RULES
OF
DEPARTMENT OF COMMUNITY HEALTH

CHAPTER 111-8
HEALTHCARE FACILITY REGULATION

111-8-9
BLOOD LABELING

TABLE OF CONTENTS

111-8-9-.01 Definitions.

Unless a different meaning is required by the context, the following terms as used in these rules and regulations shall have the meaning hereinafter respectively ascribed to them:

(a) "Act" means "The Blood Labeling Act" (O.C.G.A. § 31-24-1 et seq.);

(b) "Person" means any individual, blood bank, clinical laboratory, hospital, firm, corporation or any other entity;

(c) "Department" means the Georgia Department of Community Health;

(d) "Board" means the Board of Community Health;

(e) "Clinical Laboratory" means a single facility for the biological, microbiological, serological, immunological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body, for the diagnosis of, recommendation of treatment of, or for the purpose of providing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, man; the term "clinical laboratory" shall include blood banks which provide through their ownership or operation a system for the collection, processing, or storage of human blood and its component parts as well as tissue banks which store human or animal tissues designed to be used for medical purposes in human beings.

(f) "Director" means a person who is responsible for the administration of the technical and scientific operation of a clinical laboratory, including supervision of procedures for testing and the reporting of results;

(g) "Blood" means whole human blood, packed red blood cells, blood platelets, concentrated leukocytes, and blood plasma. It does not include blood derivatives manufactured or processed for industrial use.

(h) "Donation" means any transaction involving the person from whom blood is withdrawn, whether he presents himself for the withdrawal of blood on his own initiative or on the initiative of another person, in which he receives no consideration other than credit through blood assurance programs or other intangible benefits.

(i) "Purchase" means any transaction involving the person from whom blood is withdrawn, whether he presents himself for the withdrawal of blood on his own initiative or on the initiative of another person, in which he receives a monetary consideration in any form. Time off from work granted by an employer for the purpose of giving blood shall not be considered a direct monetary

consideration.

(j) "Industrial use" means a use of blood in which the blood is modified by physical or chemical means to produce derivatives for therapeutic or pharmaceutic biologicals and laboratory reagents or controls.

(k) "Transfusion" means a use of blood in which the blood is administered to a human being for treatment of sickness or injury.

Authority: O.C.G.A. §§ 31-2-5, 31-2-7 and 31-24-1 et seq.

111-8-9-.02 Criteria for Donor Selection.

No blood may be withdrawn from any individual in this State for transfusion or industrial use unless he qualifies to be a blood donor under the laws of this State. Criteria for donor selection shall conform to those required in accordance with provisions of the act providing for the control and operation of clinical laboratories (O.C.G.A. § 31-22-1 et seq.) and the Rules and Regulations as adopted and promulgated thereunder entitled "Rules and Regulations for Licensure of Clinical Laboratories".

Authority: O.C.G.A. §§ 31-2-3, 31-2-5 and 31-2-7.

111-8-9-.03 Labeling of Containers of Blood; Certificates for Out-of-State Blood.

(1) It shall be the responsibility of the licensed laboratory director to assure the legal requirement that every unit of blood drawn from an individual and any components derived by physical processes (including plasmapheresis for transfusions and blood for auto transfusions), shall have affixed to each container of such blood or components, a label which indicates whether the blood was obtained by purchase or donation. The label must be affixed prior to bleeding of the donor. The label shall meet the following specifications:

(a) Labels shall state that content is "Blood From Paid Donor" or "Blood From Volunteer Donor".

(b) Labels must be affixed in a prominent position, in such manner as not to obscure any other necessary identifying labels, and using non-toxic permanent type adhesive which is non-leachable through plastic blood bag.

(c) If incorporated into the product label, the wording must be easily read, with block lettering in size described below:

(d) If a separate label is used, such label must be:

1. No less than 3/8 inch by 1¼ inch in overall size;

2. With black letters on an orange background; and

3. Using bold Helvetica or similar block letters, capital height no less than five (5) points in size. See example below.

BLOOD FROM VOLUNTEER DONOR	BLOOD FROM PAID DONOR

(e) If blood is received from out-of-state with individual labels which meets the above specifications, it need not have an additional label applied.

(2) The director of any blood bank who receives blood from a federally licensed blood bank in another state shall be responsible for acquiring a certificate from the out-of-state blood bank certified by its director, indicating which blood units in each shipment were acquired by "donation" or "purchase" as defined in these regulations. If he holds a certificate which certifies that the blood was received by donation, he may label such blood as donated blood. If he cannot obtain such a certificate, he shall label each unit of blood as blood acquired by purchase. In those instances

where the supplying out-of-state blood bank draws blood exclusively from volunteer donors, only one certificate per year, acquired in advance, will be required.

(3) The certificate accompanying each shipment of blood or the single annual certificate shall be signed by the Director in whose name the blood bank is federally licensed or an individual authorized by him and so recorded.

(4) All certificates from out-of-state blood banks shall be retained by the receiving Georgia bank for at least five years.

(5) All costs for both certificates and labels shall be borne by the blood bank involved.

Authority: O.C.G.A. §§ 31-2-5, 31-2-7 and 31-24-1 et seq.

111-8-9-.04 Unlabeled Blood, Medical Record, Removal of Label.

(1) No person may administer blood, transfer, or offer to transfer, blood or blood components for transfusion purposes by any type of transaction unless the container of such blood is labeled as required by these regulations. The label may not be removed before or during the administration of the blood or blood components.

(2) A record must be maintained in the blood bank to identify the source of each unit as by "donation" or "purchase".

(3) The identification numbers of the unit(s) of blood transfused shall be recorded in the patient's medical record by the person authorized to administer the blood. Records accompanying each unit of blood or blood products leaving a Blood Bank shall indicate whether such unit was acquired by donation or purchase.

Authority: O.C.G.A. §§ 31-2-5, 31-2-7 and 31-24-5.

111-8-9-.05 Blood and Blood Components: Industrial Uses.

Blood and blood components, including salvage plasma, may be used and transferred for industrial uses without regard to whether its original acquisition was by purchase or donation.

Authority: O.C.G.A. §§ 31-2-5, 31-2-7 and 31-24-5.

111-8-9-.06 Administration.

Determination of fulfillment of these requirements shall be made by the Department of Community Health as a part of, and using the procedures of the Act providing for the control and operation of clinical laboratories (O.C.G.A. § 31-22-1 et seq.).

Authority: O.C.G.A. §§ 31-2-5, 31-2-7 and 31-24-7.

111-8-9-.07 Punishment for Violations.

Any person violating the provisions of the Act on which these Rules are based shall be guilty of a misdemeanor and upon conviction thereof shall be punished as for a misdemeanor.

Authority: O.C.G.A. §§ 31-2-5, 31-2-7 and 31-24-8.

111-8-9-.08 Enforcement.

The administration and enforcement of these rules and regulations shall be in accordance with the provisions of the Act providing for the control and operation of clinical laboratories (O.C.G.A. § 31-22-1 et seq.), and in compliance with the applicable minimum requirements as prescribed by the Georgia Administrative Procedure Act (O.C.G.A. § 50-13-1 et seq.).

Authority: O.C.G.A. §§ 31-2-5, 31-2-7, 31-2-8 and 50-13-1 et seq.