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THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 2006 Session of 1995

INTRODUCED BY STURLA, VANCE, KUKOVICH, CAPPABIANCA, COY, KREBS, CLARK, ROEBUCK, DALEY, ROONEY, STABACK, LAUGHLIN, TIGUE, MELIO, BATTISTO, RAYMOND, ITKIN, HENNESSEY, READSHAW, STERN, BAKER, JOSEPHS, CURRY, MILLER, ZIMMERMAN, MIHALICH, RICHARDSON, TRELLO, SCHULER, DeLUCA, WOZNIAK, YOUNGBLOOD, STEELMAN, BOSCOLA AND BELFANTI, SEPTEMBER 20, 1995

REFERRED TO COMMITTEE ON HEALTH AND HUMAN SERVICES, SEPTEMBER 20, 1995

AN ACT

Providing options for blood transfusions to persons undergoing certain medical procedures; and further providing for duties of attending physicians, duties of health care facilities, duties of blood banks, disposal of blood and payment of service fees.

The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

Section 1. Short title.

This act shall be known and may be cited as the Blood Safety Act.

Section 2. Definitions.

The following words and phrases when used in this act shall have the meanings given to them in this section unless the context clearly indicates otherwise:

"Allogeneic blood." Blood that is donated on a voluntary basis without designating or knowing who the recipient is and which complies with all the requirements of the United States

Food and Drug Administration.

"Attending physician." The physician who is designated by the patient to perform a medical or surgical procedure.

"Autologous blood." Blood donated by a person for his own use.

"Biohazardous blood product." A blood product which has tested positive for one or more of the viral marker assays performed by licensed blood collectors.

"Blood." This term shall include blood components and whole blood.

"Blood bank." Any place, organization, institution or establishment that is operated wholly or in part for the purpose of obtaining, storing, processing, preparing for transfusing or selling human blood products derived from single blood units, whether such procedures are done for direct therapeutic use or for storage for future use of such products and whether such a place, organization, institution or establishment is operated on a charitable, commercial or nonprofit basis.

"Blood components." Any part or fraction of single units of whole blood or any material derived from single units of such blood, excluding albumin, rhogam and gammo globulin or other components which cannot transmit infectious agents.

"Department." The Department of Health of the Commonwealth.

"Designated blood." Blood donated for a specifically indicated recipient of the donated blood other than the donor and which complies with all the requirements of the United States Food and Drug Administration.

"Health care facility." A general or special hospital, including tuberculosis and psychiatric hospitals, rehabilitation facilities, skilled nursing facilities, kidney disease treatment

centers, including free-standing hemodialysis units, intermediate care facilities and ambulatory surgical facilities, both profit and nonprofit and including those operated by an agency of State or local government, but shall not include an office used exclusively for private or group practice by physicians or dentists, nor a program which renders treatment or care for drug or alcohol abuse or dependence, unless located within, by or through a health care facility, a facility providing treatment solely on the basis of prayer or spiritual means in accordance with the tenets of any church or religious denomination, nor a facility operated by a religious organization for the purpose of providing health care services exclusively to clergymen or other persons in a religious profession who are members of the religious denominations operating the facility.

"Informed consent." For the purposes of this act and of any proceedings arising under this act, the consent of a patient to the performance of health care services by a physician if, prior to consent having been given, the physician provided information to the patient about the proposed procedure, treatment or diagnosis that a reasonable patient would consider material to that decision whether or not to undergo the procedure or treatment.

"Transfusion." The act of transferring blood into the body of a person.

"Whole blood." The fluid that circulates in the heart, arteries, capillaries and veins of a human body carrying nourishment and oxygen to and bringing away waste products from all parts of the body.

Section 3. Duties of attending physicians.

(a) Informed consent.--Whenever it is anticipated that a transfusion may be necessary during a medical or surgical procedure, the attending physician shall, prior to performing a medical or surgical procedure, inform the patient or guardian or designated surrogate that a blood transfusion may be necessary during the procedure and of the options of predonating for autologous blood transfusions, receiving allogeneic blood transfusions or receiving designated blood transfusions, the risks and benefits of each of these alternatives and the risks of not receiving any transfusions if a transfusion becomes necessary and shall obtain the patient's informed consent in writing.

(b) Documentation.--The attending physician shall note on the patient's medical record, which shall be maintained in the office of the attending physician, that the patient or guardian or designated surrogate was advised of the opportunity to receive an autologous, allogeneic or designated blood transfusion, the risks of these alternatives and the risks of not receiving the transfusion if a transfusion becomes necessary.

(c) Predonation time.--If there are no medical contraindications or the medical or surgical procedure is not performed on an emergency basis, the attending physician shall allow adequate time, prior to the medical or surgical procedure, for predonation to occur.

(d) Waiver of predonation.--The patient or guardian or designated surrogate may waive the option to predonate autologous blood or have designated blood donated on his behalf. This waiver shall be in writing and made a part of the patient's record that is maintained in the office of the attending

physician. If the patient or guardian or designated surrogate waives the option to predonate autologous blood or have designated blood donated on his behalf, the attending physician shall not incur any liability for failure to allow predonation to occur.

Section 4. Duties of health care facilities.

(a) Option information.--All health care facilities shall assist, when possible, with the facilitation, promulgation and dissemination of information regarding the options available to a patient regarding the predonation of autologous blood, receiving allogeneic blood or receiving designated blood, the risks and benefits of each of these alternatives and the risks of not receiving any transfusion if a transfusion becomes necessary and shall obtain the patient's informed consent in writing.

(b) Documentation.--The health care facility shall note on the patient's record maintained at the facility as to whether the patient was informed by his attending physician of the blood transfusion options available. If the attending physician has failed to advise the patient of these options, the health care facility shall be responsible for advising the patient of these options, the risks and benefits of these alternatives and the risks of not receiving any transfusion if a transfusion becomes necessary and shall obtain the patient's informed consent in writing. The health care facility shall not incur any liability for failure to allow the predonation to occur if the patient has waived the option to predonate autologous blood or have designated blood donated on his behalf. This waiver shall be in writing.

(c) Acceptance of autologous or designated blood.--A health

care facility which performs a transfusion shall be required to accept autologous or designated blood for a potential transfusion to a patient if the blood meets the regulations of the United States Food and Drug Administration and is received from a blood bank located within this Commonwealth and licensed by the department. Autologous or designated blood which is received from a blood bank located outside this Commonwealth must be licensed by the state in which it is located and must also meet the regulations of the United States Food and Drug Administration. All autologous and designated blood must be tested and prepared in accordance with the standards approved by the department, except that autologous blood which is biohazardous may only be accepted with the written permission of the attending physician and the health care facility.

Section 5. Duties of blood banks.

(a) Option information.--All blood banks shall assist, when possible, with the facilitation, promulgation and dissemination of information regarding the options available to a patient regarding the predonation of autologous blood, receiving allogeneic blood or designated blood, the risks and benefits of each of these alternatives and the risks of not receiving any transfusion if a transfusion becomes necessary.

(b) Dissemination of information.--All blood banks shall assist with the facilitation, promulgation and dissemination of current information regarding the safety of available transfusion options to the medical community.

(c) Fees.--A blood bank which collects autologous or designated blood shall inform the donor of the blood or his guardian or designated surrogate or the intended recipient of the blood, in the case of a designated blood donation, of all

the fees that the blood bank charges to process, store, transport or otherwise prepare the blood for transfusion.

Section 6. Disposal of unused autologous and designated blood.

In cases where a medical or surgical procedure is performed and a transfusion was not performed or there is unused autologous or designated blood, that blood shall be held for a minimum of 21 days after the date of donation or a minimum of seven days after the date the procedure was performed or was scheduled to be performed for which the blood was originally donated, for possible use, unless the useful life of the blood has expired.

Section 7. Payment of service fee by health care facilities.

A health care facility which accepts autologous or designated blood and similar blood components shall pay a service fee to the blood bank which provides the blood or blood components. Insurance providers shall not deny payment of additional fees for autologous blood costs if allogeneic blood transfusions are covered in the policy. Any additional fees for designated blood over and above allogeneic blood fees, unless medically indicated, may be rejected for payment unless otherwise covered in the policy.

Section 8. Exemptions.

The attending physician or the health care facility where the medical or surgical procedure is to be performed shall not be required to provide the patient or his guardian or designated surrogate with an explanation of the transfusion options under this act if medical contraindications exist or the medical or surgical procedure is performed on an emergency basis.

Section 9. Liability.

No physician shall be liable for a failure to obtain an

informed consent in the event of an emergency which prevents consulting the patient. No physician shall be liable for failure to obtain an informed consent if it is established by a preponderance of the evidence that furnishing the information in question to the patient would have resulted in a seriously adverse effect on the patient or on the therapeutic process to the material detriment of the patient's health.

Section 10. Effective date.

This act shall take effect in 60 days.