January 25, 2013

HOUSE BILL No. 1038

DIGEST OF HB 1038 (Updated January 23, 2013 6:47 pm - DI 77)

Citations Affected: IC 16-18; IC 16-41; IC 35-42.

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. Makes conforming changes.

Effective: July 1, 2013.

Brown T, Clere, Brown C

January 7, 2013, read first time and referred to Committee on Public Health.
January 24, 2013, amended, reported — Do Pass.

C o p y

January 25, 2013

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.

C o p y

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:

SECTION 1. IC 16-18-2-36.9 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2013]: **Sec. 36.9. "Blood", for purposes of IC 16-41-12, has the meaning set forth in IC 16-41-12-2.5.**

SECTION 2. IC 16-18-2-96.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2013]: **Sec. 96.5. "Distributed for use", for purposes of IC 16-41-12, has the meaning set forth in IC 16-41-12-5.5.**

SECTION 3. IC 16-18-2-183.2 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2013]: **Sec. 183.2. "Human cells, tissues, or cellular or tissue-based products" or "HCT/Ps", for purposes of IC 16-41-12, has the meaning set forth in 21 CFR 1271.3(d).**

SECTION 4. IC 16-41-12-1 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2013]: Sec. 1. As used in this chapter, "autologous donation" means the removal and storage of blood

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

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

(1) Human blood.

(2) Human blood components.

(3) Human blood derivatives.

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

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

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

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

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

(1) to a researcher; or

(2) for further manufacturing;

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

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

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

C o p y

~~products~~ collected under this chapter, including the following:

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

(2) Other tests determined by the state department.

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

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

(A) ~~whole~~ blood;

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

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

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

by a bank, storage facility, or hospital; and

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

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

(b) A hospital, physician, or other person is not required to perform another screening test on ~~whole~~ blood **or** plasma ~~blood products, or blood derivatives~~ that: ~~are~~

(1) is provided by a blood center if the blood **or plasma** is labeled indicating that the blood **or plasma** has been tested as required under section ~~13~~ **13(b)** of this chapter; **or**

(2) is provided by a blood center under section 13(h) of this chapter and the blood or plasma is labeled as required by 21 CFR 606.121(h).

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

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

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

C o p y

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

(1) blood; **or**

(2) plasma;

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

~~(4) a blood derivative;~~

in Indiana unless the blood center has certified to the state department that the blood has undergone a screening test **as required** under this chapter.

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

(1) present medical and scientific practices in the field; ~~and~~

(2) rules and regulations of the federal Food and Drug Administration; and

(3) any other ~~proper~~ procedure that should be followed to reasonably ensure the safety of the donor and recipient of ~~whole~~ blood. ~~plasma, blood products, and blood derivatives.~~

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

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

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

(d) Except for:

(1) a sample retained to perform a confirmatory test;

(2) **blood or plasma** units used for research purposes or in the production of pharmaceutical products if the blood center **or the manufacturer of the pharmaceutical products** has obtained approval from the federal Food and Drug Administration; ~~or~~

(3) an autologous donation for stem cell transplantation; **or**

(4) other autologous donations of blood or HCT/Ps if:

(A) the blood center agrees to distribute for use; and

C o p y

(B) the attending physician has been informed of the screening test results;

the blood center shall dispose of a blood donation after an inconclusive or repeatedly reactive screening test has been performed. The disposal must be made under rules adopted by the state department under this chapter and IC 16-41-16.

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

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

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

~~(1) Blood center that furnished the blood.~~

~~(2) Unit number assigned to the blood.~~

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

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

(h) Subject to 21 CFR 610.40(g), a blood center may distribute for use blood or plasma before the completion of the screening test in a documented medical emergency.

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

(1) Name.

(2) Address.

(3) Date of birth.

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

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

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

C o p y

NOTICE

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

(2) This blood center reports to the state department of health the name and address of a blood donor when a confirmatory test of the blood donor's blood confirms the presence of antibodies to the human immunodeficiency virus (HIV).

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

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

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

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

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

(4) Identification and screening of donors.

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

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

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

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

(9) Proficiency testing.

(10) All sanitary conditions within the blood center and the blood

C o p y

center's surroundings needed to protect the public and the employees.

(11) A quality assurance program.

SECTION 16. IC 16-41-12-20 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2013]: Sec. 20. (a) Except as provided in subsection (c), a responsible head (as defined in 21 CFR 600.10(a)) shall supervise the operations of a blood center.

(b) Except as provided in subsection (d), each blood center must employ a medical director who is a licensed physician and who:

(1) is certified or eligible for certification in:

(A) clinical pathology; or

(B) the operation of a blood bank;

by the American Board of Pathology; or

(2) has:

(A) received a minimum of one (1) year of specialized training in blood banking; or

(B) equivalent experience and training.

(c) The medical director shall supervise and is responsible for the following:

(1) The proper performance of all medical procedures in the blood center.

(2) The continuous application of quality assurance procedures in the blood center.

(d) A blood center collecting blood ~~products~~ exclusively for further manufacturing or research purposes under programs subject to and licensed by the federal Food and Drug Administration must employ a medical director who is a licensed physician to supervise the donor screening process. A blood center that utilizes blood ~~products~~ for a purpose other than manufacturing or research under this subsection is subject to the penalties described in section 21 of this chapter.

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

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

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

C o p y

(d) This section does not apply to:

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

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

(A) research purposes; **or**

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

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

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COMMITTEE REPORT

Mr. Speaker: Your Committee on Public Health, to which was referred House Bill 1038, has had the same under consideration and begs leave to report the same back to the House with the recommendation that said bill be amended as follows:

Page 3, line 23, after "that" insert ":".

Page 3, line 23, after "are" begin a new line block indented and insert:

"**(1)**".

Page 3, line 25, strike "13" and insert "**13(b)**".

Page 3, line 25, delete "chapter." and insert "chapter; **or**".

Page 3, between lines 25 and 26, begin a new line block indented and insert:

"**(2) is provided by a blood center under section 13(h) of this chapter and the blood or plasma is labeled as required by 21 CFR 606.121(h).**".

Page 5, line 19, delete "A" and insert "**Subject to 21 CFR 610.40(g), a**".

Page 6, line 7, strike "or a".

Page 6, line 8, strike "blood component".

Page 6, delete line 42.

Page 7, delete lines 1 through 15, begin a new paragraph and insert:

"SECTION 16. IC 16-41-12-20 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2013]: Sec. 20. (a) Except as provided in subsection (c), a responsible head (as defined in 21 CFR 600.10(a)) shall supervise the operations of a blood center.

(b) Except as provided in subsection (d), each blood center must employ a medical director who is a licensed physician and who:

(1) is certified or eligible for certification in:

(A) clinical pathology; or

(B) the operation of a blood bank;

by the American Board of Pathology; or

(2) has:

(A) received a minimum of one (1) year of specialized training in blood banking; or

(B) equivalent experience and training.

(c) The medical director shall supervise and is responsible for the following:

(1) The proper performance of all medical procedures in the blood center.

(2) The continuous application of quality assurance procedures in

C o p y

the blood center.

(d) A blood center collecting blood ~~products~~ exclusively for further manufacturing or research purposes under programs subject to and licensed by the federal Food and Drug Administration must employ a medical director who is a licensed physician to supervise the donor screening process. A blood center that utilizes blood ~~products~~ for a purpose other than manufacturing or research under this subsection is subject to the penalties described in section 21 of this chapter.".

Page 7, line 21, delete "IC 16-41-12-2.5)," and insert "**IC 16-41-12-2.5)**".

Page 7, line 21, strike "a blood".

Page 7, line 22, strike "component,".

Page 7, line 30, strike "or a blood component".

Page 7, line 32, strike "or blood component".

Page 7, line 34, strike "a blood component,".

Renumber all SECTIONS consecutively.

and when so amended that said bill do pass.

(Reference is to HB 1038 as introduced.)

CLERE, Chair

Committee Vote: yeas 11, nays 0.

C o p y