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L.D. 1435

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HEALTH AND HUMAN SERVICES

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STATE OF MAINE

SENATE

124TH LEGISLATURE

FIRST REGULAR SESSION

COMMITTEE AMENDMENT "A" to S.P. 519, L.D. 1435, Bill, "An Act To Amend Sentinel Events Reporting Laws To Reduce Medical Errors and Improve Patient Safety"

Amend the bill by striking out everything after the enacting clause and before the summary and inserting the following:

'**Sec. 1. 22 MRSA §8752,** as enacted by PL 2001, c. 678, §1 and affected by §3 and corrected by RR 2001, c. 2, Pt. A, §37 and affected by §38 and amended by PL 2007, c. 324, §17, is further amended to read:

§8752. Definitions

As used in this chapter, unless the context otherwise indicates, the following terms have the following meanings.

1. Division. "Division" means the Department of Health and Human Services, Division of Licensing and Regulatory Services ~~within the Bureau of Medical Services~~.

2. Health care facility. "Health care facility" or "facility" means a state institution as defined under Title 34-B, chapter 1 or a health care facility licensed by the division, except that it does not include a facility licensed as a nursing facility or licensed under chapter ~~1665~~ 1664. "Health care facility" includes a general and specialty hospital, an ambulatory surgical facility, an end-stage renal disease facility and an intermediate care facility for persons with mental retardation or developmental disabilities.

2-A. Immediate jeopardy. "Immediate jeopardy" means a situation in which the provider's noncompliance with one or more conditions of participation in the federal Medicare program has caused, or is likely to cause, serious injury, harm or impairment to or death of a patient.

3. Major permanent loss of function. "Major permanent loss of function" means sensory, motor, physiological or intellectual impairment that was not present at the time of admission and requires continued treatment or imposes persistent major restrictions in activities of daily living.

3-A. Near miss. "Near miss" means an event or situation that did not produce patient injury, but only because of chance, which may include, but is not limited to, robustness of the patient or a fortuitous, timely intervention.

3-B. Root cause analysis. "Root cause analysis" means a structured process for identifying the causal or contributing factors underlying adverse events. The root cause analysis follows a predefined protocol for identifying these specific factors in causal categories.

~~**4. Sentinel event.** "Sentinel event" means:~~

~~A. One of the following that is 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 or that results from the elopement of a hospitalized inpatient who lacks the capacity, as defined in Title 18-A, section 5-801, subsection (c), to make decisions:~~

~~(1) An unanticipated death; or~~

~~(2) A major permanent loss of function that is not present when the patient is admitted to the health care facility;~~

~~B. Surgery on the wrong patient or wrong body part;~~

~~C. Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities;~~

~~D. Suicide of a patient in a health care facility where the patient receives inpatient care;~~

~~E. Infant abduction or discharge to the wrong family; or~~

~~F. Rape of a patient.~~

4-A. Sentinel event. "Sentinel event" means:

A. An unanticipated death, or patient transfer to another health care facility, 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;

B. A major permanent loss of function 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 that is present at the time of the discharge of the patient. If within 2 weeks 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 section 8753, subsection 2;

C. An unanticipated perinatal death or major permanent loss of function in an infant with a birth weight over 2,500 grams that is unrelated to the natural course of the infant's or mother's illness or underlying condition or proper treatment of that illness or underlying condition in a health care facility; and

D. Other serious and preventable events as identified by a nationally recognized quality forum and determined in rules adopted by the department pursuant to section 8756.

Sec. 2. 22 MRSA §8753, as enacted by PL 2001, c. 678, §1 and affected by §3, is amended to read:

§8753. Mandatory reporting of sentinel events

A health care facility shall ~~report to~~ notify the division ~~a sentinel event that occurs to a patient while the patient is in the health care facility as provided in this section~~ whenever a sentinel event has occurred, as provided in this chapter.

1. Notification. A health care facility shall notify the division of ~~the occurrence of~~ a sentinel event by the next business day after the ~~sentinel~~ event ~~has~~ occurred or the next business day after the facility ~~determines~~ discovers that the event occurred. The notification must include the date and time of notification, the name of the health care facility and the type of sentinel event pursuant to section 8752, subsection ~~4~~ 4-A.

2. Reporting. ~~A~~ The health care facility shall file a written report no later than 45 days following the notification of the occurrence of a sentinel event pursuant to subsection 1. The written report must be signed by the chief executive officer of the facility and must contain the following information:

A. Facility name and address;

B. Name, title and phone number of the contact person for the facility;

C. The date and time of the sentinel event;

D. The type of sentinel event and a brief description of the sentinel event; and

~~E. Identification of clinical and organizational systems or processes that may have contributed to the sentinel event;~~

~~F. Identification of changes that could be made that would reduce the risk of such a sentinel event occurring in the future; and~~

~~G. A brief description of any corrective action taken or planned.~~

H. A thorough and credible root cause analysis. A root cause analysis is thorough and credible only in accordance with the following.

(1) A thorough root cause analysis must include: a determination of the human and other factors most directly associated with the sentinel event and the processes and systems related to its occurrence; an analysis of the underlying systems and processes to determine where redesign might reduce risk; an inquiry into all areas appropriate to the specific type of event; an identification of risk points and their potential contributions to the event; a determination of potential improvement in processes or systems that would tend to decrease the likelihood of such an event in the future or a determination, after analysis, that no such improvement opportunities exist; an action plan that identifies changes that can be implemented to reduce risks or formulates a rationale for not undertaking such changes; and, where improvement actions are planned, an identification of who is responsible for implementation, when the action will be implemented and how the effectiveness of the action will be evaluated.

(2) A credible root cause analysis must include participation by the leadership of the health care facility and by the individuals most closely involved in the processes and systems under review, is internally consistent without contradictions or unanswered questions, provides an explanation for all findings, including those identified as "not applicable" or "no problem," and includes the consideration of any relevant literature.

(3) The root cause analysis submitted to the division may exclude protected professional competence review information pursuant to the Maine Health Security Act.

3. Cooperation. A health care facility that has filed a notification or a report of the occurrence of a sentinel event under this section shall cooperate with the division as necessary for the division to fulfill its duties under section 8754.

4. Immunity. A person who in good faith reports a near miss, a suspected sentinel event or a sentinel event or provides a root cause analysis pursuant to this chapter is immune from any civil or criminal liability for the act of reporting or participating in the review by the division. "Good faith" does not include instances when a false report is made and the person reporting knows the report is false. This subsection may not be construed to bar civil or criminal action regarding perjury or regarding the sentinel event that led to the report.

5. Near miss notification. A health care facility may notify the division of the occurrence of a near miss. Should a facility report a near miss, the notification must include the date and time of notification, the name of the health care facility and the type of event or situation pursuant to section 8752, subsection 4-A that is related to the near miss.

Sec. 3. 22 MRSA §8753-A is enacted to read:

§8753-A. Standardized procedure

A health care facility shall have a written standardized procedure for the identification of sentinel events. The division shall develop the standardized reporting and notification procedures by adoption of routine technical rules under Title 5, chapter 375, subchapter 2-A.

Sec. 4. 22 MRSA §8754, sub-§1, as enacted by PL 2001, c. 678, §1 and affected by §3, is amended to read:

1. Initial review; other action. Upon receipt of a notification or report of a sentinel event, the division shall complete an initial review and may take such other action as the division determines to be appropriate under applicable rules and within the jurisdiction of the division. Upon receipt of a notification or report of a suspected sentinel event the division shall determine whether the event constitutes a sentinel event and complete an initial review and may take such other action as the division determines to be appropriate under applicable rules and within the jurisdiction of the division. The division may conduct on-site reviews of medical records and may retain the services of consultants when necessary to the division.

A. The division may conduct on-site visits to health care facilities to determine compliance with this chapter.

B. Division personnel responsible for sentinel event oversight shall report to the division's licensing section only incidences of immediate jeopardy and each condition of participation in the federal Medicare program related to the immediate jeopardy for which the provider is out of compliance.

Sec. 5. 22 MRSA §8754, sub-§3, as enacted by PL 2001, c. 678, §1 and affected by §3, is amended to read:

3. Confidentiality. 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 privileged information.

A. Privileged and confidential information under this subsection is not:

(1) Subject to public access under Title 1, chapter 13, except for data developed from the reports that do not identify or permit identification of the health care facility;

(2) Subject to discovery, subpoena or other means of legal compulsion for its release to any person or entity; or

(3) Admissible as evidence in any civil, criminal, judicial or administrative proceeding.

B. The transfer of any information to which this chapter applies by a health care facility to the division or to a national organization that accredits health care facilities may not be treated as a waiver of any privilege or protection established under this chapter or other laws of this State.

C. The division shall take appropriate measures to protect the security of any information to which this chapter applies.

D. This section may not be construed to limit other privileges that are available under federal law or other laws of this State that provide for greater peer review or confidentiality protections than the peer review and confidentiality protections provided for in this subsection.

E. For the purposes of this subsection, "privileged and confidential information" does not include:

(1) Any final administrative action;

(2) Information independently received pursuant to a 3rd-party complaint investigation conducted pursuant to department rules; or

(3) Information designated as confidential under rules and laws of this State.

This subsection does not affect the obligations of the department relating to federal law.

Sec. 6. 22 MRSA §8754, sub-§4, as enacted by PL 2001, c. 678, §1 and affected by §3, is amended to read:

4. Report. The division shall ~~develop~~ submit an annual report by February 1st each year to the Legislature, health care facilities and the public that includes summary data of the number and types of sentinel events of the prior calendar year by type of health care facility, rates of change and other analyses and an outline of areas to be addressed for the upcoming year. ~~The report must be submitted by February 1st each year.~~

Sec. 7. 22 MRSA §8755, as enacted by PL 2001, c. 678, §1 and affected by §3, is repealed and the following enacted in its place:

§8755. Compliance

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

2. Penalties. When the division determines that a health care facility failed to report a sentinel event pursuant to this chapter, the health care facility is subject to a penalty imposed in conformance with Title 5, chapter 375, subchapter 4 and payable to the State of not more than $10,000 per violation. If the facility in good faith notified the division of a suspected sentinel event and the division later determines it is a sentinel event, the facility is not subject to a penalty for that event. Funds collected pursuant to this section must be deposited in a dedicated special revenue account to be used to support sentinel event reporting and education.

3. Administrative hearing and appeal. To contest the imposition of a penalty under this section, a health care facility must submit to the division a written request for an administrative hearing within 10 days of notice of imposition of a penalty pursuant to this section. Judicial appeal must be in accordance with Title 5, chapter 375, subchapter 7.

4. Injunction. Notwithstanding any other remedies provided by law, the Office of the Attorney General may seek an injunction to require compliance with the provisions of this chapter.

5. Enforcement. The Office of the Attorney General may file a complaint with the District Court seeking injunctive relief for violations of this chapter.

Sec. 8. Authority to submit legislation. After reviewing recommendations in the CY 2008 Sentinel Events report dated April 28, 2009, the Joint Standing Committee on Health and Human Services may submit legislation related to the recommendations of the report to the Second Regular Session of the 124th Legislature.'

SUMMARY

This amendment replaces the bill. It removes the definition of "health care facility acquired infection," modifies the definitions of "major permanent loss of function" and "sentinel event" and modifies notification requirements related to transfers of patients from one facility to another. It removes provisions related to mandatory reporting of suspected sentinel events, immunity for expressions of regret or apologies, the Department of Health and Human Services' responsibility for determining the reportability of sentinel events and the confidentiality of records for final administrative actions. The amendment also gives the Joint Standing Committee on Health and Human

Services authority to submit a bill related to the recommendations of the CY 2008 Sentinel Events report dated April 28, 2009 to the Second Regular Session of the 124th Legislature.

The amendment retains the addition and modification of several provisions that relate to requirements for hospitals to follow standardized procedures for the identification, notification and reporting requirements. The amendment also retains the addition of root cause analysis to the reporting requirements while adding a provision to exclude protected professional competence review information from the root cause analysis submitted to the department's Division of Licensing and Regulatory Services. The amendment maintains the provision related to immunity for good faith reporting of near misses, suspected or actual sentinel events or root cause analysis as well as the provision on voluntary notification of a near miss.

The amendment requires the division to determine whether a suspected sentinel event constitutes a sentinel event, to complete an initial review and to take other action within the jurisdiction of the division. It retains provisions allowing the division to conduct on-site visits and to report immediate jeopardy to the division's licensing section, but adds language to clarify that personnel responsible for sentinel event oversight shall report only immediate jeopardy as defined in the Maine Revised Statutes, Title 22, section 8752, subsection 2-A and each condition of participation in the federal Medicare program related to the immediate jeopardy for which the provider is out of compliance.

This amendment maintains the provisions related to compliance, which increases the penalty for violations and authorizes the division to collect the penalty without going to court. The amendment reduces the penalty from the bill's proposal of $25,000 per unreported sentinel event to $10,000 per violation. It retains other provisions from the bill related to administrative hearings, appeals and injunctive relief.

FISCAL NOTE REQUIRED

(See attached)

Approved: 05/25/09 mac

124th MAINE LEGISLATURE

LD 1435 **LR 1908(02)**

An Act To Amend Sentinel Events Reporting Laws To Reduce Medical Errors and Improve Patient Safety

Fiscal Note for Bill as Amended by Committee Amendment "A"
Committee: Health and Human Services
Fiscal Note Required: Yes

Fiscal Note

Minor cost increase - General Fund
Minor revenue increase - General Fund
Minor revenue increase - Other Special Revenue Funds

Correctional and Judicial Impact Statements

Increases the number of civil suits.

The collection of additional filing fees may also increase General Fund revenue by minor amounts.

Fiscal Detail and Notes

The Department of Health and Human Services may experience an increase in Other Special Revenue Funds revenue from penalties.