient safety program.
  - 2.1.1.1 One or more qualified individuals or an interdisciplinary group manages the safety program.
  - 2.1.1.2 The scope of the safety program includes the full range of safety issues, from near misses to sentinel events.
  - 2.1.1.3 All departments within the hospital participate in the safety program.
  - 2.1.1.4 As part of the safety program, the hospital creates procedures for responding to systems failures (Responses might include continuing to provide care, treatment, and service to those affected, containing the risk to others, and preserving factual information for subsequent analysis).
  - 2.1.1.5 The hospital provides and encourages the use of systems for blame-free internal reporting of any sentinel event or near miss, as defined here.

- 2.1.2 The state's sentinel event reporting system described herein and the hospital's corresponding internal compliance practices are communicated to all clinical staff.
- 2.1.3 In accordance with its written policies, the hospital conducts thorough and credible root causes analyses in response to sentinel events as defined herein.
- 2.1.4 To improve safety and to reduce the risk of sentinel events, the hospital analyzes and uses information about system failures and the results of any proactive risk assessments.
- 2.1.5 The hospital disseminates lessons learned from root causes analyses to all staff who provide services for the specific situation.

**Division Response.** CMS requirements for hospital quality assurance programs do not address sentinel event reporting, which is a state-level mandatory program. The CMS Conditions of Participation lack the specificity needed to comply with Maine's Sentinel Event Reporting Act.

A review of the Joint Commission statistics through 2008, the most recent period for which the information is reported, shows there were over 800 sentinel event reports. Of this number, approximately 300 were identified either through media or other means, and were not reported directly by the hospitals. In the 2009 Sentinel Event Report published by the Maine Department of Health and Human Services, a quarter of the sentinel events were found by the Department through audit of facilities. Section 2.1 is intended to ensure that each entity with reporting requirements has systems in place to discover cases that need to be reported.

One concern with adopting the Joint Commission language mandating a hospital-wide patient safety program is that portions of it are beyond the scope of this rulemaking. For example, the suggestion that the hospital be required to create procedures for responding to system failures goes beyond requirements necessary to implement the Sentinel Event Reporting Act. That being said, the Division is modifying Sections 2.1 and 2.2 to mitigate the impact of some of the requirements that may be overly burdensome, and align the language with the Joint Commission for consistency, where possible (The 'strike-out' and 'underline' version that follows is used here to more easily identify the changes). ~~The commenter's concerns regarding staff education were understood by the Division to refer to Section 2.2 rather than 2.3 and the Division agreed to revise Section 2.2 to address the commenter's concerns.~~ **Therefore, Sections 2.1 and 2.2 are changed to read as follows:**

**2.1 Notification and Reporting System.** A health care facility must have a Sentinel Event Notification and Reporting System as part of its hospital-wide, integrated patient safety program for all departments, programs, and services within the facility that includes but is not limited to:

**2.1.1 ~~Discovery Policy~~System.** ~~A Discovery System with~~ Each health care facility shall have policies and procedures for identifying that detail a systematic process for identifying specific categories of cases including but not limited to Near Miss Events (Section 1.15), Serious Adverse Events, and events that resulted in a sentinel event (Section 1.22). The written policies and procedures must include but are not limited to the following:

**2.1.1.1** Copy of the current Sentinel Events Reporting law, 22 M.R.S.A. Chapter 1684.

- 2.1.1.2 Copy of the current Rules Governing the Reporting of Sentinel Events, 10-144 C.M.R. Ch. 114.
- 2.1.1.3 Procedures for preservation of evidence~~procedures~~, including but not limited to the following:
  - 2.1.1.3.1 Procedure for sequestering equipment involved in the event.
  - 2.1.1.3.2 Procedure for sequestering other evidence including but not limited to medication vials and intravenous (IV) administration bags.
  - 2.1.1.3.3 ~~2.1.1.4~~Procedure for identifying clinical indications for requesting an autopsy.
- 2.1.1.4 Procedure for periodically reviewing a sample of death logs, transfer logs, patient complaints, patient records submitted for case review, ~~and~~ resuscitation reviews and other records as a quality assurance mechanism to assure that cases are being identified and reported.
- 2.1.1.5 Procedure for communicating the definition of a sentinel event throughout the organization.

2.1.2 **Notification Policy.** Facility sentinel event notification policies and procedures ~~that~~ shall include but are not limited to the following:

- 2.1.2.1 Facility procedure for notifying the SET.
- 2.1.2.2 Facility procedure that identifies the person responsible in the facility for the notification of the SET and, in the absence of that person, the identification of the alternate person responsible for the notification of the SET.

2.1.3 **Investigation and Reporting Policies.** Facility investigation and reporting policies and procedures including but not limited to the following:

- 2.1.3.1 Facility procedure for conducting a RCA.
- 2.1.3.2 Facility procedure that ensures corrective actions are implemented and evaluated for effectiveness.
- 2.1.3.3 The identity of one or more qualified individuals or an interdisciplinary group that manages the safety program.

2.2 **Staff Education.** Each health care facility shall include in new employee orientation and provide to all individuals with privileges: Maintain documentation of education during new employee orientation and annually to all staff, and individuals with privileges, at all levels regarding:

- 2.2.1 The facility's Sentinel Event Notification and Reporting System policies and procedures.
- 2.2.2 ~~Maine rules regarding mandatory reporting of sentinel events,~~ Information regarding the voluntary reporting of near miss events, and the standardized procedures for notification and reporting sentinel events.
- 2.2.3 Facility internal processes for notifying leadership.
- 2.2.4 Facility responsibility to implement action plans.
- 2.2.5 Facility responsibility to annually attest that all sentinel events were reported to the SET.

**Section 2.4 Annual Attestation.**

**Comment.** This section describes the annual written statement to the SET that health care facilities complied with the sentinel event reporting requirements of Maine law. The commenter objects to so such a requirement as unprecedented and unnecessary. Hospitals are required to comply with countless state and federal laws. Annual attestation of compliance with any single one would be superfluous and a waste of private and public resources. Accordingly, the commenter recommends that Section 2.4 be deleted.

If the annual attestation continues as a requirement, the commenter recommends three amendments to the current form. First, the form references the attestation section of the rule as 2.7, but the current draft of the proposed rule lists the attestation requirement in Section 2.4. Second, the annual period covered by the attestation form is absent. So, the Administrator is being asked to sign an open-ended declaration, which s/he clearly cannot do unless s/he has been the Administrator at that hospital since the inception of the sentinel event reporting program. Accordingly, the quote above the Administrator signature line should be amended to include the dates, e.g. "I affirm that our facility has reported all Sentinel Events to the Division of Licensing and Regulatory Services for the period of January 1, 2009 through December 31, 2009." Finally, there needs to be a provision for situations where the Administrator changes during the course of the year because an individual can only attest for the time period for which s/he has been at that particular hospital.

- 2.4** ~~2.7 Annual Attestation~~ notification. By January 30<sup>TH</sup> of each year, on a department-approved form ~~approved by the SET,~~ each healthcare facility must send the SET a written attestation ~~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.

**Division Response.** Health care facilities are frequently required to attest that they are in substantial compliance with CMS Conditions of Participation, and those attestations are relied upon by the Department and CMS in licensing and certification activities. Attestation requirements are found in Section 2.4 of the proposed rules because amendments required a renumbering of the sections and the information that is in the current rule at Section 2.7 is in the proposed rule at Section 2.4. The Division shall include the reporting period and change the reference from 2.7 to 2.4 when it edits the form once these rules are adopted. The Division believes that facilities will be able to establish attestation policies that will address how

attestations will be made when there are changes in Chief Executive Officers to satisfy these requirements. **No change is made to Section 2.4.**

**Section 3.2.1 Notification not delayed by internal deliberatons.**

**Comment.** The commenter understands that the SET welcomes reports of suspected sentinel events; however, the statute only mandates reporting of certain defined “sentinel events.” Therefore, the rule cannot require reporting of suspected sentinel events. The hospital must, and will, notify the SET of a “sentinel event” the next business day after the “sentinel event” occurred or the next business day after the facility discovers that the “sentinel event” occurred. The definition of a sentinel event is complex. Sometimes it is immediately obvious that an event meets the definitions, e.g. surgery on the wrong patient. Other circumstances are not as clear and may require some inquiry or investigation before ascertaining whether it is or is not a sentinel event under this proposed rule. Therefore, the notification requirement outlined in Section 3.1 is appropriate: “The health care facility must notify the SET of a sentinel event (Section 1.22) by the next business day after the event occurred or the next business day after the facility discovers that the event occurred.” However, Section 3.2.1 must be amended as follows to allow necessary inquiry, if any, to take place:

- 3.2.1 Notification of the discovery of a sentinel event must not be delayed beyond the next business day after the event occurred or the next business day after the facility discovers that the event occurred ~~secondary to internal deliberations or pending autopsy or medical examiner results.~~

**Division Response.** Since it is the SET that determines whether a sentinel event has occurred, internal deliberations or waiting for autopsy results can adversely affect the conduct of a thorough and credible RCA. Evidence may be destroyed, for example. Sentinel event reporting requires a great deal of collaboration with the SET since it is the SET that determines whether an event meets the required definitions. The facility has 45 days to complete the reporting process, including the results of the RCA. If in that period of time, additional evidence determines that the report did not involve a sentinel event, the SET can make that determination at that time. Necessary inquiry can still take place. **No change is made to Section 3.2.1.**

**Section 3.2.2 Notification faxed to SET**

**Comment.** In the Division’s response to commenter’s preliminary comments, the Division proposed to add the ability for reporting sentinel events via encrypted email, which is already available. Therefore, the commenter recommends explicitly adding encrypted email as a permissible notification option, as follows:

- 3.2.2 Within 1 business day of the discovery of a sentinel event, the health care facility must send ~~a facsimile of the department-~~ approved sentinel event notification form to the SET by facsimile or encrypted e-mail.

**Division Response.** The Division agrees to make this change as proposed by the commenter. **Section 3.2.2 is changed to read as follows:**

- 3.2.2. Within 1 business day of the discovery of a sentinel event, the healthcare facility must send the department-approved sentinel

event notification form to the SET by facsimile or encrypted e-mail.

**Section 3.2.3 Notification and telephone confirmation.**

**Comment.** Section 3.2.3 requires that the facility not only notify the SET of a sentinel event by fax (or encrypted email), but also call the SET on the same day to confirm that the SET received the notification and possibly schedule an on-site SET visit. The commenter believes that the hospital has met its statutory obligation to report a sentinel event when it sends the department-approved sentinel event notification form by fax or encrypted email to the SET. The notification from the hospital may arrive to the SET office fax machine when the team is away on another site visit, during weekends, holidays, state shut-down days or off-hours or other days/times when the SET is unavailable. Therefore, this proposed language imposes a legal requirement that hospitals cannot always comply with due to circumstances completely beyond their control. In addition, the SET should review the notification form and call the facility as appropriate for any necessary follow-up. Accordingly, the commenter recommends deleting Section 3.2.3 as it exceeds the statutory boundaries and imposes a legal requirement that cannot be implemented due to the state's business hours.

~~**3.2.3** — The day the notification facsimile is sent to the SET, the facility must telephone the SET to confirm its receipt of the notification facsimile and, at the discretion of the SET, schedule an on-site SET visit.~~

**Division Response.** The Division has the statutory authority to prescribe reporting processes in these rules. However, in an effort to reduce unnecessary administrative burdens, and to address the valid concerns about the business hours and operational needs of the SET, **Section 3.2.3 is deleted.**

**Section 3.3.2.1.1 Functional Evidence form.**

**Comment.** This section references a "Functional Evidence form" that was not included with the proposed rule nor were we able to access it on-line so we cannot provide comment on it.

~~**3.3.2.1.1** Within 14 days of discharge from a health care facility, if evidence is discovered that the major loss of function was not permanent, the facility must submit the department-approved Functional Evidence form with supporting documentation to the SET, and a RCA of the event is not required.~~

**Division Response.** This form will be developed by the time these rules are adopted. The department is not required to include all department-approved forms with rulemaking. **No change is made to Section 3.3.2.1.1.**

**Sections 3.3.2.2 and 3.3.2.3 Discharge Follow-up Notification.**

**Comment.** These sections impose a legal obligation on hospitals to examine all patients 48 hours after discharge to determine whether or not certain sentinel events have occurred since discharge. However the enabling statute (22 MRS 8752 (4-A)) defines "sentinel events" as occurrences "in a health care facility." Therefore, the proposed rule exceeds statutory boundaries by requiring reporting of sentinel events that occur outside of the health care facility and may be outside of hospital control and/or reasonable knowledge.

In addition, while hospitals already have mechanisms in place for identifying unexpected deaths or harm, implementing and documenting a follow-up contact with every single hospital

discharge would be unduly burdensome and expensive, given that there were 155,000 hospital discharges in the last year in Maine. In just one tertiary care center alone, there were over 29,000 discharges in the last year.

**Division Response.** The commenter has not interpreted this rule correctly. Sections 3.3.2.2 and 3.3.2.3 state:

**3.3.2.2** A facility is required to submit to the SET notification regarding a sentinel event involving a death or major permanent loss of function within 48 hours of treatment or procedure in an emergency department, ambulatory surgical facility, or end stage renal disease facility that is unrelated to the natural course of the patient's illness or underlying condition; or unrelated to the proper treatment of that illness or underlying condition in a healthcare facility.

**3.3.2.3** A facility is required to submit notification regarding the suicide of a patient within 48 hours of discharge from a healthcare facility.

The purpose of these sections of the rule is not to identify sentinel events that occurred outside of a healthcare facility. Rather, it is to provide sufficient time for the facility to discover whether a sentinel event occurred as a result of treatment in the emergency department, ambulatory surgical facility or end state renal disease facility. It is within the statutory authority of the Department to make this part of the notification process. **No change is made to Sections 3.3.2.2 and 3.3.2.3.**

**Section 3.4.1 SET Case Review: copy of medical record.**

**Comment.** Although not historically a requirement, the commenter understands that the Division's current application of this proposed section is to require that hospitals mail a copy of the medical record to the SET in advance of any on-site review. The commenter requests that such requests will be issued judiciously, rather than as a matter of routine, as printing/ mailing entire medical records is unduly burdensome. As outlined in the CMS memo to the State Survey Agency Directors, August 14, 2009, while the state must have unrestricted access to the medical record, state survey staff shall make reasonable efforts to avoid the printing of entire medical records.

**3.4** **SET Case Review.** Upon receipt of a notification or report of a sentinel event, the SET completes an initial review and may take other action that it determines to be appropriate pursuant to these rules. The facility must comply with the following requirements for the SET case review:

**3.4.1** Provide a copy of the patient's medical record.

**Division Response.** When licensing staff are on-site doing reviews, many medical records are reviewed as part of the sampling process. In the case of an SET review, it is generally a single case. While this requirement will be used judiciously, it is one way in which on-site reviews can be more focused if the record is made available ahead of time. **No change was suggested, and no change is made to Section 3.4.1.**

**Changes made in response to Legal Review.** Based on the legal review by the Office of the Attorney General, DLRS made the following changes to the rules.

1. Minor changes to the format that are non-substantive.
2. Relocated the following sections without making any substantive changes:
  - Moved “Immediate Jeopardy” from Section 7.3 to Section 3.5.
  - Moved “Immunity” from Section 7.1 to Section 8.1.
  - Moved “Consultant” from Section 6.3 to Section 7.1.1.1 and edited for clarity.
3. For consistency throughout the rule, the following nonsubstantive changes were made:
  - For consistency with the definition of sentinel event (1.22), the following is added to the definition of major permanent loss of function:

**1.14.3** is unrelated to the natural course of the patient's illness or underlying condition or proper treatment of that illness or underlying condition in a health care facility.

- For consistency with Sections 3.3.2.2 and 3.3.2.1.1, corrected the following by changing ‘24’ to ‘48’ and ‘2 weeks; to ’14 days:’

**1.22.2.1** For the purposes of ESRDs, the term “discharge” means within 48 hours of a treatment.

**1.22.2.2** If within 14 days of discharge from the facility, evidence is discovered that the major loss of function was not permanent, the health care facility is not required to submit a report pursuant to 22 M.R.S.A. § 8753 (2);

- For clarification and consistency, deleted last sentence in Section 2.3 because this sentence is part of Section 7.1.2. For clarity and consistency, added the underlined words to Section 7.1.2:

**2.3** ~~All information collected or developed as a result of an initial or onsite SET review is confidential and privileged information.~~

**7.1.2** Notifications and reports concerning sentinel events, near miss events, and suspected 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.

- For consistency with the § 8753 of the statute, added the following to Section 3.1:

**3.1** **Notification by next business day.** The healthcare facility must notify the SET of a sentinel event (Section 1.22) by the next business day after the event occurred or the next business day after the facility discovers that the event occurred. The notification must include but is not limited to the date and time of notification, the name of the health care facility, the type of sentinel event, and the date and time the sentinel event occurred.

- For consistency with Sections 3.1 and 1.22.2, added the following to Sections 3.3.2.1, 3.3.2.2 and 3.3.2.3:

**3.3.2.1** A facility is required to submit to the SET notification by the next business day after the event occurred or the next business day after the facility discovers that the event occurred regarding a sentinel event involving a patient with a major permanent loss of function that is present at the time of discharge that is unrelated to the natural course of the patient's illness or underlying condition or proper treatment of that illness or underlying condition in a health care facility.

**3.3.2.2** A facility is required to submit to the SET notification by the next business day after the event occurred or the next business day after the facility discovers that the event occurred when a sentinel event involving a death or major permanent loss of function occurs within 48 hours of treatment or procedure in an emergency department, ambulatory surgical facility, or end stage renal disease facility that is unrelated to the natural course of the patient's illness or underlying condition; or unrelated to the proper treatment of that illness or underlying condition in a healthcare facility.

**3.3.2.3** A facility is required to submit to the SET notification by the next business day after the event occurred or the next business day after the facility discovers that the event occurred when the suicide of a patient occurs within 48 hours of discharge from a healthcare facility.

- Deleted from rules and placed in Departmental policies.

~~**5.2** **Annual Near Miss Focus Areas.** Each September, the SET shall announce the selected specific targeted near miss areas that shall be the focus of in-depth analysis for the next calendar year. Near miss data shall be collected from self-reporting healthcare facilities and SET activities, including record reviews. The goal of an annual targeted focus is to provide meaningful data and analysis of lessons learned from near miss events.~~

- Deleted from rules because it is not necessary for inclusion in the rules.

~~**8.1** **Oversight.** The division shall place primary emphasis on ensuring effective corrective action by the facility.~~