SECOND REGULAR SESSION

# SENATE BILL NO. 916

**94TH GENERAL ASSEMBLY**

INTRODUCED BY SENATOR GOODMAN.

Pre-filed January 8, 2008, and ordered printed.

TERRY L. SPIELER, Secretary.

4188S.01I



## AN ACT

To amend chapter 197, RSMo, by adding thereto fourteen new sections relating to reporting, analysis, and dissemination of information about medical records.

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

Section A. Chapter 197, RSMo, is amended by adding thereto fourteen new sections, to be known as sections 197.551, 197.554, 197.557, 197.560, 197.563, 197.566, 197.569, 197.572, 197.575, 197.578, 197.581, 197.584, 197.587, and 197.590, to read as follows:

**197.551. 1. As used in sections 197.551 to 197.590, the following terms shall mean:**

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

**(2) "Identifiable information", information that is presented in a form and manner that allows the identification of any provider, patient, or reporter of patient safety work product. With respect to patients, such information includes any individually identifiable health information as that term is defined in the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, as amended;**

**(3) "Non-identifiable information", information presented in a form and manner that prevents the identification of any provider, patient, or reporter of patient safety work product. With respect to patients, such information must be de-identified consistent with the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, as amended;**

**(4) "Patient safety organization", an entity which:**

**(a) Is organized as an independent not-for-profit corporation**

**under section 501(c)(3) of the Internal Revenue Code and chapter 355, RSMo;**

**(b) Meets the criteria for certification as a patient safety organization under the federal Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. 299b-21, et seq and, one year after the effective date of federal regulations promulgated to implement such act, meets the statutory and regulatory criteria for certification as a patient safety organization under the act;**

**(c) Has a governing board that includes representatives of hospitals, physicians, and a federally-recognized quality improvement organization that contracts with the federal government to review medical necessity and quality assurance in the Medicare program;**

**(d) Conducts, as the organization's primary activity, efforts to improve patient safety and the quality of health care delivery;**

**(e) Collects and analyzes patient safety work product that is submitted by providers;**

**(f) Develops and disseminates evidence-based information to providers with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices;**

**(g) Utilizes patient safety work product to carry out activities limited to those described under sections 197.551 to 197.590 and for the purposes of encouraging a culture of safety and of providing direct feedback and assistance to providers to effectively minimize patient risk;**

**(h) Maintains confidentiality with respect to identifiable information;**

**(i) Implements appropriate security measures with respect to patient safety work product;**

**(j) Submits, if authorized by its governing board and certified by federal law and regulation, nonidentifiable information to a national patient safety database;**

**(k) Provides technical support to health care providers in the collection, submission, and analysis of data and for patient safety activities as described in sections 197.554 and 197.566; and**

**(l) May establish a formula for fees or assessments for the performance of activities as described in sections 197.554 and 197.566;**

**(5) "Patient safety work product", any data, reports, records,**

**memoranda, analyses, deliberative work, statements, root cause analyses, or reportable incident prevention plans or processes that are:**

**(a) Created or developed by a provider solely for the purposes of reporting to a patient safety organization;**

**(b) Reported to a patient safety organization;**

**(c) Requested by a patient safety organization, including the contents of such request;**

**(d) Reported to a provider by a patient safety organization;**

**(e) Created by a provider to evaluate corrective actions following a report by or to a patient safety organization;**

**(f) Created or developed by a patient safety organization; or**

**(g) Reported to a national patient safety database under federal law and regulation.**

**Patient safety work product shall not include information, documents, or records otherwise available from original sources merely because they were collected for or submitted to a patient safety organization. Patient safety work product also shall not include documents, investigations, records, or reports otherwise required by law;**

**(6) "Provider", any physician, hospital, ambulatory surgical center, assisted living facility, residential care facility, skilled nursing facility, intermediate care facility, dentist, registered or licensed practical nurse, optometrist, podiatrist, pharmacist, chiropractor, professional physical therapist, psychologist, hospice, home health agency and any other person or entity that provides health care services under the authority of a license or certificate;**

**(7) "Reportable incident", an occurrence of a serious reportable event in health care;**

**(8) "Reportable incident prevention plan", a written plan that:**

**(a) Defines, based on a root cause analysis, specific changes in organizational policies and procedures designed to reduce the risk of similar incidents occurring in the future or that provides a rationale acceptable to the department that no such changes are warranted;**

**(b) Sets deadlines for the implementation of such changes;**

**(c) Establishes who is responsible for making the changes; and**

**(d) Provides a mechanism for evaluating the effectiveness of such changes;**

**(9) "Root cause analysis", a structured process for identifying basic or causal factors that underlie variation in performance, including but not limited to the occurrence or possible occurrence of a reportable incident. A root cause analysis focuses primarily on systems and process rather than individual performance and progresses from special causes in clinical processes to common causes in organizational processes and identifies potential improvements in processes or systems that would tend to decrease the likelihood of such events in the future, or determines after analysis that no such improvement opportunities exist;**

**(10) "Serious reportable event in health care", as initially defined by the National Quality Forum in its March 2002 report and subsequently updated by the National Quality Forum, including all criteria established for identifying such events.**

**197.554. 1. A hospital shall report each reportable incident to a patient safety organization and to the department under sections 197.551 to 197.566. The department shall, by rule, define the form and content of information submitted. The department may require the use of a reporting format prior to the adoption of rules. Such rules shall protect patient confidentiality by requiring that patient-identifying data, as well as the identities of healthcare professionals and facility employees, be redacted from information provided to the patient safety organization or the department. The department's rules may provide for identification of the patient using an alternative patient identification system. The department shall design the reporting system so that a hospital may file by electronic means the reports required under this section and shall also encourage a facility to use the electronic filing option when that option is feasible. The department may consult with experts and organizations familiar with patient safety when developing the format for reporting and in further defining reportable incidents in order to be consistent with industry standards.**

**2. The hospital's initial report of the incident shall be submitted to the patient safety organization as soon as is reasonably and practically possible, but no later than fifteen working days after discovery of the incident. The initial report shall include a description of immediate actions taken by the hospital to minimize the risk of harm**

**to patients and prevent a reoccurrence and shall also provide verification that the hospital's patient safety and performance improvement review processes are responding to the reportable incident. Upon receiving a hospital's notice of a reportable incident, the patient safety organization shall forward the incident report and the description of immediate actions to the department. The hospital shall, within forty-five days after the incident occurs, submit a completed root cause analysis and a reportable incident prevention plan to the patient safety organization, which shall forward such analysis and plan to the department.**

**3. Upon request of the hospital, a patient safety organization may provide technical assistance in the development of a root cause analysis or reportable incident prevention plan relating to a reportable incident.**

**197.557. 1. Upon receiving notice of a reportable incident under section 197.554, the department shall investigate the incident. Based on its findings, the department shall determine whether the hospital's response is expected to be sufficient to reduce the risk of future occurrences of that type of reportable incident. The department also shall verify in subsequent licensure surveys or follow-up visits or contacts that the reportable incident prevention plan is being implemented as approved and the results of an evaluation mechanism for the plan are reviewed.**

**2. The department may by rule charge a fee for investigating and responding to reports of reportable incidents under sections 197.551 to 197.566. Any such fee shall not exceed the reasonable cost of such investigative and administrative activities.**

**3. The department shall periodically evaluate the performance of the patient safety organization regarding report submission processes and its reviews of reportable incident prevention plans and root cause analyses submitted by hospitals.**

**4. If the department determines that the reportable incident prevention plan initially submitted by the hospital is not sufficient to reduce the risk of future occurrences of that specific incident, the department shall provide notice to the hospital of such determination. In doing so, the department shall provide the hospital with specific areas of concern. The hospital shall have twenty days to resubmit a**

**revised reportable incident prevention plan. A reportable incident prevention plan shall be deemed approved by the department unless written notice of a deficiency is provided to the hospital within thirty days after the plan is submitted or resubmitted to the department for review.**

**197.560. 1. If a reportable incident is disclosed to the department and a patient safety organization under sections 197.551 to 197.566 and a reportable incident prevention plan and root cause analysis is submitted and approved by the department, the incident shall not be deemed to be grounds for a finding of a licensure deficiency under sections 197.010 to 197.120, except as otherwise authorized by section 197.563.**

**2. The provisions of this section shall not be construed to:**

**(1) Restrict the availability of information gleaned from original sources;**

**(2) Limit the disclosure or use of information regarding a reportable incident to:**

**(a) State or federal agencies or law enforcement under law or regulation; or**

**(b) Health care facility accreditation agencies.**

**3. Nothing in sections 197.551 to 197.566 shall modify the duty of a hospital to report disciplinary actions or medical malpractice actions against a health care professional under law.**

**197.563. 1. The department shall promulgate rules establishing criteria for defining cases in which reportable incidents have occurred in a hospital with a frequency or possible pattern of adverse outcomes so as to necessitate departmental intervention to protect the public. The department may impose license sanctions against such hospitals based on such reportable incidents, notwithstanding the provisions of subsection 1 of section 197.560.**

**2. In developing such criteria, the department shall consult with affected organizations, which shall include but not be limited to the patient safety organization and representatives of hospitals of diverse size and geographic location.**

**197.566. The patient safety organization shall, in collaboration with the department, publish an annual report to the public on reportable incidents. The first report shall include twelve months of**

**reported data and shall be published not more than fifteen months after the effective date of rules promulgated by the department to implement the provisions of sections 197.551 to 197.563. The report shall show the number and rate per patient encounter by region and by category of reportable incident, as such categories are established by the National Quality Forum in defining reportable incidents, and may identify reportable incidents by type of facility. The report shall outline, in aggregate, reportable incident prevention plans and the finding of root cause analyses, and shall make recommendations for modifications of state health care options. The report shall include recommendations for any additions, deletions, or modifications to the reportable incidents. For purposes of the annual report, the state shall be divided into no fewer than three regions, with the St. Louis metropolitan area being one of the regions.**

**197.569. A hospital may report adverse events other than reportable incidents to a patient safety organization and the department under sections 197.551 to 197.566 and such reports shall be subject to the same protections and requirements as provided by sections 197.551 to 197.566 for reportable incidents.**

**197.572. No person shall disclose the actions, decisions, proceedings, discussions, or deliberations occurring at a meeting of a patient safety organization except to the extent necessary to carry out one or more of the purposes of a patient safety organization. A meeting of the patient safety organization shall include any meetings of the patient safety organization; its staff; its governing board; any and all committees, work groups and task forces of the patient safety organization, whether or not formally appointed by the governing board, its president or its chairperson; and any meeting in any setting in which patient safety work product is discussed in the normal course of carrying out the business of the patient safety organization. The proceedings and records of a patient safety organization shall not be subject to discovery or introduction into evidence in any civil action against a provider arising out of the matter or matters that are the subject of consideration by a patient safety organization. Information, documents, or records otherwise available from original sources shall not be immune from discovery or use in any civil action merely because they were presented during proceedings of a patient safety**

**organization. This section shall not be construed to prevent a person from testifying to or reporting information obtained independently of the activities of a patient safety organization or which is public information.**

**197.575. Patient safety work product shall be privileged and confidential and shall not be disclosed for any purpose and, further, shall not be subject to disclosure in any criminal, civil, or administrative proceeding.**

**197.578. 1. Any reference to or offer into evidence of the jury or other fact-finder or admission into evidence of patient safety work product during any proceeding that is contrary to the provisions of sections 197.551 to 197.566 shall constitute grounds for a mistrial or a similar termination of the proceedings and reversible error on appeal from any judgment or order entered in favor of a party who so discloses or offers into evidence patient safety work product.**

**2. The prohibition against discovery, disclosure, or admission into evidence of patient safety work product is in addition to any other protections provided by law.**

**197.581. A patient safety organization may disclose nonidentifiable information and nonidentifiable aggregate trend data identifying the number and types of patient safety events that occur. A patient safety organization shall publish educational and evidence-based information from the summary reports that can be used by all providers to improve the care provided.**

**197.584. 1. The confidentiality of patient safety work product shall in no way be impaired or otherwise adversely affected solely by reason of the submission of the same to a patient safety organization. The confidentiality of patient safety work product submitted in compliance with sections 197.551 to 197.587 to a patient safety organization shall not be adversely affected if the entity later ceases to meet the statutory definition of a patient safety organization.**

**2. The exchange or disclosure of patient safety work product by a patient safety organization shall not constitute a waiver of confidentiality or privilege by the health care provider that submitted the data.**

**197.587. Any provider furnishing services to a patient safety organization shall not be liable for civil damages as a result of such**

**acts, omissions, decisions, or other such conduct in connection with the lawful duties on behalf of a patient safety organization, except for acts, omissions, decisions, or conduct done with actual malice, fraudulent intent, or bad faith.**

**197.590. 1. Any hospital that reports a reportable incident shall not charge for or bill any entity, including third party payors and patients, for all services related to the reportable incident. If a third party payor denies a claim, in whole or in part, because there is no coverage for services that resulted in any of the reportable incidents described in this section, then the health care professional or facility that provided such services is prohibited from billing the patient for such services.**

**2. For purposes of this section, "third party payor" means a health carrier as defined in section 376.1350, RSMo, an organization entering into a preferred provider arrangement, and a third party administrator for a self-funded health benefit plan.**

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