SENATE BILL No. 207

DIGEST OF INTRODUCED BILL

Citations Affected: IC 16-18-2; IC 16-40-5; IC 34-30-15-1.

Synopsis: Medical adverse event reporting. Requires a health care facility to file, with an agency selected by the state department of health, patient safety incident reports concerning certain acts that have caused or could have caused harm to a patient. Allows other persons to file the reports. Requires the agency to receive, process, and summarize the reports. Makes the reports and certain other information confidential. Requires the state department of health to study and develop quality indicators for infections and establish infection monitoring systems as part of the health care quality indicator data program.

Effective: July 1, 2007.

Dillon

January 8, 2007, read first time and referred to Committee on Health and Provider Services.

Introduced

First Regular Session 115th General Assembly (2007)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type.~~

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~*this style type*~~ reconciles conflicts between statutes enacted by the 2006 Regular Session of the General Assembly.

SENATE BILL No. 207

A BILL FOR AN ACT to amend the Indiana Code concerning health.

Be it enacted by the General Assembly of the State of Indiana:

SECTION 1. IC 16-18-2-7.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2007]: **Sec. 7.5. "Adverse drug event", for purposes of IC 16-40-5, has the meaning set forth in IC 16-40-5-1.**

SECTION 2. IC 16-18-2-10, AS AMENDED BY P.L.101-2006, SECTION 23, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2007]: Sec. 10. **(a) "Agency", for purposes of IC 16-40-5, has the meaning set forth in IC 16-40-5-2.**

(b) "Agency", for purposes of IC 16-41-37, has the meaning set forth in IC 16-41-37-1.

SECTION 3. IC 16-18-2-158.1 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2007]: **Sec. 158.1. "Harm", for purposes of IC 16-40-5, has the meaning set forth in IC 16-40-5-3.**

SECTION 4. IC 16-18-2-161 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2007]: Sec. 161. (a) "Health care facility" includes:

(1) hospitals licensed under IC 16-21-2, private mental health institutions licensed under IC 12-25, and tuberculosis hospitals established under IC 16-11-1 (before its repeal);

(2) health facilities licensed under IC 16-28; and

(3) rehabilitation facilities and kidney disease treatment centers.

(b) "Health care facility", for purposes of IC 16-28-13, has the meaning set forth in IC 16-28-13-0.5.

(c) "Health care facility", for purposes of IC 16-40-5, has the meaning set forth in IC 16-40-5-4.

SECTION 5. IC 16-40-5 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2007]:

Chapter 5. Patient Safety Programs

Sec. 1. As used in this chapter, "adverse drug event" means an event involving medication that causes, could have caused, or leads to patient harm while the health care facility controls the medication.

Sec. 2. As used in this chapter, "agency" means:

(1) a governmental agency; or

(2) a private nongovernmental entity;

that does not have regulatory authority over a health care facility.

Sec. 3. As used in this chapter, "harm" means:

(1) death; or

(2) temporary or permanent impairment of a body function or structure that requires intervention for the patient, including an increase in monitoring of the patient's condition, a change in therapy, or active medical or surgical treatment.

Sec. 4. As used in this chapter, "health care facility" means the following:

(1) An abortion clinic licensed under IC 16-21-2.

(2) An ambulatory outpatient surgical center licensed under IC 16-21-2.

(3) A birthing center licensed under IC 16-21-2.

(4) A community mental health center (as defined in IC 12-7-2-38).

(5) A community mental retardation and other developmental disabilities center (as defined in IC 12-7-2-39).

(6) A community or migrant health center (as defined in IC 16-46-5-1).

(7) A health facility licensed under IC 16-28-2 or IC 16-28-3.

(8) A home health agency licensed under IC 16-27-1.

(9) A hospice program licensed under IC 16-25-3.

(10) A hospital licensed under IC 16-21-2.

(11) A maternal and child health clinic (as defined in IC 16-46-5-5).

(12) A methadone clinic subject to IC 12-23-18.

(13) A psychiatric hospital (as defined in IC 12-7-2-151).

Sec. 5. The state department shall enter into an agreement with an agency for the administration of this chapter.

Sec. 6. (a) A health care facility shall report to the agency referred to in section 5 of this chapter each event, as the state department determines by rule, that causes or could have caused harm to a patient. An incident report made under this section must include information required by the state department.

(b) A health care facility, a health care professional, or an individual may file with the agency referred to in section 5 of this chapter an incident report that alleges that a health care facility or a health care professional, by an action taken or a failure to act, caused or could have caused harm to a patient, including harm that resulted from or could have resulted from:

(1) an adverse drug event; or

(2) an unexpected infection, including an infection that was probably acquired in the health care facility.

Sec. 7. (a) Except for information in an incident report that discloses the commission of a criminal offense, the following information contained in an incident report filed under section 6 of this chapter is confidential and may not be disclosed:

(1) The name of the person who made the incident report.

(2) The name of the patient.

(3) The name of any individual involved in the reported incident.

(4) The name of the health care facility involved in the reported incident.

(5) The date of the reported incident.

(6) Any other contents of the incident report submitted under section 6 of this chapter.

(b) Except in the case of an incident report disclosing the commission of a criminal offense, the following are also confidential and may not be disclosed:

(1) Any information obtained or produced by the agency administering this chapter in analyzing or processing an incident report filed under section 6 of this chapter.

(2) Any other information that would identify a person or health care facility described in subsection (a)(1) through

(a)(4).

(c) Except in the case of a report that discloses the commission of a criminal offense, summary patient safety reports prepared under this chapter by the agency administering this chapter may not be used in disciplinary actions or civil proceedings.

Sec. 8. A health care facility shall establish an analysis process and designate a responsible individual, a peer review committee, or other panel allowed by the state department to investigate each event that the state department requires to be reported.

Sec. 9. (a) The agency administering this chapter may contact a person who submits an incident report to obtain further information.

(b) The agency is not required to analyze or include in the summary patient safety report an incident report that is submitted anonymously.

Sec. 10. The agency administering this chapter shall do the following:

(1) Prepare incident reporting forms.

(2) Receive incident reports.

(3) Analyze the incident reports received under subdivision (2).

(4) Prepare and distribute summary patient safety reports containing the agency's findings and recommendations based on information received under this chapter. Summary patient safety reports must be prepared and distributed not less than every three (3) months to the state department. However, the state department may require more timely reports from the agency concerning certain types of incidents or patterns of incidents.

Sec. 11. (a) The state department shall distribute, as the state department determines is necessary, relevant patient safety information to health care facilities, health care organizations, and governmental agencies.

(b) The state department shall work with health care facilities, health care organizations, and governmental agencies to develop protocols and procedures to reduce and eliminate harm and adverse events to patients.

Sec. 12. The state department may adopt rules under IC 4-22-2 to administer this chapter.

SECTION 6. IC 34-30-15-1 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2007]: Sec. 1. (a) **Except as provided in subsection (e),** all proceedings of a peer review committee

are confidential.

(b) All communications to a peer review committee shall be privileged communications.

(c) **Except as provided in subsection (e),** neither the personnel of a peer review committee nor any participant in a committee proceeding shall reveal any content of:

(1) communications to;

(2) the records of; or

(3) the determination of;

a peer review committee outside of the peer review committee.

(d) However, the governing board of:

(1) a hospital;

(2) a professional health care organization;

(3) a preferred provider organization (including a preferred provider arrangement or reimbursement agreement under IC 27-8-11); or

(4) a health maintenance organization (as defined in IC 27-13-1-19) or a limited service health maintenance organization (as defined in IC 27-13-34-4);

may disclose the final action taken with regard to a professional health care provider without violating the provisions of this section.

(e) A health care facility (as defined in IC 16-40-5-4) may use a peer review committee to report, as required by IC 16-40-5-6, to the agency administering IC 16-40-5, events, as the state department determines by rule, that have caused or could have caused harm to a patient.

SECTION 7. [EFFECTIVE JULY 1, 2007] **(a) The definitions in IC 16-40-5, as added by this act, apply to this SECTION.**

(b) Notwithstanding IC 16-40-5, as added by this act, and IC 34-30-15-1, as amended by this act, a health care facility is not required before July 1, 2008, to report to the agency administering IC 16-40-5, events, as the state department determines by rule, that have caused or could have caused harm to a patient.

(c) Notwithstanding IC 16-40-5, as added by this act, the agency administering IC 16-40-5 is required to accept an incident report filed by a health care facility, a health care professional, or an individual before July 1, 2008.

(d) This SECTION expires July 1, 2009.

SECTION 8. [EFFECTIVE JULY 1, 2007] **(a) Notwithstanding IC 16-40-4, as part of the health care quality indicator data program, the state department of health shall, before December 31, 2007:**

(1) study and develop quality indicators for infections; and

(2) where the state department of health determines appropriate, establish infection monitoring systems.

(b) This SECTION expires July 1, 2008.