

SESSION OF 2006

**SUPPLEMENTAL NOTE ON SUBSTITUTE FOR
HOUSE BILL NO. 2829**

As Amended by House Committee of the Whole

Brief*

Sub. for HB 2829 would enact new law requiring regulation and inspection of office-based surgery facilities by the Secretary of Health and Environment. Clinics or facilities inspected pursuant to the bill would be charged a fee to cover the cost of the inspection. The bill specifically would not apply to medical facilities licensed under Kansas law.

Key Definitions

Several terms would be defined by the bill. Among the definitions that are key to understanding the scope of the bill are the following:

“Office-based surgery” would be defined as any surgery or other special procedure requiring anesthesia, analgesia or sedation which is performed by a physician in a clinical location other than a state-licensed medical facility, and which results in a patient stay of less than 24 hours. The term does not include minor surgery.

“Minor surgery” would be defined to be surgery that can be safely and comfortably performed under local or topical anesthesia, without more than an oral sedative or analgesic in minimal doses and where complications requiring hospitalization could not be reasonably foreseen.

“Special procedure” would be defined to be a patient care service that requires contact with the human body with or without instruments in a potentially painful manner, for a diagnostic or therapeutic procedure requiring anesthesia. The term does not include minor surgery.

“Surgery” would include manual or operative procedures that

*Supplemental notes are prepared by the Legislative Research Department and do not express legislative intent. The supplemental note and fiscal note for this bill may be accessed on the Internet at <http://www.kslegislature.org>

involve the removal or structural alteration of human tissue by any means, including the use of lasers, performed upon the human body in order to preserve health, terminate pregnancy, diagnose or treat disease, repair injury, correct deformity or defect, prolong life or relieve suffering, or for aesthetic, reconstructive or cosmetic purposes. The definition states that surgery specifically includes, but is not limited to, incision or curettage of tissue or an organ, suture or other repair of tissue or an organ, a closed or open reduction of a fracture, extraction of tissue from the uterus and insertion of natural or artificial implants.

Standards for Office-Based Surgery Facilities

The Secretary of Health and Environment would be required to adopt rules and regulations that establish standards for clinics and other facilities where office-based surgery and special procedures are performed. The Secretary would be required to consult with the State Board of Healing Arts in the development of those regulations. While establishing those regulations, the Secretary also would be required to consider standards adopted to regulate ambulatory surgical centers under Kansas law, guidelines for office-based surgery and special procedures approved by the Kansas Medical Society House of Delegates in 2002, and guidelines for office-based surgery and special procedures approved by the State Board of Healing Arts. The regulations would have to provide for protection of the identity of patients and health care providers.

Rules and regulations adopted to implement the bill would have to be in place as temporary regulations within 60 days of the effective date of the act. Permanent rules and regulations under the act would have to be adopted by January 1, 2007. Facilities covered by the act at the time rules and regulations are adopted would have a maximum of 30 days from the time of adoption to comply with the rules and regulations.

Rules and regulations adopted pursuant to the act would not apply to facilities accredited by the Joint Commission on Accreditation of Health Care Organizations.

The standards established by the Secretary would have to promote the safety of patients. The standards would have to include at least the following:

- Qualifications and supervision of nonphysician personnel excluding licensed nurses and registered nurse anesthetists;

- Facility safety and sanitation;
- Equipment requirements, sanitation, testing and maintenance;
- Patient screening, assessment and monitoring;
- Selection of procedures to be performed;
- Anesthesia services;
- Peri-operative care;
- Emergencies and patient transfers; and
- Quality assurance and peer review.

Inspections

The Secretary would be required to conduct unannounced inspections of facilities covered by the act on a routine basis at least once every five years. The Secretary would be required to forward the results of inspections to the Board of Healing Arts or the State Board of Nursing, or both, when a facility is found to be out of compliance with the act. As soon as possible after the effective date of rules and regulations adopted pursuant to the act, the Secretary would be required to conduct unannounced inspections of any covered facility where abortions are performed.

The Board of Healing Arts would be required to forward complaints it receives regarding facilities covered by the act to the Secretary. The Secretary also would be required to conduct inspections in a timely manner upon receipt of a complaint.

Enforcement and Penalties

The Secretary would be authorized to issue corrective orders when an inspection of a facility covered by the act reveals that the facility is out of compliance with the rules and regulations adopted to implement the bill. The corrective order would have to be in writing and would be served on the facility personally or by certified mail. The clinic or facility would have a maximum of 30 days during which to correct the deficiency identified in the corrective order. If the deficiency presents an extreme hazard to the health and safety of a patient, the Secretary could order correction in less than 30 days.

A follow-up inspection would be conducted at the end of the correction period. If the clinic or facility is found to be non-compliant at the time of the follow-up inspection, the corrective order would become an open record and the Secretary could restrict the performance of office-based surgeries or special procedures at the facility. In addition to restrictions, the Secretary could levy a maximum \$5,000 civil fine for each violation or for each day a violation continues. In addition, if the Secretary determines that continued performance of office-based surgeries and special procedures at a non-compliant facility poses a threat of potential harm to patients, the Secretary could enjoin performance of covered procedures until a hearing could be conducted. The hearing would be conducted under the requirements of the Administrative Procedure Act.

The Secretary would be required to consider all relevant factors when imposing penalties under the act. Specifically, the Secretary would have to consider the extent of harm caused by the violation, the nature and persistence of the violation, the length of time during which the violation occurred and any corrective action taken. The Secretary could not impose a penalty under the act until the violator had been provided with written notice stating the alleged violation, the penalty to be imposed, and the right of the clinic or facility to a hearing. The facility would have 15 days to request a hearing under the Administrative Procedure Act. All actions of the Secretary in connection with enforcement and imposition of penalties under the act would be subject to review pursuant to the Act for Judicial Review and Civil Enforcement of Agency Actions.

Fees

The Secretary would be required to assess inspection fees on all facilities inspected pursuant to the act. The fee would have to cover all costs associated with the inspection. The fee schedule would be set in rules and regulations adopted by the Secretary.

Background

The bill as amended by the House Committee of the Whole is nearly identical to the introduced version of the bill. The bill as passed by the House differs from the introduced version by including:

- “Termination of pregnancy” specifically in the definition of surgery;

- A time limit for adoption of temporary and permanent rules and regulations;
- A requirement that a corrective order would become an open record if a facility is found to be in non-compliance during a follow-up inspection;
- A requirement that facilities pay a fee to cover the cost of inspections under the act; and
- A specific exemption from the act for facilities accredited by the Joint Commission on Accreditation of Health Care Organizations.

The substitute bill recommended by the House Health Committee included the substance of 2005 HB 2503 which was vetoed.

At the House Health and Human Services Committee hearing on the introduced version of the bill, Rep. Nancy Kirk spoke in support of the bill. Opponents of the bill included representatives of the Kansas Association of Nurse Anesthetists, the Kansas Association of Osteopathic Medicine, the Kansas Medical Society, and the Kansas Board of Healing Arts.

The fiscal note prepared by the Division of the Budget on the introduced version of the bill states that the Department of Health and Environment estimated the fiscal impact of HB 2829 would result in expenditure of \$2,009,155 from the State General Fund in FY 2007. The fiscal note for the introduced version of the bill would not be relevant to the House version of the bill which would require facilities to pay the cost of inspections.