

Pursuant to the authority vested in the Council on Human Blood and Transfusion Services and the Commissioner by section 3121(5) of the Public Health Law, Subpart 58-2 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Subdivision (g) of section 58-2.6 is amended to read as follows:

(g) Until issued, whole blood and red cell components shall be stored continuously in a refrigerator either with a fan for circulating air, or of a capacity and design to ensure that the proper temperature is maintained throughout, and equipped with automatic temperature recording and an audible alarm. Such blood components must be visually inspected during storage at regular intervals determined by the blood bank director. Periodic verification of alarm function, in accordance with the manufacturer's recommendations, shall be documented. Storage shall be at one to six degrees Celsius. No items other than specimens, tissue, or reagents shall be stored in a refrigerator in which whole blood and red blood cell components are stored. Temperature records shall be available for inspection for at least five years. Autogeneic units shall be stored in a separate, specifically designated portion of the refrigerator.

Subdivision (a) of section 58-2.10 is amended to read as follows:

(a) Complete and accurate records of blood, blood components and derivatives released for allogeneic or autogeneic transfusion shall be kept for [seven] 10 years or six months after the expiration date of the individual product, whichever is later, by the blood bank preparing the product and by the institution using the product. Such records shall be open to inspection by the department and shall include the information specified in

sections 58-2.11 and 58-2.12 of this Subpart. For all collected or distributed blood, blood components and derivatives, the donor's name, address, telephone number, social security number and any other information which would directly or indirectly identify the blood donor of any specific unit shall not be disclosed by the blood bank to any person or entity except upon the written consent of the donor or except to the department and other agencies which issue clinical laboratory and/or blood bank permits to the facility whose records are requested.

Section 58-2.20 is hereby repealed.

Subdivision (i) of section 58-2.25 is amended to read as follows:

(i) All records of transfusions of blood recovered intraoperatively or postoperatively shall be available to the department for inspection for at least [seven] 10 years after each transfusion. Summary records, listing the patient's name, the medical record number and procedures performed, shall be kept of all such procedures, separate from the patient's chart.

Subdivision (h) of section 58-2.27 is amended to read as follows:

(h) All records pertaining to reinfusion procedures shall be retained for a minimum of [seven] 10 years.

NOTICE OF CONSENSUS RULE-MAKING

Statutory Authority:

The authority for these regulations is contained in Section 3121(5) of the Public Health Law.

Basis:

Subpart 58-2 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York establishes regulatory requirements for all aspects of blood banking, including personnel qualifications, donor screening and care, record keeping, and certain technical specifications.

Pursuant to Title 42 of the Code of Federal Regulations, subdivision (g) of section 58-2.6 has been deemed less stringent than federal regulations since there was no requirement for visual inspection of whole blood and red cell components during storage. Likewise, sections 58-2.10, 58-2.25 and 58-2.27 were deemed less stringent than federal regulations since record retention is required for only seven, rather than ten years. This change qualifies as consensus rulemaking because it makes conforming changes necessary to comply with federal rules. Since affected parties must comply with both federal rules and state regulations, achieving parity between these two bodies of requirements reduces confusion and administrative burden. As such, affected parties are unlikely to object to these changes.

Pursuant to Chapter 316 of the Laws of 2024, ambulance services and advanced life support first response services are allowed to store and distribute blood and initiate and administer blood transfusions in the absence of a blood bank permit otherwise required for these activities under Article 5, Title V of Public Health Law. Therefore,

ambulance services and advanced first response services are not legally defined as blood banks and ambulance transfusion service approvals, as defined in section 58-2.20, are no longer required for these activities. Consequently, section 58-2.20 is being repealed. This qualifies as consensus rulemaking because it repeals a regulatory provision that is no longer applicable to any person. The affected parties, which are ambulance services and advanced first response services, are aware of the statutory changes through outreach by the Department and are unlikely to object to this regulatory change.

STATEMENT IN LIEU OF JOB IMPACT STATEMENT

No job impact statement is required pursuant to Section 201-a(2)(a) of the State Administrative Procedure Act. It is apparent, from the nature of the proposed amendment, that it will not have an adverse impact on jobs and employment opportunities.