HOUSE BILL No. 1533

DIGEST OF INTRODUCED BILL

Citations Affected: IC 16-18-2; IC 16-34-3; IC 35-51-16-1.

Synopsis: Abortion inducing drugs. Specifies that only a physician who meets certain conditions may administer to a pregnant woman an abortion inducing drug, and sets forth the procedure the physician must follow. Requires a physician who learns of an adverse event following the use of an abortion inducing drug to report the adverse event to the Food and Drug Administration and the medical licensing board. Specifies that the reports of adverse events maintained by the medical licensing board are public records. Establishes a Class A misdemeanor for a violation concerning distribution of an abortion inducing drug and for failure to report an adverse event.

Effective: July 1, 2013.

Morris

January 22, 2013, read first time and referred to Committee on Public Policy.

Introduced

First Regular Session 118th General Assembly (2013)

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 2012 Regular Session of the General Assembly.

HOUSE BILL No. 1533

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 16-18-2-1.6 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2013]: **Sec. 1.6. "Abortion inducing drug", for purposes of IC 16-34-3, has the meaning set forth in IC 16-34-3-1.**

SECTION 2. IC 16-18-2-7.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2013]: **Sec. 7.5. "Adverse event", for purposes of IC 16-34-3, has the meaning set forth in IC 16-34-3-2.**

SECTION 3. IC 16-18-2-101.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2013]: **Sec. 101.5. "Drug label", for purposes of IC 16-34-3, has the meaning set forth in IC 16-34-3-3.**

SECTION 4. IC 16-34-3 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2013]:

Chapter 3. Abortion Inducing Drugs

Sec. 1. (a) As used in this chapter, "abortion inducing drug"

means a medicine, drug, or substance prescribed or dispensed with the intent of terminating a clinically diagnosable pregnancy with the knowledge that the termination will, with reasonable likelihood, cause the death of the fetus. The term includes the off-label use of a drug known to have abortion inducing properties if the drug is prescribed with the intent of causing an abortion.

(b) The term does not include a drug or substance that may be known to cause an abortion when the drug is being prescribed for another medical indication.

Sec. 2. As used in this chapter, "adverse event" means an undesirable experience associated with the use of an abortion inducing drug. The term includes the following incidents:

(1) Death.

(2) Life threatening occurrence.

(3) Hospitalization.

(4) Disability or permanent damage.

(5) Congenital anomaly or birth defect of the fetus.

(6) Medical intervention required to prevent permanent impairment or damage.

Sec. 3. As used in this chapter, "drug label" means the pamphlet or document accompanying an abortion inducing drug that:

(1) outlines the protocol tested and authorized by the federal Food and Drug Administration;

(2) sets forth how the drug is to be used; and

(3) has been agreed upon by the drug manufacturer applying for authorization of the drug by the federal Food and Drug Administration.

Sec. 4. (a) It is unlawful for an individual to knowingly give, sell, dispense, administer, prescribe, or otherwise provide an abortion inducing drug to a pregnant woman for the purpose of inducing an abortion or enabling an individual to induce an abortion unless the individual meets the following requirements:

(1) The individual is a physician licensed under IC 25-22.5.

(2) The individual follows the drug label protocol for the abortion inducing drug.

(b) Before giving, selling, dispensing, administering, prescribing, or otherwise providing an abortion inducing drug to a pregnant woman, a physician licensed under IC 25-22.5 shall do the following:

(1) Examine in person the pregnant woman.

(2) Document the following information on the pregnant woman's medical chart:

(A) The gestational age of the fetus.

(B) The intrauterine location of the fetus.

(3) Provide the following information to the pregnant woman:

(A) A copy of the drug label.

(B) The physician's telephone number and the name of the hospital where the physician has admitting privileges as required in IC 16-34-2-4.5.

(C) The information required in IC 16-34-2-1.1.

(c) A physician licensed under IC 25-22.5 who gives, sells, dispenses, administers, prescribes, or otherwise provides an abortion inducing drug to a pregnant woman shall schedule a follow-up appointment with the woman approximately fourteen (14) days after administration of the abortion inducing drug to:

(1) confirm that the pregnancy is terminated by conducting ultrasound imaging; and

(2) assess the degree of bleeding experienced by the pregnant woman.

(d) The physician described in subsection (c) shall make a reasonable effort to ensure that the pregnant woman returns for the follow-up appointment described in subsection (c), including recording in the pregnant woman's medical records the date and time of the follow-up appointment, a brief description of the efforts by the physician and the physician's staff to ensure that the pregnant woman returns for the follow-up appointment, and the name of the individuals who made those efforts.

Sec. 5. (a) A physician licensed under IC 25-22.5 who gives, sells, dispenses, administers, prescribes, or otherwise provides an abortion inducing drug to a pregnant woman and who is aware of a subsequent adverse event from the abortion inducing drug shall report the adverse event not later than three (3) days following the physician's knowledge of the adverse event to the following:

(1) The federal Food and Drug Administration through the federal Medwatch reporting system.

(2) The medical licensing board of Indiana.

(b) The medical licensing board of Indiana shall maintain and compile a report of each adverse event reported to the board under subsection (a). A report compiled under this subsection is a public record and is open to inspection. The report may not contain information that personally identifies a pregnant woman who experienced the adverse event described in subsection (a).

Sec. 6. (a) A person who intentionally, knowingly, or recklessly violates this chapter commits an unlawful activity related to an

abortion inducing drug, a Class A misdemeanor. A pregnant woman upon whom the drug induced abortion is performed may not be assessed a penalty under this section.

(b) In addition to the criminal penalty under subsection (a), a person who violates this chapter may be subject to disciplinary sanctions under IC 25-1-9 and civil liability for wrongful death and medical malpractice.

SECTION 5. IC 35-51-16-1, AS ADDED BY P.L.70-2011, SECTION 1, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2013]: Sec. 1. The following statutes define crimes in IC 16:

IC 16-19-12-1 (Concerning the state department of health).
IC 16-20-9-1 (Concerning local health departments).
IC 16-21-2-2.5 (Concerning licensure of hospitals).
IC 16-21-5-3 (Concerning licensure of hospitals).
IC 16-21-6-12 (Concerning hospital financial disclosure law).
IC 16-21-7-5 (Concerning hospitals).
IC 16-25-5-8 (Concerning hospices).
IC 16-25-6-1 (Concerning hospices).
IC 16-27-1-15 (Concerning home health agencies).
IC 16-27-2-3 (Concerning home health agencies).
IC 16-27-4-23 (Concerning home health agencies).
IC 16-28-7-5 (Concerning monitors).
IC 16-28-9-3 (Concerning monitors).
IC 16-28-9-4 (Concerning monitors).
IC 16-28-9-5 (Concerning monitors).
IC 16-30-5-1 (Concerning health planning).
IC 16-31-3-16 (Concerning emergency medical services).
IC 16-31-3-22 (Concerning emergency medical services).
IC 16-31-10-2 (Concerning emergency medical services).
IC 16-34-2-5 (Concerning abortion).
IC 16-34-2-6 (Concerning abortion).
IC 16-34-2-7 (Concerning abortion).
IC 16-34-3-6 (Concerning abortion).
IC 16-36-4-15 (Concerning medical consent).
IC 16-36-4-16 (Concerning medical consent).
IC 16-36-5-27 (Concerning medical consent).
IC 16-36-5-28 (Concerning medical consent).
IC 16-37-1-12 (Concerning vital statistics).
IC 16-37-1-13 (Concerning vital statistics).
IC 16-37-2-2.1 (Concerning vital statistics).
IC 16-37-2-19 (Concerning vital statistics).
IC 16-37-3-16 (Concerning vital statistics).

IC 16-38-5-4 (Concerning health registries).
IC 16-39-7.1-3 (Concerning health records).
IC 16-39-7.1-6 (Concerning health records).
IC 16-41-1-3 (Concerning communicable diseases).
IC 16-41-2-9 (Concerning communicable diseases).
IC 16-41-3-3 (Concerning communicable diseases).
IC 16-41-4-3 (Concerning communicable diseases).
IC 16-41-5-3 (Concerning communicable diseases).
IC 16-41-6-3 (Concerning communicable diseases).
IC 16-41-7-5 (Concerning communicable diseases).
IC 16-41-8-1 (Concerning communicable diseases).
IC 16-41-8-3 (Concerning communicable diseases).
IC 16-41-8-5 (Concerning communicable diseases).
IC 16-41-9-1.5 (Concerning communicable diseases).
IC 16-41-10-5 (Concerning communicable diseases).
IC 16-41-10-7 (Concerning communicable diseases).
IC 16-41-12-13 (Concerning communicable diseases).
IC 16-41-12-14 (Concerning communicable diseases).
IC 16-41-12-15 (Concerning communicable diseases).
IC 16-41-13-3 (Concerning communicable diseases).
IC 16-41-13-4 (Concerning communicable diseases).
IC 16-41-13-6 (Concerning communicable diseases).
IC 16-41-14-13 (Concerning communicable diseases).
IC 16-41-14-15 (Concerning communicable diseases).
IC 16-41-14-16 (Concerning communicable diseases).
IC 16-41-14-17 (Concerning communicable diseases).
IC 16-41-14-20 (Concerning communicable diseases).
IC 16-41-15-18 (Concerning communicable diseases).
IC 16-41-16-11 (Concerning communicable diseases).
IC 16-41-18-6 (Concerning prevention and treatment programs).
IC 16-41-19-10 (Concerning prevention and treatment programs).
IC 16-41-20-13 (Concerning health, sanitation, and safety).
IC 16-41-21-18 (Concerning health, sanitation, and safety).
IC 16-41-21-19 (Concerning health, sanitation, and safety).
IC 16-41-22-21 (Concerning health, sanitation, and safety).
IC 16-41-22-22 (Concerning health, sanitation, and safety).
IC 16-41-23-4 (Concerning health, sanitation, and safety).
IC 16-41-24-11 (Concerning health, sanitation, and safety).
IC 16-41-25-2 (Concerning health, sanitation, and safety).
IC 16-41-27-34 (Concerning health, sanitation, and safety).
IC 16-41-29-5 (Concerning regulation of lodging facilities and bedding materials).

IC 16-41-32-30 (Concerning regulation of lodging facilities and bedding materials).
IC 16-41-33-9 (Concerning pest control).
IC 16-41-34-8 (Concerning pest control).
IC 16-41-35-40 (Concerning radiation).
IC 16-41-38-10 (Concerning radon gas).
IC 16-42-1-16 (Concerning Uniform Food, Drug, and Cosmetic Act).
IC 16-42-1-34 (Concerning Uniform Food, Drug, and Cosmetic Act).
IC 16-42-2-8 (Concerning Uniform Food, Drug, and Cosmetic Act).
IC 16-42-2-9 (Concerning Uniform Food, Drug, and Cosmetic Act).
IC 16-42-3-12 (Concerning Uniform Food, Drug, and Cosmetic Act).
IC 16-42-4-5 (Concerning Uniform Food, Drug, and Cosmetic Act).
IC 16-42-5-26 (Concerning sanitary requirements for food establishments).
IC 16-42-5-27 (Concerning sanitary requirements for food establishments).
IC 16-42-10-13 (Concerning food).
IC 16-42-18-7 (Concerning food).
IC 16-42-19-27 (Concerning the Indiana Legend Drug Act).
IC 16-42-21-4 (Concerning the Indiana Legend Drug Act).
IC 16-44-1-1 (Concerning product labeling and inspection).
IC 16-44-2-22 (Concerning product labeling and inspection).
IC 16-46-6-12 (Concerning state health grants and programs).