IC 16-41-12

Chapter 12. Communicable Disease: Precautionary Measures for Use of Human Tissues and Blood Products; Regulation of Blood Centers

IC 16-41-12-1

Autologous donation

Sec. 1. As used in this chapter, "autologous donation" means the removal and storage of blood from a donor or patient for an intended transfusion to the same donor or patient.

As added by P.L.2-1993, SEC.24. Amended by P.L.213-2013, SEC.4.

IC 16-41-12-2

Bank

Sec. 2. As used in this chapter, "bank" has the meaning set forth in IC 29-2-16.1-1.

As added by P.L.2-1993, SEC.24. Amended by P.L.147-2007, SEC.5.

IC 16-41-12-2.5

Blood

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).

As added by P.L.213-2013, SEC.5.

IC 16-41-12-3

Blood center

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 is collected.

As added by P.L.2-1993, SEC.24. Amended by P.L.213-2013, SEC.6.

IC 16-41-12-4

Confirmatory test

Sec. 4. As used in this chapter, "confirmatory test" means a laboratory test or a series of tests approved by the state department and used in conjunction with a screening test to confirm or refute the results of the screening test for the human immunodeficiency virus (HIV) antigen or antibodies to the human immunodeficiency virus (HIV).

As added by P.L.2-1993, SEC.24.

IC 16-41-12-5

Directed donation

Sec. 5. As used in this chapter, "directed donation" means a donation of blood collected from an individual on behalf of an

intended recipient of the transfusion.
As added by P.L.2-1993, SEC.24. Amended by P.L.213-2013, SEC.7.

IC 16-41-12-5.5
Distributed for use

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.
As added by P.L.213-2013, SEC.8.

IC 16-41-12-6
Hospital

Sec. 6. As used in this chapter, "hospital" has the meaning set forth in IC 29-2-16.1-1.
As added by P.L.2-1993, SEC.24. Amended by P.L.147-2007, SEC.6.

IC 16-41-12-6.5
Human cells, tissues, or cellular or tissue-based products

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).
As added by P.L.213-2013, SEC.9.

IC 16-41-12-7
Physician

Sec. 7. As used in this chapter, "physician" has the meaning set forth in IC 29-2-16.1-1.
As added by P.L.2-1993, SEC.24. Amended by P.L.147-2007, SEC.7.

IC 16-41-12-8
Screening test

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 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.

As added by P.L.2-1993, SEC.24. Amended by P.L.213-2013, SEC.10.

IC 16-41-12-9
Storage facility

Sec. 9. As used in this chapter, "storage facility" has the meaning

set forth in IC 29-2-16.1-1.
As added by P.L.2-1993, SEC.24. Amended by P.L.147-2007, SEC.8.

IC 16-41-12-10
Surgeon
Sec. 10. As used in this chapter, "surgeon" has the meaning set forth in IC 29-2-16.1-1.
As added by P.L.2-1993, SEC.24. Amended by P.L.147-2007, SEC.9.

IC 16-41-12-11
Implied warranties; strict liability; screening tests; specification of blood use; distributions by foreign blood centers
Sec. 11. (a) The:
(1) procurement, processing, distribution, or use of:
(A) blood;
(B) plasma;
(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 blood or plasma that:
(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(b) of this chapter; or
(2) is provided by a blood center under section 13(j) of this chapter and 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).
(f) A blood center located outside Indiana may not distribute:
(1) blood; or

(2) plasma;

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.

As added by P.L.2-1993, SEC.24. Amended by P.L.213-2013, SEC.11.

IC 16-41-12-12

Rules

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;

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

(3) any other procedure that should be followed to reasonably ensure the safety of the donor and recipient of blood.

As added by P.L.2-1993, SEC.24. Amended by P.L.213-2013, SEC.12.

IC 16-41-12-13

Screening tests; blood labeling; confirmatory tests; disposal of blood; notification and referral of donors; records; violations; medical emergencies

Sec. 13. (a) Except as provided in subsection (j), a blood center shall perform a screening test on a donor's blood and obtain the results of the test before blood or plasma is distributed for use.

(b) The blood center shall label blood or plasma 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;

(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 the blood or HCT/Ps for use; and

(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.

(h) 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.

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

(j) This subsection applies when:

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

(2) the results of the screening test performed on the blood described in subsection (a) are not available at the time that the blood is to be used;

(3) the patient or the patient's representative has been provided notice that the results of the screening test performed on the blood are not available and has consented in writing to the use of the blood; and

(4) no other appropriate blood is available.

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. However, upon completion of the screening test, the blood center shall immediately provide the test results to the physician or hospital that received the blood or plasma and the physician who is responsible for the patient.

As added by P.L.2-1993, SEC.24. Amended by P.L.59-2012, SEC.1; P.L.213-2013, SEC.13.

IC 16-41-12-14

Confidentiality of information; violations

Sec. 14. (a) A person may not disclose or be compelled to disclose information collected under this chapter or under rules adopted under this chapter. This information may not be released or made public upon subpoena or otherwise, except under the following circumstances:

(1) For statistical purposes if done in a manner that does not identify any individual.

(2) With the written consent of all individuals identified in the information released.

(3) To the extent necessary to enforce public health laws or to protect the health or life of a named person.

(b) Except as provided in subsection (a), a person responsible for recording, reporting, or maintaining information required to be reported under this chapter who recklessly, knowingly, or intentionally discloses or fails to protect information classified as confidential under this section commits a Class A misdemeanor.

(c) In addition to subsection (b), a public employee who violates this section is subject to discharge or other disciplinary action under the personnel rules of the agency that employs the employee.

As added by P.L.2-1993, SEC.24.

IC 16-41-12-15

Donor information; informed consent

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.

(4) The blood donor's Social Security number, if the blood donor is receiving monetary compensation for the donation.

(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).

(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:

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 that contains antibodies for the human immunodeficiency virus (HIV) commits transferring contaminated blood, a Level 5 felony. The offense is a Level 4 felony if the offense results in the transmission of the virus to another person.

As added by P.L.2-1993, SEC.24. Amended by P.L.59-2012, SEC.2; P.L.213-2013, SEC.14; P.L.158-2013, SEC.243; P.L.168-2014, SEC.31.

IC 16-41-12-16

Blood center licensing; inspections

Sec. 16. (a) It is unlawful to operate a blood center in Indiana without a license issued by the state department under this chapter.

A blood center that applies for a license in Indiana must also be licensed or appropriately registered by the federal Food and Drug Administration and remain in compliance with all applicable federal regulations.

(b) An application for a license must be made on a form prescribed by the state department and must be accompanied by a license fee established by the state department.

(c) After inspection of an applicant's facility, if the state department finds that the applicant has complied with this chapter and the rules adopted under this chapter, the state department shall issue a license to the applicant.

(d) A license expires one (1) year after the date of issuance unless the license is renewed. A blood center may submit a renewal application on a form prescribed by the state department. The procedure and conditions for renewal are the same as the procedure and conditions established for the issuance of the original license.

(e) A person who inspects an applicant's facility under this section must have knowledge in blood banking and the nationally accepted standards of practice.

(f) For the purposes of this chapter, a hospital licensed under IC 16-21-2 that operates a blood center within the facility is subject to the rules adopted under this chapter concerning the operation of the blood center. However, the hospital may be licensed only under IC 16-21-2 and shall be surveyed concurrently, for licensure purposes, as a blood center and a hospital.

As added by P.L.2-1993, SEC.24.

IC 16-41-12-17

Rules

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.

(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.

(9) Proficiency testing.

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

(11) A quality assurance program.

As added by P.L.2-1993, SEC.24. Amended by P.L.213-2013, SEC.15.

IC 16-41-12-18

Blood shortage emergencies

Sec. 18. (a) This section does not apply to a blood center when the blood center declares a blood shortage emergency for a specific or unusual blood type for a specific patient.

(b) A blood center must have written criteria for a blood shortage emergency before the blood center may declare a blood shortage emergency. The criteria required under this section must be based on quantitative factors within the geographic region served by the blood center.

(c) A blood center must file the written criteria required under this section with the state department.

(d) Unless an emergency is declared by another regional blood center, a blood center may not declare a blood shortage emergency for the sole purpose of selling or transferring blood to another center.

(e) Whenever a blood center declares a blood shortage emergency, the blood center shall notify the state department and affirm that a blood shortage emergency exists.

As added by P.L.2-1993, SEC.24.

IC 16-41-12-19

Transfusion records; financial information; proficiency demonstrations; operation reports

Sec. 19. (a) A 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 record must be made available to the state department for inspection.

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

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

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

As added by P.L.2-1993, SEC.24.

IC 16-41-12-20

Blood center supervision; medical directors

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

As added by P.L.2-1993, SEC.24. Amended by P.L.213-2013, SEC.16.

IC 16-41-12-21

Inspections; violations

Sec. 21. (a) The state department may designate an agent who may, upon presentation of proper credentials, enter a facility to inspect for possible violations of this chapter or rules adopted under this chapter.

(b) The state department may commence an action under IC 4-21.5-3-6 or IC 4-21.5-4 for issuance of an order of compliance and civil penalty not to exceed ten thousand dollars ($10,000) per violation per day against a person who:

(1) fails to comply with this chapter or rules adopted under this chapter; or

(2) interferes with or obstructs the state department or the state department's designated agent in the performance of official duties under this chapter.

(c) The state department may commence an action to suspend or revoke a blood center's license under IC 4-21.5-3-8 or IC 4-21.5-4 if the licensee has done any of the following:

(1) Made false statements concerning material information on the license application or any other document required by the state department.

(2) Permitted unauthorized persons to perform medical or technical procedures (as defined by the state department by rule adopted under this chapter) when a licensed physician licensed to practice medicine in Indiana is not available for consultation.

(3) Demonstrated incompetence in the performance of any procedure.

(4) Performed a procedure for which approval was not granted.

(5) Operated the center in a manner considered hazardous to public health.

(6) Violated this chapter or rules adopted under this chapter.

(d) The state department may report to any other board or agency responsible for licensure, registration, or certification of health care providers, facilities, or other health care workers an individual or facility that is found to be operating in violation of this chapter or rules adopted under this chapter.

As added by P.L.2-1993, SEC.24.