SENATE FILE NO. SF0113

Medical safety event reporting.

Sponsored by: Senator(s) Massie and Representative(s) Iekel and Osborn

A BILL

for

AN ACT relating to health care facilities; providing for mandatory reporting of safety events by health care facilities to the department of health as specified; requiring an annual report of safety events by the department of health; providing definitions; providing a sunset date; providing an appropriation; and providing for an effective date.

Be It Enacted by the Legislature of the State of Wyoming:

Section 1. W.S. 35-2-912 is created to read:

35-2-912. Mandatory reporting of safety events.

(a) For purposes of this section, "safety event" means an unexpected occurrence involving death or serious

physical or psychological injury or the risk thereof, including:

(i) Surgical events. Events reportable under this paragraph are:

(A) Surgery performed on a wrong body part that is not consistent with the documented informed consent for that patient. Reportable events under this clause do not include situations requiring prompt action that occur in the course of surgery or situations whose urgency precludes obtaining informed consent;

(B) Surgery performed on the wrong patient;

(C) The wrong surgical procedure performed on a patient that is not consistent with the documented informed consent for that patient. Reportable events under this clause do not include situations requiring prompt action that occur in the course of surgery or situations whose urgency precludes obtaining informed consent;

(D) Retention of a foreign object in a patient after surgery or other procedure, excluding objects

intentionally implanted as part of a planned intervention and objects present prior to surgery that are intentionally retained; and

(E) Death during or immediately after surgery of a normal, healthy patient who has no organic, physiologic, biochemical, or psychiatric disturbance and for whom the pathologic processes for which the operation is to be performed are localized and do not entail a systemic disturbance.

(ii) Product or device events. Events reportable under this paragraph are:

(A) Patient death or serious disability associated with the use of contaminated drugs, devices or biologics provided by the facility when the contamination is the result of generally detectable contaminants in drugs, devices or biologics regardless of the source of the contamination or the product;

(B) Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as

intended. "Device" includes, but is not limited to, catheters, drains, and other specialized tubes, infusion pumps, and ventilators; and

(C) Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a facility, excluding deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism.

(iii) Patient protection events. Events reportable under this paragraph are:

(A) An infant discharged to the wrong person;

(B) Patient death or serious disability associated with patient disappearance for more than four (4) hours, excluding events involving adults who have decision making capacity; and

(C) Patient suicide or attempted suicide resulting in serious disability while being cared for in a facility due to patient actions after admission to the

facility, excluding deaths resulting from self-inflicted injuries that were the reason for admission to the facility.

(iv) Care management events. Events reportable under this paragraph are:

(A) Patient death or serious disability associated with a medication error, including, but not limited to, errors involving the wrong drug, the wrong dose, the wrong patient, the wrong time, the wrong rate, the wrong preparation, or the wrong route of administration, excluding reasonable differences in clinical judgment on drug selection and dose;

(B) Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products;

(C) Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a facility, including events that occur within forty-two (42) days of post-delivery and

excluding deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy, or cardiomyopathy;

(D) Patient death or serious disability directly related to hypoglycemia, the onset of which occurs while the patient is being cared for in a facility;

(E) Death or serious disability, including kernicterus, associated with failure to identify and treat hyperbilirubinemia in neonates during the first twenty-eight (28) days of life. "Hyperbilirubinemia" means bilirubin levels greater than thirty (30) milligrams per deciliter;

(F) Stage three (3) or four (4) ulcers acquired after admission to a facility, excluding progression from stage two (2) to stage three (3) if stage two (2) was recognized upon admission; and

(G) Patient death or serious disability due to spinal manipulative therapy.

(v) Environmental events. Events reportable under this paragraph are:

(A) Patient death or serious disability associated with an electric shock while being cared for in a facility, excluding events involving planned treatments such as electric countershock;

(B) Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances;

(C) Patient death or serious disability associated with a burn incurred from any source while being cared for in a facility;

(D) Patient death or serious injury associated with a fall while being cared for in a facility; and

(E) Patient death or serious disability associated with the use or lack of restraints or bedrails while being cared for in a facility.

(vi) Criminal events. Events reportable under this paragraph are:

(A) Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider;

(B) Abduction of a patient of any age;

(C) Sexual assault on a patient within or on the grounds of a facility; and

(D) Death or significant injury of a patient or staff member resulting from a physical assault that occurs within or on the grounds of a facility.

(b) Each licensed health care facility located within this state shall designate a patient safety officer and shall provide the department with the officer's name and contact information. Through the patient safety officer, each facility shall report to the department the occurrence of any safety event occurring after June 30, 2005 and described in subsection (a) of this section in the following manner:

(i) A person who is employed by a health care facility shall, within twenty-four (24) hours after becoming aware of a safety event at the health care facility, notify the patient safety officer of the facility of the safety event. The patient safety officer shall, within fifteen (15) days after receiving notification, report the safety event;

(ii) If the patient safety officer of a health care facility personally discovers or becomes aware, in the absence of notification by another employee, of a safety event at the health care facility, the patient safety officer shall, within fifteen (15) days after discovering or becoming aware of the safety event, report the safety event.

(c) Safety event reports shall be filed in a format specified by the department and shall identify the facility but shall not include any identifying information for any of the health care professionals, facility employees or patients involved. The department may consult with experts and organizations familiar with patient safety when developing the format for reporting and in further defining

events in order to be consistent with industry standards. The department may design the reporting system so that a facility may file by electronic means the reports required under this section. The department shall encourage a facility to use the electronic filing option when that option is feasible for the facility.

(d) In fulfilling the reporting requirements specified under this section, the department shall use, when practical, information already being generated by the health care facility as a result of the reporting requirements of other health care programs.

(e) Any notice, report, document and any other information compiled or disseminated pursuant to the provisions of this section is confidential, is not admissible in evidence in any administrative or legal proceeding conducted in this state and is not a public record.

(f) The department shall collect and maintain reports received pursuant to this section and shall have the authority to adopt rules and regulations to implement reporting procedures and standards required by this

section. On or before December 31 of each year beginning in 2006, the department shall prepare and publish a report and analysis of all reported safety events for the previous year, including a trend analysis and recommendations for systemic improvements that are likely to enhance patient safety and health care. The department may convene a panel of health care experts to review the data and compile the report. The report shall be made available to the public and copies forwarded to the governor, the health care commission and the joint labor, health and social services interim committee. In its annual report and any other public document, the department shall ensure that all referenced information is aggregated so as not to reveal the identity of any specific person or health care facility.

(g) Any act authorized or required by this section shall be subject to the confidentiality, immunity and whistle blowing provisions of W.S. 35-2-910(a) and (b).

(h) Nothing in this section shall be construed to limit or reduce any other reporting requirements for health care facilities under any state or federal law, or limit or

reduce the department's authority over health care facilities under any state or federal law.

(j) This section is repealed effective June 30, 2010.

Section 2. W.S. 35-2-609(b) by creating a new paragraph (v) and 35-2-901(a)(xxiv) are amended to read:

35-2-609. Disclosure without patient's authorization.

(b) A hospital may disclose health care information about a patient without the patient's authorization if the disclosure is:

(v) Pursuant to W.S. 35-2-912.

35-2-901. Definitions; applicability of provisions.

(a) As used in this act:

(xxiv) "This act" means W.S. 35-2-901 through ~~35-2-910~~ 35-2-912.

Section 3. There is appropriated from the general fund to the department of health two hundred fifty thousand dollars ($250,000.00) for the period beginning July 1, 2005 and ending June 30, 2006 to implement the purposes of this act. The department of health shall present in its standard budget request for the 2007-2008 biennium a funding request for the medical safety event reporting program created by this act.

Section 4. This act is effective immediately upon completion of all acts necessary for a bill to become law as provided by Article 4, Section 8 of the Wyoming Constitution.

(END)

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