

Secretary. Appeals shall be submitted in writing within 30 days of rejection of the application. The Secretary may:

(i) Deny the appeal; or

(ii) Direct the OPTN to take action consistent with the Secretary's response to the appeal.

(c) *Corporate status of the OPTN.* (1) The OPTN shall be a private, not-for-profit entity.

(2) The requirements of this section do not apply to any parent, sponsoring, or affiliated organization of the OPTN, or to any activities of the contracting organization that are not integral to the operation of the OPTN. Such an organization is free to establish its own corporate procedures.

(3) No OPTN member is required to become a member of any organization that is a parent, sponsor, contractor, or affiliated organization of the OPTN, to comply with the by-laws of any such organization, or to assume any corporate duties or obligations of any such organization.

(d) *Effective date.* The organization designated by the Secretary as the OPTN shall have until June 30, 2000, or six months from its initial designation as the OPTN, whichever is later, to meet the requirements of this section, except that the Secretary may extend such period for good cause.

[63 FR 16332, Apr. 2, 1998, as amended at 63 FR 35847, July 1, 1998; 64 FR 56658, Oct. 20, 1999]

§ 121.4 OPTN policies: Secretarial review and appeals.

(a) The OPTN Board of Directors shall be responsible for developing, with the advice of the OPTN membership and other interested parties, policies within the mission of the OPTN as set forth in section 372 of the Act and the Secretary's contract for the operation of the OPTN, including:

(1) Policies for the equitable allocation of cadaveric organs in accordance with § 121.8;

(2) Policies, consistent with recommendations of the Centers for Disease Control and Prevention, for the testing of organ donors and follow-up of transplant recipients to prevent the spread of infectious diseases;

(3) Policies that reduce inequities resulting from socioeconomic status, including, but not limited to:

(i) Ensuring that payment of the registration fee is not a barrier to listing for patients who are unable to pay the fee;

(ii) Procedures for transplant hospitals to make reasonable efforts to obtain from all available sources, financial resources for patients unable to pay such that these patients have an opportunity to obtain a transplant and necessary follow-up care;

(iii) Recommendations to private and public payers and service providers on ways to improve coverage of organ transplantation and necessary follow-up care; and

(iv) Reform of allocation policies based on assessment of their cumulative effect on socioeconomic inequities;

(4) Policies regarding the training and experience of transplant surgeons and transplant physicians in designated transplant programs as required by § 121.9;

(5) Policies for nominating officers and members of the Board of Directors; and

(6) Policies on such other matters as the Secretary directs.

(b) The Board of Directors shall:

(1) Provide opportunity for the OPTN membership and other interested parties to comment on proposed policies and shall take into account the comments received in developing and adopting policies for implementation by the OPTN; and

(2) Provide to the Secretary, at least 60 days prior to their proposed implementation, proposed policies it recommends to be enforceable under § 121.10 (including allocation policies). These policies will not be enforceable until approved by the Secretary. The Board of Directors shall also provide to the Secretary, at least 60 days prior to their proposed implementation, proposed policies on such other matters as the Secretary directs. The Secretary will refer significant proposed policies to the Advisory Committee on Organ Transplantation established under § 121.12, and publish them in the FEDERAL REGISTER for public comment.

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The Secretary also may seek the advice of the Advisory Committee on Organ Transplantation established under §121.12 on other proposed policies, and publish them in the FEDERAL REGISTER for public comment. The Secretary will determine whether the proposed policies are consistent with the National Organ Transplant Act and this part, taking into account the views of the Advisory Committee and public comments. Based on this review, the Secretary may provide comments to the OPTN. If the Secretary concludes that a proposed policy is inconsistent with the National Organ Transplant Act or this part, the Secretary may direct the OPTN to revise the proposed policy consistent with the Secretary's direction. If the OPTN does not revise the proposed policy in a timely manner, or if the Secretary concludes that the proposed revision is inconsistent with the National Organ Transplant Act or this part, the Secretary may take such other action as the Secretary determines appropriate, but only after additional consultation with the Advisory Committee on the proposed action.

(c) The OPTN Board of Directors shall provide the membership and the Secretary with copies of its policies as they are adopted, and make them available to the public upon request. The Secretary will publish lists of OPTN policies in the FEDERAL REGISTER, indicating which ones are enforceable under §121.10 or subject to potential sanctions of section 1138 of the Social Security Act. The OPTN shall also continuously maintain OPTN policies for public access on the Internet, including current and proposed policies.

(d) Any interested individual or entity may submit to the Secretary in writing critical comments related to the manner in which the OPTN is carrying out its duties or Secretarial policies regarding the OPTN. Any such comments shall include a statement of the basis for the comments. The Secretary will seek, as appropriate, the comments of the OPTN on the issues raised in the comments related to OPTN policies or practices. Policies or practices that are the subject of critical comments remain in effect during

the Secretary's review, unless the Secretary directs otherwise based on possible risk to the health of patients or to public safety. The Secretary will consider the comments in light of the National Organ Transplant Act and the 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.

[63 FR 16332, Apr. 2, 1998, as amended at 64 FR 56658, Oct. 20, 1999]

§ 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