

reasonableness or adequacy of the fee schedule and projected revenues. This submission is due at least three months before the beginning of the OPTN's fiscal year. The Secretary will approve, modify, or disapprove the amount of the fee within a reasonable time of receiving the OPTN's submission.

[63 FR 16332, Apr. 2, 1998, as amended at 64 FR 56659, Oct. 20, 1999]

§ 121.6 Organ procurement.

The suitability of organs donated for transplantation shall be determined as follows:

(a) *Tests.* An OPTN member procuring an organ shall assure that laboratory tests and clinical examinations of potential organ donors are performed to determine any contraindications for donor acceptance, in accordance with policies established by the OPTN.

(b) *HIV.* The OPTN shall adopt and use standards for preventing the acquisition of organs from individuals known to be infected with human immunodeficiency virus.

(c) *Acceptance criteria.* Transplant programs shall establish criteria for organ acceptance, and shall provide such criteria to the OPTN and the OPOs with which they are affiliated.

[63 FR 16332, Apr. 2, 1998, as amended at 64 FR 56659, Oct. 20, 1999]

§ 121.7 Identification of organ recipient.

(a) *List of potential transplant recipients.* (1) An OPTN member procuring an organ shall operate the OPTN computer match program within such time as the OPTN may prescribe to identify and rank potential recipients for each cadaveric organ procured.

(2) The rank order of potential recipients shall be determined for each cadaveric organ using the organ specific allocation criteria established in accordance with § 121.8.

(3) When a donor or donor organ does not meet a transplant program's donor acceptance criteria, as established under § 121.6(c), transplant candidates of that program shall not be ranked among potential recipients of that organ and shall not appear on a roster of potential recipients of that organ.

(b) *Offer of organ for potential recipients.* (1) Organs shall be offered for potential recipients in accordance with policies developed under § 121.8 and implemented under § 121.4.

(2) Organs may be offered only to potential recipients listed with transplant programs having designated transplant programs of the same type as the organ procured.

(3) An organ offer is made when all information necessary to determine whether to transplant the organ into the potential recipient has been given to the transplant hospital.

(4) A transplant program shall either accept or refuse the offered organ for the designated potential recipient within such time as the OPTN may prescribe. A transplant program shall document and provide to the OPO and to the OPTN the reasons for refusal and shall maintain this document for one year.

(c) *Transportation of organ to potential recipient*—(1) *Transportation.* The OPTN member that procures a donated organ shall arrange for transportation of the organ to the transplant hospital.

(2) *Documentation.* The OPTN member that is transporting an organ shall assure that it is accompanied by written documentation of activities conducted to determine the suitability of the organ donor and shall maintain this document for one year.

(3) *Packaging.* The OPTN member that is transporting an organ shall assure that it is packaged in a manner that is designed to maintain the viability of the organ.

(d) *Receipt of an organ.* Upon receipt of an organ, the transplant hospital responsible for the potential recipient's care shall determine whether to proceed with the transplant. In the event that an organ is not transplanted into the potential recipient, the OPO which has a written agreement with the transplant hospital must offer the organ for another potential recipient in accordance with paragraph (b)(2) of this section.

(e) *Wastage.* Nothing in this section shall prohibit a transplant program from transplanting an organ into any medically suitable candidate if to do otherwise would result in the organ not being used for transplantation. The