

**CONFERENCE COMMITTEE REPORT
DIGEST FOR EHB 1038**

Citations Affected: IC 16-18-2; IC 16-41-12; IC 35-42-1-7; IC 35-45-21-1.

Synopsis: Blood donation testing. Conference committee report for EHB 1038. Defines "blood" for purposes of regulating blood centers. Excludes: (1) blood and plasma used for research purposes; and (2) human cells, tissues, or cellular or tissue-based products; from the requirement that materials tested with an inconclusive result be disposed of. Requires a blood center to obtain a blood donor's Social Security number if the blood donor receives monetary compensation for the donation. Allows a blood center to distribute blood or plasma before the completion of a screening test in a documented medical emergency and sets forth requirements applying to distributions under those circumstances. Amends the exception to the crime of transferring contaminated body fluids for a person who is an autologous blood donor. Makes conforming changes. **(This conference committee report: (1) provides that, immediately after the screening test for blood or plasma that has been distributed in a documented medical emergency, the results must be sent to the physician or hospital that received the blood or plasma, and the physician who is responsible for the patient; (2) makes changes conforming to HEA 1006; and (3) makes technical changes.)**

Effective: July 1, 2013; July 1, 2014.

Adopted Rejected

CONFERENCE COMMITTEE REPORT

MR. SPEAKER:

Your Conference Committee appointed to confer with a like committee from the Senate upon Engrossed Senate Amendments to Engrossed House Bill No. 1038 respectfully reports that said two committees have conferred and agreed as follows to wit:

that the House recede from its dissent from all Senate amendments and that the House now concur in all Senate amendments to the bill and that the bill be further amended as follows:

- 1 Delete everything after the enacting clause and insert the following:
- 2 SECTION 1. IC 16-18-2-36.9 IS ADDED TO THE INDIANA
- 3 CODE AS A **NEW SECTION** TO READ AS FOLLOWS
- 4 [EFFECTIVE JULY 1, 2013]: **Sec. 36.9. "Blood", for purposes of**
- 5 **IC 16-41-12, has the meaning set forth in IC 16-41-12-2.5.**
- 6 SECTION 2. IC 16-18-2-96.5 IS ADDED TO THE INDIANA
- 7 CODE AS A **NEW SECTION** TO READ AS FOLLOWS
- 8 [EFFECTIVE JULY 1, 2013]: **Sec. 96.5. "Distributed for use", for**
- 9 **purposes of IC 16-41-12, has the meaning set forth in**
- 10 **IC 16-41-12-5.5.**
- 11 SECTION 3. IC 16-18-2-183.2 IS ADDED TO THE INDIANA
- 12 CODE AS A **NEW SECTION** TO READ AS FOLLOWS
- 13 [EFFECTIVE JULY 1, 2013]: **Sec. 183.2. "Human cells, tissues, or**
- 14 **cellular or tissue-based products" or "HCT/Ps", for purposes of**
- 15 **IC 16-41-12, has the meaning set forth in IC 16-41-12-6.5.**
- 16 SECTION 4. IC 16-41-12-1 IS AMENDED TO READ AS
- 17 FOLLOWS [EFFECTIVE JULY 1, 2013]: Sec. 1. As used in this
- 18 chapter, "autologous donation" means the removal and storage of blood
- 19 **or blood components** from a donor or patient for an intended
- 20 transfusion to the same donor or patient.
- 21 SECTION 5. IC 16-41-12-2.5 IS ADDED TO THE INDIANA

1 CODE AS A NEW SECTION TO READ AS FOLLOWS
 2 [EFFECTIVE JULY 1, 2013]: **Sec. 2.5. (a) As used in this chapter,**
 3 **"blood" means any of the following:**

- 4 (1) **Human blood.**
- 5 (2) **Human blood components.**
- 6 (3) **Human blood derivatives.**

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

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

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

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

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

- 26 (1) **to a researcher; or**
- 27 (2) **for further manufacturing;**

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

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

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

- 41 (1) Tests for antibodies to the human immunodeficiency virus
 42 (HIV).
- 43 (2) Other tests determined by the state department.

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

- 46 (1) procurement, processing, distribution, or use of:
 - 47 (A) ~~whole~~ blood;
 - 48 (B) plasma; ~~blood products; blood derivatives;~~
 - 49 (C) **human cells, tissues, or cellular or tissue-based**
 50 **products; or**
 - 51 (D) other human tissue, such as corneas, bones, or organs;

1 by a bank, storage facility, or hospital; and
 2 (2) injection, transfusion, or transplantation of any of the human
 3 tissue listed in subdivision (1) into the human body by a hospital,
 4 physician, or surgeon, whether or not any remuneration is paid;
 5 is the rendition of a service and not the sale of a product. Such services
 6 do not give rise to an implied warranty of merchantability or fitness for
 7 a particular purpose, nor do the services give rise to strict liability in
 8 tort.

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

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

15 **(2) is provided by a blood center under section 13(j) of this**
 16 **chapter and is labeled as required by 21 CFR 606.121(h).**

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

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

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

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

31 (1) blood; ~~or~~

32 (2) plasma;

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

34 ~~(4) a blood derivative;~~

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

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

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

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

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

49 SECTION 13. IC 16-41-12-13, AS AMENDED BY P.L.59-2012,
 50 SECTION 1, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE

1 JULY 1, 2013]: Sec. 13. (a) **Except as provided in subsection (j)**, a
 2 blood center shall perform a screening test on a donor's blood and
 3 obtain the results of the test before blood ~~or plasma a blood product, or~~
 4 a ~~blood derivative~~ is distributed for use.

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

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

13 (d) Except for:

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

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

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

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

21 (A) **the blood center agrees to distribute the blood or**
 22 **HCT/Ps for use; and**

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

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

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

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

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

37 (1) Blood center that furnished the blood.

38 (2) Unit number assigned to the blood.

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

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

44 (i) **A blood center may not ship any blood or plasma before the**
 45 **completion of the screening test except in a documented medical**
 46 **emergency, as described in subsection (j).**

47 (j) **This subsection applies when:**

48 (1) **a health care provider has determined that a patient is in**
 49 **imminent danger of death;**

50 (2) **the results of the screening test performed on the blood**
 51 **described in subsection (a) are not available at the time that**

1 minimum standards and specific requirements for operation of a blood
2 center, including the following:

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

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

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

12 (4) Identification and screening of donors.

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

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

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

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

21 (9) Proficiency testing.

22 (10) All sanitary conditions within the blood center and the blood
23 center's surroundings needed to protect the public and the
24 employees.

25 (11) A quality assurance program.

26 SECTION 16. IC 16-41-12-20 IS AMENDED TO READ AS
27 FOLLOWS [EFFECTIVE JULY 1, 2013]: Sec. 20. (a) Except as
28 provided in subsection (c), a responsible head (as defined in 21 CFR
29 600.10(a)) shall supervise the operations of a blood center.

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

32 (1) is certified or eligible for certification in:

33 (A) clinical pathology; or

34 (B) the operation of a blood bank;

35 by the American Board of Pathology; or

36 (2) has:

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

39 (B) equivalent experience and training.

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

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

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

46 (d) A blood center collecting blood ~~products~~ exclusively for further
47 manufacturing or research purposes under programs subject to and
48 licensed by the federal Food and Drug Administration must employ a
49 medical director who is a licensed physician to supervise the donor
50 screening process. A blood center that utilizes blood ~~products~~ for a

1 purpose other than manufacturing or research under this subsection is
2 subject to the penalties described in section 21 of this chapter.

3 SECTION 17. IC 35-42-1-7, AS AMENDED BY P.L.59-2012,
4 SECTION 3, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE
5 JULY 1, 2013]: Sec. 7. (a) As used in this section, "**component**" means
6 ~~plasma, platelets, or serum of a human being.~~ "**blood**" has the
7 **meaning set forth in IC 16-41-12-2.5.**

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

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

16 (d) This section does not apply to:

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

22 (2) a person who transfers blood, a ~~blood component~~, semen, or
23 another body fluid that contains the human immunodeficiency
24 virus (HIV) for research purposes; or

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

27 SECTION 18. IC 35-45-21-1, AS ADDED BY HEA1006-2013,
28 SECTION 547, IS AMENDED TO READ AS FOLLOWS
29 [EFFECTIVE JULY 1, 2014]: Sec. 1. (a) As used in this section,
30 "**component**" means ~~plasma, platelets, or serum of a human being.~~
31 "**blood**" has the **meaning set forth in IC 16-41-12-2.5.**

32 (b) A person who recklessly, knowingly, or intentionally donates,
33 sells, or transfers blood a ~~blood component~~, or semen for artificial
34 insemination (as defined in IC 16-41-14-2) that contains the human
35 immunodeficiency virus (HIV) commits transferring contaminated
36 body fluids, a Level 5 felony.

37 (c) However, the offense under subsection (b) is a Level 3 felony if
38 it results in the transmission of the human immunodeficiency virus
39 (HIV) to any person other than the defendant.

40 (d) This section does not apply to:

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

46 (2) a person who transfers blood a ~~blood component~~, semen, or
47 another body fluid that contains the human immunodeficiency
48 virus (HIV) for research purposes; or

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

1 SECTION 19. [EFFECTIVE JULY 1, 2013] (a) **The general**
2 **assembly recognizes that HEA 1038-2013 amends IC 35-42-1-7 and**
3 **that HEA 1006-2013 repeals IC 35-42-1-7. The general assembly**
4 **intends to repeal IC 35-42-1-7 as provided in HEA 1006-2013.**
5 **(b) This SECTION expires December 31, 2014.**
 (Reference is to EHB 1038 as reprinted April 2, 2013.)

Conference Committee Report
on
Engrossed House Bill 1038

Signed by:

Representative Clere
Chairperson

Senator Miller Patricia

Representative Harris

Senator Breaux

House Conferees

Senate Conferees