House File 2215 - Introduced

HOUSE FILE 2215
BY BRADLEY

(COMPANION TO SF 2038 BY LOFGREN)

A BILL FOR

An Act relating to the reporting of serious reportable events, and providing penalties.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

Section 1. NEW SECTION. **135S.1 Definitions.**

As used in this chapter, unless the context otherwise requires:

1. *"Director"* means the director of inspections, appeals, and licensing, or the director's designee.

2. *"Facility"* means a hospital as defined in section 135B.1, an ambulatory surgical center as defined in section 135R.1, or a pregnancy resource center.

3. *"Health care professional"* means an individual licensed under chapter 148 to practice medicine and surgery or osteopathic medicine and surgery, a physician assistant licensed under chapter 148C, a podiatrist licensed under chapter 149, an advanced registered nurse practitioner licensed under chapter 152, an advanced practice registered nurse under chapter 152E, or a pharmacist licensed under chapter 155A.

4. *"Pregnancy resource center"* means a nonprofit entity that provides pregnancy support services as defined in section 217.41C.

5. *"Serious injury"* means any of the following:

a. A physical or mental impairment that substantially limits one or more of the major life activities of an individual or a loss of bodily function, if the impairment or loss lasts more than seven days or is still present at the time of discharge from an inpatient health care facility.

b. The loss of a body part.

6. *"Surgery or other invasive procedure"* includes the treatment of disease, injury, or deformity by manual or operative methods, including invasive testing.

Sec. 2. NEW SECTION. **135S.2 Facility reporting requirements.**

1. *a.* Each facility shall report to the director the occurrence of an applicable serious reportable event described in this section as soon as is reasonably and practicably possible, but no later than fifteen working days after discovery of the event.

b. The report shall be filed in a format specified by the director and shall identify the facility but shall not include any identifying information for any of the health care professionals, facility employees, or patients involved.

c. The director may consult with experts and organizations familiar with patient safety when developing the format for reporting and in further defining serious reportable events in order to be consistent with industry standards.

2. Serious reportable events under this section include all of the following:

a. Surgical events including all of the following:

(1) Surgery or other invasive procedure performed on a wrong body part that is inconsistent with the documented informed consent for that patient. Serious reportable events under this subparagraph do not include situations requiring prompt action that occur in the course of surgery or situations whose urgency precludes obtaining informed consent.

(2) Surgery or other invasive procedure performed on the wrong patient.

(3) The wrong surgery or other invasive procedure performed on a patient that is inconsistent with the documented informed consent for that patient. Serious reportable events under this subparagraph do not include situations requiring prompt action that occur in the course of surgery or situations whose urgency precludes obtaining informed consent.

(4) Retention of a foreign object in a patient after surgery or other invasive procedure, excluding objects intentionally implanted as part of a planned intervention and objects present prior to surgery that are intentionally retained.

(5) Death during or immediately after surgery or other invasive procedure 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.

b. Product or device events including all of the following:

(1) Death or serious injury of a patient 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.

(2) Death or serious injury of a patient 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.

(3) Death or serious injury of a patient 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.

c. Patient protection events including all of the following:

(1) Discharge to the wrong person of a patient of any age who does not have decision-making capacity.

(2) Death or serious injury of a patient associated with a patient disappearance, excluding events involving adults who have decision-making capacity.

(3) Suicide, attempted suicide resulting in serious injury, or self-harm of a patient resulting in serious injury or death of the patient while being cared for in a facility due to the patient's actions after admission to the facility, excluding the death of a patient resulting from self-inflicted injuries that were the reason for admission to the facility.

d. Care management events including all of the following:

(1) Death or serious injury of a patient 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.

(2) Death or serious injury of a patient associated with unsafe administration of blood or blood products.

(3) Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy while being cared for in a facility, including events that occur within forty-two calendar days postdelivery and excluding deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy, or cardiomyopathy.

(4) Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy.

(5) Stage 3 or 4 or unstageable ulcers acquired after admission to a facility, excluding progression from stage 2 to stage 3 if stage 2 was recognized upon admission.

(6) Artificial insemination with the wrong donor sperm or wrong egg.

(7) Death or serious injury of a patient associated with a fall while being cared for in a facility.

(8) The irretrievable loss of an irreplaceable biological specimen.

(9) Death or serious injury of a patient resulting from the failure to follow up or communicate laboratory, pathology, or radiology test results.

e. Environmental events including all of the following:

(1) Death or serious injury of a patient associated with an electric shock while being cared for in a facility, excluding events involving planned treatments such as electric countershock.

(2) 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.

(3) Death or serious injury of a patient associated with a burn incurred from any source while being cared for in a facility.

(4) Death or serious injury of a patient associated with the use or lack of restraints or bedrails while being cared for in

a facility.

f. Potential criminal events including all of the following:

(1) Any instance of care ordered by or provided by someone impersonating a health care professional.

(2) Abduction of a patient of any age.

(3) Sexual assault on a patient within or on the grounds of a facility.

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

g. Radiologic events including death or serious injury of a patient associated with the introduction of a metallic object into the magnetic resonance imaging.

Sec. 3. NEW SECTION. **135S.3 Root cause analysis and corrective action plan.**

1. Following the occurrence of a serious reportable event as specified under section 135S.2, a facility shall conduct a root cause analysis of the event.

2. Following the analysis, the facility shall do one of the following:

a. Implement a corrective action plan to address the findings of the analysis.

b. Report to the director any reasons for not taking corrective action.

3. If the root cause analysis and the implementation of a corrective action plan are already completed at the time an event is required to be reported, the findings of the analysis and the corrective action plan shall be included in the report of the event.

4. If the root cause analysis is completed, but implementation of a corrective action plan is not completed at the time an event is required to be reported, the findings of the root cause analysis and a copy of the proposed corrective action plan shall be filed with the director within sixty working days of the event.

Sec. 4. NEW SECTION. **135S.4 Electronic reporting.**

1. The director shall design the serious reportable event reporting system to allow a facility to file the reports required under this chapter by electronic means.

2. The director shall encourage a facility to use the electronic filing option when that option is feasible for the facility.

Sec. 5. NEW SECTION. **135S.5 Relation to other law and duties —— confidentiality of data.**

1. *a.* Serious reportable events described under section 135S.2 do not constitute child abuse as defined in section 232.68 or dependent adult abuse as defined in section 235B.2, and are excluded from the reporting requirements of chapters 232 and 235B, if the facility makes a determination within twenty-four hours of discovery of the serious reportable event that this chapter is applicable and the facility files the reports required under this chapter in a timely fashion.

b. A facility that determines a serious reportable event described in section 135S.2 has occurred shall inform persons within the facility who are mandatory reporters of child abuse under section 232.69 or dependent adult abuse under section 235B.3. A mandatory reporter otherwise required to report child abuse or dependent adult abuse is relieved of the duty to report an event the facility determines to be reportable under section 135S.2.

c. The protections and immunities applicable to reporting of child abuse under section 232.73 and dependent adult abuse under section 232.68 are not affected by this section.

2. *a.* If a serious reportable event is reported by a facility in compliance with this chapter, no other state agency or licensing board is required to conduct an investigation of or obtain or create investigative data based upon other reports of the same event.

b. If a facility is required to report a serious reportable event pursuant to another state law that meets the requirements

for compliance with this chapter, the department shall recognize the report as compliance with this chapter in lieu of a report made under this chapter if the department is provided a copy of the report.

3. *a.* Data contained in the following records are confidential records under section 22.7:

(1) Reports of serious reportable events made to the director by a professional licensing board.

(2) Serious reportable event reports, findings of root cause analyses, and corrective action plans filed by a facility under this chapter.

(3) Records created or obtained by the director in reviewing or investigating the reports, findings, and corrective action plans under subparagraph (2).

b. For purposes of this subsection, the reporting facility is the subject of the report or data under chapter 22.

Sec. 6. NEW SECTION. **135S.6 Director duties and responsibilities —— penalties.**

1. The director shall establish a serious reportable event reporting system designed to facilitate quality improvement in the health care system. The reporting system shall not be designed to punish errors by health care professionals or facility employees.

2. The reporting system shall require and consist of all of the following:

a. Mandatory reporting by facilities of the applicable serious reportable events described in section 135S.2.

b. Mandatory completion of a root cause analysis and a corrective action plan by the facility, and the reporting of the findings of the analysis and the plan to the director, or the reporting of reasons for not taking corrective action.

c. Analysis of reported information by the director to determine patterns of systemic failure in the health care system and successful methods to correct the failures.

d. Sanctions against facilities for failure to comply with

reporting system requirements.

e. Communication from the director to facilities, health care consumers, and the public to maximize the use of the reporting system to improve health care quality.

3. In establishing the serious reportable event reporting system, the director shall not select from or between alternate acceptable medical practices.

4. The director shall do all of the following:

a. Analyze serious reportable event reports, corrective action plans, and findings of the root cause analyses to determine patterns of systemic failure in the health care system and successful methods to correct these failures.

b. Communicate to individual facilities the director's conclusions, if any, regarding a serious reportable event reported by a facility.

c. Communicate with relevant health care facilities any recommendations for corrective action resulting from the director's analysis of submissions from facilities.

d. Publish an annual report, available on the internet site of the department of inspections, appeals, and licensing, that does all of the following:

(1) Describes, by facility type, serious reportable events reported by facilities.

(2) Outlines, in aggregate, the findings of root cause analyses and corrective action plans.

(3) Makes recommendations for modifications of state health care operations.

5. *a.* The director shall take steps necessary to determine if required serious reportable event reports, the findings of the root cause analyses, and corrective action plans are filed in a timely manner.

b. The director may do any of the following:

(1) Sanction a facility for failure to file a timely serious reportable event report, conduct a root cause analysis, implement a corrective action plan, or provide the findings of

a root cause analysis or corrective action plan in a timely fashion.

(2) Place conditions on the license under which a facility operates if the facility fails to develop and implement a corrective action plan, or report to the director the reason a corrective action is not needed.

6. The director may collaborate with the department of health and human services to administer this section.

Sec. 7. NEW SECTION. **135S.7 Reports from licensing boards.**

1. The board of medicine, the board of physician assistants, the board of nursing, the board of pharmacy, and the board of podiatry shall maintain a record of all complaints that come to the attention of the respective board that in the judgment of the board qualify as a serious reportable event under section 135S.2. Within thirty working days of making a determination that an event qualifies as a serious reportable event, the respective board shall forward a report of the event to the director, including the name and address of the facility involved, the date of the event, and information known to the board regarding the event. The report shall not include any identifying information of any health care professional, facility employee, or patients involved.

2. The director shall forward a report received under subsection 1 to the facility named in the report.

3. *a.* The facility shall determine whether the event has been previously reported under this chapter, and shall notify the director as to whether the event has been previously reported.

b. If the event has not been previously reported, the facility shall make a determination whether the event is reportable under this chapter. If the facility determines the event is reportable, the date of discovery of the event for purposes of this chapter shall be as follows:

(1) If the director determines the facility knew or reasonably should have known about the occurrence of the event,

the date the event occurred shall be the date of discovery of the event and the facility shall be considered out of compliance with this chapter.

(2) If the director determines the facility did not know about the occurrence of the event, the date the facility receives the report from the director shall be the date of discovery of the event.

c. If the facility determines the event was not reportable under this chapter, the facility shall notify the director of that determination.

Sec. 8. NEW SECTION. **135S.8 Interstate coordination and reports.**

1. The director shall report the list of serious reportable events described under section 135S.2 to the national quality forum, and through the national quality forum to other states.

2. The director shall monitor communications by the national quality forum of amendments to the list of serious reportable events maintained by the forum and shall report any modification to the list to the general assembly.

3. The director shall also monitor efforts in other states to establish a list of serious reportable events and shall make recommendations to the general assembly as necessary for modifications to the list of serious reportable events under this chapter to maximize uniformity with the list maintained by the national quality forum and by other states.

EXPLANATION

The inclusion of this explanation does not constitute agreement with the explanation's substance by the members of the general assembly.

This bill relates to the reporting of serious reportable events by facilities including hospitals, ambulatory surgical centers, and pregnancy resource centers.

The bill provides definitions used in the bill.

The bill requires each facility to report to the director (director) of the department of inspections, appeals, and licensing (DIAL) the occurrence of an applicable serious

reportable event described in the bill as soon as is reasonably and practicably possible, but no later than 15 working days after discovery of the event. Reports shall be filed in a format specified by the director of DIAL 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 director may consult with experts and organizations familiar with patient safety when developing the format for reporting and in further defining serious reportable events in order to be consistent with industry standards.

Serious reportable events under the bill include surgical events, product or device events, patient protection events, care management events, environmental events, potential criminal events, and radiologic events detailed in the bill.

The bill requires that following the occurrence of a serious reportable event, a facility shall conduct a root cause analysis of the event, and following the analysis shall either implement a corrective action plan to address the findings of the analysis or report to the director any reasons for not taking corrective action. If the root cause analysis and the implementation of a corrective action plan are already completed at the time an event is required to be reported, the findings of the analysis and the corrective action plan shall be included in the report of the event. If the root cause analysis is completed but the implementation of a corrective action plan is not completed at the time an event is required to be reported, the findings of the root cause analysis and a copy of the proposed corrective action plan shall be filed with the director within 60 days of the event.

The director shall design the serious reportable event reporting system to allow a facility to file the required reports by electronic means and shall encourage a facility to use the electronic filing option when that option is feasible for the facility.

The bill provides that serious reportable events under the bill do not constitute child abuse or dependent adult abuse and are excluded from the child abuse and dependent adult abuse reporting requirements, if the facility makes a determination within 24 hours of discovery of the serious reportable event that the provisions of the bill apply and the facility files the reports required under the bill in a timely fashion.

A facility that determines a serious reportable event has occurred must inform persons within the facility who are mandatory reporters of child abuse or dependent adult abuse. A mandatory reporter otherwise required to report child abuse or dependent adult abuse is relieved of the duty to report an event the facility determines to be a serious reportable event under the bill. The bill does not affect the protections and immunities applicable to reporting of child abuse and dependent adult abuse.

Additionally, if a serious reportable event is reported by a facility in compliance with the bill, no other state agency or licensing board is required to conduct an investigation of or obtain or create investigative data based upon other reports of the same event. Also, if a facility is required to report a serious reportable event pursuant to another state law that meets the requirements for compliance with the bill, DIAL shall recognize the report as compliance with the bill in lieu of a report made under the bill if DIAL is provided a copy of the report.

Reports of serious reportable events made to the director by a professional licensing board; serious reportable event reports, findings of root cause analyses, and corrective action plans filed by a facility under the bill; and records created or obtained by the director in reviewing or investigating the reports, findings, and corrective action plans are confidential records under Code section 22.7.

The director shall establish a serious reportable event reporting system requiring and consisting of mandatory

reporting by facilities of the serious reportable events described in the bill; mandatory completion of a root cause analysis and a corrective action plan by the facility, and the reporting of the findings of the analysis and the plan to the director or the reporting of reasons for not taking corrective action; analysis of reported information by the director to determine patterns of systemic failure in the health care system and successful methods to correct these failures; sanctions against facilities for failure to comply with reporting system requirements; and communication from the director to facilities, health care consumers, and the public to maximize the use of the reporting system to improve health care quality.

The director shall analyze serious reportable event reports, corrective action plans, and findings of the root cause analyses to determine patterns of systemic failure in the health care system and successful methods to correct these failures; communicate to facilities the director's conclusions regarding a serious reportable event reported by a facility; communicate with relevant health care facilities any recommendations for corrective action resulting from the director's analysis of submissions from facilities; and publish an annual report. The director shall take steps necessary to determine if serious reportable event reports, the findings of the root cause analyses, and corrective action plans are filed in a timely manner. The director may sanction a facility for failure to file a timely serious reportable event report, conduct a root cause analysis, implement a corrective action plan, or provide the findings of a root cause analysis or corrective action plan in a timely fashion; or place conditions on the license under which a facility operates if the facility fails to develop and implement a corrective action plan or report to the director the reason a corrective action is not needed.

The director may collaborate with the department of health

and human services to administer the director's duties and responsibilities.

The bill requires the boards of medicine, physician assistants, nursing, pharmacy, and podiatry to maintain a record of complaints that come to the attention of the respective board, that in the judgment of the board qualify as serious reportable events. Within 30 working days of making a determination that an event qualifies as a serious reportable event, the respective board shall forward a report of the event to the director, including the name and address of the facility involved, the date of the event, and information known to the board regarding the event. The report shall not include any identifying information of any health care professional, facility employee, or patients involved. The director shall then forward the report to the facility named in the report and the facility shall determine whether the event has been previously reported and shall notify the director as to whether the event has been previously reported. If the event has not been previously reported, the facility shall make a determination whether the event is reportable and if it is reportable, the date of discovery of the event, depending on the circumstances, is either the date of discovery or the date the facility receives the report from the director. If the facility determines that the event is not reportable under this Code chapter, the facility shall notify the director of that determination.

The bill requires the director to report the list of serious reportable events under the bill to the national quality forum and through the national quality forum to other states. The director shall monitor amendments to the national quality forum's list of serious reportable events and report any modification to the list to the general assembly. The director shall also monitor efforts in other states to establish a list of serious reportable events and shall make recommendations to the general assembly, as necessary, for modifications to the

list under the bill to maximize uniformity with the national list and the lists of other states.