FIRST REGULAR SESSION

HOUSE BILL NO. 626

93RD GENERAL ASSEMBLY

INTRODUCED BY REPRESENTATIVE SCHAAF.

Read 1st time February 23, 2005 and copies ordered printed.

STEPHEN S. DAVIS, Chief Clerk

1291L.05I

AN ACT

To amend chapter 197, RSMo, by adding thereto seven new sections relating to health care data collection and reporting.

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

Section A. Chapter 197, RSMo, is amended by adding thereto seven new sections, to be known as sections 197.130, 197.132, 197.140, 197.142, 197.144, 197.145, and 197.146, to read as follows:

197.130. As used in this section and section 197.132, the following terms mean:

(1) "Charge data", information submitted by hospitals of its uniform list of current charges for leading procedures and diagnoses;

(2) "Charges by payer", information submitted by hospitals on amount billed to Medicare, Medicaid, other government sources and all nongovernment sources combined as one data element;

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

(4) "Financial data", information submitted by hospitals drawn from financial statements which includes the balance sheet, income statement, charity care and bad debt and charges by payer, prepared in accordance with generally accepted accounting principles;

(5) "Hospital", the same meaning as such term is defined in section 197.020;

(6) "Patient abstract data", data submitted by hospitals which includes but is not limited to date of birth, sex, race, zip code, county of residence, facility identification and address, admission hour and date, type of admission, source of admission, discharge hour

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.

and date, discharge status, principal and other diagnoses codes, including external causes, conditions codes, principal and other procedures codes and dates, diagnosis codes present at discharge, total billed charges incurred by revenue code, referring physician identification, admitting physician identification, attending physician identification, operating physician identification, disposition of the patient and expected source of payment with sources categorized according to Medicare, Medicaid, other government, workers' compensation, all commercial payors coded with a common code, self-pay, no charge and other, and any other data as required by rule of the department;

(7) "Performance outcome data", all of the following information listed in subdivision (6) of this section for each of one hundred conditions and procedures required by the department under subsections 1 and 2 of section 197.132: volume of cases, average patient charges, length of stay, readmission rates, mortality rates, complication rates, and infection rates.

197.132. 1. Beginning April 1, 2006, the department shall collect data on the most common one hundred conditions and procedures for hospitals as specified by the department under subsection 2 of this section from hospitals as necessary to generate the reports required by this section. Hospitals shall provide such data in compliance with this section.

2. No later than March 1, 2006, the department shall establish by rule a list of the most common one hundred inpatient and outpatient conditions and procedures for hospitals for which performance outcomes data will be made publicly available. The department shall convene a group of technical experts to actively seek input on the list of such conditions and procedures. Such group shall include an equal number of representatives from the following:

(1) Practicing health care professionals and hospitals;

(2) Clinical and health services researchers knowledgeable in standards-based health care information systems;

(3) Patient groups;

(4) Health care purchasers;

(5) Health insurers; and

(6) Health care information technology industry.

When determining which inpatient and outpatient conditions and procedures to be disclosed, the agency and group of technical experts shall consider the variation in costs, variation in outcomes and magnitude of variations, and other relevant information so that the disclosed list of conditions and procedures will assist consumers in differentiating

between hospitals when making health treatment decisions.

3. No later than July 1, 2006, the department shall promulgate rules specifying the standards and procedures for the collection, analysis, risk adjustment, and reporting of the conditions and procedures as required by this section.

4. For each of the conditions and procedures required under subsections 1 and 2 of this section:

(1) All hospitals shall at least annually provide to the department charge data and financial data in a format required by the department;

(2) No later than thirty days after the end of each calendar quarter, each hospital shall electronically report to the department patient abstract data for each patient who was admitted to or received outpatient or emergency services at the hospital.

The department shall specify by rule the method of electronic submission of the data under this section and section 197.130, and in accordance with the uniform standards of the federal electronic transaction standards and code sets required by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended.

5. The department shall not require the resubmission of data which has been submitted to the department of health and senior services or the department of social services under any other provision of law. The department of health and senior services shall accept data submitted by associations or related organizations on behalf of hospitals by entering into binding agreements negotiated with such associations or related organizations to obtain data required under this section and section 197.130.

6. (1) The collection, compilation, analysis, and dissemination of information obtained by the department under the provisions of this section and section 197.130 shall be performed in a manner that protects the confidentiality of individual patients and meets the requirements of state and federal law, including the Gramm-Leach-Bliley Act (12 U.S.C. Section 1811, et. seq.) and the Health Insurance Portability and Accountability Act privacy regulations (45 C.F.R. Part 164). Reports and studies prepared by the department based upon such information shall be public information and may identify individual hospitals.

(2) The department of health and senior services shall authorize the use of patient abstract data by a person or entity, including but not limited to a government agency, research organization, and organizations in the private sector for purposes of clinical performance measurement, including making information available to compare individual hospitals based on performance outcomes data, promoting evidence-based medicine and best practices, patient safety and quality improvement, public health research, and other

purposes as determined by the department. The department shall determine reasonable fees to be charged to the requesting entity for providing electronic access to such data. All fees collected under this section shall be deposited in a special fund and shall be used solely to pay for the collection and public disclosure of hospital data to assist consumers in making informed health care decisions. Patient abstract data released under this subsection shall not include patient identifiers.

(3) The department shall not use or release any information provided under this section and section 197.130 which would enable any person to determine any hospital's negotiated discounts with specific preferred provider organizations or other managed care organizations. The department shall not release data in a form which could be used to identify a patient.

7. By July 1, 2006, the department shall:

(1) Use the patient abstract data collected from hospitals under this section and section 197.130 to make available on its Internet web site and in a written format, upon request, performance outcomes data for each hospital for the one hundred inpatient and outpatient conditions and procedures required by subsections 1 and 2 of this section. Such public data shall be updated on a quarterly basis. The department shall risk-adjust the performance outcomes data for case mix and severity of illness, if applicable, under a procedure specified by rule of the department;

(2) Make available on its Internet web site educational information on each condition or procedure, including but not limited to an explanation of the condition and/or procedure, potential side effects, alternative treatments and costs, and additional resources that can assist consumers in making an informed health care decision. Such resources may be made available by linking consumers to credible national resources such as, but not limited to, the National Library of Medicine;

(3) Make available additional information on its Internet web site, including definitions of the data, the age of the data, an explanation of the methodology used to risk adjust the data, and an explanation of why the data may differ from hospital to hospital. The agency shall provide guidance to consumers on how to use such information to make informed health care decisions;

(4) Post all information required by this section on its Internet web site in language that is understandable to laypersons and accessible to consumers using an interactive query system to allow for the comparison of performance outcomes data between all hospitals licensed in the state for each of the one hundred inpatient and outpatient procedures;

(5) Develop and implement an outreach campaign designed to make health care

performance outcomes data understandable and usable for consumers.

8. (1) The department shall undertake a reasonable number of studies and publish information, including at least an annual consumer guide by January first of each year, in collaboration with the advisory group established in subsection 2 of this section based upon the information obtained under this section and section 197.130. The department shall allow all hospitals and associations and related organizations who have submitted data which will be provided on the Internet web site under subsection 7 of this section and used in any report to verify the accuracy of the data prior to its publication or release for general use. The department may include any comments of a hospital, at the option of the hospital, and associations and related organizations on the Internet web site or in the publication if the department does not change the web site or publication based upon those comments.

(2) The department shall study the most effective methods for public disclosure of hospital performance outcomes data and evaluate the value of disclosing additional measures that are adopted by the National Quality Forum, the Joint Commission on Accreditation of Healthcare Organizations, or similar national entity that establishes standards to measure the performance of hospitals. The department shall post its findings on the department's Internet web site and report its findings to the governor and the general assembly by January 1, 2007.

9. Failure of any hospital to report data under this section and section 197.130 may result in licensure sanctions. Any hospital which continually and substantially, as these terms are defined by rule, fails to comply with the provisions of this section shall not be allowed to participate in any program administered by the state or to receive any moneys from the state.

10. A hospital aggrieved by the department's determination of ineligibility for state moneys under subsection 9 of this section may appeal as provided in section 197.071 or section 197.221, RSMo.

11. No information obtained or disclosed by the department under this section shall be used as the basis for a cause of action against any person or entity required to report information or who is the subject of such reported information. Any information obtained or disclosed as a result of the reporting under this section shall not be admissible in a court of law.

12. The department of health may promulgate rules providing for collection of data and publication required under this section. 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, 2005, shall be invalid and void.

197.140. 1. Sections 197.140 to 197.146 shall be known and may be cited as the "Missouri Adverse Health Care Event Reporting Act of 2005".

2. As used in sections 197.140 to 197.146, the following terms shall mean:

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

(2) "Director", the director of the department of health and senior services;

(3) "Hospital", a hospital licensed under this chapter;

(4) "Serious disability":

(a) A physical or mental impairment that substantially limits one or more of the major life activities of an individual;

(b) A loss of bodily function, if the impairment or loss lasts more than seven days or is still present at the time of discharge from a hospital; or

(c) Loss of a body part;

(5) "Surgery", the treatment of disease, injury, or deformity by manual or operative methods. Surgery includes endoscopies and other invasive procedures.

197.142. 1. Beginning July 1, 2006, each hospital in this state shall report to the director of the department of health and senior services the occurrence of any of the adverse health care events described in subsections 2 to 7 of this section as soon as is reasonably and practically possible, but no later than fifteen working days after discovery of the event. The report shall be filed in a format specified by the director and shall identify the facility but shall not include any identifying information for any of the health care professionals, facility employees, or patients involved. The director may consult with experts and organizations familiar in further defining events to be consistent with industry standards.

2. The following surgical events are reportable:

(1) Surgery performed on a wrong body part that is not consistent with the documented informed consent for the patient. Reportable events under this subdivision do not include situations requiring prompt action that occur in the course of surgery or situations whose urgency precludes obtaining informed consent;

(2) Surgery performed on the wrong patient;

(3) The wrong surgical procedure performed on a patient that is not consistent with

the documented informed consent for such patient. Reportable events under this subdivision do not include situations requiring prompt action that occur in the course of surgery or situations whose urgency precludes obtaining informed consent;

(4) 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; and

(5) Death during or immediately after surgery of a normal healthy patient who has no organic, psychological, biochemical, or psychiatric disturbance and for whom the pathologic processes for which the operation is to be performed are localized and do not entail a systemic disturbance.

3. The following product device events are reportable:

(1) Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the facility when the contamination is the result of generally detectable contaminants in drugs, devices, or biologics regardless of the source of the contamination or the product;

(2) Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended. "Device" includes but is not limited to catheters, drains, and other specialized tubes, infusion pumps, and ventilators; and

(3) Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a facility, excluding deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism.

4. The following patient prevention events are reportable:

(1) An infant discharged to the wrong person;

(2) Patient death or serious disability associated with patient disappearance for more than four hours, excluding events involving adults who have decision-making capacity; and

(3) Patient suicide or attempted suicide resulting in serious disability while being cared for in a facility due to patient actions after admission to the facility, excluding deaths resulting from self-inflicted injuries that were the reason for the admission to the facility.

5. The following care management events are reportable:

(1) Patient death or serious disability associated with a medication error, including but not limited to errors involving the wrong drug, the wrong dose, the wrong patient, the wrong time, the wrong rate, the wrong preparation, or the wrong route of administration, excluding reasonable differences in clinical judgment on drug selection and dose;

(2) Patient death or serious disability associated with a hemolytic reaction due to

the administration of ABO-incompatible blood or blood products;

(3) Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a facility, including events that occur within forty-two days postdelivery and excluding deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy, or cardiomyopathy;

(4) Patient death or serious disability directly related to hypoglycemia, the onset of which occurs while the patient is being cared for in a facility;

(5) Death or serious disability, including kernicterus, associated with failure to identify and treat hyperbilirubinemia in neonates during the first twenty-eight days of life;

(6) Stage 3 or 4 ulcers acquired after admission to a facility, excluding progression from stage 2 or stage 3 if stage 2 was recognized upon admission; and

(7) Patient death or serious disability due to spinal manipulative therapy.

6. The following environmental events are reportable:

(1) Patient death or serious disability associated with an electric shock while being cared for in a facility, excluding events involving planned treatments such as electric countershock;

(2) Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances;

(3) Patient death or serious disability associated with a burn incurred from any source while being cared for in a facility;

(4) Patient death associated with a fall while being cared for in a facility; and

(5) Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a facility.

7. The following criminal events are reportable:

(1) Any instance of care ordered by or provided by an individual impersonating a physician, nurse, pharmacist, or other licensed health care provider;

(2) Abduction of a patient of any age;

(3) Sexual assault on a patient within or on the grounds of a facility; and

(4) Death or significant injury of a patient or staff member resulting from a physical assault that occurs within or on the grounds of a facility.

8. Following the occurrence of an adverse health care event, the facility shall conduct a root cause analysis of the event. Following the analysis, the facility shall:

(1) Implement a corrective action plan to implement the findings of the analysis; or

(2) Report to the director any reasons for not taking corrective action.

If the root cause analysis and the implementation of a corrective action plan are complete at the time an event is required to be reported, the findings of the analysis and the corrective action plan shall be included in the report of the event. The findings of the root cause analysis and a copy of the corrective action plan shall otherwise be filed with the director within sixty days of the event.

9. The director shall design the reporting system so that a facility may file by electronic means the reports required under this section. The director shall encourage a facility to use the electronic filing option when such option is feasible for the facility.

10. A facility that determines that an event described in subsections 2 to 7 of this section has occurred shall inform any persons employed by the facility who are mandated reporters under state law of such determination.

197.144. 1. On or before July 1, 2006, the director shall establish an adverse health event reporting system designed to facilitate quality improvement in the health care system. The reporting system shall not be designed to punish errors by health care providers or health care facility employees. The reporting system shall consist of:

(1) Mandatory reporting by facilities of the adverse health care events listed in section 197.142;

(2) Mandatory completion of a root cause analysis and a corrective action plan by the facility and reporting of the findings of the analysis and the plan to the director or reporting of reasons for not taking corrective action as required in section 197.142;

(3) Analysis of reported information by the director to determine patterns of systemic failure in the health care system and successful methods to correct such failures;

(4) Sanctions against facilities for failure to comply with reporting system requirements; and

(5) Communication from the director to facilities, health care purchasers, and the public to maximize the use of the reporting system to improve health care quality.

2. The director shall:

(1) Analyze adverse event reports, corrective action plans, and findings of the root cause analyses to determine patterns of system failure in the health care system and successful methods to correct such failures;

(2) Communicate to individual facilities the director's conclusions, if any, regarding an adverse event reported by the facility;

(3) Communicate with relevant health care facilities any recommendations for corrective actions resulting from the director's analysis of submissions from facilities; and

(4) Publish an annual report:

(a) Describing, by facility, adverse events reported;

(b) Outlining, in aggregate, corrective action plans and the findings of root cause analyses; and

(c) Making recommendations for modifications of state health care options.

3. The director shall take steps necessary to determine if adverse event reports, the findings of the root cause analyses, and corrective action plans are filed in a timely manner. The director may sanction a facility for:

(1) Failure to file a timely adverse event report as required by section 197.142; or

(2) Failure to conduct a root cause analyses, to implement a corrective action plan, or to provide the findings of a root cause analysis or correction action plan in a timely fashion as required under section 197.142.

4. If a facility fails to develop and implement a corrective action plan or report to the director why corrective action is not needed, the director may suspend, revoke, fail to renew, or place conditions on the license under which the facility operates.

5. The department of health and senior services may promulgate rules to implement the provisions of sections 197.140 to 197.144. 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 sections 197.140 to 197.144 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. Sections 197.140 to 197.144 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, 2005, shall be invalid and void.

197.145. No information obtained or disclosed by the department under sections 197.140 to 197.146 shall be used as the basis for a cause of action against any person or entity required to report information or who is the subject of such reported information. Any information obtained or disclosed as a result of the reporting under sections 197.140 to 197.146 shall not be admissible in a court of law.

197.146. Pursuant to section 23.253, RSMo, of the Missouri Sunset Act:

(1) The provisions of the new program authorized under sections 197.140 to 197.144 shall automatically sunset six years after the effective date of sections 197.140 to 197.144 unless reauthorized by an act of the general assembly; and

(2) If such program is reauthorized, the program authorized under sections 197.140 to 197.144 shall automatically sunset twelve years after the effective date of the reauthorization of sections 197.140 to 197.144; and

(3) Sections 197.140 to 197.146 shall terminate on September first of the calendar

year immediately following the calendar year in which the program authorized under sections 197.140 to 197.144 is sunset.