

§ 121.4

42 CFR Ch. I (10–1–99 Edition)

(iii) Other organizations, institutions, and individuals that have an interest in the fields of organ donation or transplantation.

(2) To apply for membership in the OPTN:

(i) An OPO shall provide to the OPTN the name and address of the OPO, and the latest year of designation under section 1138(b) of the Social Security Act;

(ii) A transplant hospital shall provide to the OPTN the name and address of the hospital, a list of its transplant programs by type of organ; and

(iii) Any other organization, institution, or individual eligible under paragraph (c)(1)(iii) of this section shall demonstrate to the OPTN an interest in the fields of organ donation or transplantation.

(3) The OPTN shall accept or reject as members entities or individuals described in paragraph (c)(1)(iii) of this section within 90 days.

(4) Applicants rejected for membership in the OPTN may appeal to the 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.

(d) *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.

(e) *Effective date.* The organization designated by the Secretary as the OPTN shall have six months from October 1, 1998, or six months from its initial designation as the OPTN, whichever is later, to meet the board com-

position requirements of paragraph (a) of this section. The organization designated by the Secretary as the OPTN shall have six months from October 1, 1998, or six months from initial designation as the OPTN, whichever is later, to meet any other 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]

§ 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 patients in need of a transplant are listed without regard to ability to pay or source of payment;

(ii) Procedures for transplant hospitals to make reasonable efforts to make available from their own resources, or obtain from other 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, at least 30 days prior to their proposed implementation, proposed policies to the Secretary, who may provide comments and/or objections within a reasonable time, or may publish the policies in the FEDERAL REGISTER to obtain comments from the public. The Board of Directors shall indicate which of the proposed policies it recommends be enforceable under § 121.10. If the Secretary seeks public comments, these comments will be considered and may affect subsequent response to the OPTN. The OPTN shall take into account any comments the Secretary may provide. If the Secretary objects to a policy, the OPTN may be directed to revise the policy consistent with the Secretary's direction. If the OPTN does not revise the policy in a timely manner or if the Secretary otherwise disagrees with its content, the Secretary may take such other action as the Secretary determines appropriate.

(c) The OPTN Board of Directors shall provide the membership and the Secretary with copies of the policies as they are adopted, and make them available to the public upon request. The Secretary will publish lists of these documents in the FEDERAL REGISTER, indicating which ones are subject to the special compliance requirements and 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) The OPTN, or its members, or other individuals, or entities objecting to policies developed by the OPTN or

the Secretary may submit appeals to the Secretary in writing. Any such appeal shall include a statement of the basis for the appeal. The Secretary will seek the comments of the OPTN on the issues raised in the appeal of an OPTN-developed policy. Policies remain in effect during the appeal. The Secretary may:

(1) Deny the appeal;

(2) Direct the OPTN to revise the policies consistent with the Secretary's response to the appeal, or

(3) Take such other action as the Secretary determines appropriate.

(e) The OPTN shall implement policies and:

(1) Provide information to OPTN members about these policies and the rationale for them.

(2) Update policies developed in accordance with this section to accommodate scientific and technological advances.

§ 121.5 Listing requirements.

(a) A transplant hospital which is an OPTN member may list individuals only for a designated transplant program.

(b) Transplant hospitals shall assure that individuals are placed on the national 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 national list. The amount of such fee 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 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.