FIRST REGULAR SESSION

SENATE BILL NO. 346

96TH GENERAL ASSEMBLY

INTRODUCED BY SENATOR WRIGHT-JONES.

Read 1st time February 24, 2011, and ordered printed.

TERRY L. SPIELER, Secretary.

1264S.02I

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,

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

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

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

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

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

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

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

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

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

to the department.

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

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

7. If the medical harm event contributed to the death of a patient, the health care facility shall include that event as a contributing cause on the patient's death certificate.

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

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

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

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

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

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

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

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

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

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

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

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

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

(2) Be funded by the patient safety trust fund created in section

192.1321; and

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

8. The department may promulgate rules to implement the provisions of sections 192.1300 to 192.1333. Any rule or portion of a rule, as that term is defined in section 536.010, that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536 and, if applicable, section 536.028. This section and chapter 536 are nonseverable and if any of the powers vested with the general assembly pursuant to chapter 536 to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2011, shall be invalid and void.

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

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

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

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

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

(4) Contain text written in plain language that includes a discussion of findings, conclusions, and trends concerning the overall patient safety in the state, including a comparison to prior years, and the methods the department used to check for the accuracy of health

care facility reports.

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

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

5. The first report required under subsection 2 of this section shall be submitted and published no later than December 31, 2012. Following the initial report, the department shall publish these reports annually.

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

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

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

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

3. The state treasurer shall be custodian of the fund and may approve disbursements from the fund in accordance with sections 30.170 and 30.180. Notwithstanding the provisions of section 33.080, to the contrary, any moneys remaining in the fund at the end of the biennium shall not revert to the credit of the general revenue

fund. The state treasurer shall invest moneys in the fund in the same manner as other funds are invested. Any interest and moneys earned on such investments shall be credited to the fund.

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

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

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

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

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

(1) On the department licensing website;

(2) On each health care facility's website;

(3) In public areas in health care facilities; and

(4) On all health care facility correspondence and billing documents.

192.1333. Beginning December 1, 2011, the department shall

assess an annual patient safety surcharge on licensing fees for those health care facilities required to report under sections 192.1300 to 192.1333. The amount shall be determined by the department and promulgated by rule.

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