

**RULES OF
DEPARTMENT OF COMMUNITY HEALTH
HEALTHCARE FACILITY REGULATION**

REPEAL CHAPTER 290-5-34

AND

REPLACE WITH NEW CHAPTER 111-8-09

RULES AND REGULATIONS FOR BLOOD LABELING

SYNOPSIS OF PROPOSED RULE CHANGES

STATEMENT OF PURPOSE: The Department of Community Health proposes to repeal the Rules for Blood Labeling by replacing the Chapter number 290-5-34 with a new Chapter number 111-8-09. This change is necessary to reflect that the enforcement of the blood labeling rules is the responsibility of the Department of Community Health rather than the Department of Human Resources, which has since been renamed as the Department of Human Services. These rules are being proposed pursuant to the authority granted the Department of Community Health in O.C.G.A. §§ 31-2-5, 31-2-6 and 31-2-7.

The proposed rules restate existing rules applicable to collection and labeling blood. In the formulation of the proposed new rules, the Department has considered the economic costs associated with the regulations and the impact on small businesses in the state. To the extent possible, the proposed rules do not impose excessive regulatory costs on the regulated entities while supporting the quality of care being delivered and the health and safety of the participants receiving care.

MAIN FEATURES OF THE PROPOSED RULES: The proposed Rules for Blood Labeling, Chapter 111-8-09, set forth the existing standards for blood labeling. These proposed Rules do not change the existing rules except to replace the Chapter number and the name of the Department and update legal references throughout. The proposed rules include the following features:

- Substitution of Community Health for Human Resources in the definitions of the Department and Board and the restatement of all existing Definitions in Rule 111-8-09-.01.

- Restatement of existing provisions for Criteria for Donor Selection in Rule 111-8-09-.02.
- Restatement of existing provisions for Labeling of Containers of Blood; Certificates for Out-of-State Blood in Rule 111-8-09-.03.
- Restatement of existing provisions for Unlabeled Blood, Medical Record, Removal of Label in Rule 111-8-09-.04.
- Restatement of existing provisions for Blood and Blood Components: Industrial Uses in Rule 111-8-09-.05.
- Restatement of existing provisions for Administration in Rule 111-8-09-.06.
- Restatement of existing requirements for Punishment for Violations in Rule 111-8-09-.07.
- Restatement of existing requirements for Enforcement in Rule 111-8-09-.08.
- Inclusion of updated references to the Official Code of Georgia Annotated throughout.

**RULES
OF
DEPARTMENT OF HUMAN
RESOURCES
PUBLIC HEALTH**

**CHAPTER 290-5-34
BLOOD LABELING**

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290-5-34-.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" (Georgia Laws 1976, p. 353 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 Human Resources;

(d) "Board" means the State Board of Human Resources;

(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,

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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 pharmaceutical 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 Ga. L. 1970, p. 531, as amended by Ga. L. 1971, p. 247; Ga. L. 1976, p. 353 et seq.

Administrative History. Original Rule was filed on September 23, 1977; effective October 13, 1977.

290-5-34-.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 (Georgia Laws 1970, p. 531 et seq. as amended by Georgia Laws 1971, p. 247) and the Rules and Regulations as adopted and promulgated thereunder entitled "Rules and Regulations for Licensure of Clinical Laboratories".

Authority Ga. L. 1970, p. 531, as amended by Ga. L. 1971, p. 247; Ga. L. 1976, p. 353 et seq.

Administrative History. Original Rule was filed on September 23, 1977; effective October 13, 1977.

290-5-34-.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 1/4 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 Ga. L. 1970, p. 531, as amended by Ga. L. 1971, p. 247; Ga. L. 1976, p. 353 et seq.

Administrative History. Original Rule was filed on September 23, 1977; effective October 13, 1977.

290-5-34-.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 Ga. L. 1970, p. 531, as amended by Ga. L. 1971, p. 247; Ga. L. 1976, p. 353 et seq.

Administrative History. Original Rule was filed on September 23, 1977; effective October 13, 1977.

~~290-5-34-.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 Ga. L. 1970, p. 531, as amended by Ga. L. 1971, p. 247; Ga. L. 1976, p. 353 et seq.~~

~~**Administrative History.** Original Rule was filed on September 23, 1977; effective October 13, 1977.~~

~~290-5-34-.06 Administration.~~

~~Determination of fulfillment of these requirements shall be made by the Department of Human Resources as a part of, and using the procedures of the Act providing for the control and operation of clinical laboratories (Georgia Laws 1970, p. 531 et seq. as amended by Georgia Laws 1971, p. 247).~~

~~Authority Ga. L. 1970, p. 531, as amended by Ga. L. 1971, p. 247; Ga. L. 1976, p. 353 et seq.~~

~~**Administrative History.** Original Rule was filed on September 23, 1977; effective October 13, 1977.~~

~~290-5-34-.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 Ga. L. 1970, p. 531, as amended by Ga. L. 1971, p. 247; Ga. L. 1976, p. 353 et seq.~~

~~**Administrative History.** Original Rule was filed on September 23, 1977; effective October 13, 1977.~~

~~290-5-34-.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 (Georgia Laws 1970, p. 531 et seq. as amended by Georgia Laws 1971, p. 247), and in compliance with the applicable minimum requirements as prescribed by the Georgia Administrative Procedure Act (Georgia Laws 1964, p. 338 as amended).~~

~~Authority Ga. L. 1970, p. 531, as amended by Ga. L. 1971, p. 247; Ga. L. 1976, p. 353 et seq.~~

~~**Administrative History.** Original Rule was filed on September 23, 1977; effective October 13, 1977.~~

**RULES
OF
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FACILITY REGULATION**

**CHAPTER 290-5-34111-8-09
BLOOD LABELING**

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290-5-34111-8-09.01 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" (~~Georgia Laws 1976, p. 353 et seq.~~ 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 ~~Human Resources~~Community Health;
- | (d) "Board" means the ~~State~~ Board of ~~Human Resources~~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 pharmaceutical 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 ~~Ga. L. 1970, p. 531, as amended by Ga. L. 1971, p. 247; Ga. L. 1976, p. 353 et seq. O.C.G.A. §§ 31-2-5, 31-2-7, and 31-24-1 et seq.~~ **Administrative History.** Original Rule was filed on September 23, 1977; effective October 13, 1977.

290-5-34111-8-09-.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 (~~Georgia Laws 1970, p. 531 et seq. as amended by Georgia Laws 1971, p. 247 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 ~~Ga. L. 1970, p. 531, as amended by Ga. L. 1971, p. 247; Ga. L. 1976, p. 353 et seq. O.C.G.A. §§ 31-2-5, 31-2-7 and 31-2-3~~ **Administrative History.** Original Rule was filed on September 23, 1977; effective October 13, 1977.

290-5-34111-8-09-.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 ~~Ga. L. 1970, p. 531, as amended by Ga. L. 1971, p. 247; Ga. L. 1976, p. 353 et seq.~~ O.C.G.a. §§ 31-2-5, 31-2-7, and 31-24-1 et seq. **Administrative History.** Original Rule was filed on September 23, 1977; effective October 13, 1977.

| **290-5-34111-8-09-.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 ~~Ga. L. 1970, p. 531, as amended by Ga. L. 1971, p. 247; Ga. L. 1976, p. 353 et seq. O.C.G.A. §§ 31-2-5, 31-2-7 and 31-24-5.~~ **Administrative History.** Original Rule was filed on September 23, 1977; effective October 13, 1977.

290-5-34111-8-09-05 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 ~~Ga. L. 1970, p. 531, as amended by Ga. L. 1971, p. 247; Ga. L. 1976, p. 353 et seq. O.C.G.A. §§ 31-2-5, 31-2-7 and 31-24-6.~~ **Administrative History.** Original Rule was filed on September 23, 1977; effective October 13, 1977.

290-5-34111-8-09-06 Administration.

Determination of fulfillment of these requirements shall be made by the Department of ~~Human Resources~~Community Health as a part of, and using the procedures of the Act providing for the control and operation of clinical laboratories (~~Georgia Laws 1970, p. 531 et seq. as amended by Georgia Laws 1971, p. 247~~O.C.G.A. § 31-22-1 et seq.).

Authority ~~Ga. L. 1970, p. 531, as amended by Ga. L. 1971, p. 247; Ga. L. 1976, p. 353 et seq. O.C.G.A. §§ 31-2-5, 31-2-7 and 31-24-7.~~ **Administrative History.** Original Rule was filed on September 23, 1977; effective October 13, 1977.

290-5-34111-8-09-07 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 ~~Ga. L. 1970, p. 531, as amended by Ga. L. 1971, p. 247; Ga. L. 1976, p. 353 et seq. O.C.G.A. §§ 31-2-5, 31-2-7 and 31-24-8.~~ **Administrative History.** Original Rule was filed on September 23, 1977; effective October 13, 1977.

290-5-34111-8-09-08 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 (~~Georgia Laws 1970, p. 531 et seq. as amended by Georgia Laws 1971, p. 247 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 (~~Georgia Laws 1964, p. 338 as amended O.C.G.A. § 50-13-1 et seq.~~).

| Authority ~~Ga. L. 1970, p. 531, as amended by Ga. L. 1971, p. 247; Ga. L. 1976, p. 353 et seq. O.C.G.A. §§ 31-2-5, 31-2-7, 31-2-8 and 50-13-1 et seq.~~ **Administrative History.** Original Rule was filed on September 23, 1977; effective October 13, 1977.