

§ 121.5

regulations under this part and may consult with the Advisory Committee on Organ Transplantation established under §121.12. After this review, the Secretary may:

- (1) Reject the comments;
 - (2) Direct the OPTN to revise the policies or practices consistent with the Secretary's response to the comments; or
 - (3) Take such other action as the Secretary determines appropriate.
- (e) The OPTN shall implement policies and shall:
- (1) Provide information to OPTN members about these policies and the rationale for them; and
 - (2) Update policies developed in accordance with this section to accommodate scientific and technological advances.
 - (3) Identify all covered body parts in any policies specific to vascularized composite allografts, defined in §121.2.

[63 FR 16332, Apr. 2, 1998, as amended at 64 FR 56658, Oct. 20, 1999; 78 FR 40042, July 3, 2013]

§ 121.5 Listing requirements.

- (a) A transplant hospital which is an OPTN member may list individuals, consistent with the OPTN's criteria under §121.8(b)(1), only for a designated transplant program.
- (b) Transplant hospitals shall assure that individuals are placed on the waiting list as soon as they are determined to be candidates for transplantation. The OPTN shall advise transplant hospitals of the information needed for such listing.
- (c) An OPTN member shall pay a registration fee to the OPTN for each transplant candidate it places on the waiting list. The amount of such fee shall be calculated to cover (together with contract funds awarded by the Secretary) the reasonable costs of operating the OPTN and shall be determined by the OPTN with the approval of the Secretary. No less often than annually, and whether or not a change is proposed, the OPTN shall submit to the Secretary a statement of its proposed registration fee, together with such supporting information as the Secretary finds necessary to determine the reasonableness or adequacy of the fee schedule and projected revenues. This

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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.