(2) A written request for an exception or alternative described in paragraph (a) of this section must:

(i) Identify the specified lots, batches, or other units of the biological product that would be subject to the exception or alternative;

(ii) Identify the labeling provision(s) listed in paragraph (f) of this section that are the subject of the exception or alternative request;

(iii) Explain why compliance with such labeling provision(s) could adversely affect the safety, effectiveness, or availability of the specified lots, batches, or other units of the biological product that are or will be included in the Strategic National Stockpile;

(iv) Describe any proposed safeguards or conditions that will be implemented so that the labeling of the product includes appropriate information necessary for the safe and effective use of the product, given the anticipated circumstances of use of the product;

(v) Provide a draft of the proposed labeling of the specified lots, batches, or other units of the biological product subject to the exception or alternative; and

(vi) Provide any other information requested by the Center Director in support of the request.

(c) The Center Director must respond in writing to all requests under this section.

(d) A grant of an exception or alternative under this section will include any safeguards or conditions deemed appropriate by the Center Director so that the labeling of product subject to the exception or alternative includes the information necessary for the safe and effective use of the product, given the anticipated circumstances of use.

(e) If you are a sponsor receiving a grant of a request for an exception or alternative to the labeling requirements under this section:

(1) You need not submit a supplement under § 601.12(f)(1) through (f)(2) of this chapter; however,

(2) You must report any grant of a request for an exception or alternative under this section as part of your annual report under § 601.12(f)(3) of this chapter.

(f) The Center Director may grant an exception or alternative under this section to the following provisions of this chapter, to the extent that the requirements in these provisions are not explicitly required by statute:

(1) § 610.60;
(2) § 610.61(c) and (e) through (r);
(3) § 610.62;
(4) § 610.63;
(5) § 610.64;
(6) § 610.65; and
(7) § 312.6.

[72 FR 73600, Dec. 28, 2007]

PART 630—REQUIREMENTS FOR BLOOD AND BLOOD COMPONENTS INTENDED FOR TRANSFUSION OR FOR FURTHER MANUFACTURING USE

Subpart A—General Provisions

Subpart B—Donor Eligibility Requirements

Subpart C—Donor Notification

AUTHORITY: 21 U.S.C. 321, 331, 351, 352, 355, 360, 371; 42 U.S.C. 216, 262, 264.

SOURCE: 66 FR 31176, June 11, 2001, unless otherwise noted.

Subpart A—General Provisions

SOURCE: 80 FR 29898, May 22, 2015, unless otherwise noted.

§ 630.1 Purpose and scope.

(a) *What is the purpose of subparts A, B, and C of this part?* The purpose of these subparts, together with §§ 610.40 and 610.41 of this chapter, is to provide

certain minimum criteria for each donation of blood and blood components, for:

(1) Determining the eligibility of a donor of blood and blood components;

(2) Determining the suitability of the donation of blood and blood components; and

(3) Notifying a donor who is deferred from donation.

(b) *Who must comply with subparts A, B, and C of this part?* Blood establishments that manufacture blood and blood components, as defined in §630.3(a) and (b), must comply with subparts A, B, and C of this part.

§ 630.3 Definitions.

As used in this part and in part 610, subpart E, and part 640 of this chapter:

(a) *Blood* means a product that is a fluid containing dissolved and suspended elements which was collected from the vascular system of a human.

(b) *Blood component* means a product containing a part of blood separated by physical or mechanical means.

(c) *Donor* means a person who: (1) Donates blood or blood components for transfusion or for further manufacturing use; or

(2) Presents as a potential candidate for such donation.

(d) *Eligibility of a donor* means the determination that the donor is qualified to donate blood and blood components.

(e) *Infrequent plasma donor* means a donor who has:

(1) Not donated plasma by plasmapheresis or a co-collection of plasma with another blood component in the preceding 4 weeks; and

(2) Not donated more than 12.0 liters of plasma (14.4 liters of plasma for donors weighing more than 175 pounds) in the past year.

(f) *Intimate contact with risk for a relevant transfusion-transmitted infection* means having engaged in an activity that could result in the transfer of potentially infectious body fluids from one person to another.

(g) *Physician substitute* means a trained and qualified person(s) who is:

(1) A graduate of an education program for health care workers that includes clinical training;

(2) Currently licensed or certified as a health care worker in the jurisdiction where the collection establishment is located;

(3) Currently certified in cardiopulmonary resuscitation; and

(4) Trained and authorized under State law, and/or local law when applicable, to perform the specified functions under the direction of the responsible physician.

(h) *Relevant transfusion-transmitted infection* means:

(1) Any of the following transfusion-transmitted infections:

(i) Human immunodeficiency virus, types 1 and 2 (referred to, collectively, as HIV);

(ii) Hepatitis B virus (referred to as HBV);

(iii) Hepatitis C virus (referred to as HCV);

(iv) Human T-lymphotropic virus, types I and II (referred to, collectively, as HTLV);

(v) *Treponema pallidum* (referred to as syphilis);

(vi) West Nile virus;

(vii) *Trypanosoma cruzi* (referred to as Chagas disease);

(viii) Creutzfeldt-Jakob disease (referred to as CJD);

(ix) Variant Creutzfeldt-Jakob disease (referred to as vCJD); and

(x) *Plasmodium* species (referred to as malaria).

(2) A transfusion-transmitted infection not listed in paragraph (h)(1) of this section when the following conditions are met:

(i) Appropriate screening measures for the transfusion-transmitted infection have been developed and/or an appropriate screening test has been licensed, approved, or cleared for such use by FDA and is available; and

(ii) The disease or disease agent:

(A) May have sufficient incidence and/or prevalence to affect the potential donor population; or

(B) May have been released accidentally or intentionally in a manner that could place potential donors at risk of infection.

(i) *Responsible physician* means an individual who is:

(1) Licensed to practice medicine in the jurisdiction where the collection establishment is located;

(2) Adequately trained and qualified to direct and control personnel and relevant procedures concerning the determination of donor eligibility; collection of blood and blood components; the immunization of a donor; and the return of red blood cells or other blood components to the donor during collection of blood component(s) by apheresis; and

(3) Designated by the collection establishment to perform the activities described in paragraph (i)(2) of this section.

(j) *Suitability of the donation* means a determination of whether the donation is acceptable for transfusion or for further manufacturing use.

(k) *Trained person* means an individual, including a physician substitute, who is authorized under State law, and/or local law when applicable, and adequately instructed and qualified to perform the specified functions under the direction of the responsible physician.

(*l*) *Transfusion-transmitted infection* means a disease or disease agent:

(1) That could be fatal or life-threatening, could result in permanent impairment of a body function or permanent damage to a body structure, or could necessitate medical or surgical intervention to preclude permanent impairment of body function or permanent damage to a body structure; and

(2) For which there may be a risk of transmission by blood or blood components, or by a blood derivative product manufactured from blood or blood components, because the disease or disease agent is potentially transmissible by that blood, blood component, or blood derivative product.

Subpart B—Donor Eligibility Requirements

SOURCE: 80 FR 29898, May 22, 2015, unless otherwise noted.

§ 630.5 Medical supervision.

(a) *Who must determine the eligibility of a donor*? The responsible physician must determine the eligibility of a donor of blood or blood components in accordance with this subchapter.

(b) *Which activities related to the collection of blood and blood components, other than Source Plasma and plasma collected by plasmapheresis, may the responsible physician delegate*?

(1) The responsible physician may delegate the following activities to a physician substitute or other trained person:

(i) Determining the eligibility of a donor and documenting assessments related to that determination, except the responsible physician must not delegate:

(A) The examination and determination of the donor's health required in § 630.10(f)(2) for donors with blood pressure measurements outside specified limits, or for certain more frequent donations under § 630.15(a)(1)(ii);

(B) The determination of the health of the donor required in §§ 630.10(f)(4), 630.20(a), and 640.21(e)(4) of this chapter. The responsible physician may make this determination by telephonic or other offsite consultation; or

(C) The determination of the health of the donor and the determination that the blood or blood component collected would present no undue medical risk to the transfusion recipient, as required in § 630.20(c). The responsible physician may make these determinations by telephonic or other offsite consultation.

(ii) Collecting blood or blood components;

(iii) Returning red blood cells to the donor during apheresis;

(iv) Obtaining the informed consent of a plateletpheresis donor as described in § 640.21(g) of this chapter; or

(v) Other activities provided that the Director, Center for Biologics Evaluation and Research, determines that delegating the activities would present no undue medical risk to the donor or to the transfusion recipient, and authorizes the delegation of such activities.

(2) The responsible physician need not be present at the collection site when activities delegated under paragraph (b)(1) of this section are performed, provided that the responsible physician has delegated oversight of these activities to a trained person who is adequately trained and experienced in the performance of these activities and is also adequately trained and experienced in the recognition of and response to the known adverse responses

associated with blood collection procedures.

(c) *Which activities related to the collection of Source Plasma and plasma collected by plasmapheresis may the responsible physician delegate*?

(1) *Donor eligibility and blood component collection activities.* (i) The responsible physician may delegate to a physician substitute or other trained person any of the activities described in paragraph (c)(1)(i)(A) of this section, provided that the responsible physician or a physician substitute is on the premises at the collection site:

(A) The activities listed in paragraphs (b)(1)(i) through (iii) and (b)(1)(v) of this section, with respect to Source Plasma and plasma collected by plasmapheresis. However, the responsible physician must not delegate:

(*1*) The examination and determination of the donor's health required in §630.10(f)(2) for donors with blood pressure measurements outside specified limits, or in §630.15(b)(7) for certain donors who have experienced red blood cell loss;

(*2*) The determination of the health of the donor required in §§630.10(f)(4) and 630.20(a) and (b). The responsible physician may make this determination by telephonic or other offsite consultation;

(*3*) The determination of the health of the donor and the determination that the blood component would present no undue medical risk to the transfusion recipient, as required in §630.20(c). The responsible physician may make this determination by telephonic or other offsite consultation.

(*4*) The determination related to a donor's false-positive reaction to a serologic test for syphilis in accordance with §640.65(b)(2)(iii) of this chapter; and

(*5*) The determination to permit plasmapheresis of a donor with a reactive serological test for syphilis in accordance with §640.65(b)(2)(iv) of this chapter.

(B) The collection of Source Plasma in an approved collection program from a donor who is otherwise determined to be ineligible.

(C) The collection of a blood sample in accordance with §640.65(b)(1)(i) of this chapter.

(ii) The responsible physician, who may or may not be present when these activities are performed, may delegate to a physician substitute the following activities:

(A) Approval and signature for a plasmapheresis procedure as provided in §640.65(b)(1)(ii) of this chapter; and

(B) Review and signature for accumulated laboratory data, the calculated values of each component, and the collection records in accordance with §640.65(b)(2)(i) of this chapter. However, the responsible physician must not delegate the decision to reinstate the deferred donor in accordance with that provision.

(2) *Donor immunization.* The responsible physician must not delegate activities performed in accordance with §640.66 of this chapter, except that:

(i) The responsible physician may delegate to a physician substitute or other trained person the administration of an immunization other than red blood cells to a donor in an approved collection program, provided that the responsible physician or a physician substitute is on the premises at the collection site when the immunization is administered.

(ii) The responsible physician may delegate to a physician substitute the administration of red blood cells to a donor in an approved collection program, provided that the responsible physician has approved the procedure and is on the premises at the collection site when the red blood cells are administered.

(3) *Medical history, physical examination, informed consent, and examination before immunization.* Provided that such activities are performed under the supervision of the responsible physician, the responsible physician may delegate to a physician substitute the activities described in §630.15(b)(1), (2), and (5). The responsible physician is not required to be present at the collection site when the physician substitute performs these activities under supervision.

(4) *Infrequent plasma donors.* (i) For infrequent plasma donors other than those described in paragraph (c)(4)(ii) of this section, the responsible physician may delegate to a trained person the activities listed in paragraphs

(b)(1)(i) through (iii) and (b)(1)(v) of this section and the informed consent requirements described in § 630.15(b)(2). The responsible physician or a physician substitute need not be present at the collection site when any of these activities are performed, provided that the responsible physician has delegated oversight of these activities to a trained person who is not only adequately trained and experienced in the performance of these activities but also adequately trained and experienced in the recognition of and response to the known adverse responses associated with blood collection procedures. However, the responsible physician must not delegate:

(A) The examination and determination of the donor's health required in § 630.10(f)(2) for donors with blood pressure measurements outside specified limits, or in § 630.15(b)(7) for certain donors who have experienced red blood cell loss; or

(B) The determination of the health of the donor required in § 630.10(f)(4).

(ii) For infrequent plasma donors who are otherwise ineligible or are participating in an approved immunization program, the responsible physician may delegate only in accordance with paragraphs (c)(1) through (3) of this section.

(d) *Must rapid emergency medical services be available*? Establishments that collect blood or blood components must establish, maintain, and follow standard operating procedures for obtaining rapid emergency medical services for donors when medically necessary. In addition, establishments must assure that an individual (responsible physician, physician substitute, or trained person) who is currently certified in cardiopulmonary resuscitation is located on the premises whenever collections of blood or blood components are performed.

§ 630.10 General donor eligibility requirements.

(a) *What factors determine the eligibility of a donor*? You, an establishment that collects blood or blood components, must not collect blood or blood components before determining that the donor is eligible to donate or before determining that an exception to this provision applies. To be eligible, the donor must be in good health and free from transfusion-transmitted infections as can be determined by the processes in this subchapter. A donor is not eligible if the donor is not in good health or if you identify any factor(s) that may cause the donation to adversely affect:

(1) The health of the donor; or

(2) The safety, purity, or potency of the blood or blood component.

(b) *What educational material must you provide to the donor before determining eligibility*? You must provide educational material concerning relevant transfusion-transmitted infections to donors before donation when donor education about that relevant transfusion-transmitted infection, such as HIV, is necessary to assure the safety, purity, and potency of blood and blood components. The educational material must include an explanation of the readily identifiable risk factors closely associated with exposure to the relevant transfusion-transmitted infection. You must present educational material in an appropriate form, such as oral, written or multimedia, and in a manner designed to be understood by the donor. The educational material must instruct the donor not to donate blood and blood components when a risk factor is present. When providing educational material to donors under this section, you may include in those materials the information required to be provided to donors under paragraph (g)(2)(ii)(E) of this section.

(c) *When must you determine the eligibility of a donor*? You must determine donor eligibility on the day of donation, and before collection. Except:

(1) When a donor is donating blood components that cannot be stored for more than 24 hours, you may determine the donor's eligibility and collect a sample for testing required under § 610.40 of this chapter, no earlier than 2 calendar days before the day of donation, provided that your standard operating procedures address these activities.

(2) In the event that, upon review, you find that a donor's responses to the donor questions before collection were incomplete, within 24 hours of the time of collection, you may clarify a donor's

response or obtain omitted information required under paragraph (e) of this section, provided that your standard operating procedures address these activities.

(d) *How must you determine the eligibility of a donor*? You must determine the donor's eligibility before collection of blood or blood components, by the following procedures:

(1) You must consult the records of deferred donors maintained under § 606.160(e)(1) and (2) of this chapter. Exception: If pre-collection review of the record described in § 606.160(e)(2) of this chapter is not feasible because you cannot consult the cumulative record at the collection site, you must consult the cumulative record prior to release of any blood or blood component prepared from the collection.

(2) Assure that the interval since the donor's last donation is appropriate;

(3) Assess the donor's medical history; and

(4) Perform a physical assessment of the donor.

(e) *How do you assess the donor's medical history*? Before collection you must conduct a medical history interview as described in this section to determine if the donor is in good health; to identify risk factors closely associated with exposure to, or clinical evidence of a relevant transfusion-transmitted infection; and to determine if there are other conditions that may adversely affect the health of the donor or the safety, purity, or potency of the blood or blood components or any product manufactured from the blood or blood components. Your assessment must include each of the following factors:

(1) Factors that make the donor ineligible to donate because of an increased risk for, or evidence of, a relevant transfusion-transmitted infection. A donor is ineligible to donate when information provided by the donor or other reliable evidence indicates possible exposure to a relevant transfusion-transmitted infection if that risk of exposure is still applicable at the time of donation. Information and evidence indicating possible exposure to a relevant transfusion-transmitted infection include:

(i) Behaviors associated with a relevant transfusion-transmitted infection;

(ii) Receipt of blood or blood components or other medical treatments and procedures associated with possible exposure to a relevant transfusion-transmitted infection;

(iii) Signs and/or symptoms of a relevant transfusion-transmitted infection;

(iv) Institutionalization for 72 hours or more consecutively in the past 12 months in a correctional institution;

(v) Intimate contact with risk for a relevant transfusion-transmitted infection; and

(vi) Nonsterile percutaneous inoculation.

(2) Other factors that make the donor ineligible to donate. A donor is ineligible to donate when donating could adversely affect the health of the donor, or when the safety, purity, or potency of the blood or blood component could be affected adversely. Your assessment of the donor must include each of the following factors:

(i) Symptoms of a recent or current illness;

(ii) Certain medical treatments or medications;

(iii) Travel to, or residence in, an area endemic for a transfusion-transmitted infection, when such screening is necessary to assure the safety, purity, and potency of blood and blood components due to the risks presented by donor travel and the risk of transmission of that transfusion-transmitted infection by such donors;

(iv) Exposure or possible exposure to an accidentally or intentionally released disease or disease agent relating to a transfusion-transmitted infection, if you know or suspect that such a release has occurred;

(v) Pregnancy at the time of, or within 6 weeks prior to, donation;

(vi) Whether, in the opinion of the interviewer, the donor appears to be under the influence of any drug, alcohol or for any reason does not appear to be providing reliable answers to medical history questions, or if the donor says that the purpose of donating is to obtain test results for a relevant transfusion-transmitted infection; and

(vii) The donor is a xenotransplantation product recipient.

(f) *How do you perform a physical assessment of the donor*? You must determine on the day of donation, and before collection that the donor is in good health based on the following, at a minimum:

(1) *Temperature.* The donor's oral body temperature must not exceed 37.5 °C (99.5 °F), or the equivalent if measured at another body site;

(2) *Blood pressure.* The donor's systolic blood pressure must not measure above 180 mm of mercury, or below 90 mm of mercury, and the diastolic blood pressure must not measure above 100 mm of mercury or below 50 mms of mercury. A donor with measurements outside these limits may be permitted to donate only when the responsible physician examines the donor and determines and documents that the health of the donor would not be adversely affected by donating.

(3) *Hemoglobin or hematocrit determination.* You must determine the donor's hemoglobin level or hematocrit value by using a sample of blood obtained by fingerstick, venipuncture, or by a method that provides equivalent results. Blood obtained from the earlobe is not acceptable.

(i) Allogeneic donors must have a hemoglobin level or hematocrit value that is adequate to assure donor safety and product potency. The following minimum standards apply.

(A) Female allogeneic donors must have a hemoglobin level that is equal to or greater than 12.5 grams of hemoglobin per deciliter of blood, or a hematocrit value that is equal to or greater than 38 percent. Recognizing that lower levels are also within normal limits for female donors, you may collect blood from female allogeneic donors who have a hemoglobin level between 12.0 and 12.5 grams per deciliter of blood, or a hematocrit value between 36 and 38 percent, provided that you have taken additional steps to assure that this alternative standard is adequate to ensure that the health of the donor will not be adversely affected due to the donation, in accordance with a procedure that has been found acceptable for this purpose by FDA.

(B) Male allogeneic donors must have a hemoglobin level that is equal to or greater than 13.0 grams of hemoglobin per deciliter of blood, or a hematocrit value that is equal to or greater than 39 percent.

(ii) An autologous donor must have a hemoglobin level no less than 11.0 grams of hemoglobin per deciliter of blood, or a hematocrit value no less than 33 percent.

(4) *Pulse.* The donor's pulse must be regular and between 50 and 100 beats per minute. A donor with an irregular pulse or measurements outside these limits may be permitted to donate only when the responsible physician determines and documents that the health of the donor would not be adversely affected by donating.

(5) *Weight.* The donor must weigh a minimum of 50 kilograms (110 pounds).

(6) *Skin examination.* (i) The donor's phlebotomy site must be free of infection, inflammation, and lesions; and

(ii) The donor's arms and forearms must be free of punctures and scars indicative of injected drugs of abuse.

(g) *Are there additional requirements for determining the eligibility of the donor*? You must obtain the following from the donor on the day of donation:

(1) *Proof of identity and postal address.* You must obtain proof of identity of the donor and a postal address where the donor may be contacted for 8 weeks after donation; and

(2) *Donor's acknowledgement.* (i) Prior to each donation, you must provide information to the donor addressing the elements specified in paragraphs (g)(2)(ii)(A) through (E) of this section and obtain the donor's acknowledgement that the donor has reviewed the information. You must establish procedures in accordance with § 606.100 of this chapter to assure that the donor has reviewed this material, and provide for a signature or other documented acknowledgement.

(ii) The donor acknowledgement must not include any exculpatory language through which the donor is made to waive or appear to waive any of the donor's legal rights. It must, at a minimum clearly address the following:

(A) The donor has reviewed the educational material provided under paragraph (b) of this section regarding relevant transfusion-transmitted infections;

(B) The donor agrees not to donate if the donation could result in a potential risk to recipients as described in the educational material;

(C) A sample of the donor's blood will be tested for specified relevant transfusion-transmitted infections;

(D) If the donation is determined to be not suitable under § 630.30(a) or if the donor is deferred from donation under § 610.41 of this chapter, the donor's record will identify the donor as ineligible to donate and the donor will be notified under § 630.40 of the basis for the deferral and the period of deferral;

(E) The donor has been provided and reviewed information regarding the risks and hazards of the specific donation procedure; and

(F) The donor has the opportunity to ask questions and withdraw from the donation procedure.

(h) *What must you do when a donor is not eligible*? You must not collect blood or blood components from a donor found to be ineligible prior to collection based on criteria in §§ 630.10 or 630.15, or deferred under § 610.41 of this chapter or § 630.30(b)(2), unless this subchapter provides an exception. You must defer donors found to be ineligible and you must notify the donor of their deferral under § 630.40.

§ 630.15 Donor eligibility requirements specific to Whole Blood, Red Blood Cells and Plasma collected by apheresis.

(a) *What additional donor eligibility requirements apply when you, an establishment that collects blood or blood components, collect Whole Blood or Red Blood Cells by apheresis*?

(1) *Donation frequency must be consistent with protecting the health of the donor*.

(i) For a collection resulting in a single unit of Whole Blood or Red Blood Cells collected by apheresis, donation frequency must be no more than once in 8 weeks, and for apheresis collections resulting in two units of Red Blood Cells, the donor must not donate more than once in 16 weeks.

(ii) The limitations in paragraph (a)(1)(i) of this section apply unless the responsible physician examines the donor at the time of donation and one of the following conditions exists:

(A) The donation is for autologous use as prescribed by the donor's physician and the responsible physician determines and documents that the donation may proceed; or

(B) The donation is a dedicated donation based on the intended recipient's documented exceptional medical need and the responsible physician determines and documents that the health of the donor would not be adversely affected by donating.

(2) *Therapeutic phlebotomy*. When a donor who is determined to be eligible under § 630.10 undergoes a therapeutic phlebotomy under a prescription to promote the donor's health, you may collect from the donor more frequently than once in 8 weeks for collections resulting in a single unit of Whole Blood or Red Blood Cells, or once in 16 weeks for apheresis collections resulting in two units of Red Blood Cells, provided that the container label conspicuously states the disease or condition of the donor that necessitated phlebotomy. However, no labeling for the disease or condition is required under this section if:

(i) The donor meets all eligibility criteria;

(ii) The donor undergoes a therapeutic phlebotomy as prescribed by a licensed health care provider treating the donor for:

(A) Hereditary hemochromatosis; or

(B) Another disease or condition, when the health of a donor with that disease or condition will not be adversely affected by donating, and the donor's disease or condition will not adversely affect the safety, purity, and potency of the blood and blood components, or any products manufactured from them, and the collection is in accordance with a procedure that has been found acceptable for this purpose by FDA; and

(iii) You perform without charge therapeutic phlebotomies for all individuals with that disease or condition.

(b) *What additional donor eligibility requirements apply when you, an establishment that collects blood or blood components, collect Source Plasma or plasma by plasmapheresis*?

(1) *Medical history and physical examination.* Except as provided in § 630.25:

(i) The responsible physician must conduct an appropriate medical history and physical examination of the donor on the day of the first donation or no more than 1 week before the first donation and at subsequent intervals of no longer than 1 year.

(ii) The responsible physician must examine the donor for medical conditions that would place the donor at risk from plasmapheresis. If the donor is determined to be at risk, you must defer the donor from donating.

(iii) The responsible physician must conduct a new medical history and physical examination of a donor who does not return for 6 months.

(2) *What requirements apply to obtaining informed consent*?

(i) The responsible physician must obtain the informed consent of a plasma donor on the first day of donation or no more than 1 week before the first donation, and at subsequent intervals of no longer than 1 year.

(ii) The responsible physician must obtain the informed consent of a plasma donor who does not return within 6 months of the last donation.

(iii) The responsible physician must explain the risks and hazards of the procedure to the donor. The explanation must include the risks of a hemolytic transfusion reaction if the donor is given the cells of another donor and the risks involved if the donor is immunized. The explanation must be made in such a manner that the donor may give their consent and has a clear opportunity to refuse the procedure.

(iv) If a donor is enrolled in a new program, such as an immunization or special collection program, the responsible physician must again obtain an informed consent specific for that program.

(3) *Weight.* You must weigh a donor at each donation.

(4) *Total protein level.* You must determine the donor's total plasma protein level before each plasmapheresis procedure. The donor must have a total plasma protein level of no less than 6.0 grams per deciliter and no more than 9.0 grams per deciliter in a plasma sample or a serum sample.

(5) *Examination before immunization.* (i) No more than 1 week before the first immunization injection for the production of high-titer antibody plasma, the responsible physician must conduct an appropriate medical history and physical examination, as described in paragraph (b)(1) of this section, in addition to assessing the general donor eligibility requirements under § 630.10. It is not necessary to repeat the medical history and physical examination requirement in paragraph (b)(1) of this section, if the immunized donor's plasma is collected within 3 weeks of the first immunization injection.

(ii) You are not required to repeat the medical history and physical examination required under paragraph (b)(1) of this section for a donor currently participating in a plasmapheresis collection program and determined to be eligible under § 630.10 unless the medical history and physical examination are due under paragraph (b)(1)(i) or (b)(1)(iii) of this section.

(6) *Deferral of donors due to red blood cell loss.* (i) You must defer a donor from donating plasma by plasmapheresis for 8 weeks if the donor has donated a unit of Whole Blood, or a single unit of Red Blood Cells by apheresis. However, you may collect plasma by plasmapheresis after a donation of Whole Blood or a single unit of Red Blood Cells by apheresis after at least 2 calendar days have passed, provided that the extracorporeal volume of the apheresis device is less than 100 milliliters.

(ii) You must defer a donor from donating plasma by plasmapheresis for a period of 16 weeks if the donor donates two units of Red Blood Cells during a single apheresis procedure;

(iii) You must defer a donor for 8 weeks or more if the cumulative red blood cell loss in any 8 week period could adversely affect donor health.

(7) *Exceptions to deferral due to red blood cell loss.* You are not required to defer a Source Plasma donor from donating plasma by plasmapheresis due

to red blood cell loss if the following conditions are met:

(i) The responsible physician examines the donor at the time of the current donation and determines and documents that the donor is in good health and the donor's health permits the plasmapheresis;

(ii) The donor's plasma possesses a property, such as an antibody, antigen, or protein deficiency that is transitory, of a highly unusual or infrequent specificity, or of an unusually high titer;

(iii) The special characteristics of the donor's plasma and the need for plasmapheresis of the donor under §630.20(b) are documented at your establishment; and

(iv) The extracorporeal volume of the apheresis device is less than 100 milliliters.

(8) *Malaria.* Freedom from risk of malaria is not required for a donor of Source Plasma.

(9) You must comply with other requirements for collection of plasma in part 640 of this chapter and this part including restrictions on frequency of collection as specified in §§640.32 and 640.65 of this chapter.

§630.20 Exceptions for certain ineligible donors.

After assessing donor eligibility under §§630.10 and 630.15, an establishment may collect blood and blood components from a donor who is determined to be not eligible to donate under any provision of §630.10(e) and (f) or §630.15(a) if one of the following sets of conditions are met:

(a) The donation is for autologous use only as prescribed by the donor's physician, the donor has a hemoglobin level no less than 11.0 grams of hemoglobin per deciliter of blood or a hematocrit value no less than 33 percent, and the responsible physician determines and documents that the donor's health permits the collection procedure; or

(b) The donation is collected under a Source Plasma collection program which has received prior written approval from the Director, Center for Biologics Evaluation and Research, to collect plasma for further manufacturing use into in vitro products for which there are no alternative sources, the donor meets the criteria in §630.10(f)(1) through (6), and the responsible physician determines and documents for each donation that the donor's health permits the collection procedure, and the collection takes place under the medical oversight specified in the approved plasmapheresis program.

(c) The donation is restricted for use solely by a specific transfusion recipient based on documented exceptional medical need, and the responsible physician determines and documents that the donor's health permits the collection procedure, and that the donation presents no undue medical risk to the transfusion recipient.

§630.25 Exceptions from certain donor eligibility requirements for infrequent plasma donors.

For an infrequent plasma donor who is not participating in an immunization program, establishments are not required to:

(a) Perform a medical history and physical examination of the donor under §630.15(b)(1);

(b) Perform a test for total protein under §630.15(b)(4);

(c) Determine the total plasma or serum protein and immunoglobulin composition under §640.65(b)(1)(i) of this chapter; or

(d) Review the data and records as required in §640.65(b)(2)(i) of this chapter.

§630.30 Donation suitability requirements.

(a) *When is a donation suitable*? A donation is suitable when:

(1) The donor is not currently deferred from donation as determined by review of the records of deferred donors required under §606.160(e) of this chapter;

(2) The results in accordance with §§630.10 through 630.25 indicate that the donor is in good health and procedures were followed to ensure that the donation would not adversely affect the health of the donor;

(3) The results in accordance with §630.10(e) indicate that the donor is free from risk factors for, or evidence of, relevant transfusion-transmitted infections and other factors that make the donor ineligible to donate;

(4) The donor's blood is tested in accordance with § 610.40 of this chapter, and is negative or nonreactive, unless an exception applies under § 610.40(h) of this chapter; and

(5) The donation meets other requirements in this subchapter.

(b) *What must you do when the donation is not suitable*? (1) You must not release the donation for transfusion or further manufacturing use unless it is an autologous donation, or an exception is provided in this chapter.

(2) You must defer the donor when a donation is determined to be unsuitable based on the criteria in paragraphs (a)(1) through (4) of this section.

(3) You must defer the donor of bacterially contaminated platelets when the contaminating organism is identified in accordance with § 606.145(d) of this chapter as likely to be associated with a bacterial infection that is endogenous to the bloodstream of the donor.

(4) You must notify the deferred donor in accordance with the notification requirements in § 630.40.

§ 630.35 Requalification of previously deferred donors.

Establishments may determine a deferred donor to be eligible as a donor of blood and blood components if, at the time of the current collection, the donor meets the eligibility criteria in this part, except for the record of the previous deferral, and you determine that the criteria that were the basis for the previous deferral are no longer applicable. Criteria for the previous deferral are no longer applicable if the following conditions are met:

(a) The previous deferral was for a defined period of time and that time period has passed, or the deferral was otherwise temporary, such as a deferral based on eligibility criteria described in §§ 630.10(f)(1) through (5) or 630.15(b)(4); or

(b) For a donor deferred for reasons other than under § 610.41(a) of this chapter, you determine that the donor has met criteria for requalification by a method or process found acceptable for such purpose by FDA.

Subpart C—Donor Notification

SOURCE: 80 FR 29898, May 22, 2015, unless otherwise noted.

§ 630.40 Requirements for notifying deferred donors.

(a) *Notification of donors.* You, an establishment that collects blood or blood components, must make reasonable attempts to notify any donor, including an autologous donor, who has been deferred based on the results of tests for evidence of infection with a relevant transfusion-transmitted infection(s) as required by § 610.41(a) of this chapter; any donor who has been deferred as required under § 630.30(b)(3) because their donated platelets have been determined under § 606.145(d) of this chapter to be contaminated with an organism that is identified as likely to be associated with a bacterial infection that is endogenous to the bloodstream of the donor; and any donor who has been determined not to be eligible as a donor based on eligibility criteria under §§ 630.10 and 630.15. You must attempt to obtain the results of further testing required under § 610.40(e) of this chapter prior to notifying a donor of the deferral. If notification occurs prior to receipt of such results, you must also notify a deferred donor of the results of the further testing. You must notify a donor as described in paragraph (b) of this section.

(b) *Content of notification.* You must provide the following information to a donor deferred or determined not to be eligible as a donor as described in paragraph (a) of this section:

(1) That the donor is deferred or determined not to be eligible for donation and the reason for that decision;

(2) Where appropriate, the types of donation of blood or blood components that the donor should not donate in the future;

(3) Where applicable, the results of tests for evidence of infection due to relevant transfusion-transmitted infection(s) that were a basis for deferral under § 610.41 of this chapter, including results of further testing as required in § 610.40(e) of this chapter; and,

(4) Where appropriate, information concerning medical followup and counseling.

(c) *Time period for notification.* You must make reasonable attempts to notify the donor within 8 weeks after determining that the donor is deferred or determined not to be eligible for donation as described in paragraph (a) of this section. You must document that you have successfully notified the donor or when you are unsuccessful that you have made reasonable attempts to notify the donor.

(d) *Autologous donors.* (1) You also must provide the following information to the referring physician of an autologous donor who is deferred based on the results of tests for evidence of infection with a relevant transfusion-transmitted infection(s) or whose platelets indicate evidence of a bacterial infection that is endogenous to the bloodstream of the donor as described in paragraph (a) of this section:

(i) Information that the autologous donor is deferred based on the results of tests for evidence of infection due to relevant transfusion-transmitted infection(s), as required under §610.41 of this chapter, and the reason for that decision;

(ii) Where appropriate, the types of donation of blood or blood components that the autologous donor should not donate in the future; and

(iii) The results of tests for evidence of infection due to relevant transfusion-transmitted infection(s), that were a basis for deferral under §610.41 of this chapter, including results of further testing as required in §610.40(e) of this chapter.

(2) You must make reasonable attempts to notify the autologous donor's referring physician within 8 weeks after determining that the autologous donor is deferred as described in paragraph (a) of this section. You must document that you have successfully notified the autologous donor's referring physician or when you are unsuccessful that you have made reasonable attempts to notify the physician.

[66 FR 31176, June 11, 2001. Redesignated and amended at 80 FR 29898, May 22, 2015]

PART 640—ADDITIONAL STANDARDS FOR HUMAN BLOOD AND BLOOD PRODUCTS

Subpart A—Whole Blood

Subpart B—Red Blood Cells

Subpart C—Platelets

Subpart D—Plasma

Subpart E [Reserved]

Subpart F—Cryoprecipitate

Subpart G—Source Plasma