

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:

Section 58-2.14 [Collection of Source Plasma] Reserved.

## **NOTICE OF CONSENSUS RULE-MAKING**

### **Statutory Authority:**

Pursuant to section 3121(5) of the Public Health Law the Council on Human Blood and Transfusion Services, subject to approval by the Commissioner, has the power to enact, amend and repeal, rules and regulations establishing minimum standards for the proper collection, processing, fractionation, storage, distribution, and supply of human blood or blood derivatives, for the purpose of transfusions.

### **Basis:**

Subpart 58-2 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) establishes regulatory requirements for all aspects of blood banking, including personnel qualifications, donor screening and care, record keeping, and certain technical specifications. In particular, section 58-2.14 addresses these aspects for blood banks collecting “source plasma” that is utilized in the manufacture of blood derivatives such as Rho(D) immune globulin and anti-SARS Cov-2 immunoglobulin.

Pursuant to recently adopted legislation found in Chapter 675 of the Laws of 2021, source plasma donation centers are now exempt from the definition of a blood bank and the Department of Health must adopt new regulations specific to the operation of these entities and consistent with federal regulations for source plasma collection.

Section 58-2.14 of 10 NYCRR regulates source plasma donation centers as blood banks and is more stringent than federal regulations for source plasma. Repealing these

regulations is therefore necessary since source plasma donation centers are now exempt from blood banking requirements pursuant to L. 2021, Ch. 675 and the requirements in section 58-2.14 are no longer applicable to any person.

## **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.