CHAPTER 8

COLLECTION, PROCESSING, STORAGE AND DISTRIBUTION OF BLOOD

Authority

N.J.S.A. 26:1A-7 and 26:2A-7.

Source and Effective Date

R.2005 d.283, effective August 1, 2005.
See: 36 N.J.R. 4261(a), 37 N.J.R. 3815(a).

Chapter Expiration Date

Chapter 8, Collection, Processing, Storage and Distribution of Blood, expires on August 1, 2010.

Chapter Historical Note

Chapter 8, Collection, Processing, Storage and Distribution of Blood, was filed and became effective prior to September 1, 1969.

Pursuant to Executive Order No. 66(1978), Chapter 8, Collection, Processing, Storage and Distribution of Blood, was readopted as R.1989 d.246, effective April 12, 1989. See: 21 N.J.R. 407(a), 21 N.J.R. 1412(a).

Pursuant to Executive Order No. 66(1978), Chapter 8, Collection, Processing, Storage and Distribution of Blood, was readopted as R.1994 d.229, effective April 12, 1994. See: 26 N.J.R. 1057(a), 26 N.J.R. 2025(a). Pursuant to Executive Order No. 66(1978), Chapter 8 expired on April 12, 1999.

Chapter 8, Collection, Processing, Storage and Distribution of Blood, was adopted as new rules by R.1999 d.288, effective August 16, 1999. See: 31 N.J.R. 947(a), 31 N.J.R. 2373(c).

Chapter 8, Collection, Processing, Storage and Distribution of Blood, was readopted by R.2005 d.283, effective August 1, 2005. See: Source and Effective Date. See, also, section annotations.

Subchapter 13, Hematopoietic Progenitor Cells, was adopted as new rules by R.2005 d.283, effective October 3, 2005. See: 36 N.J.R. 4261(a), 37 N.J.R. 3815(a).

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SUBCHAPTER 1. GENERAL PROVISIONS

8:8-1.1 Compliance

(a) Persons, known as licensees, for the purpose of this chapter, shall operate blood banks in this State and shall meet the qualifications and conduct blood banks in accordance with N.J.S.A. 26:2A-2 et seq. and all rules in this chapter.

(b) Failure to comply with N.J.S.A. 26:2A-2 et seq. and with this chapter shall be cause for revocation of license and imposition of penalties as prescribed by N.J.S.A. 26:2A-2 et seq.

Amended by R.1994 d.350, effective August 1, 1994.
See: 26 N.J.R. 1057(a), 26 N.J.R. 3171(a).
Amended by R.2005 d.283, effective October 3, 2005.
See: 36 N.J.R. 4261(a), 37 N.J.R. 3815(a).
Rewrote (a).

8:8-1.2 Definitions

For the purpose of this chapter, the terms listed below shall be defined and interpreted as follows:

"AABB Standards" means the "Standards for Blood Banks and Transfusion Services," 23rd Edition (2004), incorporated herein by reference as amended and supplemented and the "Standards for Cellular Therapy Product Services," First Edition (2004), incorporated herein by reference as amended and supplemented, both of which publications are published by the American Association of Blood Banks, 8101 Glenbrook Road, Bethesda, MD 20814-2749, (301) 907-6977, www.aabb.org.

"Accident" means a non-preventable occurrence.

"Additive solution system" means blood preservative systems designed primarily for the extended storage of red blood cells. These systems utilize a second preservative solution for red cell storage in addition to the anticoagulant solution necessary for whole blood collection.

"Allogeneic" means the collection of blood or blood components for subsequent transfusion to an individual other than the donor. The term "allogeneic" is also known as homologous.

"Autologous donation/transfusion" means the collection of blood and blood components from a donor/recipient for subsequent reinfusion into the same individual. The term "autologous" is also known as autogeneic.

"Blood bank" means any commercial or noncommercial activity involving the handling of blood or plasma, intended to be used for therapeutic or prophylactic purposes, which participates in any of the following operations: collection, processing, storage, distribution or administration of blood.

"Blood components" means those preparations that are separated from whole blood and are intended for use as final products for therapeutic purposes, for further manufacturing, or as products used for in vitro testing.

"Broker" means procuring, selling and distributing of blood, blood components or blood products without engaging in processing, alteration or other manipulation of the blood component.

"Center for Biologics Evaluation and Research (CBER)" means the U.S. Food and Drug Administration (FDA), Department of Health and Human Services.

"Clinical practitioner" means a physician currently licensed to practice in New Jersey; an advanced practice nurse currently certified under the New Jersey Advanced Practice Nurse Certification Act; or a physician assistant licensed under the Physician Assistant Licensing Act, acting within the rules governing those professions. Where authorized under this chapter, clinical practitioners shall be permitted to order transfusions and procedures related to the collection or donation of blood and blood products. Advanced practice nurses shall order only according to specific written joint protocols established with the collaborating physician and physician assistants, according to specific protocols established with the supervising physician.

"Closed system" means a system in which the blood container is not entered or air introduced.

"Code of Federal Regulations" means the current Code of Federal Regulations, as amended and supplemented, Title 21, parts 600 through 640.

"Collection" means the procedure for obtaining blood by donor or recipient phlebotomy.