

SECOND REGULAR SESSION

# SENATE BILL NO. 1264

94TH GENERAL ASSEMBLY

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INTRODUCED BY SENATOR BRAY.

Read 1st time February 28, 2008, and ordered printed.

TERRY L. SPIELER, Secretary.

5318S.011

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## AN ACT

To amend chapter 197, RSMo, by adding thereto eleven new sections relating to adverse health events.

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

Section A. Chapter 197, RSMo, is amended by adding thereto eleven new sections, to be known as sections 197.850, 197.853, 197.856, 197.859, 197.862, 197.865, 197.868, 197.871, 197.874, 197.877, and 197.880, to read as follows:

**197.850. 1. As used in sections 197.850 to 197.880, the following terms shall mean:**

(1) "Ambulatory surgical center", as the term is defined in section 197.200;

(2) "Authority", the patient safety authority established under section 197.856;

(3) "Board", the board of directors of the patient safety authority;

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

(5) "Employee protection", protection for a person who is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms of employment by the person's employer because of a lawful act taken by the person in furtherance of an action under sections 197.850 to 197.880. Such protections include the person being entitled to reinstatement with the same seniority status the person would have had but for the discrimination, not less than two times the amount of back pay, two percent interest on the back pay, and compensation for any special damages sustained as a result of the discrimination, including litigation costs and reasonable attorney's fees;

(6) "Fund", the patient safety trust fund established under section

21 **197.859;**

22 (7) "Health care worker", an employee, independent contractor,  
23 licensee or other individual authorized to provide services in a medical  
24 facility;

25 (8) "Incident", an event, occurrence, or situation involving the  
26 clinical care of a patient in a medical facility which could have injured  
27 the patient but did not either cause an unanticipated injury or require  
28 the delivery of additional health care services to the patient. The term  
29 does not include a serious event;

30 (9) "Infrastructure", structures related to the physical plant and  
31 service delivery systems necessary for the provision of health care  
32 services in a medical facility;

33 (10) "Licensee", an individual who is all of the following:

34 (a) Licensed or certified by the state to provide professional  
35 services in this state; and

36 (b) Employed by or authorized to provide professional services  
37 in a medical facility;

38 (11) "Medical facility", an ambulatory surgical center or hospital;

39 (12) "Patient safety officer", an individual designated by a  
40 medical facility under section 197.871;

41 (13) "Serious event", an event, occurrence or situation involving  
42 the clinical care of a patient in a medical facility that results in death  
43 or compromises patient safety and results in an unanticipated injury  
44 requiring the delivery of additional health care services to the  
45 patient. The term does not include an incident.

197.853. 1. There is established a body corporate and politic to  
2 be known as the "Patient Safety Authority". The powers and duties of  
3 the authority shall be vested in and exercised by a board of directors.

4 2. The board of the authority shall consist of eleven members and  
5 shall be appointed in accordance with the following:

6 (1) A physician appointed by the governor;

7 (2) Four public members appointed by the governor;

8 (3) A health care worker residing in this state who is a licensed  
9 physician and is appointed by the governor, who shall serve an initial  
10 term of three years;

11 (4) A health care worker residing in this state who is a licensed  
12 nurse and is appointed by the governor, who shall serve an initial term

13 of three years;

14 (5) A health care worker residing in this state who is a licensed  
15 pharmacist and is appointed by the governor, who shall serve an initial  
16 term of two years;

17 (6) A health care worker residing in this state who is employed  
18 by a hospital and is appointed by the governor, who shall serve an  
19 initial term of two years; and

20 (7) Two residents of this state, one of whom is a health care  
21 worker and one of whom is not a health care worker, appointed by the  
22 governor, who shall each serve a term of four years.

23 3. With the exceptions of the members in subdivisions (1) and (2)  
24 of subsection 2 of this section, members of the board shall serve for  
25 terms of four years after completion of the initial terms designated in  
26 subsection 2 and shall not be eligible to serve more than two full  
27 consecutive terms.

28 4. A majority of the members of the board shall constitute a  
29 quorum. Notwithstanding any other provision of law, action may be  
30 taken by the board at a meeting upon a vote of the majority of its  
31 members present in person or through the use of amplified telephonic  
32 equipment if authorized by the bylaws of the board.

33 5. The board shall meet at the call of the chairperson or as may  
34 be provided in the bylaws of the board. The board shall hold meetings  
35 at least quarterly. Meetings of the board may be held anywhere within  
36 this state.

37 6. The board shall meet and select the chair and vice chair. The  
38 authority shall be formed within sixty days of the effective date of this  
39 section.

197.856. 1. The authority shall do all of the following:

2 (1) Adopt bylaws necessary to implement sections 197.850 to  
3 197.880;

4 (2) Employ staff as necessary to implement sections 197.850 to  
5 197.880;

6 (3) Make, execute and deliver contracts and other instruments;

7 (4) Apply for, solicit, receive, establish priorities for, allocate,  
8 disburse, contract for, administer and spend moneys in the fund, and  
9 other funds that are made available to the authority from any source  
10 consistent with the purposes of sections 197.850 to 197.880;

11           **(5) Contract with a for-profit or not-for-profit entity or entities,**  
12 **other than a health care provider, to do the following:**

13           **(a) Collect, analyze and evaluate data regarding reports of**  
14 **serious events and incidents, including the identification of**  
15 **performance indicators and patterns in frequency or severity at certain**  
16 **medical facilities or in certain regions of this state;**

17           **(b) Transmit to the authority recommendations for changes in**  
18 **health care practices and procedures which may be instituted for the**  
19 **purpose of reducing the number and severity of serious events and**  
20 **incidents;**

21           **(c) Directly advise reporting medical facilities of immediate**  
22 **changes that can be instituted to reduce serious events and incidents;**  
23 **and**

24           **(d) Conduct reviews in accordance with subsection 2 of this**  
25 **section;**

26           **(6) Receive and evaluate recommendations made by the entity or**  
27 **entities contracted with in accordance with subdivision (5) of this**  
28 **subsection and report those recommendations to the department, which**  
29 **shall have no more than thirty days to approve or disapprove the**  
30 **recommendations;**

31           **(7) After consultation and approval by the department, issue**  
32 **recommendations to medical facilities on a facility-specific or on a**  
33 **state-wide basis regarding changes, trends, and improvements in health**  
34 **care practices and procedures for the purpose of reducing the number**  
35 **and severity of serious events and incidents. Prior to issuing**  
36 **recommendations, consideration shall be given to the following factors**  
37 **that include expectation of improved quality care, implementation**  
38 **feasibility, other relevant implementation practices and the cost impact**  
39 **to patients, payors and medical facilities on a continuing basis and**  
40 **shall be published and posted on the department's and the authority's**  
41 **publicly accessible website; and**

42           **(8) Meet with the department for purposes of implementing**  
43 **sections 197.850 to 197.880.**

44           **2. A health care worker who has complied with section 197.868,**  
45 **may file an anonymous report regarding a serious event with the**  
46 **authority. Upon receipt of the report, the authority shall give notice**  
47 **to the affected medical facility that a report has been filed. The**

48 authority shall conduct its own review of the report unless the medical  
49 facility has already commenced an investigation of the serious  
50 event. The medical facility shall provide the authority with the results  
51 of its investigation no later than thirty days after receiving notice  
52 pursuant to this section. If the authority is dissatisfied with the  
53 adequacy of the investigation conducted by the medical facility, the  
54 authority shall perform its own review of the serious event and may  
55 refer a medical facility and any involved licensee to the department for  
56 failure to report pursuant to subdivisions (5) and (6) of section 197.880.

57 3. (1) The authority shall report no later than May 1, 2009, and  
58 annually thereafter, to the department and the general assembly on the  
59 authority's activities in the preceding year. The report shall include:

60 (a) A schedule of the year's meetings;

61 (b) A list of contracts entered into pursuant to subdivision (5) of  
62 subsection 2 of this section, including the amounts awarded to each  
63 contractor;

64 (c) A summary of the fund receipts and expenditures, including  
65 a financial statement and balance sheet;

66 (d) The number of serious events and incidents reported by  
67 medical facilities on a geographical basis;

68 (e) The information derived from the data collected, including  
69 any recognized trends concerning patient safety;

70 (f) The number of anonymous reports filed and reviews  
71 conducted by the authority;

72 (g) The number of referrals to licensure boards for failure to  
73 report under sections 197.850 to 197.880; and

74 (h) Recommendations for statutory and regulatory changes  
75 which may help improve patient safety in the state.

76 (2) The report shall be distributed to the director of the  
77 department of health and senior services, governor, and the general  
78 assembly.

79 (3) The annual report shall be made available for public  
80 inspection and shall be posted on the department's Internet website.

197.859. 1. There is hereby established the "Patient Safety Trust  
2 Fund" to be administered by the authority. The state treasurer shall be  
3 custodian of the fund and may approve disbursements from the fund in  
4 accordance with sections 30.170 and 30.180, RSMo. Upon appropriation,

5 money in the fund shall be used solely for the administration of  
6 sections 197.850 to 197.880. Any moneys remaining in the fund at the  
7 end of the biennium shall revert to the credit of the general revenue  
8 fund. The state treasurer shall invest moneys in the fund in the same  
9 manner as other funds are invested. Any interest and moneys earned  
10 on such investments shall be credited to the fund.

11 2. Beginning December 31, 2008, each medical facility shall pay  
12 the department a surcharge on its licensing fee as necessary to provide  
13 sufficient revenues to operate the authority. The total assessment for  
14 all medical facilities shall not exceed five million dollars. The  
15 department shall transfer the total assessment amount to the fund  
16 within thirty days of receipt.

17 3. For each succeeding calendar year, the department shall  
18 determine and assess each medical facility its proportionate share of  
19 the authority's budget. The total assessment amount shall not exceed  
20 five million dollars.

21 4. Moneys in the fund shall be expended by the authority to  
22 implement sections 197.850 to 197.880.

23 5. In the event that the fund is discontinued or the authority is  
24 dissolved by operation of law, any balance remaining in the fund, after  
25 deducting administrative costs of liquidation, shall be returned to the  
26 medical facilities in proportion to their financial contributions to the  
27 fund in the preceding licensing period.

28 6. If, after thirty days notice, a medical facility fails to pay a  
29 surcharge levied by the department under sections 197.850 to 197.880,  
30 the department may assess an administrative penalty of one thousand  
31 dollars per day until the surcharge is paid.

197.862. The department shall do all of the following:

2 (1) Review and approve patient safety plans in accordance with  
3 section 197.862;

4 (2) Receive reports of serious events and infrastructure failures  
5 under section 197.880;

6 (3) Investigate serious events and infrastructure failures;

7 (4) In conjunction with the authority, analyze and evaluate  
8 existing health care procedures and approve recommendations issued  
9 by the authority pursuant to subdivisions (6) and (7) of subsection 1 of  
10 section 197.856;

11           **(5) Meet with the authority for purposes of implementing**  
12 **sections 197.850 to 197.880.**

**197.865. 1. A medical facility shall develop, implement and**  
2 **comply with an internal patient safety plan that shall be established for**  
3 **the purpose of improving the health and safety of patients. The plan**  
4 **shall be developed in consultation with the licensees providing health**  
5 **care services in the medical facility.**

6           **2. A patient safety plan shall:**

7           **(1) Designate a patient safety officer as set forth in section**  
8 **197.871;**

9           **(2) Establish a patient safety committee as set forth in section**  
10 **197.874;**

11           **(3) Establish a system for the health care workers of a medical**  
12 **facility to report serious events and incidents which shall be accessible**  
13 **twenty-four hours a day, seven days a week;**

14           **(4) Prohibit any retaliatory action against a health care worker**  
15 **for reporting a serious event or incident in accordance with the**  
16 **employee protection described under section 197.850;**

17           **(5) Provide for written notification to patients in accordance**  
18 **with subsection 2 of section 197.868.**

19           **3. Within sixty days from the effective date of sections 197.850 to**  
20 **197.880, a medical facility shall submit its patient safety plan to the**  
21 **department for approval consistent with the requirements of this**  
22 **section. Unless the department approves or rejects the plan within**  
23 **sixty days of receipt, the plan shall be deemed approved.**

24           **4. Upon approval of the patient safety plan, a medical facility**  
25 **shall notify all health care workers of the medical facility of the patient**  
26 **safety plan. Compliance with the patient safety plan shall be required**  
27 **as a condition of employment or credentialing at the medical facility.**

**197.868. 1. A health care worker who reasonably believes that a**  
2 **serious event or incident has occurred shall report the serious event or**  
3 **incident according to the patient safety plan of the medical facility**  
4 **unless the health care worker knows that a report has already been**  
5 **made. The report shall be made immediately or as soon thereafter as**  
6 **reasonably practicable, but in no event later than twenty-four hours**  
7 **after the occurrence or discovery of a serious event or incident.**

8           **2. A medical facility, through an appropriate designee, shall**

9 provide written notification to a patient affected by a serious event or,  
10 with the consent of the patient, to an available family member or  
11 designee within seven days of the occurrence or discovery of a serious  
12 event. If the patient is unable to give consent, the notification shall be  
13 given to an adult member of the immediate family. If an adult member  
14 of the immediate family cannot be identified or located, notification  
15 shall be given to the closest adult family member. For unemancipated  
16 patients who are under eighteen years of age, the parent or guardian  
17 shall be notified in accordance with this subsection. The notification  
18 requirements of this subsection shall not constitute an acknowledgment  
19 or admission of liability.

20 3. A health care worker who reports the occurrence of a serious  
21 event or incident in accordance with subsections 1 or 2 of this section  
22 shall not be subject to any retaliatory action for reporting the serious  
23 event or incident and shall be entitled to the employee protection  
24 described under section 197.850.

25 4. Nothing in this section shall limit a medical facility's ability  
26 to take appropriate disciplinary action against a health care worker for  
27 failure to meet defined performance expectations or to take corrective  
28 action against a licensee for unprofessional conduct, including making  
29 false reports or failure to report serious events under sections 197.800  
30 and 197.830.

197.871. A patient safety officer of a medical facility shall do all  
2 of the following:

- 3 (1) Serve on the patient safety committee;
- 4 (2) Ensure the investigation of all reports of serious events and  
5 incidents;
- 6 (3) Take such action as is immediately necessary to ensure  
7 patient safety as a result of any investigation; and
- 8 (4) Report to the patient safety committee regarding any action  
9 taken to promote patient safety as a result of investigations commenced  
10 under this section.

197.874. 1. A hospital's patient safety committee shall be  
2 composed of the medical facility's patient safety officer and at least  
3 three health care workers of the medical facility and two residents of  
4 the community served by the medical facility who are not agents,  
5 employees or contractors of the medical community served by the



6 medical facility. No more than one member of the patient safety  
7 committee shall be a member of the medical facility's board of  
8 trustees. The committee shall include members of the medical facility's  
9 medical and nursing staff. The committee shall meet at least monthly.

10 2. An ambulatory surgical center's patient safety committee shall  
11 be comprised of the medical facility's patient safety officer and at least  
12 one health care worker of the medical facility and one resident of the  
13 community served by the ambulatory surgical center who is not an  
14 agent, employee or contractor of the ambulatory surgical center. No  
15 more than one member of the patient safety committee shall be a  
16 member of the facility's board of governance. The committee shall  
17 include members of the medical facility's medical and nursing  
18 staff. The committee shall meet at least quarterly.

19 3. A patient safety committee of a medical facility shall do all of  
20 the following:

21 (1) Receive reports from the patient safety officer pursuant to  
22 section 197.871;

23 (2) Evaluate investigations and actions of the patient safety  
24 officer on all reports;

25 (3) Review and evaluate the quality of patient safety measures  
26 utilized by the medical facility. A review shall include the  
27 consideration of reports made under subdivision (5) of subsection 1 and  
28 subsection 2 of section 197.856, subdivision (3) of subsection 2 of section  
29 197.865 and subsection 1 of section 197.868;

30 (4) Make recommendations to eliminate future serious events  
31 and incidents;

32 (5) Report to the administrative officer and governing body of  
33 the medical facility on a quarterly basis regarding the number of  
34 serious events and incidents and its recommendations to eliminate  
35 future serious events and incidents.

197.877. 1. Any documents, materials or information solely  
2 prepared or created for the purpose of compliance with subsection 2 of  
3 section 197.874 or of reporting under subdivision (5) of subsection 1 and  
4 subsection 2 of section 197.877, subdivision (2) of subsection 1 or  
5 subsection 3 of section 197.862, subdivision (3) of subsection 2 of section  
6 197.865, subsection 1 of section 197.868, subdivision (4) of section  
7 197.871, subdivision (5) of subsection 2 of section 197.874 or section

8 197.880 which arise out of matters reviewed by the patient safety  
9 committee pursuant to the governing board of a medical facility are  
10 confidential and shall not be discoverable or admissible as evidence in  
11 any civil or administrative action or proceeding. Any documents,  
12 materials, records or information that would otherwise be available  
13 from original sources shall not be construed as immune from discovery  
14 or use in any civil or administrative action or proceeding merely  
15 because they were presented to the patient safety committee or  
16 governing board of a medical facility.

17 2. No person who performs responsibilities for or participates in  
18 meetings of the patient safety committee or governing board of a  
19 medical facility shall be allowed to testify as to any matters within the  
20 knowledge gained by the person's responsibilities or participation on  
21 the patient safety committee or governing board of a medical facility,  
22 provided, however, the person shall be allowed to testify as to any  
23 matters within the person's knowledge which was gained outside of the  
24 person's responsibilities or participation on the patient safety  
25 committee or governing board of a medical facility.

26 3. The confidentiality protections set forth in subsections 1 and  
27 2 of this section shall only apply to the documents, materials, or  
28 information prepared or created pursuant to the responsibilities of the  
29 patient safety committee or governing board of a medical facility.

30 4. Except as set forth in subsection 6 of this section, any  
31 documents, materials or information received by the authority or  
32 department from the medical facility, health care worker, patient safety  
33 committee or governing board of a medical facility solely prepared or  
34 created for the purpose of compliance with subsection 2 of section  
35 197.874 or for the reporting required in subsection 1 of this section,  
36 shall not be discoverable or admissible as evidence in any civil or  
37 administrative action or proceeding. Any records received by the  
38 authority or department from the medical facility, health care worker,  
39 patient safety committee or governing board of a medical facility  
40 pursuant to the requirements of sections 197.850 to 197.880 shall not be  
41 discoverable from the department or the authority in any civil or  
42 administrative action or proceeding. Documents, materials, records, or  
43 information may be used by the authority or department to comply  
44 with the reporting requirements under subsection 7 of this section and

45 (7) of subsection 1 or subsection 3 of section 197.856 or subsection 2 of  
46 section 197.862.

47 5. (1) Except as set forth in subdivision (2) of this subsection, no  
48 current or former employee of the authority or the department shall be  
49 allowed to testify as to any matters gained by reason of his or her  
50 review of documents, materials, records or information submitted to  
51 the authority by the medical facility or health care worker pursuant to  
52 the requirements of sections 197.850 to 197.880.

53 (2) Subdivision (1) of this subsection does not apply to findings  
54 or actions by the department or the secretary of state which are public  
55 records.

56 6. In the event an original source document as set forth in  
57 subsection 1 of this section is determined by a court of competent  
58 jurisdiction to be unavailable from the health care worker or medical  
59 facility in a civil action or proceeding, then in that circumstance alone  
60 the department may be required pursuant to a court order to release  
61 that original document to the party identified in the court order.

62 7. Any documents, materials or information made confidential by  
63 subsection 1 of this section shall not be subject to chapter 610, RSMo.

64 8. Notwithstanding any other provision of law, no person  
65 providing information or services to the patient safety committee,  
66 governing board of a medical facility, authority, or department shall be  
67 held by reason of having provided such information or services to have  
68 violated any criminal law, or to be civilly liable under law, unless such  
69 information is false and the person providing such information knew  
70 or had reason to believe that such information was false and was  
71 motivated by malice toward any person directly affected by such  
72 action.

197.880. 1. A medical facility shall report the occurrence of a  
2 serious event to the department and the authority within twenty-four  
3 hours of the medical facility's confirmation of the occurrence of the  
4 serious event. The report to the department and the authority shall be  
5 in the form and manner prescribed by the authority in consultation  
6 with the department and shall not include the name of any patient or  
7 any other identifiable individual information.

8 2. A medical facility shall report the occurrence of an incident  
9 to the authority in a form and manner prescribed by the authority and

10 shall not include the name of any patient or any other identifiable  
11 individual information.

12 3. A medical facility shall report the occurrence of an  
13 infrastructure failure to the department within twenty-four hours of  
14 the medical facility's confirmation of the occurrence or discovery of the  
15 infrastructure failure. The report to the department shall be in a form  
16 and manner prescribed by the department.

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