Blood Banks

Effective date: 9/27/15

**Summary of Express Terms**

This proposed amendment to Subpart 58-2 updates practice standards, reflects changes in nomenclature and technology, and provides clarification of provisions pertinent to blood banks and transfusion services. The title of the Subpart is also expanded to clarify that laboratories performing immunohematology testing are subject to these requirements.

Section 58-2.1 definitions for the terms *blood bank, blood donation center, transfusion service* and *reinfusion procedure* are amended. The definition of *blood components* is revised to include plasma frozen within 24 hours after phlebotomy and specifically exclude lymphocytes collected from a hematopoietic progenitor cell donor. The definition for *holding facility* is replaced by a definition for *distribution facility. Ambulance transfusion service* and *hospital* are defined in new subdivisions (ae) and (af), respectively.

Section 58-2.2 as modified, alters the qualifications for allogeneic blood donors by removing an obsolete provision pertaining to acute respiratory diseases, expanding options for review and acceptance of donors who are 76 years of age or older, and clarifying the timing of opportunities provided for donor self-exclusion.

Section 58-2.3(e) is amended to permit infectious disease testing to be performed on a donor blood specimen collected prior to the donation of such a component.

Section 58-2.4(a) clarifies the locations at which blood collection activities may be conducted, to include a blood donation center, a self-contained blood collection vehicle, and a temporary collection operation conducted by a blood bank. A new subdivision (d) stipulates that

persons collecting blood for transfusion must be trained in recognition of donor reactions, and that a nurse or other qualified person specially trained to address donor reactions be present.

Section 58-2.6(a), which details locations for collection of blood, is repealed, as this requirement is now addressed in Section 58-2.4(a). Subdivisions (b), (c) and (d) of Section 58-2.6 are renumbered as subdivisions (a), (b) and (c), respectively. Requirements for storage of collected whole blood during transport are moved from Section 58-2.6(g) to the new subdivision (d) and limitations on duration of storage for whole blood units from which platelets will be separated are deleted. Labeling requirements now in paragraph (3) of renumbered subdivision (c) replace the existing provisions in subdivision (e), which are duplicative of Section 58-2.4(b) as amended. The labeling provisions of renumbered Section 58-2.6 (e)(2)(vi) are amended to eliminate the requirement for biohazard labeling of autogeneic blood and blood components from patient-donors testing positive for antibodies to hepatitis B core antigen. Provisions regarding storage temperature for thawed plasma, and duration of storage for thawed cryoprecipitate intended for factor VIII replacement, are moved from Section 58-2.6(f) to (h). Section 58-2.6(h) extends the allowable shelf life of non-cellular components stored at a temperature not higher than minus 65 degrees Celsius to seven years. Provisions regarding duration of storage for thawed red blood cells are moved from Section 58-2.6(f) to subdivision (j), and the allowable shelf life for red blood cells deglycerolized using a closed system is extended to 14 days. Subdivisions (g), (h) and (j) are also amended to clarify that periodic verification of refrigerator, freezer and liquid nitrogen alarm function must be documented. Section 58-2.6(l) adds a requirement that entry ports be protected from water contamination by positioning or a protective overwrap when blood components are thawed in a waterbath. The

amendment also adds ambulance transfusion services to the listing in Section 58-2.6(m) of entities to which blood and blood components may be released.

Section 58-2.7(a) adds a requirement that blood specimens intended for pretransfusion testing be labeled at the patient's side at the time of collection. Subdivision (d) is amended to specify that all quality control records associated with testing be retained for five years.

Section 58-2.8(b) is amended to clarify the department's expectation that regulated parties comply with federal rules for reporting errors and accidents to federal authorities. Section 58-2.8(c) expands requirements for procedure manuals to include written procedures for: transfusion-related testing; release of blood and blood components to limited transfusion services and ambulance transfusion services; and the administration of blood components, including prevention of transfusion reactions. Section 58-2.8(c) also stipulates that written procedures for emergency release of uncrossmatched blood must expressly require completion of compatibility testing following such release and that evaluation of reported transfusion reactions be prompt.

Section 58-2.9(b) is amended to expand the circumstances under which blood components may be issued prior to completion of infectious disease testing. Section 58-2.9(c) allows release of autogeneic blood from a patient-donor whose blood tests positive for human immunodeficiency virus (HIV) or hepatitis C virus (HCV) nucleic acid, or antibodies to HCV, if authorized in writing by the patient-donor's physician. Section 58-2.9(c) requires that transfusion services issuing blood components to ambulance transfusion services perform required testing on their own premises, and deletes an inaccurate reference to limited transfusion services. Subdivision (g), specifying circumstances under which more than one unit of blood may be released at one time for a particular patient, is repealed and replaced with a more flexible requirement that the director of transfusion services specify in a written policy the permissible

circumstances for simultaneous issuance of multiple units. Two new subdivisions, numbered (m) and (n), are added to Section 58-2.9 to detail the requirements for transport containers for blood components issued to a limited transfusion service or an ambulance transfusion service, respectively.

Section 58-2.11(a)(4) allows the identity of the phlebotomist collecting the blood for transfusion to be recorded by methods other than his or her signature.

Section 58-2.12(a) modifies the requisites for records to be kept when blood and blood components are issued for transfusion, clarifying that the unit identification code and blood group must be recorded and that a visual inspection and location of any remote storage must be documented. Section 58-2.12(d) is also amended to specify that these recordkeeping requirements apply to blood components issued to ambulance transfusion services.

Section 58-2.13 is repealed and replaced by a new Section 58-2.13.

Section 58-2.15(d) decreases hemoglobin/hematocrit requirements for some double red blood cell donors, provided conformance is maintained with United States Food and Drug Administration (F.D.A.) requirements for the apheresis device.

Section 58-2.16(a) has been modified to include an ambulance transfusion service as an entity to which blood can be issued. Section 58-2.16(a)(1)(iv) clarifies the department's expectation that regulated parties comply with federal requirements for reporting serious unexpected transfusion reactions. Section 58-2.16(b), concerning transfusion committees, is modified to remove the requirement for majority attendance at meetings, add expertise in clinical medicine as possible qualification for membership, and specify an option for review of a representative sample of transfusions. Section 58-2.16(d) is modified to combine similar existing requirements pertaining to the administration of blood components. Section 58-2.16(e),

as modified, simplifies the language detailing the individuals authorized to initiate transfusions and perform patient and unit identification at the patient's side. Section 58-2.16(f) clarifies the requirements for identification of a transfusion recipient. Section 58-2.16(g) clarifies that transfusions outside a health care setting do not include those in an ambulance. Renumbered subdivision (j) of Section 58-2.16 supplies examples of options for autogenic blood transfusion that, if available at a given institution, must be made known to staff physicians through the transfusion committee.

A new Section 58-2.16(h) adds provisions to permit advanced life support emergency medical technicians with specialized training to monitor transfusions and initiate additional units during interfacility transport to facilitate expeditious transport of patients requiring transfusion during transport.

A misplaced reference to the use of a validated computer system has been moved from subdivision (a) to subdivision (c) of Section 58-2.17. Section 58-2.17(a) clarifies that the requirement for ABO reverse grouping of an intended transfusion recipient is not applicable to infants under four months of age. Section 58-2.17(b) adds a provision allowing the use of maternal serum or plasma in testing for unexpected antibodies. Provisions regarding compatibility testing in the case of infants under four months of age are moved from Section 58-2.20 to Section 58-2.17(c). Section 58-2.17(e) is repealed in light of substantial redundancy with subdivision (c) as modified.

Section 58-2.18 is repealed and replaced by a new Section 58-2.18, which clarifies the records required when blood components are transfused and eliminates a requirement that the quantity of material transfused be recorded.

Section 58-2.19 adds requirements that records regarding infusion of derivatives include

the manufacturer's name, the name of the person administering the product, and documentation of identification of the recipient and visual inspection of the product.

Section 58-2.20 is repealed and replaced by a new Section 58-2.20, which adds requirements for approval of ambulance transfusion services.

Section 58-2.21(a) clarifies that a limited transfusion service may not operate in New York State without approval of the department.

The provisions of Section 58-2.22 are repealed, and the section is reserved for later use.

A new Section 58-2.27(a) clarifies that entities performing reinfusion procedures must either hold a department laboratory permit or be approved by the department as a limited reinfusion service.

Pursuant to the authority vested in the Council on Human Blood and Transfusion Services by Section 3121(5) of the Public Health Law and with the approval of the Commissioner of Health, Subpart 58-2 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended as follows, to be effective 60 days after publication of a Notice of Adoption in the New York State *Register*.

The title to Subpart 58-2 and the list of section titles are amended to read as follows:

Subpart 58-2

Blood Banks and Laboratories Performing Immunohematology Testing

Section

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58-2.13 [Blood donation centers]Distribution facilities

58-2.14 Serial plasmapheresis

58-2.15 Collection of blood components by apheresis

58-2.16 Required standards for transfusions

58-2.17 Laboratory tests to be performed prior to allogeneic or autogeneic transfusion

58-2.18 Records to be kept when blood or blood component transfusions are performed

58-2.19 Records to be kept when [plasma]derivatives are infused

58-2.20 [Neonatal transfusions]Ambulance transfusion services

58-2.21 Limited transfusion services

58-2.22 [Holding facilities]Reserved

Subdivisions (a), (b), (d), (m), (n) and (u) of section 58-2.1 are amended, and new subdivisions (ae) and (af) are added to read as follows:

(a) *Blood bank* means a facility for the collection, processing, storage or distribution of human blood, human blood components or [blood] derivatives, or the performance of reinfusion procedures. A blood bank shall employ a qualified director for administrative purposes and, if blood collection is performed, a qualified medical director.

(b) *Blood donation center* means a [facility,] fixed [or mobile, that is] satellite location operated by a blood bank and used for the collection of whole blood [, plasma or cytapheresis products, or separation of whole] and/or blood [into] components.

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(d) *Blood components* means those preparations separated from a single donation of whole blood, or collected by apheresis, intended for direct use in transfusion, including, but not limited to plasma, fresh frozen plasma, plasma frozen within 24 hours after phlebotomy (FP24), red blood cells, washed red blood cells, leukocyte-reduced red blood cells, platelets, granulocytes, and cryoprecipitate, but does not include lymphocytes collected from a donor of hematopoietic progenitor cells, as defined in Subpart 58-5.

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(m) [*Holding*] *Distribution facility* means a facility at which blood [is] and blood components are temporarily stored [but which does not offer any other blood banking services] prior to distribution.

(n) *Transfusion service* means a service [which] that issues blood [,] or blood components [or blood derivatives] for administration into a person, but does not include a limited transfusion service or an ambulance transfusion service.

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(u) *Reinfusion procedure* means the withdrawal of [a small amount of] blood or a component thereof from a patient, its processing [by addition of substances or by culturing,] and administration of the product so obtained, in whole or in part, into the same patient for diagnostic or therapeutic purposes. [Reinfusion procedures shall] Such processing may include, but is not [be] limited to, separation (*e.g.* into platelet-rich plasma or fibrin glue), radioisotopic tagging, and genetic and immunologic manipulation [, but shall not include processing of whole blood units into components for autogeneic reinfusion, such as platelet concentrates, packed red blood cells and plasma]. Reinfusion procedures shall not include presurgical autogeneic collection, normovolemic hemodilution, intraoperative blood recovery or postoperative blood recovery.

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(ae) *Ambulance transfusion service* means an ambulance service certified by the department that administers blood components during transport from one hospital to another hospital.

(af) *Hospital*, for the purposes of this Subpart, means a general hospital.

Paragraph (1) of subdivision (b) of section 58-2.2 is repealed and paragraphs (2), (3), (4), (5), (6), (7), (8) and (9) of section 58-2.2 are renumbered to be paragraphs (1), (2), (3), (4), (5), (6), (7) and (8), respectively. Subdivisions (c) and (d) of section 58-2.2 are amended to read as follows:

(c) For allogeneic collection[s], a person may not be accepted as a blood donor:

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(4) who is [more than 75] 76 years of age or older, except that donors [over 75] who are 76 or older may be accepted after satisfactory case-by-case review of the donor by the medical director or [physician] his/her designee;

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(d) For allogeneic collection:

(1) All donors shall be given educational materials on risk activities for HIV infection and shall be advised that persons at risk for HIV infection should refrain from donating blood.

(2) Each donor shall be provided the opportunity to indicate confidentially, at the time of donation or after donation, that blood collected [is] may be unsuitable for transfusion.

Subdivisions (e) and (h) of section 58-2.3 are amended to read as follows:

(e) If multiple patient-dedicated blood components are donated by a single donor to support a particular patient, that donor's blood may be screened for all analytes specified in subdivision (a) of this section every 30 days, rather than at each donation. If the clinically useful shelf life of a blood component precludes completion of the required testing prior to component expiration, screening for all analytes specified in subdivision (a) of this section may be performed on a donor blood specimen collected prior to the donation, as permitted by the F.D.A.

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(h) Errors or accidents in collecting, testing or processing of donor blood that are not detected prior to distribution and that may affect the safety [or purity] of any product or health of the donor or recipient shall be reported to the department's Wadsworth Center within seven calendar days of such an error or its discovery and, if required, to federal authorities.

Subdivisions (a) and (b) of section 58-2.4 are amended, and a new subdivision (d) of section 58-2.4 is added, to read as follows:

(a) Collection of blood for transfusion shall be performed under the direction of the medical director. Medical services for emergency care of the donor shall be available. Blood for transfusion shall be collected only on the premises of a blood bank, at a blood donation center approved by the department, in a self-contained blood collection vehicle operated by a blood bank, or at a temporary collection operation conducted by a blood bank. Each blood bank shall inform the department, upon request, of the location of all blood collection activities and the provisions made for the handling of medical emergencies. Prior to collection of blood for testing, a signed form must be obtained from the donor or person legally authorized to consent on behalf of such donor, in which the donor or the person legally authorized to consent acknowledges that he/she has been provided with written materials stating that HIV testing for donor screening purposes shall be performed in conjunction with all donations.

(b) *Quantity limitations.* Allogeneic and autogeneic donors may give a maximum of 550 milliliters of whole blood in addition to pilot samples [of up to 30 milliliters] sufficient for all testing to be performed.

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(d) Persons collecting blood for transfusion shall be trained, under the direction of the medical director, to recognize donor reactions. Whenever donor collection procedures are performed, a nurse or other qualified person specially trained to recognize and address donor reactions shall be immediately available, and a physician shall be available by telephone for consultation.

Subdivisions (a) and (e) of section 58-2.6 and paragraph (3) of subdivision (d) of section 58-2.6 are repealed. Subdivisions (b), (c) and (d) of section 58-2.6 are renumbered to be subdivisions (a), (b) and (c), respectively. New subdivisions (d) and (e) of section 58-2.6 are added to read as follows:

(d) Blood in transit shall be refrigerated at one to 10 degrees Celsius, preferably at four to six degrees Celsius, with the exception of units from which platelets will be separated, which may be stored at room temperature.

(e) *Labeling requirements.*

(1) For allogeneic collection, the container and the attached pilot blood specimens shall be legibly labeled at the time of collection with the associated unit's identification code. The container label shall indicate the date of expiration. As soon as available, the results of ABO and Rh grouping tests shall be affixed to component containers.

(2) With the exception of units collected in an operating room which never leave the immediate proximity of the patient, for autogeneic collection, the following information shall appear on a label or tag attached to the blood container:

(*i*) the identification of the collecting facility;

(*ii)* the patient's name and if available, the name of the hospital or limited transfusion service where the patient is to be transfused and the patient's birth date or identifier. This tag shall be removed if the unit is subsequently used for allogeneic transfusion;

(*iii*) ABO and Rh group;

(*iv)* date of expiration;

(*v*) if the unit does not qualify for allogeneic transfusion, a prominent label to read "For autologous use only" or similar wording;

(*vi*) an autogeneic unit from a donor who has tested positive or reactive on any of the tests required in section 58-2.3(a) of this Subpart, with the exception of anti-HBc, within the previous 30 days shall be labeled as a biohazard unless confirmatory testing has been negative. The exterior of the shipping container shall not contain any information identifying the donor; and

(*vii*) a label bearing the donor classification statement "Autologous donor" shall be permanently affixed to the unit.

Subdivisions (f), (g), (h), (j), (l) and (m) of section 58-2.6 are amended to read as follows:

(f) The blood shall be collected in the manner appropriate for the container employed. Following collection, the container shall be sealed securely. If a container is opened or entered in any way, the blood component must be transfused within 24 hours or discarded, unless a sterile connecting device which maintains a functionally closed system has been utilized for entry. [After deglycerolizing, frozen red blood cells shall be transfused or refrozen within 24 hours, or shall be discarded. If a refrozen unit is subsequently rethawed and deglycerolized, a notation indicating such previous thawing and deglycerolizing shall be made on a label or tag attached to the blood unit, or on accompanying paperwork. After thawing of fresh frozen plasma, the blood component shall be transfused immediately or stored at between one and six degrees Celsius. Plasma stored in the liquid state for more than 24 hours shall be released only for medical indications other than replacement of labile coagulation factors. Cryoprecipitate intended for factor VIII replacement must be transfused within six hours after thawing.]

(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. Periodic verification of alarm function, in accordance with the manufacturer's recommendations, shall be documented. Storage shall be at [a temperature of not less than] one [degree Celsius nor more than] 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. [Blood in transit shall be refrigerated at a temperature between one degree Celsius and ten degrees Celsius, preferably between four degrees Celsius and six degrees Celsius, with the exception of units from which platelets will be separated. Units which will be used as a source of platelets shall be stored at room temperature, preferably at 20 to 24 degrees Celsius, until platelets are separated, but for no more than eight hours.] Autogeneic units shall be stored in a separate, specifically designated portion of the refrigerator.

(h) Until issued, cryoprecipitate, fresh frozen plasma, FP24, and cryoprecipitate-poor plasma shall be stored continuously at a temperature not higher than minus 18 degrees Celsius for up to one year or, with F.D.A. approval, at a temperature not higher than minus 65 degrees Celsius for up to seven years, in a freezer equipped with automatic temperature recording and an audible alarm. Periodic verification of alarm function, in accordance with the manufacturer's recommendations, shall be documented. [Storage time shall not exceed one year.] Such frozen components shall not be relabeled as different components and released for transfusion, but may be used for fractionation into derivatives. After thawing, plasma shall be transfused immediately or stored at one to six degrees Celsius. Cryoprecipitate intended for factor VIII replacement shall be transfused within six hours after thawing. Freezer temperature records shall be available for inspection for at least five years.

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(j) Until issued, frozen red blood cells shall be stored at a temperature [no] not higher than minus 65 degrees Celsius in a freezer equipped with automatic temperature recording and audible alarm, or in liquid nitrogen. Liquid nitrogen levels must be mechanically or visually monitored daily. Periodic verification of alarm function, in accordance with the manufacturer's recommendations, shall be documented. Storage time shall not exceed 10 years. Freezer temperature or liquid nitrogen level records shall be available for inspection for at least five years. After thawing, red blood cells shall be transfused or refrozen within 24 hours or discarded, unless deglycerolized using a closed system that allows a 14-day expiration date, as approved by the F.D.A. If a refrozen unit is subsequently rethawed and deglycerolized, a notation indicating such previous thawing and deglycerolizing shall be made on a label or tag attached to the blood unit, or on accompanying paperwork.

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(l) Fresh frozen plasma, cryoprecipitate, FP24 and frozen red blood cells shall be thawed only in a water bath at a temperature not exceeding 38 degrees Celsius, with entry ports protected from water contamination by positioning or a protective overwrap, or in another device specially designed for such thawing. If a water bath is used for thawing, its temperature shall be recorded each day of such use. Temperature records shall be available for inspection for at least five years. Maintenance and operation of all equipment for processing or preparation of blood components shall conform to the manufacturer's instructions and shall follow a protocol approved by the director of transfusion services.

(m) Except for blood recovered intraoperatively or postoperatively, or collected for use in a reinfusion procedure, all blood intended for transfusion shall, upon collection, become the

responsibility of the blood collection service. Disposition of blood collected by phlebotomy shall be at the discretion of the director of the collection service until the blood is transferred to a transfusion service, at which time its disposition shall be at the discretion of the director of transfusion services. The director of the blood bank shall ensure that during any transport blood is packed and handled appropriately, and only by authorized individuals. No directed or autogeneic blood unit or component shall be transported to a transfusion service unless the director of the receiving transfusion service or his/her designee has authorized such transport. A transfusion service which has granted standing authorization for receipt of blood shall be given specific notice prior to each shipment. Disposition of blood recovered intraoperatively or postoperatively shall be at the discretion of the intraoperative or postoperative blood collection service, unless the blood is transferred to the hospital blood bank for storage, at which time its disposition shall be at the discretion of the director of transfusion services. Blood banks shall not release blood or blood components [or blood] intended for transfusion to any site or entity in New York State not [permitted] holding a department permit as a collection service or transfusion service, or approved by the department as a limited transfusion service or an ambulance transfusion service.

Subdivision (a) and (d) of section 58-2.7 are amended to read as follows:

(a) [Labeling of] Blood specimens intended for pre-transfusion testing shall be labeled at the patient's side at the time of collection. Such labeling shall include the patient's name, patient's identification number, and date of collection. Identification of the person collecting the specimen shall be recorded.

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(d) Negative controls run on each day of use are not required for anti-human globulin and antibody screening cells, provided manufacturers' instructions are followed. New lots of reagents shall be thoroughly evaluated, but antibody identification cell panels need not be tested with a known antibody. All test procedures to be used shall be determined by the blood bank director and shall be documented in the standard operating procedure manual. If no negative reactions are observed on a given test run, an investigation shall be performed and controls run. [Such] All quality control records shall be [accessible to laboratory personnel engaged in immunohematology testing and to the department] retained for five years.

Subdivisions (b), (c) and (d) of section 58-2.8 are amended to read as follows:

(b) The standard operating procedure manual shall include a written procedure for documenting errors or accidents in collection, testing, processing, storage or distribution that may affect the safety or purity of any product, or health of the donor or recipient. [If the error or accident is not detected prior to issuance of the blood, blood components or derivatives, the error or accident shall be reported immediately to the receiving facility.] All such errors and accidents not detected prior to product distribution shall also be reported to the department's Wadsworth Center within seven calendar days of discovery[,] and, if required, to federal authorities.

(c) The standard operating procedure manual shall include written policies and [protocols] procedures regarding the following, for activities performed at the site:

(1) use and maintenance of blood warming devices;

(2) type of infusion sets and filters for all components;

(3) [inspection] issuance of components, which must include visual inspection prior to issuance;

(4) type of personnel [who may remove] authorized to issue components;

(5) for collecting facilities, obtaining blood or components from other institutions during emergency situations;

(6) all transfusion-related testing, prenatal testing, and neonatal testing;

(7) prompt evaluation of reported transfusion reactions and other adverse events;

(8) emergency release of uncrossmatched blood, which must include compatibility testing performed after release;

(9) method validation requirements;

(10) professional qualifications of personnel who may collect blood specimens for pretransfusion testing; [and]

(11) specimen and labeling requirements for pretransfusion samples[.];

(12) release of blood and blood components to limited transfusion services and ambulance transfusion services; and

(13) administration of blood components, including prevention of transfusion reactions.

(d) The policies and procedures specified in the standard operating procedure manual shall be followed at all times. If deviations are identified, appropriate corrective action shall be taken and documented.

Subdivisions (b), (c) and (d) of section 58-2.9 are amended to read as follows:

(b) Except in an emergency or except as indicated in section 58-2.3(c) or (d) of this Subpart, blood and blood components shall not be made available for allogeneic transfusion, unless a donor blood sample reacts negatively to tests required in section 58-2.3(a) of this Subpart, and testing specified in section 58-2.3(f) of this Subpart has been completed. Untested or incompletely tested blood, including blood from directed donations and cytapheresis

collections, shall not be issued if a fully tested blood component is available, except in the case of autogeneic donations, as specified in section 58-2.3(a) of this Subpart. Cytapheresis units for which testing has not been completed may be distributed to a hospital by the facility collecting the units, but such components may not be issued by a transfusion service until testing is complete, except in the case of a life-threatening emergency or when the clinically useful shelf life of the component precludes completion of testing prior to issuance. The release of cytapheresis components from a donor found to have a positive result for anti-HBc may be permitted upon the authorization of the health care provider ordering the transfusion and the written authorization of the medical director or [physician]designee who is a physician, provided that such authorization documents the indication and justification for such release. Such components shall be labeled with all positive test results. Blood from a donor whose blood specimen reacts positively in [a test] testing for syphilis and is nonreactive in confirmatory testing shall be appropriately labeled and may be used for plasma fractionation. Blood from a donor whose blood specimen reacts positively in [tests] testing for anti-HBc shall be appropriately labeled and may be used for plasma fractionation. Blood from a donor whose blood specimen reacts positively in [tests] testing for HBsAg, [HIV or HCV nucleic acid] HIV nucleic acid, HCV nucleic acid, or antibodies to HCV, HIV-1, HIV-2, or HTLV-I/II shall be appropriately labeled and may not be used for allogeneic transfusion or for fractionation. Blood from a donor whose blood [sample] specimen reacts positively in [tests] testing for HBsAg, HIV nucleic acid, HCV nucleic acid, or antibodies to HCV, HIV-1 and/or HIV-2 may not be used for autogeneic transfusion without the written authorization of the patient's physician and, if drawn by another facility, the director of the transfusion service receiving the unit.

(c) Blood, blood components and derivatives shall be issued only if ordered by a licensed physician or other person authorized by law. Recipients shall receive whole blood of the same ABO group or compatible red blood cells. Rho (D)-negative recipients shall receive Rho (D)-negative blood, except for reasonable exempting circumstances as determined by the director of transfusion services. Rho (D)-positive recipients may receive Rho (D)-positive or Rho (D)-negative whole blood or red blood cells. In an emergency, appropriately documented in the records, blood may be released for transfusion prior to the completion of compatibility tests. Any transfusion service which issues blood components for transfusion [at] by a limited transfusion service or ambulance transfusion service shall perform the required tests on its own premises [unless the limited transfusion service holds the required permit issued by the department to perform such tests].

(d) Whole blood, red blood cells, plasma [or] and other blood components [and derivatives] shall be inspected visually immediately prior to issuance. If the color or physical appearance is abnormal or there is indication or suspicion of microbial contamination, the unit [or units] of whole blood [,] or blood components [or derivatives] shall not be issued for transfusion.

Subdivision (g) of section 58-2.9 is repealed, and a new subdivision (g) is added to read as follows:

(g) The director of transfusion services shall establish a written policy that specifies the circumstances under which more than one unit of red blood cells for a particular patient may be issued simultaneously for transfusion within a hospital without documented approval of the director of transfusion services or [physician] designee who is a physician.

Subdivision (j) of section 58-2.9 is amended, and new subdivisions (m) and (n) are added to read as follows:

(j) After issuance, red blood cells may be stored at room temperature for up to one hour or by refrigerating at [between] one [and] to six degrees Celsius. Red blood cells kept at room temperature for more than one hour may not be returned to the blood bank and later reissued for transfusion unless the temperature of the component is documented not to have risen above 10 degrees Celsius. If refrigerated, red blood cells shall be stored in a refrigerator designed for the purpose of storing blood, except that a cooler with suitable coolant may be used for refrigeration, provided that the temperature of the blood is maintained at [between] one [and] to 10 degrees Celsius.

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(m) Blood components issued to a limited transfusion service shall be transported in a leak-resistant, crush-resistant and puncture-resistant container that has been validated to maintain the appropriate temperature for the anticipated duration of storage and that has a label indicating the issuing transfusion service.

(n) Blood components issued to an ambulance transfusion service shall be transported in a leak-resistant, crush-resistant and puncture-resistant container that has been validated to maintain the appropriate temperature for the anticipated duration of transport and that has a label indicating the intended receiving hospital's blood bank.

Subdivision (a) of section 58-2.11 is amended to read as follows:

(a) Every blood bank shall maintain [a] records of each container of blood or blood components collected or prepared therein. The records shall contain the following information:

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(4) signature of or other unique identifier provided by the phlebotomist;

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(8) if a donor is determined to be unsuitable for donation based on donor history, laboratory test results or implication in a case of transfusion-transmitted disease according to the protocol of the blood collection service, a record of the donor's name and identifying information. Blood from such a donor shall not be released, even if results of testing on subsequent donations are negative, unless the donor has been approved for reentry into the donor pool by the director of the blood bank or designee who is a physician.

Subdivisions (a) and (d) of section 58-2.12 are amended to read as follows:

(a) For blood and blood components, [logbook] records of the following information, [where relevant] as applicable, shall be kept in the blood bank and made available to the department for inspection:

(1) source;

(2) [donor] unit identification code upon receipt and, if different, upon issuance;

(3) unit ABO and Rh groups;

(4) expiration date;

(5) results of [compatibility tests] all pretransfusion testing;

(6) disposition of the unit, including remote storage location, if any, and intended recipient's name [if administered] or, if the name is unknown, identification code;

(7) [signature or initials of the] identification of the station code or person [removing] taking possession of the unit;

(8) documentation of visual inspection;

[(8)] (9) date and time of [issue] issuance; and

[(9)] (10) results of all tests associated with the investigation of all transfusion reactions, with the conclusions reached and the report signed, or approved by electronic equivalent, by the director of the blood bank or a qualified physician designated by the director of the blood bank.

* * * *

(d) These recordkeeping requirements shall also apply to blood components issued to limited transfusion services and to blood components issued to ambulance transfusion services.

Section 58-2.13 is repealed, and a new section 58-2.13 is added to read as follows:

Distribution facilities. A blood bank may operate a distribution facility, provided the department is notified, in advance, of the location and activities to be performed at the site.

Subdivision (d) of section 58-2.15 is amended to read as follows:

(d) *Volume and frequency of apheresis.* Extracorporeal blood volume shall not exceed 15 percent of the donor's estimated blood volume. No more than 12.0 liters of plasma shall be removed per year from a donor weighing 175 pounds or less, and no more than 14.4 liters shall be removed per year from a donor weighing more than 175 pounds. The interval between procedures shall be at least 48 hours. The above volume and frequency requirements may be waived upon written authorization of the supervising physician, provided the donor meets all other eligibility requirements. Red blood cell loss shall not exceed 300 milliliters per eight weeks, unless the following requirements are met:

(1) for male donors, the donor's weight is at least 130 pounds;

(2) for female allogeneic donors, the donor's weight is at least 150 pounds;

(3) for female autogeneic donors, the donor's weight is at least 130 pounds;

(4) the allogeneic donor's hemoglobin content is [13.3] 12.5 grams per deciliter or greater, or hematocrit is [40] 38 percent or greater, and the donor meets the hemoglobin/hematocrit and weight requirements for use of the apheresis device, as approved by the F.D.A.;

(5) the autogeneic donor's hemoglobin content is [12.0] 11.0 grams per deciliter or greater, or hematocrit is [36] 33 percent or greater, and the donor meets the hemoglobin/hematocrit and weight requirements for use of the apheresis device, as approved by the F.D.A.;

Subdivisions (a), (b), (d), (e), (f) and (g) of section 58-2.16 are amended to read as follows:

(a) Transfusion services. Every institution which performs transfusions or supplies blood to a limited transfusion service[s] or ambulance transfusion service shall designate a physician who is a member of the staff as director of transfusion services. Such physician must be licensed and currently registered in New York State. [The director of the blood bank, if a physician, may be so designated.] The premises, equipment, procedure manuals, records, and all blood, blood components and derivatives shall be available for inspection by the department.

(1) It shall be the responsibility of the chief executive officer or other person in charge of each institution and of the director of transfusion services to determine that:

* * * *

(iv) serious unexpected reactions and incidents involving [transfusions] blood components that have been issued by the transfusion service are reported to the department's

Wadsworth Center, with sufficient detail to facilitate evaluation and investigation, within seven calendar days of the reaction or incident, or its discovery[,] and, if required, to federal authorities; and

* * * *

(3) If blood [is] components are issued to a limited transfusion service or an ambulance transfusion service, the director of transfusion services of the issuing facility and the director of the limited transfusion service or ambulance transfusion service performing the transfusion shall ensure compliance with all requirements of this Part.

(b) Each [facility which transfuses blood] institution that performs transfusions or supplies blood to a limited transfusion [services] service and/or an ambulance transfusion service shall have a transfusion committee [which] that meets at least quarterly [or more frequently as required by the department]. The committee shall:

(1) be composed of at least five members [, a majority of whom are present at each meeting];

(2) include members with expertise in clinical medicine and/or transfusion medicine and who are qualified to review the appropriateness and technical aspects of a transfusion [, such as, but not limited to, the director of transfusion services, blood bank supervisor or pathologist]; and

(3) review all or a representative sample of transfusions of all categories of blood and blood products issued by the facility for [all sites at which transfusions are performed] administration at any location, including all intraoperative and postoperative recovery procedures.

* * * *

(d) Whole blood, red blood cells, plasma, or other components and derivatives shall be prepared and administered by methods generally accepted by the F.D.A. or American Association of Blood Banks and/or by other methods approved by the department as in conformance with generally accepted laboratory principles. [For blood and blood components, the person initiating the transfusion shall be a physician, registered nurse, physician assistant, nurse practitioner, licensed practical nurse or board-certified cardiovascular perfusionist (intraoperatively). A licensed practical nurse shall initiate transfusions only following satisfactory completion of a transfusion training program meeting criteria specified by the department and by the New York State Education Department and only when a registered nurse, physician assistant, or a physician is immediately available on site.] No medications except physiologic saline for intravenous use shall be added to, mixed with, or administered in the same line with a blood component unless approved for this use by F.D.A. and there is documentation available to show that the addition is safe and does not adversely affect the blood component. A filter meeting F.D.A. requirements shall be incorporated into the intravenous administration set to be used for blood or blood component transfusions.

(e) [No medications except physiologic saline for intravenous use shall be added to or mixed with blood for transfusion unless they have been approved for this use by F.D.A. and there is documentation available to show that the addition is safe and does not adversely affect the blood component.] In a health care setting, the person initiating transfusion of blood or blood components shall be a:

(1) physician;

(2) registered nurse;

(3) physician assistant;

(4) nurse practitioner;

(5) board-certified cardiovascular perfusionist (intraoperatively); or

(6) licensed practical nurse who has completed a transfusion training program meeting criteria specified by the department and by the New York State Education Department, when supervised by a registered nurse, physician assistant, or a physician who is immediately available on site.

(f) In a health care setting, following comparison of the [blood product] unit's label with all accompanying information, the person initiating [the] transfusion of a blood component shall, at the patient's side, immediately prior to initiating the transfusion, positively identify the recipient and the blood [product] component to be transfused [or infused], using the patient's name and a unique numerical or alphanumerical identifier. [For administration of a blood component, one] One additional person, [who must be a physician, registered nurse, physician assistant, nurse practitioner, licensed practical nurse or board-certified cardiovascular perfusionist (intraoperatively),] authorized to initiate transfusion, and who is not a licensed practical nurse if the person initiating the transfusion is a licensed practical nurse, shall also so identify the recipient and the blood component, unless another procedure to ensure accurate identification is used, in which case a single identification [is] shall be sufficient. [At least one person identifying the patient and blood component at the patient's side shall be a physician, registered nurse, physician assistant, nurse practitioner, or board-certified cardiovascular perfusionist (intraoperatively).] Each identification procedure shall be documented in writing by each participant. Two persons authorized to initiate blood transfusions shall be immediately available during a blood component transfusion and for 30 minutes afterward, except for transfusion of a patient enrolled in a chronic transfusion program who has no history of adverse

reactions. A blood component recipient's vital signs shall be serially recorded, in accordance with written policies and procedures. If the person recording the vital signs is a licensed practical nurse, all measurements outside of established parameters shall be reported to a registered nurse, physician, physician assistant, or nurse practitioner for assessment and action. Such notification shall be documented.

(g) For transfusions outside a health care setting, including those in [patient homes] a patient's home, but not including those in an ambulance, the person initiating the transfusion and monitoring the patient shall be a physician, registered nurse, physician assistant, or nurse practitioner. Following comparison of the blood product label with all accompanying information, this person shall, at the patient's side, immediately prior to initiating the transfusion, positively identify the recipient and the blood product to be transfused or infused, using the patient's name and a unique numerical or alphanumerical identifier. [Such] Each such identification procedure shall be documented in writing. [The person administering the transfusion] A person authorized to monitor transfusions and another competent adult, other than the recipient, shall be immediately available at all times during a transfusion. Both persons shall be available for 30 minutes afterwards, except for transfusions of patients enrolled in a chronic transfusion program who have no history of adverse reactions. The recipient's vital signs shall be monitored serially and documented, in accordance with written policies and procedures.

Subdivisions (h), (i) and (j) of section 58-2.16 are renumbered to be subdivisions (i), (j) and (k); a new subdivision (h) is added, and newly renumbered subdivision (j) is amended, to read as follows:

(h) Transfusions during transport between hospitals may be administered only by a registered nurse, nurse practitioner, physician assistant, physician, or emergency medical technician certified at the critical care or paramedic level, provided such emergency medical technician has received training in blood administration in accordance with requirements established by the department and is performing these services as part of an ambulance transfusion service approved by the department. Blood components to be issued to an ambulance transfusion service must be ordered by a health care provider caring for the patient using a standard order form approved by the department. The transfusion service issuing the blood components shall be made aware that the blood is intended for possible administration during transport between hospitals and shall be informed of the destination hospital. Blood components intended for possible administration during transport shall be packed in a suitable container validated to maintain the appropriate temperature for the anticipated duration of transport. Prior to departure, the identification of the patient and of any blood components to be transported for possible administration during transport shall be verified in accordance with subdivision (f) of this section. In addition, a registered nurse, physician assistant, nurse practitioner, or physician shall verify, at the patient's side, the identification of the patient and all blood units, with the qualified person who will be caring for the patient during transport.

* * * *

[(i)](j) Each institution, through its transfusion committee, shall develop and implement procedures to encourage the use of autogeneic blood whenever medically indicated. These procedures shall include a mechanism for informing staff physicians of the risks and benefits of autogeneic blood and the options for autogeneic blood transfusion available at the institution, including, but not limited to, intraoperative blood recovery, isovolemic hemodilution and

presurgical deposit, as applicable. These procedures shall also include a mechanism to encourage physicians to inform their patients of such options whenever medically indicated.

Subdivision (e) of section 58-2.17 is repealed, subdivision (f) is renumbered to be subdivision (e), and subdivisions (a), (b) and (c) are amended to read as follows:

(a) Tests shall be performed to determine the ABO and Rho (D) groups of each recipient [and each unit to be transfused] in accordance with procedures approved by the department pursuant to this Subpart. ABO grouping tests shall include both forward and reverse grouping [except in the case of hospital transfusion services verifying a blood group determination performed elsewhere, in which case forward grouping alone may be performed], except that reverse grouping is not required for infants under four months of age. Prior to transfusion, the ABO group of all units of whole blood and red blood cell components, as well as the Rh group of all such units labeled as Rh-negative, shall be confirmed using a sample obtained from an attached segment [or using a validated computer system]. Any discrepancies shall be reported in writing to the collecting facility and resolved prior to issuance of the blood for transfusion purposes.

(b) [All] Serum or plasma from each recipient [blood] or, in the case of an infant under four months of age, the infant's mother, shall be tested for unexpected alloantibodies using reagent red blood cells that meet F.D.A. standards, are intended for this purpose and are not pooled. Methods of testing for unexpected alloantibodies shall demonstrate sensitizing and hemolytic antibodies.

(c) Except in cases necessitating emergency release of group-compatible blood, or [except] in the case of transfusion of a volume of blood or blood components exceeding the

recipient's expected normal blood volume in a 24-hour period, compatibility between recipient and donor blood shall be determined. If a clinically significant antibody has been detected, or if there is a history of presence of such an antibody, [the] compatibility [test] testing shall include an antiglobulin phase crossmatch. If no clinically significant antibody has been detected, and there is no known history of presence of such an antibody, the crossmatching procedure to be used may be determined by the director of transfusion services, but shall, at minimum, consist of an immediate spin test or [verification of the blood group of the recipient, and of the blood or blood component to be transfused] use of a validated computer system, except that crossmatching is not required for infants under four months of age.

Section 58-2.18 is repealed, and a new section 58-2.18 is added to read as follows:

Records to be kept when blood or blood component transfusions are performed. The following information shall be included on the recipient's chart or in records maintained in the blood bank:

(a) date of the transfusion;

(b) name(s) of the person(s) who performed the transfusion and who attended the recipient during the transfusion;

(c) for each unit:

(1) blood component transfused;

(2) unit identification code;

(3) unit ABO and Rh groups;

(4) start time and completion time; and

(5) description of any adverse reaction and the results of related investigation.

(d) in the case of emergency issuance of uncrossmatched blood, the signature of the physician authorizing such emergency release.

Section 58-2.19 is amended to read as follows:

Records to be kept when [plasma] derivatives are infused. The following information shall be included on the recipient's chart or in records maintained in the blood bank or pharmacy:

(a) product name, manufacturer, lot number, and expiration date;

(b) documentation of visual inspection prior to infusion;

(c) name of person administering the product;

(d) documentation of identification of the recipient;

[(b)] (e) date of infusion and quantity of material infused; and

[(c)] (f) description of any adverse reaction and the results of [investigations] related [to this reaction] investigation.

Section 58-2.20 is repealed, and a new section 58-2.20 is added to read as follows:

Ambulance Transfusion Services

(a) No person shall own or operate an ambulance transfusion service in New York State unless approved by the department. An inspection may be conducted prior to departmental approval. Ambulance transfusion services shall comply with the provisions in this Part governing transfusions in general.

(b) Ambulance transfusion services shall have a written agreement with all hospitals issuing blood components to the ambulance transfusion service for possible administration during transport to another hospital, except in cases when no ground or air, as needed, ambulance

transfusion service with an agreement in place is available. The agreement shall be subject to the prior approval of the department. The agreement shall:

(1) specify the division of responsibilities for ensuring compliance with the provisions of this Subpart;

(2) include a statement that ambulance transfusion service personnel will have adequately completed training in administering blood components according to a curriculum approved by the department; and

(3) include the written approval of the issuing facility's director of transfusion services and the director of the ambulance transfusion service.

(c) A qualified licensed physician shall provide general supervision of ambulance transfusion service personnel continuing and/or initiating transfusions and shall be responsible for ensuring that such personnel have adequate training and experience.

(d) Any order for a transfusion to be continued and/or initiated in an ambulance shall be documented on an order form approved by the department, and shall specify:

(1) the blood component(s) to be transfused;

(2) the number of units to be transfused;

(3) the rate of infusion;

(4) any special instructions; and

(5) any actions, including transfusion of additional units, to be taken based on circumstances that may arise.

(e) Every transfusion administered in an ambulance must be documented on a transfusion record approved by the department. Such documentation must include:

(1) date of the transfusion;

(2) name of the person who performed the transfusion and who attended the recipient during the transfusion.

(3) for each unit:

(i) blood component transfused;

(ii) unit identification code;

(iii) unit ABO and Rh groups; and

(iv) start time and completion time.

(f) Any adverse reaction shall be documented on a prehospital care report. Such documentation shall include a description of the adverse reaction and actions taken in response.

(g) Any ambulance in which a transfusion is performed by an ambulance transfusion service shall maintain an inventory of isotonic saline and any supplies needed for blood administration and for monitoring transfusion recipients, and have a means to communicate with medical control. All medications, equipment and supplies necessary for the management of adverse reactions shall be immediately available. Medical waste disposal must be undertaken, in collaboration with the receiving hospital, using containers and procedures found acceptable to the department pursuant to Part 70 of this Title.

Subdivision (a) and paragraphs (2) and (7) of subdivision (b) of section 58-2.21 are amended to read as follows:

(a) No person shall own or operate a limited transfusion service in New York State unless approved by the department. An inspection may be conducted prior to departmental approval. Limited transfusion services shall comply with the provisions in this Part governing transfusions in general.

(b) Limited transfusion services shall have a written agreement with an issuing facility holding a permit in blood services-transfusion. The agreement shall specify the division of responsibilities for [assuring conformity] ensuring compliance with the provisions of this Part. The agreement shall be subject to the prior approval of the department. [An inspection may be conducted prior to departmental approval.] The agreement shall include:

* * * *

(2) the procedures for transport and storage of blood and means to [assure] ensure compliance with such procedures;

* * * *

(7) recordkeeping procedures as required in sections [58-2.12,] 58-2.18 and 58-2.19 of this Subpart, clearly describing [responsibility] responsibilities for maintenance of records and their location.

Section 58-2.22 is repealed and reserved for later use.

Subdivisions (a), (b) and (f) of section 58-2.27 are repealed and subdivisions (g), (h) and (i) of section 58-2.27 are renumbered to be subdivisions (f), (g) and (h). New subdivisions (a) and (b) are added, and newly renumbered subdivision (g) is amended, to read as follows:

(a) All entities performing reinfusion procedures or any part thereof shall hold a valid department permit in the category of blood services – transfusion or be approved by the department as a limited reinfusion service. Such limited reinfusion services are subject to inspection by the department.

(b) All reinfusion procedures shall comply with written protocols approved by the director of transfusion services and the transfusion committee of the facility where the reinfusion

is to be performed, the director of the hospital department where the product is reinfused, and the hospital department or facility where processing for the reinfusion procedure is performed, if different. These protocols shall include procedures for collection, labeling, handling, processing and reinfusion of the product. All reinfusion procedures performed in hospitals shall be reviewed by the hospital transfusion committee.

* * * *

[h](g) All errors or accidents during processing or reinfusion procedures, [which] that may pose a substantial risk to the patient[,] shall be reported to the department's Wadsworth Center, with sufficient detail to facilitate evaluation and investigation, within seven calendar days of the error or accident, or its discovery.

## REGULATORY IMPACT STATEMENT

**Statutory Authority:**

Article 31 of the Public Health Law (PHL) establishes the department's authority to protect the public health, safety and welfare through oversight of the collection, processing, fractionation, storage, distribution, transfusion, and supply of human blood and blood products. The New York State (NYS) Council on Human Blood and Transfusion Services (Blood Council) is authorized by Section 3121(5) to enact, amend and repeal rules and regulations setting forth minimum standards for these processes as applicable to blood and blood products, subject to the approval of the Commissioner of Health.

**Legislative Objectives:**

The Blood Council has proposed this revision of 10 NYCRR Subpart 58-2 to update practice standards in order to promote safe blood bank operation. The amendment is consistent with the legislative mandate that the department oversee the blood supply and ensure that the safety of blood donors and transfusion recipients is not compromised.

**Needs and Benefits:**

This regulatory amendment is necessitated by advances in medical technology and the need to codify practice standards and eliminate obsolete requirements, afford regulated parties with greater flexibility in complying with department regulations, clarify regulatory intent, and provide for safe transfusion of blood components during interfacility transport of patients. Several changes are intended to align the department's rules with federal requirements.

To reflect technological advances and increase availability of blood components, the proposed amendment extends the expiration date of red cells deglycerolized in a closed system to 14 days, as approved by the U.S. Food and Drug Administration (F.D.A.). Provisions for plasma frozen within 24 hours after phlebotomy are added and the shelf life of non-cellular components is extended to seven years for frozen storage at or below -65°C.

This amendment would provide for department oversight of any ambulance service offering transfusion during interfacility transport. The proposed amendment does not require that ambulance services seek approval as an ambulance transfusion service. In fact, it is estimated that only 50 of the 619 advanced life support (ALS) providers would apply. The proposed regulation allows certain emergency medical technicians (EMTs), with specific additional training, to administer transfusions during interhospital transport, obviating the need for a registered nurse (RN) to accompany the patient. Requirements for training and structured paperwork are intended to ensure that trained EMTs perform transfusion-related procedures in a safe manner. Patients requiring transfusion during interhospital transport could receive optimal medical care without delay. The amendment would not permit blood transfusion in the field or during initial transport to a hospital. However, it is not intended that an approved ambulance transfusion service would be prohibited from transporting a patient from an approved limited transfusion service to a hospital if a medical emergency arises requiring blood transfusion during transport.

Transfusion recipient safety is enhanced by the addition of requirements that:

- frozen components be thawed in a water bath in a manner that protects the entry ports from contamination;
- the inspection of components prior to issuance be documented;

• patient specimens be labeled at the bedside;

• routine compatibility testing be completed after emergency release of uncrossmatched blood, to facilitate needed actions; and

• records for infusion of derivatives include the manufacturer's name.

To help prevent inadvertent transfusion of contaminated blood components, the list of infectious disease markers requiring written authorization of the patient-donor's physician is expanded.

Several changes are proposed to provide regulated parties with compliance flexibility, including:

• permitting "identification" of phlebotomists collecting blood rather than requiring their signature; and removal of the requirement for records to be retained in logbook format, thereby affording facilities options for electronic records;

• allowing the release of components when their clinically useful shelf-life precludes completion of testing prior to issuance;

• allowing infectious disease testing to be performed on a donor specimen collected prior to the donation when the clinically useful shelf-life precludes completion of testing prior to unit expiration;

• making blood count requirements for apheresis donors less restrictive;

• eliminating the time limit for platelet production;

• allowing inspection of derivatives at any time prior to infusion; and

• expanding options for acceptance of allogeneic blood donors who are 76 years of age or older.

To clarify regulatory intent, the proposed amendment:

• combines requirements pertaining to administration of blood components;

• simplifies the language detailing the persons authorized to initiate transfusions;

• specifies types of locations at which blood for transfusion be may collected;

• clarifies that hospital reporting of incidents to the department applies to only blood components that have been issued by the transfusion service;

• specifies that the transfusion committee is to review "all or a representative sample" of transfusions;

• codifies expectations that Subpart 58-2 pertains to laboratories performing immunohematology testing;

• specifies that the timing of opportunities for blood donors to indicate confidentially that their blood may be unsuitable for transfusion may be at the time of or after donation; and

• details requirements for reinfusion procedures.

Several changes are proposed, as advised by the U.S. Centers for Medicare and Medicaid Services, in order for NYS to retain its state-exempt status for laboratory oversight. These include:

• clarifying the expectation that facilities report errors, accidents and serious adverse reactions to federal authorities;

• expanding standard operating procedure manual requirements to include "the prevention of transfusion reactions";

• requiring that the evaluation of reported transfusion reactions must be "prompt"; and

• adding a requirement that verification of alarm function for refrigerators and freezers be documented.

The amendment eliminates obsolete provisions, including requirements that:

• an autogeneic unit from a donor with antibodies to hepatitis B core antigen (anti-HBc) be labeled as biohazardous;

• donors be free of acute respiratory diseases; and

• hospitals issuing components to limited transfusion services perform all testing onsite.

**Costs:**

Regulated parties would incur minimal costs to modify some written procedures. Approximately one hour of staff time would be required to complete ambulance transfusion service application forms. Ambulance services would incur some costs to provide required training (approximately four hours in duration) for some existing personnel. Training of new personnel could be incorporated into existing training programs. Duplication of training materials is estimated to cost less than $50.

Because interfacility transfusion should not change the total number of transfusions, costs incurred by hospitals for associated supplies should not increase. It may be necessary to purchase insulated coolers, at approximately $30 each, to maintain blood components at the proper transport temperature. Normal saline is the only solution that can be run in the same line during a transfusion. Some ambulance services may need to purchase saline solution ($170/case of 24 500 mL bags). The cost of the saline, medications for treating transfusion reactions and any other supplies could be recouped through ambulance service fees. Hospitals transferring patients would realize some cost savings, as RNs would no longer be needed to accompany patients.

The department would incur costs in approving ambulance transfusion services and monitoring compliance. Development of training materials and application packets would

require approximately 20 hours of staff time. Processing the 50 anticipated applications would require approximately 100 hours to review applications, issue approval documents, and update databases. Costs for monitoring compliance include one-time costs of revising inspection-related documents and training blood bank inspectors, estimated at under $1,000, and recoverable through Clinical Laboratory Inspection and Reference fees.

**Local Government Mandates:**

The proposed regulations impose no new program, service, duty, or responsibility on any county, city, town or village government. The four counties and one city that operate hospital-based blood banks would be affected to the same extent as other regulated parties. The vast majority of interhospital transport is currently performed by commercial ambulance services; it is not anticipated that municipal ambulance services would seek approval to offer transfusion services.

**Paperwork:**

Blood banks may need to modify some written procedures to implement the amendment. Ambulance services that choose to offer transfusion services would need to revise written protocols, and comply with some additional recordkeeping requirements.

**Duplication:**

This proposed amendment does not duplicate any other State regulations, as 10 NYCRR Subpart 58-2 is the only State regulation governing the collection, processing, distribution, and transfusion of blood.

**Alternatives:**

The Blood Council is charged with ensuring a safe and adequate blood supply through promulgation and amendment of regulations. No alternatives would adequately protect the public health, recognize technological advances, and allow the least burdensome practices, consistent with national standards.

Failure to adopt changes in technical standards could adversely affect the blood supply. Failure to extend the expiration date of deglycerolized red cells to 14 days, and the shelf life of frozen non-cellular components to seven years at or below -65°C, would likely result in reduced availability for NYS patients. Failure to protect the entry ports of frozen components while thawing in a water bath could result in transfusion of bacterially contaminated components. Not requiring bedside labeling of patient specimens could increase the chance of specimen mislabeling and consequent issuance of incompatible blood, increasing the chance of fatal transfusion reactions. Failure to include the manufacturer's name in medical records of patients receiving derivatives would hinder identification of patients who received a recalled product. Components with a very short shelf-life (*e.g.*, 24 hours) may outdate before the completion of infectious disease testing. Failure to allow issuance of a component when the clinically useful shelf-life precludes completion of testing could forestall needed patient therapy. Leaving blood count requirements for apheresis donors unchanged would result in deferral of suitable donors. Retaining the eight-hour time limit for platelet production would adversely affect platelet inventories when blood is collected in outlying areas.

Failure to allow some EMTs to administer blood during interfacility transport would adversely affect emergency medical care. Hospital nurses may not be immediately available to accompany patients, so some patients would encounter delays in transfer. Authorization to

initiate and monitor blood transfusions cannot be extended to all EMTs because those at the basic level do not have the prerequisite knowledge base and skill set. In contrast, EMTs certified at the critical care or paramedic level have received training in IV therapy, and would need to build on this knowledge through additional training in transfusion basics and transfusion reaction recognition/management. An alternative would be to restrict this practice to EMTs certified at the paramedic level, as suggested by some commenters. However, this would severely hinder patient care, as many rural communities lack sufficient personnel so trained. Based upon its experience with certifying EMTs and approving training curricula, the department believes that EMTs certified at the critical care level, with additional training, would have sufficient knowledge and skills to transfuse patients safely. Additionally, the department intends to develop a training curriculum to ensure adequate training.

Elements of the proposed amendment were carefully considered and all viable options were identified and evaluated. The best options were selected based on their merits, with the ultimate goal of ensuring the availability of blood components and preserving or increasing patient safety.

**Federal Standards:**

The F.D.A. has established blood donor standards and requirements governing blood products shipped in interstate commerce. New York, however, exercises regulatory oversight of facilities and services. Specifically, Subpart 58-2 applies to NYS-permitted blood banks operating in the state. State regulations provide greater detail regarding the collection, processing and use of blood products, while maintaining consistency with F.D.A. regulations.

**Compliance Schedule:**

The department has notified, via mail, affected parties with a permit for blood collection and/or transfusion, in order to solicit preliminary comments regarding the proposed amendments. Ambulance services have been notified via State and regional advisory councils and regional program agencies. Revisions have been made based on comments received. Current regulated parties (blood banks) and ambulance services that may wish to seek approval as an ambulance transfusion service have been afforded notice sufficient for compliance with the amended regulations within 60 days of publication of a Notice of Adoption in the State *Register*.

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## REGULATORY FLEXIBILITY ANALYSIS FOR SMALL BUSINESSES AND LOCAL GOVERNMENTS

**Effect of Rule:**

Of the 235 blood banks located in New York State (NYS) holding a permit for blood collection and/or transfusion, only three are small businesses. The vast majority of blood banks are operated by hospitals or are blood centers with more than 100 employees. Four counties and one city operate hospital-based blood banks.

The proposed revisions would extend regulatory oversight by the department's Blood and Tissue Resources Program (BTRP) to any ambulance service seeking to offer, as a service, transfusion of patients during interhospital transport. The proposed amendment does not require that ambulance services seek approval as an ambulance transfusion service; in fact, only a fraction of ambulance services providing advanced life support services (ALS) also perform interhospital transport.

Of the 1,096 ambulance services that operate in NYS, 619 provide ALS services and are eligible to apply for approval as an ambulance transfusion service. Of these, 68 are owned/operated by municipalities. The vast majority of interhospital transport is performed by commercial ambulance services, and it is not anticipated that municipal ambulance services would seek approval to offer transfusion services.

**Compliance Requirements:**

The department believes that the small businesses approved to collect blood components would likely not be affected by this amendment. Most facilities operated by local governments would be affected by at least one proposed change, but not in an adverse manner. The

department has determined that the proposed amendment, once adopted, would not impose burdensome reporting, recordkeeping, training or other compliance requirements on small businesses (*e.g.*, ambulance services seeking approval as ambulance transfusion services) or local governments (including government-operated hospitals and ambulance services). The proposed amendment does not require that ambulance services seek approval as an ambulance transfusion service. Should an ambulance service be approved as an ambulance transfusion service, its ALS personnel would require training in the administration of blood components, as well as the recognition of and response to transfusion reactions. This provision is intended to promote safety for transfusion recipients and would minimize liability risk for ambulance services and individual personnel. A standardized training curriculum developed by BTRP, in conjunction with the department's Bureau of Emergency Medical Services, would include standard didactic training and additional training at the regional level.

**Professional Services:**

No professional services would be needed.

**Compliance Costs:**

The department has determined that the proposed amendment, once adopted, would have no adverse economic impact on small businesses or local governments. Small businesses and local governments that operate blood banks implementing the proposed requirements would incur the same minimal compliance costs and receive the same benefits as private entities.

Ambulance services, including small businesses and those operated by local governments, that choose to seek approval as an ambulance transfusion service would not

encounter significant cost increases in complying with the amendment. It is estimated that approximately one hour of staff time would be required to complete the ambulance transfusion service application forms. While training of new personnel could be incorporated into existing training programs, ambulance services would incur some costs to provide required training for some existing personnel. It is estimated that this training can be accomplished in four hours. The cost of duplicating training materials is estimated to be less than $50.

Hospitals transferring patients to another hospital would provide a blood administration set with each unit of blood issued, so that ambulance services would not need to purchase such supplies. Allowing in-ambulance transfusion should not change the total number of units transfused, so that costs incurred by hospitals for associated supplies are not expected to increase. Some blood banks and ambulance transfusion services, however, may need to purchase insulated coolers for the storage of blood components at the proper temperature during interhospital transport. A 16-quart (15-liter) hard-sided cooler may be purchased for approximately $30. Since normal saline is the only solution that can be run in the same line during a transfusion, ambulance transfusion services not currently stocking normal saline may need to purchase it. The solution can be purchased in 500-mL bags for $170 per 24-bag case. Ambulance transfusion services may need to stock some additional medications to be administered in case of a transfusion reaction. However, the cost of additional supplies could be recouped in fees charged by the ambulance transfusion services. Local government-operated hospitals arranging for transport would realize some cost savings, as an RN would no longer be needed to accompany a patient being transferred, solely to meet regulatory requirements.

**Economic and Technological Feasibility:**

The proposed changes present no economic or technical difficulties to small businesses or local governments. Although some revisions to procedures and recordkeeping practices may be necessary, the modifications would be straightforward and easily implemented by existing staff.

Transporting patients requiring transfusions from one hospital to another may prove to be a source of income for ambulance services approved as an ambulance transfusion service.

**Minimizing Adverse Impact:**

The proposed amendment would impose no adverse economic impact on small businesses or local government facilities presently in compliance with established industry standards. This amendment was developed with the goal of minimizing any burdens on regulated parties. The requirements for transfusions during interhospital transport, including required training of EMTs certified at the critical care or paramedic level, would minimize liability risk for ambulance services and individual personnel. Training of new personnel could be incorporated into existing training programs.

**Small Business and Local Government Participation:**

The department has notified regulated parties, including the small businesses and those operated by a local government, regarding the proposed regulation, in order to solicit comments. Recommended revisions have been incorporated, as appropriate, based on comments received.

## RURAL AREA FLEXIBILITY ANALYSIS

**Types and Estimated Numbers of Rural Areas:**

One-hundred fourteen (49 percent) of the 235 blood banks in New York State (NYS) with a department permit for collection and/or transfusion are located in rural counties, as are 287 (48 percent) of the 619 ambulance services providing advanced life support (ALS) services in NYS.

**Reporting, Recordkeeping and Other Compliance Requirements; and Professional Services:**

Most blood banks approved to collect and/or transfuse blood components would be affected by some of the provisions of the proposal, but not in an adverse manner. The amendments would impose no adverse effects on blood banks located in rural areas, as full compliance would not significantly increase overall costs or reporting or recordkeeping requirements. The costs for regulated parties in rural areas would be the same as for regulated parties in urban areas.

This amendment would not impose a burden on public or private entities in rural areas. Many of the proposed revisions are less restrictive than those in existing regulations. Regulated parties may, but would not be required to, modify present practices to comply with the proposed provisions that are less restrictive than current requirements.

This proposed amendment would extend regulatory oversight to any ambulance service seeking approval as an ambulance transfusion service. The service's ALS personnel would require additional training in blood administration procedures. The standardized training

curriculum developed by the department's Blood and Tissue Resources Program, in conjunction with the department's Bureau of Emergency Medical Services, would be made available to the ambulance transfusion service medical director or his/her designee regardless of location. No additional professional services would be needed. No significant adverse impact is anticipated for ambulance transfusion services located in rural areas. Ambulance services choosing to offer transfusion during transport, including those located in rural counties, would need to comply with some additional recordkeeping and reporting requirements.

**Costs:**

Full compliance with the amendment would not increase significantly overall costs for regulated parties, including those located in rural counties. Regulated parties in rural areas implementing the revised requirements may need to modify their standard operating procedure manuals, incurring minimal costs. However, savings would be realized, as an RN would no longer be needed to accompany a patient being transferred, solely to meet regulatory requirements. This provision would result in more efficient utilization of nursing staff within the rural hospital setting, and could decrease hospital expenses and help alleviate nursing shortages. It is estimated that approximately one hour of staff time would be expended by ambulance services to complete the ambulance transfusion service application forms. While training of new personnel could be incorporated into existing training programs, ambulance services would incur some costs to provide required training for some existing personnel. It is estimated that this training can be accomplished in four hours. The cost of duplicating training materials is estimated to be less than $50. Providing transfusion as an additional service during interhospital transport may prove to be a source of income for ambulance services approved as an ambulance transfusion service.

Hospitals arranging for transport would provide a blood administration set with each unit of blood issued, so ambulance services would not need to purchase these supplies. Allowing for in-ambulance transfusion should not change the total number of units transfused, so that costs incurred by hospitals for associated supplies are not expected to increase. Some hospital blood banks and ambulance transfusion services, however, may need to purchase insulated coolers for storage of blood components at the proper temperature during interhospital transport. A 16-quart (15-liter) hard-sided cooler may be purchased for approximately $30. Since normal saline is the only solution that can be run in the same line during a transfusion, ambulance transfusion services not currently stocking normal saline might need to purchase the solution. Normal saline can be purchased in 500-mL bags for $170 per 24-bag case. Ambulance transfusion services may need to stock some additional medications to be administered in case of a transfusion reaction. However, the cost of additional supplies could be recouped in fees charged by ambulance transfusion services. Hospitals arranging for transport would realize some cost savings, as an RN would no longer be needed to accompany a patient being transferred, solely to meet regulatory requirements.

**Minimizing Adverse Impact:**

The proposed amendment would confer no significant adverse impact on blood banks in rural areas that are presently in compliance with established industry standards. These amendments were developed with the intent of minimizing any burdens on regulated parties and increasing compliance flexibility by offering various alternatives.

**Rural Area Participation:**

The department has notified regulated parties, including those in rural areas, regarding the proposed regulation in order to solicit comments. Changes have been made based on comments received.

## JOB IMPACT STATEMENT FINDING

A Job Impact Statement is not included in this proposal because it is apparent, from the nature and purpose of the proposed rule, that it would not have a substantial adverse impact on jobs and employment opportunities.

## ASSESSMENT OF PUBLIC COMMENT

The public comment period for this regulation ended on September 29, 2014. The Department received six comments.

All six comments were from hospital emergency medical departments and were in support of the proposed changes.

Consequently, no changes were made to the proposed regulation.