

SECOND REGULAR SESSION

# SENATE BILL NO. 494

96TH GENERAL ASSEMBLY

INTRODUCED BY SENATOR WRIGHT-JONES.

Pre-filed December 1, 2011, and ordered printed.

TERRY L. SPIELER, Secretary.

4416S.011

## AN ACT

To amend chapter 192, RSMo, by adding thereto eleven new sections relating to reporting of medical harm events, with penalty provisions.

*Be it enacted by the General Assembly of the State of Missouri, as follows:*

Section A. Chapter 192, RSMo, is amended by adding thereto eleven new sections, to be known as sections 192.1300, 192.1303, 192.1306, 192.1309, 192.1312, 192.1315, 192.1318, 192.1321, 192.1324, 192.1327, and 192.1333, to read as follows:

**192.1300. Sections 192.1300 to 192.1333 may be cited as the "Medical Harm Disclosure Act". For purposes of sections 192.1300 to 192.1333, the following terms shall mean:**

(1) "Department", the department of health and senior services;

(2) "Health care facility", hospitals as defined in section 197.020 and long-term care facilities licensed under chapter 198;

(3) "Medical harm event", harm to a patient as a result of medical care or in a health care setting. It may include, but should not be limited to, the National Quality Forum's List of Serious Reportable Events, and should include the following categories of events:

(a) Surgical and related anesthesia events including unexpected complications and deaths, surgery performed on a wrong body part, surgery performed on the wrong patient, the wrong surgical procedure performed on a patient, and retention of a foreign object in a patient after surgery or other procedure, excluding objects intentionally implanted as part of a planned intervention and objects present prior to surgery that are intentionally retained;

(b) Medication events related to professional practice, or health care products, procedures, and systems, including, but not limited to,

20 prescribing, prescription order communications, product labeling,  
21 packaging and nomenclature, compounding, dispensing, distribution,  
22 administration, education, monitoring, and use;

23 (c) Product or device events related to the use or function of a  
24 device in patient care in which the device is used or functions other  
25 than as intended, including, but not limited to, catheters, infusion  
26 pumps, or ventilators;

27 (d) Care management events including, but not limited to, stage  
28 3 or 4 pressure ulcers acquired after admission to a health facility,  
29 failure to rescue, intravenous injuries, and maternal death or serious  
30 disability associated with labor or delivery, including events that occur  
31 within forty-two days post-delivery;

32 (e) Environmental deaths including, but not limited to,  
33 unintended electric shock, delivery of the wrong gas or contaminated  
34 toxic substance, burns incurred from any source, patient falls, and  
35 harm associated with the use of restraints or bed rails; and

36 (f) Death of a previously healthy person while undergoing  
37 medical care.

192.1303. 1. A health care facility shall report a medical harm  
2 event to the department not later than five days after the event has  
3 been detected, or, if that event is an ongoing urgent or emergent threat  
4 to the welfare, health, or safety of patients, personnel, or visitors, not  
5 later than twenty-four hours after the adverse event has been  
6 detected. The reports shall be made on a form prescribed by the  
7 department.

8 2. The report shall indicate the level of medical harm to the  
9 patient, such as whether it resulted in serious injury or death, using  
10 the format developed by the department.

11 3. On a quarterly basis, each health care facility that has had no  
12 medical harm events to report during that quarter shall affirmatively  
13 declare this fact to the department, using a form developed by the  
14 department.

15 4. Each health care facility shall create facility-wide patient  
16 safety programs to routinely review patient records for medical harm,  
17 analyze these events to determine if they were preventable and  
18 implement changes to prevent similar harmful events. Each health care  
19 facility shall provide an annual summary of its patient safety program

20 to the department.

21           5. Each health care facility shall inform the patient, the party  
22 responsible for the patient, or an adult member of the immediate family  
23 in cases of death or serious bodily injury, of the medical harm event by  
24 the time the report is made to the department.

25           6. Each health care facility shall interview patients, family  
26 members, and parties responsible for the patient about medical harm  
27 events and document a detailed summary of that interview in the  
28 patient's medical record.

29           7. If the medical harm event contributed to the death of a  
30 patient, the physician or authorized person under subsection 4 of  
31 section 193.145, shall include that event as a contributing cause on the  
32 patient's death certificate.

33           8. If the health care facility is a division or subsidiary of another  
34 entity that owns or operates multiple hospitals, long-term care  
35 facilities, or related organizations, a report shall be made for the each  
36 specific division or subsidiary and not aggregately for multiple health  
37 care facilities or related organizations.

38           9. Nothing in this section shall be interpreted to change or  
39 otherwise affect reporting requirements regarding reportable diseases  
40 or unusual occurrences, as provided by law in chapters 191, 192, 197  
41 and 198.

          192.1306. 1. There is hereby established within the department  
2 a "Medical Harm Reporting Advisory Committee". The director of the  
3 department shall appoint the members, including representatives from  
4 public and private health care facilities, direct care nursing staff,  
5 physicians, epidemiologists with expertise in patient safety, academic  
6 researchers, consumer organizations, health insurers, health  
7 maintenance organizations, organized labor, and purchasers of health  
8 insurance, such as employers. The advisory committee shall have a  
9 majority of members representing interests other than those of health  
10 care facilities.

11           2. The advisory committee shall assist the department in the  
12 development of all aspects of the department's methodology for  
13 collecting, analyzing, and disclosing the information collected under  
14 sections 192.1300 to 192.1333, including collection methods, formatting,  
15 evaluation of methods used and the methods and means for release and

16 dissemination.

17           3. Members shall serve on the committee without compensation  
18 but may be reimbursed for their actual and necessary expenses from  
19 moneys appropriated to the department for that purpose. Meetings of  
20 the advisory committee shall be open to the public under chapter 610.

          192.1309. 1. The department shall, with the advice of the  
2 advisory committee created in section 192.1306, develop guidelines for  
3 health care facilities in identifying medical harm events.

4           2. The department shall create standardized reporting formats  
5 for health care facilities to use to comply with all provisions of sections  
6 192.1300 to 192.1333.

7           3. In developing the methodology for collecting the data on  
8 medical harm events, the department and advisory committee shall use  
9 the forms developed by the Agency for Healthcare Research and  
10 Quality as "Common Formats", or a similar standardized collection  
11 method.

12           4. In developing the methodology for analyzing the data, the  
13 department shall include a standardized method of categorizing the  
14 level of harm experienced by the patient, such as the National  
15 Coordinating Council for Medication Errors Reporting and Prevention  
16 (NCCMERP) Index for Categorizing Errors.

17           5. The department shall at least quarterly check the accuracy of  
18 information reported by health care facilities under sections 192.1300  
19 to 192.1333 by comparing the information with other available data  
20 such as patient safety indicators from hospital patient discharge data,  
21 complaints filed with the licensing division, death certificates,  
22 inspection and survey reports, and medical malpractice  
23 information. The department shall annually conduct random reviews  
24 of health care facility medical records.

25           6. The data collection, analysis and validation methodologies  
26 shall be disclosed to the public.

27           7. Every three years, the department shall have an independent  
28 audit conducted by a state university not affiliated with any health  
29 care facility required to report under sections 192.1300 to 192.1333. The  
30 audit shall:

31           (1) Assess the accuracy of reporting by health care facilities,  
32 especially seeking to identify underreporting;

33           **(2) Be funded by the patient safety trust fund created in section**  
34 **192.1321; and**

35           **(3) Be available to the public on the department's website within**  
36 **one month of receiving the final report.**

37           **8. The department may promulgate rules to implement the**  
38 **provisions of sections 192.1300 to 192.1333. Any rule or portion of a**  
39 **rule, as that term is defined in section 536.010, that is created under**  
40 **the authority delegated in this section shall become effective only if it**  
41 **complies with and is subject to all of the provisions of chapter 536 and,**  
42 **if applicable, section 536.028. This section and chapter 536 are**  
43 **nonseverable and if any of the powers vested with the general assembly**  
44 **pursuant to chapter 536 to review, to delay the effective date, or to**  
45 **disapprove and annul a rule are subsequently held unconstitutional,**  
46 **then the grant of rulemaking authority and any rule proposed or**  
47 **adopted after August 28, 2012, shall be invalid and void.**

**192.1312. 1. Each quarter, the department shall publish details**  
2 **of the fines assessed to health care facilities for failure to report**  
3 **medical harm events under section 192.1324, and shall issue a news**  
4 **release about that publication.**

5           **2. The department shall annually submit a report to the general**  
6 **assembly detailing medical harm events reported at each health care**  
7 **facility required to report under sections 192.1300 to 192.1333. The**  
8 **report may include policy recommendations, as appropriate. The**  
9 **report shall:**

10           **(1) Be published on the department's website at the same time**  
11 **it is submitted to the general assembly;**

12           **(2) Include health care facility-specific information on the**  
13 **number and type of medical harm events reported, the level of harm to**  
14 **patients, fines assessed and enforcement actions taken, and the**  
15 **quarterly affirmation by health care facilities in which no medical**  
16 **harm events have occurred;**

17           **(3) Provide information in a manner that stratifies the data**  
18 **based on characteristics of the health care facilities, such as number of**  
19 **patient admissions and patient days in each health care facility; and**

20           **(4) Contain text written in plain language that includes a**  
21 **discussion of findings, conclusions, and trends concerning the overall**  
22 **patient safety in the state, including a comparison to prior years, and**

23 the methods the department used to check for the accuracy of health  
24 care facility reports.

25 3. Each quarter, the department shall make information  
26 regarding outcomes of inspections and investigations conducted  
27 pursuant to its hospital and long-term care facility regulatory duties  
28 under chapters 197 and 198, readily accessible to the public on the  
29 department website.

30 4. No health care facility report or department public disclosure  
31 may contain information identifying a patient, employee, or licensed  
32 health care professional in connection with a specific infection  
33 incident.

34 5. The first report required under subsection 2 of this section  
35 shall be submitted and published no later than December 31,  
36 2013. Following the initial report, the department shall publish these  
37 reports annually.

192.1315. It is the expressed intent of the general assembly that  
2 a patient's right of confidentiality shall not be violated in any  
3 manner. Patient social security numbers or any other information that  
4 could be used to identify an individual patient shall not be released  
5 notwithstanding any other provision of law.

192.1318. No health care facility shall discharge, refuse to hire,  
2 refuse to serve, retaliate in any manner, or take any adverse action  
3 against any employee, applicant for employment, or health care facility  
4 because such employee, applicant for employment, or health care  
5 facility takes or has taken any action in furtherance of the enforcement  
6 of the provisions of sections 192.1300 to 192.1333.

7 192.1321. 1. There is hereby created in the state treasury the  
8 "Patient Safety Trust Fund" which shall consist of all gifts, donations,  
9 transfers, and moneys appropriated by the general assembly, and  
10 bequests to the fund. The fund shall be administered by the  
11 department of health and senior services.

12 2. Moneys in the fund shall also come from the annual patient  
13 safety surcharge assessed under section 192.1333.

14 3. The state treasurer shall be custodian of the fund and may  
15 approve disbursements from the fund in accordance with sections  
16 30.170 and 30.180. Notwithstanding the provisions of section 33.080, to  
17 the contrary, any moneys remaining in the fund at the end of the

18 biennium shall not revert to the credit of the general revenue  
19 fund. The state treasurer shall invest moneys in the fund in the same  
20 manner as other funds are invested. Any interest and moneys earned  
21 on such investments shall be credited to the fund.

22 4. Upon appropriation, moneys from the fund shall be used for  
23 regulatory oversight and public accountability for safe health care,  
24 including the audit specified under section 192.1309.

192.1324. 1. In any case in which the department receives a  
2 report from a health care facility under section 192.1303 that indicates  
3 an ongoing threat or imminent danger of death or serious bodily harm,  
4 the department shall make an onsite inspection or investigation within  
5 forty-eight hours or two business days, whichever is greater, of the  
6 receipt of the report and shall complete that investigation within forty-  
7 five days.

8 2. If a health care facility fails to report a medical harm event  
9 under section 192.1303, the department may assess the licensee a civil  
10 penalty in an amount not to exceed one hundred dollars for each day  
11 that the adverse event is not reported following the initial five-day  
12 period or twenty-four-hour period, as applicable. If the licensee  
13 disputes a determination by the department regarding alleged failure  
14 to report an adverse event, the licensee may, within ten days, request  
15 an administrative hearing before the department under chapter  
16 536. Penalties shall be paid when appeals pursuant to those provisions  
17 have been exhausted.

18 3. The department shall be responsible for ensuring compliance  
19 with sections 192.1300 to 192.1333 as a condition of licensure under  
20 sections 197.010 to 197.120 and chapter 198, and shall enforce such  
21 compliance according to the provisions of sections 197.010 to 197.120  
22 and chapter 198.

192.1327. The department shall promote public awareness  
2 regarding where and how consumers can file complaints about health  
3 care facilities, including a requirement that information about filing  
4 complaints be posted in a visible manner:

- 5 (1) On the department licensing website;
- 6 (2) On each health care facility's website;
- 7 (3) In public areas in health care facilities; and
- 8 (4) On all health care facility correspondence and billing

9 documents.

192.1333. Beginning December 1, 2012, the department shall  
2 assess an annual patient safety surcharge on licensing fees for those  
3 health care facilities required to report under sections 192.1300 to  
4 192.1333. The amount shall be determined by the department and  
5 promulgated by rule.

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