

**Senate File 2038 - Introduced**

SENATE FILE 2038  
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**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:

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

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

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

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

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

16 4. "*Pregnancy resource center*" means a nonprofit entity  
17 that provides pregnancy support services as defined in section  
18 217.41C.

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

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

25 b. The loss of a body part.

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

29 Sec. 2. NEW SECTION. 135S.2 Facility reporting  
30 requirements.

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

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

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

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

11     *a.* Surgical events including all of the following:

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

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

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

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

30       (5) Death during or immediately after surgery or other  
31 invasive procedure of a normal, healthy patient who has no  
32 organic, physiologic, biochemical, or psychiatric disturbance  
33 and for whom the pathologic processes for which the operation  
34 is to be performed are localized and do not entail a systemic  
35 disturbance.

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

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

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

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

17     *c.* Patient protection events including all of the following:

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

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

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

29     *d.* Care management events including all of the following:

30       (1) Death or serious injury of a patient associated with a  
31 medication error including but not limited to errors involving  
32 the wrong drug, the wrong dose, the wrong patient, the wrong  
33 time, the wrong rate, the wrong preparation, or the wrong route  
34 of administration, excluding reasonable differences in clinical  
35 judgment on drug selection and dose.

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

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

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

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

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

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

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

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

23 e. Environmental events including all of the following:

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

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

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

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

1 a facility.

2 *f.* Potential criminal events including all of the following:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

10    1. *a.* Serious reportable events described under section  
11 135S.2 do not constitute child abuse as defined in section  
12 232.68 or dependent adult abuse as defined in section 235B.2,  
13 and are excluded from the reporting requirements of chapters  
14 232 and 235B, if the facility makes a determination within  
15 twenty-four hours of discovery of the serious reportable event  
16 that this chapter is applicable and the facility files the  
17 reports required under this chapter in a timely fashion.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

35 *d.* Sanctions against facilities for failure to comply with



1 reporting system requirements.

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

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

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

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

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

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

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

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

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

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

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

32 *b.* The director may do any of the following:

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

1 a root cause analysis or corrective action plan in a timely  
2 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  
8 health and human services to administer this section.

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

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

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

25 3. a. The facility shall determine whether the event  
26 has been previously reported under this chapter, and shall  
27 notify the director as to whether the event has been previously  
28 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  
2 of the event and the facility shall be considered out of  
3 compliance with this chapter.

4 (2) If the director determines the facility did not know  
5 about the occurrence of the event, the date the facility  
6 receives the report from the director shall be the date of  
7 discovery of 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  
17 national quality forum of amendments to the list of serious  
18 reportable events maintained by the forum and shall report any  
19 modification 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  
24 this chapter to maximize uniformity with the list maintained by  
25 the 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 provides definitions used in the bill.

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

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

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

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

16 The bill requires that following the occurrence of a serious  
17 reportable event, a facility shall conduct a root cause  
18 analysis of the event, and following the analysis shall either  
19 implement a corrective action plan to address the findings of  
20 the analysis or report to the director any reasons for not  
21 taking corrective action. If the root cause analysis and  
22 the implementation of a corrective action plan are already  
23 completed at the time an event is required to be reported, the  
24 findings of the analysis and the corrective action plan shall  
25 be included in the report of the event. If the root cause  
26 analysis is completed but the implementation of a corrective  
27 action plan is not completed at the time an event is required  
28 to be reported, the findings of the root cause analysis and a  
29 copy of the proposed corrective action plan shall be filed with  
30 the director within 60 days of the event.

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

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

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

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

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

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

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

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

35 The director may collaborate with the department of health

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

3 The bill requires the boards of medicine, physician  
4 assistants, nursing, pharmacy, and podiatry to maintain  
5 a record of complaints that come to the attention of the  
6 respective board, that in the judgment of the board qualify as  
7 serious reportable events. Within 30 working days of making a  
8 determination that an event qualifies as a serious reportable  
9 event, the respective board shall forward a report of the  
10 event to the director, including the name and address of the  
11 facility involved, the date of the event, and information  
12 known to the board regarding the event. The report shall  
13 not include any identifying information of any health care  
14 professional, facility employee, or patients involved. The  
15 director shall then forward the report to the facility named in  
16 the report and the facility shall determine whether the event  
17 has been previously reported and shall notify the director as  
18 to whether the event has been previously reported. If the  
19 event has not been previously reported, the facility shall make  
20 a determination whether the event is reportable and if it is  
21 reportable, the date of discovery of the event, depending on  
22 the circumstances, is either the date of discovery or the date  
23 the facility receives the report from the director. If the  
24 facility determines that the event is not reportable under this  
25 Code chapter, the facility shall notify the director of that  
26 determination.

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

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