
HOUSE BILL No. 1038

DIGEST OF INTRODUCED BILL

Citations Affected: IC 16-18-2; IC 16-41-12; IC 35-42-1-7.

Synopsis: Blood donation testing. Defines "blood" for purposes of regulating blood centers. Includes: (1) blood and plasma used for research purposes; and (2) human cells, tissues, or cellular or tissue-based products; as exceptions to the requirement of the disposal of tested materials with an inconclusive result. Removes a requirement that a blood center request an individual's Social Security number. Allows a blood center to distribute blood or plasma before the completion of a screening test in a documented medical emergency. Provides for an exception to the crime of transferring contaminated body fluids for a person who transfers fluids for a blood inventory intended for or made available for transfusion or injection to a patient.

Effective: July 1, 2013.

Brown T, Clere

January 7, 2013, read first time and referred to Committee on Public Health.

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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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HOUSE BILL No. 1038



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 16-18-2-36.9 IS ADDED TO THE INDIANA
- 2 CODE AS A **NEW** SECTION TO READ AS FOLLOWS
- 3 [EFFECTIVE JULY 1, 2013]: **Sec. 36.9. "Blood", for purposes of**
- 4 **IC 16-41-12, has the meaning set forth in IC 16-41-12-2.5.**
- 5 SECTION 2. IC 16-18-2-96.5 IS ADDED TO THE INDIANA
- 6 CODE AS A **NEW** SECTION TO READ AS FOLLOWS
- 7 [EFFECTIVE JULY 1, 2013]: **Sec. 96.5. "Distributed for use", for**
- 8 **purposes of IC 16-41-12, has the meaning set forth in**
- 9 **IC 16-41-12-5.5.**
- 10 SECTION 3. IC 16-18-2-183.2 IS ADDED TO THE INDIANA
- 11 CODE AS A **NEW** SECTION TO READ AS FOLLOWS
- 12 [EFFECTIVE JULY 1, 2013]: **Sec. 183.2. "Human cells, tissues, or**
- 13 **cellular or tissue-based products" or "HCT/Ps", for purposes of**
- 14 **IC 16-41-12, has the meaning set forth in 21 CFR 1271.3(d).**
- 15 SECTION 4. IC 16-41-12-1 IS AMENDED TO READ AS
- 16 FOLLOWS [EFFECTIVE JULY 1, 2013]: Sec. 1. As used in this
- 17 chapter, "autologous donation" means the removal and storage of blood



1 or blood components from a donor or patient for an intended
2 transfusion to the same donor or patient.

3 SECTION 5. IC 16-41-12-2.5 IS ADDED TO THE INDIANA
4 CODE AS A NEW SECTION TO READ AS FOLLOWS
5 [EFFECTIVE JULY 1, 2013]: **Sec. 2.5. (a) As used in this chapter,**
6 **"blood" means any of the following:**

7 **(1) Human blood.**

8 **(2) Human blood components.**

9 **(3) Human blood derivatives.**

10 **(b) The term does not include human cells, tissues, or cellular or**
11 **tissue-based products (HCT/Ps).**

12 SECTION 6. IC 16-41-12-3 IS AMENDED TO READ AS
13 FOLLOWS [EFFECTIVE JULY 1, 2013]: Sec. 3. As used in this
14 chapter, "blood center" includes a blood bank, a blood storage facility,
15 a plasma center, a hospital, or other facility where blood or blood
16 products are is collected.

17 SECTION 7. IC 16-41-12-5 IS AMENDED TO READ AS
18 FOLLOWS [EFFECTIVE JULY 1, 2013]: Sec. 5. As used in this
19 chapter, "directed donation" means a donation of whole blood or blood
20 components collected from an individual on behalf of an intended
21 recipient of the transfusion.

22 SECTION 8. IC 16-41-12-5.5 IS ADDED TO THE INDIANA
23 CODE AS A NEW SECTION TO READ AS FOLLOWS
24 [EFFECTIVE JULY 1, 2013]: **Sec. 5.5. (a) As used in this chapter,**
25 **"distributed for use" refers to a blood center releasing or shipping**
26 **blood for use in a blood inventory intended for or made available**
27 **for transfusion or injection to a patient.**

28 **(b) The term does not include the release or shipment of blood:**

29 **(1) to a researcher; or**

30 **(2) for further manufacturing;**

31 **as approved in writing by the federal Food and Drug**
32 **Administration.**

33 SECTION 9. IC 16-41-12-6.5 IS ADDED TO THE INDIANA
34 CODE AS A NEW SECTION TO READ AS FOLLOWS
35 [EFFECTIVE JULY 1, 2013]: **Sec. 6.5. As used in this chapter,**
36 **"human cells, tissues, or cellular or tissue-based products" or**
37 **"HCT/Ps" has the meaning set forth in 21 CFR 1271.3(d).**

38 SECTION 10. IC 16-41-12-8 IS AMENDED TO READ AS
39 FOLLOWS [EFFECTIVE JULY 1, 2013]: Sec. 8. As used in this
40 chapter, "screening test" means a laboratory screening test or a series
41 of tests **approved by the federal Food and Drug Administration and**
42 **required by the state department to be performed on blood or blood**

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1 products collected under this chapter, including the following:

2 (1) Tests for antibodies to the human immunodeficiency virus
3 (HIV).

4 (2) Other tests determined by the state department.

5 SECTION 11. IC 16-41-12-11 IS AMENDED TO READ AS
6 FOLLOWS [EFFECTIVE JULY 1, 2013]: Sec. 11. (a) The:

7 (1) procurement, processing, distribution, or use of:

8 (A) ~~whole~~ blood;

9 (B) plasma; ~~blood products; blood derivatives;~~

10 (C) **human cells, tissues, or cellular or tissue-based**
11 **products;** or

12 (D) other human tissue, such as corneas, bones, or organs;

13 by a bank, storage facility, or hospital; and

14 (2) injection, transfusion, or transplantation of any of the human
15 tissue listed in subdivision (1) into the human body by a hospital,
16 physician, or surgeon, whether or not any remuneration is paid;

17 is the rendition of a service and not the sale of a product. Such services
18 do not give rise to an implied warranty of merchantability or fitness for
19 a particular purpose, nor do the services give rise to strict liability in
20 tort.

21 (b) A hospital, physician, or other person is not required to perform
22 another screening test on ~~whole blood or plasma blood products, or~~
23 ~~blood derivatives that are~~ is provided by a blood center if the blood ~~or~~
24 **plasma** is labeled indicating that the blood ~~or plasma~~ has been tested
25 as required under section 13 of this chapter.

26 (c) An autologous blood donor may specify that the donor's blood
27 must be used for the donor. Blood that is donated under this section
28 must be tested for the human immunodeficiency virus (HIV). The
29 blood center shall reserve the donor's blood for the purposes specified
30 by the donor and shall label the blood accordingly.

31 (d) A directed blood donor may specify that the donor's blood is to
32 be used for another person. The blood center shall consider the medical
33 suitability and the wishes of the donor and recipient in making final
34 distribution of the blood.

35 (e) The blood center is subject to penalties under this chapter if the
36 blood center knowingly fails to reserve the blood for the purposes
37 specified by the recipient under this section or if the blood center fails
38 to comply with subsections (c) through (d).

39 (f) A blood center located outside Indiana may not distribute:

40 (1) blood; ~~or~~

41 (2) plasma;

42 (3) ~~a blood product;~~ or

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1 ~~(4) a blood derivative;~~
 2 in Indiana unless the blood center has certified to the state department
 3 that the blood has undergone a screening test **as required** under this
 4 chapter.

5 SECTION 12. IC 16-41-12-12 IS AMENDED TO READ AS
 6 FOLLOWS [EFFECTIVE JULY 1, 2013]: Sec. 12. The state
 7 department shall adopt rules under IC 4-22-2 to carry out the purposes
 8 of this chapter. In formulating the rules, the state department shall
 9 consider:

- 10 (1) present medical and scientific practices in the field; ~~and~~
 11 (2) **rules and regulations of the federal Food and Drug**
 12 **Administration; and**
 13 (3) any other ~~proper~~ procedure that should be followed to
 14 reasonably ensure the safety of the donor and recipient of ~~whole~~
 15 blood, ~~plasma, blood products, and blood derivatives;~~

16 SECTION 13. IC 16-41-12-13, AS AMENDED BY P.L.59-2012,
 17 SECTION 1, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE
 18 JULY 1, 2013]: Sec. 13. (a) **Except as provided in subsection (h)**, a
 19 blood center shall perform a screening test on a donor's blood and
 20 obtain the results of the test before blood ~~or plasma a blood product, or~~
 21 ~~a blood derivative~~ is distributed for use.

22 (b) The blood center shall label blood ~~or plasma a blood product, or~~
 23 ~~a blood derivative~~ before distribution **for use** by the blood center to
 24 indicate the results of the **screening** tests required by this chapter. The
 25 blood center shall also label each blood sample according to the
 26 regulations of the federal Food and Drug Administration.

27 (c) The blood center shall perform a confirmatory test on a blood
 28 donation from a donor when the screening test performed under
 29 subsection (a) yields repeatedly reactive results.

30 (d) Except for:

- 31 (1) a sample retained to perform a confirmatory test;
 32 (2) **blood or plasma** units used for research purposes or in the
 33 production of pharmaceutical products if the blood center ~~or the~~
 34 **manufacturer of the pharmaceutical products** has obtained
 35 approval from the federal Food and Drug Administration; ~~or~~
 36 (3) an autologous donation for stem cell transplantation; ~~or~~
 37 (4) **other autologous donations of blood or HCT/Ps if:**
 38 **(A) the blood center agrees to distribute for use; and**
 39 **(B) the attending physician has been informed of the**
 40 **screening test results;**

41 the blood center shall dispose of a blood donation after an inconclusive
 42 or repeatedly reactive screening test has been performed. The disposal

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1 must be made under rules adopted by the state department under this
2 chapter and IC 16-41-16.

3 (e) A blood center shall report to the state department the results of
4 each positive confirmatory test conducted under subsection (c).

5 (f) A blood center shall attempt to notify a donor and refer the donor
6 to counseling when the confirmatory test on the donor's blood is
7 inconclusive or indicates the presence of antibodies to the human
8 immunodeficiency virus (HIV).

9 ~~(g) Each health care provider that administers blood transfusions~~
10 ~~shall keep a record of the following:~~

11 ~~(1) Blood center that furnished the blood;~~

12 ~~(2) Unit number assigned to the blood;~~

13 ~~The records shall be made available to the state department for~~
14 ~~inspection.~~

15 ~~(h) (g) An employee who is responsible for conducting the~~
16 ~~screening test required under this section who knowingly or~~
17 ~~intentionally fails to conduct the screening test commits a Class A~~
18 ~~misdemeanor.~~

19 **(h) A blood center may distribute for use blood or plasma before**
20 **the completion of the screening test in a documented medical**
21 **emergency.**

22 SECTION 14. IC 16-41-12-15, AS AMENDED BY P.L.59-2012,
23 SECTION 2, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE
24 JULY 1, 2013]: Sec. 15. (a) A blood center shall require a blood donor
25 to provide to the blood center the following information:

26 (1) Name.

27 (2) Address.

28 (3) Date of birth.

29 ~~(b) A blood center shall request a blood donor to provide the blood~~
30 ~~donor's Social Security number.~~

31 ~~(c) (b) A blood center shall report the name and address of a blood~~
32 ~~donor to the state department when a confirmatory test of the blood~~
33 ~~donor's blood confirms the presence of antibodies to the human~~
34 ~~immunodeficiency virus (HIV).~~

35 ~~(d) (c) A blood center shall provide to a blood donor information to~~
36 ~~enable the blood donor to give informed consent to the procedures~~
37 ~~required by this chapter or IC 16-36. The information required by this~~
38 ~~subsection must be in the following form:~~

39 NOTICE

40 (1) This blood center performs a screening test for the human
41 immunodeficiency virus (HIV) on every donor's blood.

42 (2) This blood center reports to the state department of health the

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1 name and address of a blood donor when a confirmatory test of
 2 the blood donor's blood confirms the presence of antibodies to the
 3 human immunodeficiency virus (HIV).

4 (3) A person who recklessly, knowingly, or intentionally donates
 5 (excluding self-donations for stem cell transplantation, **other**
 6 **autologous donations, or donations not intended by the blood**
 7 **center for distribution or use**), sells, or transfers blood or a
 8 blood component that contains antibodies for the human
 9 immunodeficiency virus (HIV) commits transferring
 10 contaminated blood, a Class C felony. The offense is a Class A
 11 felony if the offense results in the transmission of the virus to
 12 another person.

13 SECTION 15. IC 16-41-12-17 IS AMENDED TO READ AS
 14 FOLLOWS [EFFECTIVE JULY 1, 2013]: Sec. 17. The state
 15 department may adopt rules under IC 4-22-2, after considering the
 16 guidelines of the federal Food and Drug Administration, for the
 17 minimum standards and specific requirements for operation of a blood
 18 center, including the following:

19 (1) Physical facilities, including refrigeration, lighting,
 20 construction, and equipment of the blood center to ensure the
 21 operation of the blood center in a manner that protects the public
 22 health.

23 (2) Testing procedures for communicable diseases transmitted by
 24 blood.

25 (3) Standards for collection, processing, storage, distribution, and
 26 proper conduct of the blood transfusion service of blood. ~~and~~
 27 ~~blood products.~~

28 (4) Identification and screening of donors.

29 (5) Qualifications for medical and laboratory personnel employed
 30 in a blood center.

31 (6) Restrictions on the use of blood and plasma donations.

32 (7) System of identifying the donor of the blood at all times,
 33 including after the blood has been administered to the recipient.

34 (8) Establishment of a system for determining the inventory level
 35 of blood in all blood centers and the coordination of the
 36 distribution of blood. ~~and blood products.~~

37 (9) Proficiency testing.

38 (10) All sanitary conditions within the blood center and the blood
 39 center's surroundings needed to protect the public and the
 40 employees.

41 (11) A quality assurance program.

42 SECTION 16. IC 16-41-12-19 IS AMENDED TO READ AS

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1 FOLLOWS [EFFECTIVE JULY 1, 2013]: Sec. 19. (a) A health care
 2 provider that administers blood transfusions shall keep a record of the
 3 following:

4 (1) Blood center that furnished the blood.

5 (2) Unit number assigned to the blood.

6 The record must be made available to the state department for
 7 inspection.

8 (b) The state department may require a blood center to submit
 9 financial information on allegations of financial impropriety involving
 10 the blood supply.

11 (c) The state department may require the demonstration of
 12 proficiency in the performance of the tests offered by the blood center.

13 (d) The state department may require the owner and director of a
 14 blood center to submit reports under oath that contain information and
 15 data concerning the technical operation of the blood center.

16 SECTION 17. IC 35-42-1-7, AS AMENDED BY P.L.59-2012,
 17 SECTION 3, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE
 18 JULY 1, 2013]: Sec. 7. (a) As used in this section, "component" means
 19 plasma, platelets, or serum of a human being.

20 (b) A person who recklessly, knowingly, or intentionally donates,
 21 sells, or transfers blood (**as defined in IC 16-41-12-2.5**), a blood
 22 component, or semen for artificial insemination (as defined in
 23 IC 16-41-14-2) that contains the human immunodeficiency virus (HIV)
 24 commits transferring contaminated body fluids, a Class C felony.

25 (c) However, the offense is a Class A felony if it results in the
 26 transmission of the human immunodeficiency virus (HIV) to any
 27 person other than the defendant.

28 (d) This section does not apply to:

29 (1) a person who, for reasons of privacy, donates, sells, or
 30 transfers blood or a blood component at a blood center (as defined
 31 in IC 16-41-12-3) after the person has notified the blood center
 32 that the blood or blood component must be disposed of and may
 33 not be used for any purpose;

34 (2) a person who transfers blood, a blood component, semen, or
 35 another body fluid that contains the human immunodeficiency
 36 virus (HIV) for:

37 (A) research purposes; or

38 (B) **a blood inventory intended for or made available for**
 39 **transfusion or injection to a patient;** or

40 (3) a person who is an autologous blood donor for stem cell
 41 transplantation.
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