FIRST REGULAR SESSION

HOUSE BILL NO. 497

95TH GENERAL ASSEMBLY

INTRODUCED BY REPRESENTATIVES ERVIN (Sponsor), COX, WOOD, FUNDERBURK, MUNZLINGER, WASSON, COOPER, SCHAD, WILSON (119), NANCE, SANDER, STREAM, SILVEY, EMERY, NOLTE, BIVINS, RUESTMAN, DAVIS AND SCHAAF (Co-sponsors).

1260L.03I D. ADAM CRUMBLISS, Chief Clerk

AN ACT

To amend chapters 191 and 197, RSMo, by adding thereto sixteen new sections relating to patient safety, with a penalty provision.

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

Section A. Chapters 191 and 197, RSMo, are amended by adding thereto sixteen new sections, to be known as sections 191.1005, 191.1008, 191.1010, 197.550, 197.553, 197.556, 197.559, 197.562, 197.565, 197.568, 197.571, 197.574, 197.577, 197.580, 197.583, and 197.586, to read as follows:

191.1005. 1. For purposes of this section, the following terms shall mean:

(1) "Estimate of cost", an estimate based on specific patient information or general assumptions about typical utilization and costs for medical services. Upon written request by a patient, a provider shall be required to provide the patient a timely estimate of cost for any elective or nonemergent health care service. Such requirement shall not apply to emergency health care services. Any estimate of cost may include a disclaimer noting the actual amount billed may be different from the estimate of cost;

(2) "Insurer", the same meaning as the term "health carrier" is defined in section 376.1350, RSMo, and includes the state of Missouri for purposes of the rendering of health care services by providers under a medical assistance program of the state.

2. Programs of insurers that publicly assess and compare the quality and cost efficiency of health care providers shall conform to the following criteria:

EXPLANATION — Matter enclosed in bold-faced brackets **[**thus**]** in the above bill is not enacted and is intended to be omitted from the law. Matter in **bold-face** type in the above bill is proposed language.

(1) The insurers shall retain, at their own expense, the services of a nationally-recognized independent health care quality standard-setting organization to review the plan's programs for consumers that measure, report, and tier providers based on their performance. Such review shall include a comparison to national standards and a report detailing the measures and methodologies used by the health plan. The scope of the review shall encompass all elements described in this section and section 191.1008;

(2) The program measures shall provide performance information that reflects consumers' health needs. Programs shall clearly describe the extent to which they encompass particular areas of care, including primary care and other areas of specialty care;

(3) Performance reporting for consumers shall include both quality and cost efficiency information. While quality information may be reported in the absence of cost-efficiency, cost-efficiency information shall not be reported without accompanying quality information;

(4) When any individual measures or groups of measures are combined, the individual scores, proportionate weighting, and any other formula used to develop composite scores shall be disclosed. Such disclosure shall be done both when quality measures are combined and when quality and cost efficiency are combined;

(5) Consumers or consumer organizations shall be solicited to provide input on the program, including methods used to determine performance strata;

(6) A clearly defined process for receiving and resolving consumer complaints shall be a component of any program;

(7) Performance information presented to consumers shall include context, discussion of data limitations, and guidance on how to consider other factors in choosing a provider;

(8) Relevant providers and provider organizations shall be solicited to provide input on the program, including the methods used to determine performance strata;

(9) Providers shall be given reasonable prior notice before their individual performance information is publicly released;

(10) A clearly defined process for providers to request review of their own performance results and the opportunity to present information that supports what they believe to be inaccurate results, within a reasonable time frame, shall be a component of any program. Results determined to be inaccurate after the reconsideration process shall be corrected;

(11) Information about the comparative performance of providers shall be accessible and understandable to consumers and providers;

(12) Information about factors that might limit the usefulness of results shall be publicly disclosed;

(13) Measures used to assess provider performance and the methodology used to calculate scores or determine rankings shall be published and made readily available to the public. Some elements shall be assessed against national standards. Examples of measurement elements that shall be assessed against national standards include: risk and severity adjustment, minimum observations, and statistical standards utilized. Examples of other measurement elements that shall be fully disclosed include: data used, how providers' patients are identified, measure specifications and methodologies, known limitations of the data, and how episodes are defined;

(14) The rationale and methodologies supporting the unit of analysis reported shall be clearly articulated, including a group practice model versus the individual provider;

(15) Sponsors of provider measurement and reporting shall work collaboratively to aggregate data whenever feasible to enhance its consistency, accuracy, and use. Sponsors of provider measurement and reporting shall also work collaboratively to align and harmonize measures used to promote consistency and reduce the burden of collection. The nature and scope of such efforts shall be publicly reported;

(16) The program shall be regularly evaluated to assess its effectiveness and any unintended consequences;

(17) Measures shall be based on national standards. The primary source shall be measures endorsed by the National Quality Forum (NQF). When non-NQF measures are used because NQF measures do not exist or are unduly burdensome, it shall be with the understanding that they will be replaced by comparable NQF-endorsed measures when available;

(18) Where NQF-endorsed measures do not exist, the next level of measures to be considered, to the extent practical, shall be those endorsed by the Ambulatory Care Quality Alliance, national accrediting organizations such as the National Committee for Quality Assurance, or the Joint Commission on the Accreditation of Healthcare Organizations and federal agencies;

(19) Supplemental measures are permitted if they address areas of measurement for which national standards do not yet exist or for which existing national standard measure requirements are unreasonably burdensome on providers or program sponsors. Supplemental measures may be used if they are part of a pilot program to assess the extent to which the measures could fill national gaps in measurement. When supplemental measures are used they shall reasonably adhere to the NQF measure criteria, including

importance, scientific acceptability, feasibility and usability, and may include sources such as provider specialty society guidelines;

(20) The public, including consumers and employers, has a right to obtain information to assist them in comparing the cost and quality of health care services and health care providers. Health carriers shall have the ability to use data for such purpose which is collected from medical claims, health care providers, or other sources, including the federal Centers for Medicare and Medicaid Services (CMS) and other entities for such purpose. Health carriers are prohibited from entering into new contracts or amending existing contracts with health care providers that limit the use of medical claims data to payment of claims or otherwise preclude health carriers from responding to the public's need for comparative cost, quality, and efficiency information, or other performance information, on health care services and health care providers. Health carriers have the right to amend existing contracts with health care providers to conform with this section. Health carriers may use claims and contracted rate data to report on cost, quality, and efficiency consistent with the patient charter or other nationally recognized standards, such as those issued by the National Committee for Quality Assurance. No health carrier or any other entity shall use such information in a manner that violates any state or federal law, including antitrust law.

191.1008. 1. Any person who sells or otherwise distributes to the public health care quality and cost efficiency data for disclosure in comparative format to the public shall identify the measure source or evidence-based science behind the measure and the national consensus, multi-stakeholder, or other peer review process, if any, used to confirm the validity of the data and its analysis as an objective indicator of health care quality.

2. Articles or research studies on the topic of health care quality or cost efficiency that are published in peer-reviewed academic journals that do not receive funding from or is affiliated with a health care insurer or by state or local government shall be exempt from the requirements of subsection 1 of this section.

3. (1) Upon receipt of a complaint of an alleged violation of this section by a person or entity other than a health carrier, the department of health and senior services shall investigate the complaint and, upon finding that a violation has occurred, shall be authorized to impose a penalty in an amount not to exceed one thousand dollars. The department shall promulgate rules governing its processes for conducting such investigations and levying fines authorized by law.

(2) Any rule or portion of a rule, as that term is defined in section 536.010, RSMo, 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, RSMo, and, if

applicable, section 536.028, RSMo. This section and chapter 536, RSMo, are nonseverable and if any of the powers vested with the general assembly pursuant to chapter 536, RSMo, 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, 2009, shall be invalid and void.

191.1010. All alleged violations of sections 191.1005 to 191.1008 by a health insurer shall be investigated and enforced by the department of insurance, financial institutions and professional registration under the department's powers and responsibilities to enforce the insurance laws of this state in accordance with chapter 374, RSMo.

197.550. As used in sections 197.550 to 197.586, the following terms shall mean:

(1) "Identifiable information", information that is presented in a form or 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 that is 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 nonprofit corporation under Section 501(c)(3) of the Internal Revenue Code of 1986, as amended, and applicable state law governing nonprofit 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 or advisory committee that includes representatives of hospitals, physicians, an employer or group representing employers, an insurance company or group representing insurance companies, the long-term care industry, 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 under 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 197.553 and 197.562;

(4) "Patient safety work product", the same meaning as such term is 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", the same meaning as such term is 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 this section;

(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 structure 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 organization 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 exists;

(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.

197.553. 1. Beginning January 1, 2010, a hospital shall report each reportable incident to a federally-designated patient safety organization, as defined by the federal Patient Safety and Quality Improvement Act of 2005, as amended. 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 is discovered, 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. If the patient safety organization finds the initial report, root cause analysis, or reportable incident prevention plan to be insufficient, the hospital shall have two attempts to correct. If such attempts are unsuccessful, the hospital shall conduct the process with the department of health and senior services. If a hospital chooses not to provide an initial report, root cause analysis, or reportable incident prevention plan to a federally-designated patient safety organization within the specified time frames, the hospital shall submit all three elements to the department of health and senior services.

3. All hospitals shall establish a policy whereby the patient or the patient's legally authorized representative is notified of the occurrence of a serious reportable event in health care. Such notification shall be provided not later than one business day after the hospital or its agent becomes aware of the occurrence. The time, date, participants, and content of the notification shall be documented in the patient's medical record. The provision of notice to a patient under this section shall not, in any action or proceeding, be considered an acknowledgment or admission of liability.

197.556. Under paragraphs (f) and (g) of subdivision (3) of section 197.550 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.

197.559. 1. The provisions of sections 197.550 to 197.586 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 197.550 to 197.586 shall modify the duty of a hospital to report disciplinary actions or medical malpractice actions against a health care professional under law.

197.562. The department of health and senior services 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 of reportable events by the then current National Quality Forum category of reportable incident 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 for the previous year shall be made public no later than April thirtieth. 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. To provide the department with this data, hospitals shall report errors quarterly to the department. Such reports shall include the type of error, rate of error, whether death or serious disability occurred, and whether a root cause analysis and a reportable incident prevention plan have been submitted to the patient safety organization. The department shall determine when a frequency or pattern of harm necessitates further action.

197.565. 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:

(1) Any meetings of:

(a) The patient safety organization;

(b) The organization's staff;

(c) The organization's governing body;

(d) Any and all committees, work groups, and task forces of the organization, whether or not formally appointed by the governing body;

(e) The organization's president and chairperson; and

(2) Any meeting in any setting in which patient safety work product is discussed in the normal course of carrying out business of the patient 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.

197.568. Patient safety work product shall be privileged and confidential 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.

197.571. 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 197.550 to 197.586 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.

197.574. 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.

197.577. 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 197.550 to 197.586 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.

197.580. 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.

197.583. For any hospital that reports a reportable incident under section 197.553, a claim for payment filed by the hospital for health care services related to a reportable incident shall not be subject to section 375.300 or 375.1000, RSMo.

197.586. 1. Beginning January 1, 2010, 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 sections 197.550 to 197.586, 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 entered into a preferred provider agreement, and a third-party administrator for a self-funded health benefit plan.

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