FIRST REGULAR SESSION

SENATE BILL NO. 382

95TH GENERAL ASSEMBLY

INTRODUCED BY SENATOR SCHAEFER.

Read 1st time February 16, 2009, and ordered printed.

TERRY L. SPIELER, Secretary.

1864S.01I

AN ACT

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

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 197.551, 197.554, 197.557, 197.563, 197.566, 197.572, 197.575, 197.578, 197.581, 197.584, and 197.587, to read as follows:

197.551. As used in sections 197.551 to 197.587, the following terms shall mean:

(1) "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 defined in federal regulations promulgated under Section 264(c) of the Health Insurance Portability and Accountability Act of 1996, as amended;

(2) "Nonidentifiable 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 shall be de-identified consistent with the federal regulations promulgated under Section 264(c) of the Health Insurance Portability and Accountability Act of 1996, as amended;

(3) "Patient safety organization", any entity which:

(a) Is organized as an independent not-for-profit corporation under Section 501(c)(3) of the Internal Revenue Code of 1986, as amended, and applicable state law governing not-for-profit corporations;

(b) Meets the statutory and regulatory criteria for certification as a patient safety organization under the federal Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. Section 299b-21, et seq., as amended, and regulations promulgated thereunder;

(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 this section 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 pursuant to federal and state law and regulations;

(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 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;

(4) "Patient safety work product", as defined in federal regulations promulgated to implement the federal Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. Section 299b-21, et seq., as amended;

(5) "Provider", as defined in federal regulations promulgated to implement the federal Patient Safety and Quality Improvement Act of

2005, 42 U.S.C. Section 299b-21, et seq., as amended;

(6) "Reportable incident", an occurrence of a serious reportable event in health care as such event is defined in subdivision (9) of this subsection;

(7) "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 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;

(8) "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 processes 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 existed; and

(9) "Serious reportable event in health care", an occurrence of one or more of the actions or outcomes included in the list of serious adverse events 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. Effective six months after the effective date of initial federal regulations promulgated to implement the federal Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. Section 299b-21, et seq., a hospital shall report each reportable incident to a patient safety organization. The hospital's initial report of the incident shall be submitted to the patient safety organization no later than the close of business on the next business day following discovery of the incident. The initial report shall include a description of immediate

actions to be taken by the hospital to minimize the risk of harm to patients and prevent a reoccurrence and verification that the hospital's patient safety and performance improvement review processes are responding to the reportable incident. 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.

2. 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. Pursuant to paragraphs (f) and (g) of subdivision (3) of section 197.551 and 42 U.S.C. Section 299b-21, et seq., the patient safety organization shall assess the information provided regarding the reportable incident and furnish the hospital with a report of its findings and recommendations as to how to prevent future incidents.

197.563. 1. The provisions of sections 197.551 to 197.587 shall not be construed to:

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

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

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

(b) Health care facility accreditation agencies.

2. 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.

197.566. The patient safety organization shall 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 date data collection begins. The report shall indicate 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. For purposes of the annual report, the state shall be divided into no fewer than three

regions, with the St. Louis metropolitan statistical area being one of the regions.

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 and 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. The provisions of 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 pursuant to the federal Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. Section 299b-21, et seq., as amended, and regulations promulgated thereunder.

197.578. 1. Any reference to or offer into evidence in the presence of the jury or other fact-finder or admission into evidence of patient safety work product during any proceeding that is contrary to sections 197.551 to 197.587 shall constitute grounds for a mistrial or a similar termination of the proceeding and reversible error on appeal from any judgment or order entered in favor of any 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 who 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.