

DRAFT LANGUAGE PROVIDED BY DEPARTMENT OF HEALTH BUREAU OF HIV/AIDS FOR ORGAN AND TISSUE PROCUREMENT AND TRANSPLANTATION ADVISORY BOARD REVIEW

64D-2.005 Blood and Human Tissue Donations.

(1) The HIV test shall be performed by a laboratory licensed under Chapter 483, F.S., in compliance with the standards of the Clinical Laboratory Improvement Act of 1967 (CLIA) [42 U.S.C. 263a (1988)], or be licensed under standards equivalent to the minimum requirements of Chapter 483, F.S., in the state in which it is located, and must successfully participate in an HIV proficiency testing program, provided the clinical laboratory is qualified to perform the test.

(2) No blood, plasma, organ, skin, semen, or other human tissue from donors whose blood is reactive to HIV shall be released for transfusion or transplantation to another. Such blood shall be retested using a confirmatory test prior to release of test results outside the facility. Test results may be released immediately to the physician of an organ donation recipient, prior to confirmatory testing.

(3) The recipient's physician shall be notified of HIV confirmatory test results within 24 hours by the medical director of the facility in the event that blood, plasma, organ, skin, semen, or other tissue is transferred and is subsequently reported positive on confirmatory test. The donor or his legal representative shall also be notified in accordance with the Model Protocol for Counseling Donors.

(4) Pursuant to Section 381.0041(8), F.S., the Department of Health developed The Model Protocol for Counseling Blood Tissue or Organ Donors, effective ~~7-12-89~~ December 2011, consistent with the provisions of this section and incorporated this document by reference in this rule. This protocol provides a list of the information that shall be included in the letter of notification to donors who test positive ~~to~~ for HIV based on confirmatory testing. The Model Protocol for Counseling Donors is available through the ~~—~~Department of Health, Bureau of HIV/AIDS, 4052 Bald Cypress Way, Bin A09, Tallahassee, Florida 32399-1715.

(5) Any blood, plasma, organ, skin, semen, or other human tissue from a donor whose blood test for HIV or hepatitis is repeatedly reactive, or originating from an individual diagnosed with AIDS ~~or ARC~~, shall not be shipped or used for transfer to another, except as provided by Title 42 Part 72, Title 49 Part 173, and Title 39 Part III Code of Federal Regulations. Such human tissue shall be destroyed, treated, or disposed, in accordance with Section 381.0098, F.S., and with the rules promulgated to implement ~~Chapter 88-130, Laws of Florida,~~ Chapter 64E-16, Florida Administrative Code, relating to bio~~hazardous~~ medical waste.

(6) The blood of any human tissue donor testing negative for HIV or hepatitis at the time of donation shall not require retesting by the collecting facility when such tissue is collected for transplantation, implantation, transfusion, grafting, or any other method of transfer to another human.

Specific Authority 381.0041(10) FS. Law Implemented 381.0041 FS. History—New 7-12-89, Amended 5-1-96, Formerly 10D-93.073, Amended ___