

Senate File 48 - Introduced

SENATE FILE 48

BY LOFGREN, SALMON, SHIPLEY,
ALONS, KRAAYENBRINK, ROWLEY,
EVANS, TAYLOR, GRUENHAGEN,
CAMPBELL, and KLIMESH

A BILL FOR

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

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

unofficial

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

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

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

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

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

11 4. "*Health care professional*" means an individual licensed
12 under chapter 148 to practice medicine and surgery or osteopathic
13 medicine and surgery, a physician assistant licensed under
14 chapter 148C, a podiatrist licensed under chapter 149, an
15 advanced registered nurse practitioner licensed under chapter
16 152, an advanced practice registered nurse under chapter 152E, or
17 a pharmacist licensed under chapter 155A.

18 5. "*Pregnancy resource center*" means a nonprofit entity
19 that provides pregnancy support services as defined in section
20 217.41C.

21 6. "*Serious injury*" means any of the following:

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

27 b. The loss of a body part.

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

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

33 1. a. Each facility shall report to the director the
34 occurrence of an applicable serious reportable event described in
35 this section as soon as is reasonably and practicably possible,

1 but no later than fifteen working days after discovery of the
2 event.

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

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

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

13 a. Surgical events including all of the following:

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

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

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

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

32 (5) Death during or immediately after surgery or other
33 invasive procedure of a normal, healthy patient who has no
34 organic, physiologic, biochemical, or psychiatric disturbance and
35 for whom the pathologic processes for which the operation is

1 to be performed are localized and do not entail a systemic
2 disturbance.

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

4 (1) Death or serious injury of a patient associated with
5 the use of contaminated drugs, devices, or biologics provided
6 by the facility when the contamination is the result of
7 generally detectable contaminants in drugs, devices, or biologics
8 regardless of the source of the contamination or the product.

9 (2) Death or serious injury of a patient associated with the
10 use or function of a device in patient care in which the device
11 is used or functions other than as intended. "Device" includes
12 but is not limited to catheters, drains, and other specialized
13 tubes, infusion pumps, and ventilators.

14 (3) Death or serious injury of a patient associated with
15 intravascular air embolism that occurs while being cared for
16 in a facility, excluding deaths associated with neurosurgical
17 procedures known to present a high risk of intravascular air
18 embolism.

19 c. Patient protection events including all of the following:

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

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

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

31 d. Care management events including all of the following:

32 (1) Death or serious injury of a patient associated with a
33 medication error including but not limited to errors involving
34 the wrong drug, the wrong dose, the wrong patient, the wrong
35 time, the wrong rate, the wrong preparation, or the wrong route

1 of administration, excluding reasonable differences in clinical
2 judgment on drug selection and dose.

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

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

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

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

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

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

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

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

25 e. Environmental events including all of the following:

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

30 (2) Any incident in which a line designated for oxygen or
31 other gas to be delivered to a patient contains the wrong gas or
32 is contaminated by toxic substances.

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

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

4 f. Potential criminal events including all of the following:

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

7 (2) Abduction of a patient of any age.

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

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

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

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

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

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

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

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

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

32 4. If the root cause analysis is completed, but
33 implementation of a corrective action plan is not completed at
34 the time an event is required to be reported, the findings of the
35 root cause analysis and a copy of the proposed corrective action

1 plan shall be filed with the director within sixty working days
2 of the event.

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

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

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

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

12 1. a. Serious reportable events described under section
13 135S.2 do not constitute child abuse as defined in section 232.68
14 or dependent adult abuse as defined in section 235B.2, and are
15 excluded from the reporting requirements of chapters 232 and
16 235B, if the facility makes a determination within twenty-four
17 hours of discovery of the serious reportable event that this
18 chapter is applicable and the facility files the reports required
19 under this chapter in a timely fashion.

20 b. A facility that determines a serious reportable event
21 described in section 135S.2 has occurred shall inform persons
22 within the facility who are mandatory reporters of child abuse
23 under section 232.69 or dependent adult abuse under section
24 235B.3. A mandatory reporter otherwise required to report child
25 abuse or dependent adult abuse is relieved of the duty to report
26 an event the facility determines to be reportable under section
27 135S.2.

28 c. The protections and immunities applicable to reporting of
29 child abuse under section 232.73 and dependent adult abuse under
30 section 235B.3 are not affected by this section.

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

1 b. If a facility is required to report a serious reportable
2 event pursuant to another state law that meets the requirements
3 for compliance with this chapter, the department shall recognize
4 the report as compliance with this chapter in lieu of a report
5 made under this chapter if the department is provided a copy of
6 the report.

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

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

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

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

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

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

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

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

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

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

34 c. Analysis of reported information by the director to
35 determine patterns of systemic failure in the health care system

1 and successful methods to correct the failures.

2 d. Sanctions against facilities for failure to comply with
3 reporting system requirements.

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

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

10 4. The director shall do all of the following:

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

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

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

21 d. Publish an annual report, available on the internet site
22 of the department that does all of the following:

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

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

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

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

33 b. The director may do any of the following:

34 (1) Sanction a facility for failure to file a timely serious
35 reportable event report, conduct a root cause analysis, implement

1 a corrective action plan, or provide the findings of a root cause
2 analysis or corrective action plan in a timely fashion.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

26 EXPLANATION

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

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

32 The bill requires each facility to report to the director
33 (director) of the department of inspections, appeals, and
34 licensing (DIAL) the occurrence of an applicable serious
35 reportable event described in the bill as soon as is reasonably

1 and practicably possible, but no later than 15 working days after
2 discovery of the event. Reports shall be filed in a format
3 specified by the director of DIAL and shall identify the facility
4 but shall not include any identifying information for any of
5 the health care professionals, facility employees, or patients
6 involved.

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

11 The bill requires that following the occurrence of a serious
12 reportable event, a facility shall conduct a root cause analysis
13 of the event and shall either implement a corrective action plan
14 or report to the director any reasons for not taking corrective
15 action.

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

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

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

35 Additionally, if a serious reportable event is reported by a

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

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

16 The director shall establish a serious reportable event
17 reporting system requiring certain information as detailed in the
18 bill.

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

21 The director may collaborate with the department of health
22 and human services to administer the director's duties and
23 responsibilities.

24 The bill requires the boards of medicine, physician
25 assistants, nursing, pharmacy, and podiatry to maintain a record
26 of complaints that come to the attention of the respective board
27 and are determined to qualify as serious reportable events.
28 Within 30 working days of making a determination that an event
29 qualifies as a serious reportable event, the respective board
30 shall forward a report of the event to the director. The
31 director shall then forward the report to the facility named in
32 the report and the facility shall determine whether the event has
33 been previously reported and shall notify the director.

34 The bill requires the director to report the list of serious
35 reportable events to the national quality forum. The director

1 shall monitor amendments to the national quality forum's list of
2 serious reportable events, monitor efforts in other states, and
3 report any modification to the list to the general assembly.

unofficial