Senate File 581 - Introduced

SENATE FILE 581
BY COMMITTEE ON HEALTH AND HUMAN SERVICES

(SUCCESSOR TO SF 48)

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. *"Department"* means the department of inspections, appeals, and licensing.

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

3. *"Facility"* means a hospital as defined in section 135B.1, an ambulatory surgical center as defined in section 135R.1, or a birth center as defined in section 10A.711.

4. *"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.

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. *"Serious reportable event"* or *"event"* means an event on the list of serious reportable events endorsed by the national quality forum.

7. *"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. Each facility shall report to the director the occurrence of a serious reportable event as soon as is reasonably and practicably possible, but no later than fifteen working days

after discovery of the event.

2. 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.

3. 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.

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

1. Following the occurrence of a serious reportable event, 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. Upon the occurrence of a serious reportable event, if prior to or during a root cause analysis of the serious reportable event a facility determines the serious reportable event may constitute child abuse or dependent adult abuse, the facility 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.

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. This paragraph does not preclude the department from requiring additional reports as deemed necessary by the department.

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 serious reportable events.

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 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. 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.

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 birth centers.

The bill requires each facility to report to the director (director) of the department of inspections, appeals, and

licensing (DIAL) the occurrence of a serious reportable event 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 bill requires that following the occurrence of a serious reportable event, a facility shall conduct a root cause analysis of the event and shall either implement a corrective action plan or report to the director any reasons for not taking corrective action.

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.

Upon the occurrence of a serious reportable event, if prior to or during a root cause analysis the facility determines the serious reportable event may constitute child abuse or dependent adult abuse, the facility shall inform persons within the facility who are mandatory reporters of child abuse and dependent adult abuse.

Additionally, if a serious reportable event is reported by a facility, 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. DIAL is not precluded from requiring additional reports as deemed necessary by DIAL. 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 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 certain information as detailed in the bill.

The director shall take action relating to serious reportable events as described in the bill.

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 and are determined to 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. 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 detailed in the bill.