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.1999 d.288, effective August 16, 1999.
See: 31 N.J.R. 947(a), 31 N.J.R. 2373(c).

Executive Order No. 66(1978) Expiration Date

Chapter 8, Collection, Processing, Storage and Distribution of Blood, expires on August 16, 2004.

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: Source and Effective Date.

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SUBCHAPTER 1. GENERAL PROVISIONS

8:8–1.1 Compliance

(a) Persons operating blood banks in this State shall meet the qualifications and conduct blood banks in conformity 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).

8:8–1.2 Definitions

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

"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.

"Autologous donation/transfusion" means the collection of blood and blood components from a donor/recipient for subsequent reinfusion into the same individual.

"Blood bank" means any facility involved in the handling of human blood, blood component or products and which participates in any of the following operations: collection, processing, donor or recipient testing, storage, distribution, and administration of blood and blood components for therapeutic purposes.

"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.

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

"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.

"Commissioner" means the Commissioner of New Jersey State Department of Health and Senior Services or his or her duly authorized agent.

"Crossing over" means the transfusion of a donation of blood and/or blood components, originally collected for autologous transfusion, to a recipient other than the original donor/recipient.

"Cytapheresis" means the procedure in which blood is removed from the donor, certain cellular elements are separated, and the remaining formed elements and residual plasma are returned to the donor.

"Department" means the New Jersey State Department of Health and Senior Services.

"Designated donor" means a donor that is selected by a recipient for transfusion to this recipient at a later date.

"Directed donation" means the collection of blood or blood components from a designated donor.

"Distribution" means the transfer of blood or blood components from one blood bank facility to any other location for processing or storage or for the purpose of providing the blood for therapeutic, prophylactic or in vitro purposes.

"Donor" means and includes any individual from whom blood or components are collected by a blood bank.

"Error" means a preventable occurrence.

"Health system" means a multidivisional hospital with a blood bank and no more than three satellite blood bank facilities.

"Hemapheresis" means the process of separating freshly drawn whole blood into various blood components and products, some of which are retained while the remainder are reinfused into the donor.

"HIV antigen" means the Human Immunodeficiency Virus antigen.

"HIV–1" means the Human Immunodeficiency Virus type 1.

"HIV–2" means the Human Immunodeficiency Virus type 2.

"Homologous or allogeneic donation" means the collection of blood or blood components for subsequent transfusion to a recipient other than the donor.

"Key person" means individuals designated by the blood bank director.