Maine Hospital Association

January 28, 2010

Anne Flanagan, Assistant Director
Maine Department of Health and Human Services
Division of Licensing and Regulatory Services
11 State House Station
41 Anthony Avenue
Augusta, Maine 04333-0011

Dear Anne:

On behalf of our entire membership, the Maine Hospital Association (MHA) appreciates the opportunity to provide these comments on the proposed sentinel event reporting rules. The MHA is an Augusta-based non-profit membership organization representing all 39 community hospitals in our state. Our comments are presented by section for easy reference.

Section 1.4
We recommend that the definition of "discovery" in Section 1.4 be amended as follows:

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

These clarifications are necessary because:
- "Sentinel event" is a defined term, but an "occurrence" is not; and
- The mandatory actions under these rules are triggered by the detection of a sentinel event.

Section 1.13
We appreciate 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 (ADA), we recommend amending the definition of "major life activities" to reference the ADA as follows:

> **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,

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respiratory, circulatory, endocrine, and reproductive functions (see the federal Americans with Disabilities Act).

Section 1.23

In the interest of mutual transparency, to simply record how you have orally described your process and consistent with the confidentiality provisions of the statute, we recommend 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.

Section 2.1

In your response to our preliminary comments to this section, you invited further suggestions that outlined standardized requirements for a quality reporting system. In lieu of creating a new sentinel event notification, reporting and staff education set of requirements, we recommend adopting the existing and well-accepted national standardized set of requirements for same. Therefore, we strongly urge incorporating the applicable Joint Commission standards in place of proposed Section 2.1, 2.2 and 2.3 as follows:

2.1 Notification and Reporting System. A health care 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. 10-144 C.M.R. Ch. 114 Rules Governing the Reporting of Sentinel~~

~~**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 system 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 misses, as defined herein.

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 cause 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 cause analyses to all staff who provide services for the specific situation.

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 we have about the proposed language.

- The proposed language of Section 2.1.1 uses the inapplicable term “Serious Adverse Event.” This rule the 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 the 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 every one 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: (p.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).

Section 2.4

Section 2.4 describes the annual written statement to the state that they complied with the sentinel event reporting requirements of Maine law. We continue to object to such a requirement as unprecedented and unnecessary. Hospitals are required to comply with countless state and federal laws. Annual certification of compliance with any single one would be a superfluous waste of private and public resources. Accordingly, we recommend that Section 2.5 be deleted.

If the annual attestation continues as a requirement, we recommend 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 each 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 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.

Section 3.2.1

We understand 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 <u>beyond the next business day after the event occurred or the next business day after the facility discovers that the event occurred</u> ~~secondary to internal deliberations or pending autopsy or medical examiner results~~.

Section 3.2.2

In your response to our preliminary comments, you proposed to add the ability for reporting sentinel events via encrypted email, which is already available. Therefore, we recommend 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.

Section 3.2.3

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. We believe 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 week-ends, 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, we recommend 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.~~

Section 3.3.2.1.1

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.

Sections 3.3.2.2 and 3.3.2.3

These sections impose a legal obligation on hospitals to examine all patient 48 hours after discharge to determine whether or not certain sentinel events have occurred since discharge. However the enabling statute [22 MRSA 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

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discharges in the last year in Maine. In just one tertiary care center alone, there were over 29,000 discharges over the last year.

Section 3.4.1
Although not historically a requirement, we understand that your current application of this proposed section is to require that hospitals mail a copy of the medical record to you in advance of any on-site review. We request 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.

We would be happy to answer any questions regarding these comments and to work with the department on any revisions. As soon as it is completed, please send a copy of the department's response to all submitted comments to me at the address below. Thank you.

Sincerely,

Sandra L. Parker
Vice President & General Counsel