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(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 I and II (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

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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 col-*

lected 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

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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