
SENATE BILL No. 371

DIGEST OF INTRODUCED BILL

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

Synopsis: Abortion inducing drugs. Amends the definition of "abortion clinic" to include facilities that provide 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 related to abortion inducing drugs and maintained by the medical licensing board are public records. Makes a violation concerning distribution of an abortion inducing drug and failure to report an adverse event a Class A misdemeanor.

Effective: July 1, 2013.

Holdman

January 8, 2013, read first time and referred to Committee on Health and Provider Services.

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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.

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SENATE BILL No. 371



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

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

1 SECTION 1. IC 16-18-2-1.5, AS ADDED BY P.L.96-2005,
2 SECTION 2, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE
3 JULY 1, 2013]: Sec. 1.5. (a) "Abortion clinic", for purposes of
4 IC 16-21-2, means a freestanding entity that:
5 (1) performs surgical abortion procedures; **or**
6 (2) **provides an abortion inducing drug for the purpose of**
7 **inducing an abortion.**
8 (b) The term does not include the following:
9 (1) A hospital that is licensed as a hospital under IC 16-21-2.
10 (2) An ambulatory outpatient surgical center that is licensed as an
11 ambulatory outpatient surgical center under IC 16-21-2.
12 (3) A physician's office as long as:
13 (A) the surgical procedures performed at the physician's office
14 are not primarily surgical abortion procedures; **and**
15 (B) **abortion inducing drugs are not the primarily**
16 **dispensed or prescribed drug at the physician's office.**
17 SECTION 2. IC 16-18-2-1.6 IS ADDED TO THE INDIANA CODE



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

4 SECTION 3. IC 16-18-2-7.5 IS ADDED TO THE INDIANA CODE
5 AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY
6 1, 2013]: **Sec. 7.5. "Adverse event", for purposes of IC 16-34-3, has**
7 **the meaning set forth in IC 16-34-3-2.**

8 SECTION 4. IC 16-18-2-101.5 IS ADDED TO THE INDIANA
9 CODE AS A NEW SECTION TO READ AS FOLLOWS
10 [EFFECTIVE JULY 1, 2013]: **Sec. 101.5. "Drug label", for purposes**
11 **of IC 16-34-3, has the meaning set forth in IC 16-34-3-3.**

12 SECTION 5. IC 16-34-3 IS ADDED TO THE INDIANA CODE AS
13 A NEW CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY
14 1, 2013]:

15 **Chapter 3. Abortion Inducing Drugs**

16 **Sec. 1. As used in this chapter, "abortion inducing drug" means**
17 **a medicine, drug, or substance prescribed or dispensed with the**
18 **intent of terminating a clinically diagnosable pregnancy with the**
19 **knowledge that the termination will, with reasonable likelihood,**
20 **cause the death of the fetus. The term includes the off-label use of**
21 **a drug known to have abortion inducing properties if the drug is**
22 **prescribed with the intent of causing an abortion.**

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

- 26 (1) **Death.**
27 (2) **Life threatening occurrence.**
28 (3) **Hospitalization.**
29 (4) **Disability or permanent damage.**
30 (5) **Congenital anomaly or birth defect of the fetus.**
31 (6) **Medical intervention required to prevent permanent**
32 **impairment or damage.**

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

- 35 (1) **outlines the protocol authorized by the federal Food and**
36 **Drug Administration;**
37 (2) **sets forth how the drug is to be used; and**
38 (3) **has been agreed upon by the drug manufacturer applying**
39 **for authorization of the drug by the federal Food and Drug**
40 **Administration.**

41 **Sec. 4. (a) It is unlawful for an individual to knowingly give, sell,**
42 **dispense, administer, prescribe, or otherwise provide an abortion**

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1 inducing drug to a pregnant woman for the purpose of inducing an
2 abortion or enabling a person to induce an abortion unless the
3 individual meets the following requirements:

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

5 (2) The individual satisfies the protocol outlined in the final
6 print labeling as approved by the federal Food and Drug
7 Administration.

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

12 (1) Examine in person the pregnant woman.

13 (2) Conduct ultrasound imaging or oversee fetal ultrasound
14 imaging by an individual who is licensed or certified in
15 Indiana and whose scope of practice within the licensure or
16 certification includes conducting ultrasound imaging.

17 (3) Document the following information on the pregnant
18 woman's medical chart:

19 (A) The gestational age of the fetus.

20 (B) The intrauterine location of the fetus.

21 (4) Provide the following information to the pregnant woman:

22 (A) A copy of the final printed drug label.

23 (B) The name and telephone number for the physician in
24 which the treating physician has entered into an agreement
25 under IC 16-34-2-4.5(a)(2) concerning the management of
26 possible complications for the pregnant woman.

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

28 (5) Comply with the admitting privilege requirements set
29 forth in IC 16-34-2-4.5.

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

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

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

39 (d) The physician described in subsection (c) shall make a
40 reasonable effort to ensure that the pregnant woman returns for
41 the follow-up appointment described in subsection (c), including
42 recording in the pregnant woman's medical records the date, and

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1 time of the follow-up appointment, a brief description of the efforts
 2 by the physician and the physician's staff to ensure the woman's
 3 return, and the name of the individual who performed the efforts.

4 **Sec. 5.** A physician licensed under IC 25-22.5 that gives, sells,
 5 dispenses, administers, prescribes, or otherwise provides an
 6 abortion inducing drug to a pregnant woman shall comply with the
 7 hospital admitting privilege requirements under IC 16-34-2-4.5.

8 **Sec. 6. (a)** A physician licensed under IC 25-22.5 who gives, sells,
 9 dispenses, administers, prescribes, or otherwise provides an
 10 abortion inducing drug to a pregnant woman and who is aware of
 11 a subsequent adverse event from the abortion inducing drug shall
 12 report the adverse event not later than three (3) days following the
 13 physician's knowledge of the adverse event to the following:

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

16 (2) The medical licensing board of Indiana.

17 (b) The medical licensing board of Indiana shall do the
 18 following:

19 (1) Compile and retain the reports received under subsection
 20 (a).

21 (2) Make the reports available as public records and open to
 22 inspection. However, the medical licensing board of Indiana
 23 shall ensure that personally identifiable information
 24 contained in the reports concerning a patient are redacted
 25 before the reports are made available to the public under this
 26 section.

27 **Sec. 7. (a)** A person who intentionally, knowingly, or recklessly
 28 violates this chapter commits an unlawful activity related to an
 29 abortion inducing drug, a Class A misdemeanor. A pregnant
 30 woman upon whom the drug induced abortion is performed may
 31 not be assessed a penalty under this section.

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

36 SECTION 6. IC 35-51-16-1, AS ADDED BY P.L.70-2011,
 37 SECTION 1, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE
 38 JULY 1, 2013]: Sec. 1. The following statutes define crimes in IC 16:

39 IC 16-19-12-1 (Concerning the state department of health).

40 IC 16-20-9-1 (Concerning local health departments).

41 IC 16-21-2-2.5 (Concerning licensure of hospitals).

42 IC 16-21-5-3 (Concerning licensure of hospitals).

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- 1 IC 16-21-6-12 (Concerning hospital financial disclosure law).
 2 IC 16-21-7-5 (Concerning hospitals).
 3 IC 16-25-5-8 (Concerning hospices).
 4 IC 16-25-6-1 (Concerning hospices).
 5 IC 16-27-1-15 (Concerning home health agencies).
 6 IC 16-27-2-3 (Concerning home health agencies).
 7 IC 16-27-4-23 (Concerning home health agencies).
 8 IC 16-28-7-5 (Concerning monitors).
 9 IC 16-28-9-3 (Concerning monitors).
 10 IC 16-28-9-4 (Concerning monitors).
 11 IC 16-28-9-5 (Concerning monitors).
 12 IC 16-30-5-1 (Concerning health planning).
 13 IC 16-31-3-16 (Concerning emergency medical services).
 14 IC 16-31-3-22 (Concerning emergency medical services).
 15 IC 16-31-10-2 (Concerning emergency medical services).
 16 IC 16-34-2-5 (Concerning abortion).
 17 IC 16-34-2-6 (Concerning abortion).
 18 IC 16-34-2-7 (Concerning abortion).
 19 **IC 16-34-3-7 (Concerning abortion).**
 20 IC 16-36-4-15 (Concerning medical consent).
 21 IC 16-36-4-16 (Concerning medical consent).
 22 IC 16-36-5-27 (Concerning medical consent).
 23 IC 16-36-5-28 (Concerning medical consent).
 24 IC 16-37-1-12 (Concerning vital statistics).
 25 IC 16-37-1-13 (Concerning vital statistics).
 26 IC 16-37-2-2.1 (Concerning vital statistics).
 27 IC 16-37-2-19 (Concerning vital statistics).
 28 IC 16-37-3-16 (Concerning vital statistics).
 29 IC 16-38-5-4 (Concerning health registries).
 30 IC 16-39-7.1-3 (Concerning health records).
 31 IC 16-39-7.1-6 (Concerning health records).
 32 IC 16-41-1-3 (Concerning communicable diseases).
 33 IC 16-41-2-9 (Concerning communicable diseases).
 34 IC 16-41-3-3 (Concerning communicable diseases).
 35 IC 16-41-4-3 (Concerning communicable diseases).
 36 IC 16-41-5-3 (Concerning communicable diseases).
 37 IC 16-41-6-3 (Concerning communicable diseases).
 38 IC 16-41-7-5 (Concerning communicable diseases).
 39 IC 16-41-8-1 (Concerning communicable diseases).
 40 IC 16-41-8-3 (Concerning communicable diseases).
 41 IC 16-41-8-5 (Concerning communicable diseases).
 42 IC 16-41-9-1.5 (Concerning communicable diseases).

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- 1 IC 16-41-10-5 (Concerning communicable diseases).
- 2 IC 16-41-10-7 (Concerning communicable diseases).
- 3 IC 16-41-12-13 (Concerning communicable diseases).
- 4 IC 16-41-12-14 (Concerning communicable diseases).
- 5 IC 16-41-12-15 (Concerning communicable diseases).
- 6 IC 16-41-13-3 (Concerning communicable diseases).
- 7 IC 16-41-13-4 (Concerning communicable diseases).
- 8 IC 16-41-13-6 (Concerning communicable diseases).
- 9 IC 16-41-14-13 (Concerning communicable diseases).
- 10 IC 16-41-14-15 (Concerning communicable diseases).
- 11 IC 16-41-14-16 (Concerning communicable diseases).
- 12 IC 16-41-14-17 (Concerning communicable diseases).
- 13 IC 16-41-14-20 (Concerning communicable diseases).
- 14 IC 16-41-15-18 (Concerning communicable diseases).
- 15 IC 16-41-16-11 (Concerning communicable diseases).
- 16 IC 16-41-18-6 (Concerning prevention and treatment programs).
- 17 IC 16-41-19-10 (Concerning prevention and treatment programs).
- 18 IC 16-41-20-13 (Concerning health, sanitation, and safety).
- 19 IC 16-41-21-18 (Concerning health, sanitation, and safety).
- 20 IC 16-41-21-19 (Concerning health, sanitation, and safety).
- 21 IC 16-41-22-21 (Concerning health, sanitation, and safety).
- 22 IC 16-41-22-22 (Concerning health, sanitation, and safety).
- 23 IC 16-41-23-4 (Concerning health, sanitation, and safety).
- 24 IC 16-41-24-11 (Concerning health, sanitation, and safety).
- 25 IC 16-41-25-2 (Concerning health, sanitation, and safety).
- 26 IC 16-41-27-34 (Concerning health, sanitation, and safety).
- 27 IC 16-41-29-5 (Concerning regulation of lodging facilities and
- 28 bedding materials).
- 29 IC 16-41-32-30 (Concerning regulation of lodging facilities and
- 30 bedding materials).
- 31 IC 16-41-33-9 (Concerning pest control).
- 32 IC 16-41-34-8 (Concerning pest control).
- 33 IC 16-41-35-40 (Concerning radiation).
- 34 IC 16-41-38-10 (Concerning radon gas).
- 35 IC 16-42-1-16 (Concerning Uniform Food, Drug, and Cosmetic
- 36 Act).
- 37 IC 16-42-1-34 (Concerning Uniform Food, Drug, and Cosmetic
- 38 Act).
- 39 IC 16-42-2-8 (Concerning Uniform Food, Drug, and Cosmetic
- 40 Act).
- 41 IC 16-42-2-9 (Concerning Uniform Food, Drug, and Cosmetic
- 42 Act).

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- 1 IC 16-42-3-12 (Concerning Uniform Food, Drug, and Cosmetic
- 2 Act).
- 3 IC 16-42-4-5 (Concerning Uniform Food, Drug, and Cosmetic
- 4 Act).
- 5 IC 16-42-5-26 (Concerning sanitary requirements for food
- 6 establishments).
- 7 IC 16-42-5-27 (Concerning sanitary requirements for food
- 8 establishments).
- 9 IC 16-42-10-13 (Concerning food).
- 10 IC 16-42-18-7 (Concerning food).
- 11 IC 16-42-19-27 (Concerning the Indiana Legend Drug Act).
- 12 IC 16-42-21-4 (Concerning the Indiana Legend Drug Act).
- 13 IC 16-44-1-1 (Concerning product labeling and inspection).
- 14 IC 16-44-2-22 (Concerning product labeling and inspection).
- 15 IC 16-46-6-12 (Concerning state health grants and programs).

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