SECOND REGULAR SESSION

[TRULY AGREED TO AND FINALLY PASSED**]**

HOUSE COMMITTEE SUBSTITUTE FOR

SENATE SUBSTITUTE FOR

SENATE COMMITTEE SUBSTITUTE FOR

SENATE BILL NO. 1279

92ND GENERAL ASSEMBLY

2004

4608L.07T

AN ACT

To repeal sections 192.020, 192.067, 192.138, 192.665, 192.667, and 197.293, RSMo, and to enact in lieu thereof seventeen new sections relating to health care facilities, with penalty provisions.

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

Section A. Sections 192.020, 192.067, 192.138, 192.665, 192.667, and 197.293, RSMo, are repealed and seventeen new sections enacted in lieu thereof, to be known as sections 192.020, 192.021, 192.067, 192.131, 192.138, 192.665, 192.667, 197.150, 197.152, 197.154, 197.156, 197.158, 197.160, 197.162, 197.165, 197.293, and 197.294, to read as follows:

192.020. **1.** It shall be the general duty and responsibility of the department of health and senior services to safeguard the health of the people in the state and all its subdivisions. It shall make a study of the causes and prevention of diseases. It shall designate those diseases which are infectious, contagious, communicable or dangerous in their nature and shall make and enforce adequate orders, findings, rules and regulations to prevent the spread of such diseases and to determine the prevalence of such diseases within the state. It shall have power and authority, with approval of the director of the department, to make such orders, findings, rules and regulations as will prevent the entrance of infectious, contagious and communicable diseases into the state.

2. The department of health and senior services shall include in its list of communicable or infectious diseases which must be reported to the department methicillin-resistant staphylococcus aureus (MRSA) and vancomycin-resistant enterococcus (VRE).

192.021. This act shall be known and may be cited as the "Missouri

EXPLANATION--Matter enclosed in bold-faced brackets [thus] in this bill is not enacted and is intended to be omitted in the law.

Nosocomial Infection Control Act of 2004". The purpose of the act is to decrease the incidence of infection within health care facilities in this state.

192.067. 1. The department of health and senior services, for purposes of conducting epidemiological studies to be used in promoting and safeguarding the health of the citizens of Missouri under the authority of this chapter is authorized to receive information from patient medical records. **The provisions of this section shall also apply to the collection, analysis, and disclosure of nosocomial infection data from patient records collected pursuant to section 192.667.**

2. The department shall maintain the confidentiality of all medical record information abstracted by or reported to the department. Medical information secured pursuant to the provisions of subsection 1 of this section may be released by the department only in a statistical aggregate form that precludes and prevents the identification of patient, physician, or medical facility except that medical information may be shared with other public health authorities and coinvestigators of a health study if they abide by the same confidentiality restrictions required of the department of health and senior services **and except as otherwise authorized by the provisions of sections 192.665 to 192.667**. The department of health and senior services, public health authorities and coinvestigators shall use the information collected only for the purposes provided for in this section **and section 192.667**.

3. No individual or organization providing information to the department in accordance with this section shall be deemed to be or be held liable, either civilly or criminally, for divulging confidential information unless such individual organization acted in bad faith or with malicious purpose.

4. The department of health and senior services is authorized to reimburse medical care facilities, within the limits of appropriations made for that purpose, for the costs associated with abstracting data for special studies.

5. Any department of health and senior services employee, public health authority or coinvestigator of a study who knowingly releases information which violates the provisions of this section shall be guilty of a class A misdemeanor and, upon conviction, shall be punished as provided by law.

192.131. 1. As used in this section, the following terms shall mean:

(1) "Advisory panel", the infection control advisory panel created by section 197.165, RSMo;

(2) "Antibiogram", a record of the resistance of microbes to various antibiotics;

(3) "Antimicrobial", the ability of an agent to destroy or prevent the development of pathogenic action of a microorganism;

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

2. Every laboratory performing culture and sensitivity testing on humans in Missouri shall submit data on health care associated infections to the department in accordance with this section. The data to be reported shall be defined by regulation of the department after considering the recommendations of the advisory panel. Such data may include antibiograms and, not later than July 1, 2005, shall include but not be limited to the number of patients or isolates by hospital, ambulatory surgical center, and other facility or practice setting with methicillin-resistant staphylococcus aureus (MRSA) or vancomycin-resistant enterococcus (VRE).

3. Information on infections collected pursuant to this section shall be subject to the confidentiality protections of this chapter but shall be available in provider-specific form to appropriate facility and professional licensure authorities.

4. The advisory panel shall develop a recommended plan to use laboratory and health care provider data provided pursuant to this chapter to create a system to:

(1) Enhance the ability of health care providers and the department to track the incidence and distribution of preventable infections, with emphasis on those infections that are most susceptible to interventions and that pose the greatest risk of harm to Missouri residents;

(2) Monitor trends in the development of antibiotic-resistant microbes, including but not limited to methicillin-resistant staphylococcus aureus (MRSA) and vancomycin-resistant enterococcus (VRE) infections.

5. In implementing this section, the advisory panel and the department shall conform to guidelines and standards adopted by the centers for disease control and prevention. The advisory panel's plan may provide for demonstration projects to assess the viability of the recommended initiatives.

192.138. Other provisions of the law to the contrary notwithstanding, requirements imposed by state law or regulation that institutions defined under chapters 197, RSMo, and 198, RSMo, make notifications concerning patients who are diagnosed as having reportable infectious or contagious diseases shall apply to such institutions provided that such notifications are consistent with federal laws and rules and regulations imposed thereunder governing the confidentiality of records of patients receiving medical assistance under the provisions of federal law **[**and further provide that such institutions failing to make such notifications shall not be deemed to have violated any state law or regulation requiring notification or considered civilly liable unless such institutions acted in bad faith or with malicious purpose**]**.

192.665. As used in this section **[**and**],** section 192.667**, and sections 197.150 to**

197.165, RSMo, the following terms mean:

(1) "Charge data", information submitted by health care providers on 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) "Health care provider", hospitals as defined in section 197.020, RSMo, and ambulatory surgical centers as defined in section 197.200, RSMo;

(6) **"Nosocomial infection", as defined by the national Centers for Disease Control and Prevention and applied to infections within hospitals, ambulatory surgical centers, and other facilities;**

(7) "Nosocomial infection incidence rate", a risk-adjusted measurement of new cases of nosocomial infections by procedure or device within a population over a given period of time, with such measurements defined by rule of the department pursuant to subsection 3 of section 192.667 for use by all hospitals, ambulatory surgical centers, and other facilities in complying with the requirements of the Missouri nosocomial infection control act of 2004;

(8) "Other facility", a type of facility determined to be a source of infections and designated by rule of the department pursuant to subsection 11 of section 192.667;

(9) "Patient abstract data", data submitted by hospitals which includes but is not limited to date of birth, sex, race, zip code, county of residence, admission date, discharge date, principal and other diagnoses, including external causes, principal and other procedures, procedure dates, total billed charges, 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.

192.667. 1. All health care providers shall at least annually provide to the department charge data as required by the department. All hospitals shall at least annually provide patient abstract data and financial data as required by the department. Hospitals as defined in section 197.020, RSMo, shall report patient abstract data for outpatients and inpatients. Within one year of August 28, 1992, ambulatory surgical centers as defined in section 197.200, RSMo, shall provide patient abstract data to the department. The department shall specify by rule the types of information which shall be submitted and the

method of submission.

2. **The department shall collect data on required nosocomial infection incidence rates from hospitals, ambulatory surgical centers, and other facilities as necessary to generate the reports required by this section. Hospitals, ambulatory surgical centers, and other facilities shall provide such data in compliance with this section.**

3. No later than July 1, 2005, the department shall promulgate rules specifying the standards and procedures for the collection, analysis, risk adjustment, and reporting of nosocomial infection incidence rates and the types of infections and procedures to be monitored pursuant to subsection 12 of this section. In promulgating such rules, the department shall:

(1) Use methodologies and systems for data collection established by the federal Centers for Disease Control and Prevention National Nosocomial Infection Surveillance System, or its successor; and

(2) Consider the findings and recommendations of the infection control advisory panel established pursuant to section 197.165, RSMo.

4. The infection control advisory panel created by section 197.165, RSMo, shall make a recommendation to the department regarding the appropriateness of implementing all or part of the nosocomial infection data collection, analysis, and public reporting requirements of this act by authorizing hospitals, ambulatory surgical centers, and other facilities to participate in the federal Centers for Disease Control and Prevention's National Nosocomial Infection Surveillance System, or its successor. The advisory panel shall consider the following factors in developing its recommendation:

(1) Whether the public is afforded the same or greater access to facility-specific infection control indicators and rates than would be provided under subsections 2, 3, and 6 to 12 of this section;

(2) Whether the data provided to the public are subject to the same or greater accuracy of risk adjustment than would be provided under subsections 2, 3, and 6 to 12 of this section;

(3) Whether the public is provided with the same or greater specificity of reporting of infections by type of facility infections and procedures than would be provided under subsections 2, 3, and 6 to 12 of this section;

(4) Whether the data are subject to the same or greater level of confidentiality of the identity of an individual patient than would be provided under subsection 2, 3, and 6 to 12 of this section;

(5) Whether the National Nosocomial Infection Surveillance System, or its successor, has the capacity to receive, analyze, and report the required data for all

facilities;

(6) Whether the cost to implement the nosocomial infection data collection and reporting system is the same or less than under subsections 2, 3, and 6 to 12 of this section.

5. Based on the affirmative recommendation of the infection control advisory panel, and provided that the requirements of subsection 12 of this section can be met, the department may or may not implement the federal Centers for Disease Control and Prevention Nosocomial Infection System, or its successor, as an alternative means of complying with the requirements of subsections 2, 3, and 6 to 12 of this section. If the department chooses to implement the use of the federal Centers for Disease Control Prevention Nosocomial Infection System, or its successor, as an alternative means of complying with the requirements of subsections 2, 3, and 6 to 12 of this section, it shall be a condition of licensure for hospitals and ambulatory surgical centers which opt to participate in the federal program to permit the federal program to disclose facility-specific data to the department as necessary to provide the public reports required by the department. Any hospital or ambulatory surgical center which does not voluntarily participate in the National Nosocomial Infection Surveillance System, or its successor, shall be required to abide by all of the requirements of subsections 2, 3, and 6 to 12 of this section.

6. 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 health care providers by entering into binding agreements negotiated with such associations or related organizations to obtain data required pursuant to section 192.665 and this section. A health care provider shall submit the required information to the department of health and senior services:

(1) If the provider does not submit the required data through such associations or related organizations;

(2) If no binding agreement has been reached within ninety days of August 28, 1992, between the department of health and senior services and such associations or related organizations; or

(3) If a binding agreement has expired for more than ninety days.

[3.**]** **7.** Information obtained by the department under the provisions of section 192.665 and this section shall not be public information. Reports and studies prepared by the department based upon such information shall be public information and may identify individual health care providers. The department of health and senior services may

authorize the use of the data by other research organizations pursuant to the provisions of section 192.067. The department shall not use or release any information provided under section 192.665 and this section which would enable any person to determine any health care provider'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. Any violation of this subsection is a class A misdemeanor.

[4.**]** **8.** The department shall undertake a reasonable number of studies and publish information, including at least an annual consumer guide, in collaboration with health care providers, business coalitions and consumers based upon the information obtained pursuant to the provisions of section 192.665 and this section. The department shall allow all health care providers and associations and related organizations who have submitted data which will be used in any report to review and comment on the report prior to its publication or release for general use. The department shall include any comments of a health care provider, at the option of the provider, and associations and related organizations in the publication if the department does not change the publication based upon those comments. The report shall be made available to the public for a reasonable charge.

[5.**]** **9.** Any health care provider 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.

[6.**]** **10.** A hospital, as defined in section 197.020, RSMo, aggrieved by the department's determination of ineligibility for state moneys pursuant to subsection **[**5**]** **9** of this section may appeal as provided in section 197.071, RSMo. An ambulatory surgical center as defined in section 197.200, RSMo, aggrieved by the department's determination of ineligibility for state moneys pursuant to subsection **[**5**]** **9** of this section may appeal as provided in section 197.221, RSMo.

[7. No rule or portion of a rule promulgated under the authority of section 192.665 and this section shall become effective unless it has been promulgated pursuant to the provisions of section 536.024, RSMo.**]**

11. The department of health may promulgate rules providing for collection of data and publication of nosocomial infection incidence rates for other types of health facilities determined to be sources of infections; except that, physicians' offices shall be exempt from reporting and disclosure of infection incidence rates.

12. In consultation with the infection control advisory panel established pursuant to section 197.165, RSMo, the department shall develop and disseminate to the public reports based on data compiled for a period of twelve months. Such reports shall be updated quarterly and shall show for each hospital, ambulatory surgical center, and other facility a risk-adjusted nosocomial infection incidence

rate for the following types of infection:

(1) Class I surgical site infections;

(2) Ventilator-associated pneumonia;

(3) Central line-related bloodstream infections;

(4) Other categories of infections that may be established by rule by the department.

The department, in consultation with the advisory panel, shall be authorized to collect and report data on subsets of each type of infection described in this subsection.

13. In the event the provisions of this act are implemented by requiring hospitals, ambulatory surgical centers, and other facilities to participate in the federal Centers for Disease Control and Prevention National Nosocomial Infection Surveillance System, or its successor, the types of infections to be publicly reported shall be determined by the department by rule and shall be consistent with the infections tracked by the National Nosocomial Infection Surveillance System, or its successor.

14. Reports published pursuant to subsection 12 of this section shall be published on the department's Internet website. The initial report shall be issued by the department not later than December 31, 2006. The reports shall be distributed at least annually to the governor and members of the general assembly.

15. The Hospital Industry Data Institute shall publish a report of Missouri hospitals' and ambulatory surgical centers' compliance with standardized quality of care measures established by the federal Centers for Medicare and Medicaid Services for prevention of infections related to surgical procedures. If the Hospital Industry Data Institute fails to do so by July 31, 2008, and annually thereafter, the department shall be authorized to collect information from the Centers for Medicare and Medicaid Services or from hospitals and ambulatory surgical centers and publish such information in accordance with subsection 14 of this section.

16. The data collected or published pursuant to this section shall be available to the department for purposes of licensing hospitals and ambulatory surgical centers pursuant to chapter 197, RSMo.

17. The department shall promulgate rules to implement the provisions of section 192.131 and sections 197.150 to 197.160, RSMo. 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, 2004, shall be invalid and void.

197.150. The department shall require that each hospital, ambulatory surgical center, and other facility have in place procedures for monitoring and enforcing compliance with infection control regulations and standards. Such procedures shall be coordinated with administrative staff, personnel staff, and the quality improvement program. Such procedures shall include, at a minimum, requirements for the facility's infection control program to conduct surveillance of personnel with a portion of the surveillance to be done in such manner that employees and medical staff are observed without their knowledge of such observation, provided that this unobserved surveillance requirement shall not be considered to be grounds for licensure enforcement action by the department until the department establishes clear and verifiable criteria for determining compliance. Such surveillance also may include monitoring of the rate of use of hand hygiene products.

197.152. 1. Infection control officers as defined in federal regulation and other hospital and ambulatory surgical center employees shall be protected against retaliation by the hospital or ambulatory surgical center for reporting infection control concerns pursuant to section 197.285 and shall be entitled to the full benefits of that section. Such infection control officers shall report any interference in the performance of their duties by their supervisors to the hospital or ambulatory surgical center compliance officer established by and empowered to act pursuant to section 197.285.

2. Infection control officers as defined in federal regulation shall also have the authority to order the cessation of a practice that falls outside accepted practices as defined by appropriate state and federal regulatory agencies, accreditation organizations, or the standards adopted by the Centers for Disease Control and Prevention or the Association of Professionals in Infection Control and Epidemiology. The hospital or ambulatory surgical center may require that such a cessation order of an infection control officer be endorsed by the hospital or ambulatory surgical center chief executive officer or his or her designee before taking effect. The hospital or ambulatory surgical center infection control committee shall convene as soon as possible to review such cessation order and may overrule or sustain the directive of the infection control officer. The department shall promulgate rules governing documentation of such events.

3. Members of the medical staff who report in good faith infection control concerns to the hospital or ambulatory surgical center administration or medical

staff leadership shall not be subject to retaliation or discrimination for doing so. Nothing in this section shall prevent or shield medical staff members from being subject to professional review actions for substandard care or breach of standards established in hospital policy, rules, or medical staff bylaws.

197.154. No later than July 1, 2005, the department shall review and update its current regulations governing hospital and ambulatory surgical center infection control programs. Such standards shall be based upon nationally recognized standards and shall include, but not be limited to, standards for:

(1) Maintaining databases to be used for infection tracking;

(2) Developing hospital protocols related to aseptic technique and infection control practices including but not limited to handwashing, isolation, and other infection control policies;

(3) Developing appropriate corrective action plans and follow-ups for any deficiencies identified in hospital infection control practices;

(4) Conducting root cause analysis and follow-up of sentinel events, as defined by the Joint Commission on Accreditation of Health Organizations, attributable to nosocomial infections; and

(5) Ensuring that hospital and ambulatory surgical center policies and medical staff bylaws are in place to promote and enforce compliance with infection control policies.

197.156. For purposes of reporting nosocomial infection outbreaks as required by department rule, the term "nosocomial infection outbreaks" shall mean infections as defined by the national Centers for Disease Control and Prevention within a defined time period. The time period shall be defined by the department based upon the number of infected patients in a facility.

197.158. Every hospital and ambulatory surgery center shall, beginning June 1, 2006, provide each patient an opportunity to submit to the hospital or ambulatory surgical center administration complaints, comments, and suggestions related to the care they received or their personal observations related to the quality of care provided. The department shall promulgate rules to implement this section.

197.160. The department of health and senior services shall have access to all data and information held by hospitals, ambulatory surgical centers, and other facilities related to their infection control practices, rates, or treatments of infections. Failure to provide such access shall be grounds for full or partial licensure suspension or revocation pursuant to section 197.293, sections 197.010 to 197.100, or sections 197.200 to 197.240. If the department determines that the hospital, ambulatory surgical center, or other facility is willfully impeding access

to such information, the department shall be authorized to direct all state agencies to suspend all or a portion of state payments to such hospital until such time as the desired information is obtained by the department.

197.162. The department shall in its licensure of hospitals and ambulatory surgical centers give special attention to infection control practices and shall direct hospitals and ambulatory surgical centers to set quantifiable measures of performance for reducing the incidence of nosocomial infections in Missouri. The department shall prepare an annual report on infection control standards and compliance, which shall be shared with the governor and the general assembly.

197.165. 1. The department shall appoint an "Infection Control Advisory Panel" for the purposes of implementing section 192.667 and 192.131, RSMo.

2. Members of the infection control advisory panel shall include:

(1) Two public members;

(2) Three board-certified or board-eligible physicians licensed pursuant to chapter 334, RSMo, who are affiliated with a Missouri hospital or medical school, active members of the society for health care epidemiology of America, and have demonstrated interest and expertise in health facility infection control;

(3) One physician licensed pursuant to chapter 334, RSMo, who is active in the practice of medicine in Missouri and who holds medical staff privileges at a Missouri hospital;

(4) Four infection control practitioners certified by the certification board of infection control and epidemiology, at least two of whom shall be practicing in a rural hospital or setting and at least two of whom shall be registered professional nurses licensed under chapter 335, RSMo;

(5) A medical statistician with an advanced degree in such specialty; and

(6) A clinical microbiologist with an advanced degree in such specialty;

(7) Three employees of the department, representing the functions of hospital and ambulatory surgical center licensure, epidemiology and health data analysis, who shall serve as ex officio nonvoting members of the panel.

3. Reasonable expenses of the panel shall be paid from private donations made specifically for that purpose to the "Infection Control Advisory Panel Fund", which is hereby created in the state treasury. If such donations are not received from private sources, then the provisions of this act shall be implemented without the advisory panel.

197.293. 1. In addition to the powers established in sections 197.070 and 197.220, the department of health and senior services shall use the following standards for enforcing hospital and ambulatory surgical center licensure regulations promulgated to enforce the provisions of sections 197.010 to 197.120**, sections 197.150 to 197.165,** and sections 197.200

to 197.240:

(1) Upon notification of a deficiency in meeting regulatory standards, the hospital or ambulatory surgical center shall develop and implement a plan of correction approved by the department which includes, but is not limited to, the specific type of corrective action to be taken and an estimated time to complete such action;

(2) If the plan as implemented does not correct the deficiency, the department may either:

(a) Direct the hospital or ambulatory surgical center to develop and implement a plan of correction pursuant to subdivision (1) of this subsection; or

(b) Require the hospital or ambulatory surgical center to implement a plan of correction developed by the department;

(3) If there is a continuing deficiency after implementation of the plan of correction pursuant to subdivision (2) of this subsection and the hospital or ambulatory surgical center has had an opportunity to correct such deficiency, the department may restrict new inpatient admissions or outpatient entrants to the service or services affected by such deficiency;

(4) If there is a continuing deficiency after the department restricts new inpatient admissions or outpatient entrants to the service or services pursuant to subdivision (3) of this subsection and the hospital or ambulatory surgical center has had an opportunity to correct such deficiency, the department may suspend operations in all or part of the service or services affected by such deficiency;

(5) If there is a continuing deficiency after suspension of operations pursuant to subdivision (4) of this subsection, the department may deny, suspend or revoke the hospital's or ambulatory surgical center's license pursuant to section 197.070 or section 197.220.

2. Notwithstanding the provisions of subsection 1 of this section to the contrary, if a deficiency in meeting licensure standards presents an immediate and serious threat to the patients' health and safety, the department may, based on the scope and severity of the deficiency, restrict access to the service or services affected by the deficiency until the hospital or ambulatory surgical center has developed and implemented an approved plan of correction. Decisions as to whether a deficiency constitutes an immediate and serious threat to the patients' health and safety shall be made in accordance with guidelines established pursuant to regulation of the department of health and senior services and such decisions shall be approved by the bureau of health facility licensing in the department of health and senior services, or its successor agency, or by a person authorized by the regulations to approve such decisions in the absence of the director.

197.294. No information disclosed by the department to the public pursuant to sections 192.020, 192.021, 192.067, 192.131, 192.138, 192.665, and 192.667, RSMo, and sections 197.150, 197.152, 197.154, 197.156, 197.158, 197.160, 197.162, 197.165, and 197.293 shall be used to establish a standard of care in a private civil action.