

*Secretary* means the Secretary of Health and Human Services and any official of the Department of Health and Human Services to whom the authority involved has been delegated.

*Transplant candidate* means an individual who has been identified as medically suited to benefit from an organ transplant and has been placed on the waiting list by the individual's transplant program.

*Transplant hospital* means a hospital in which organ transplants are performed.

*Transplant physician* means a physician who provides non-surgical care and treatment to transplant patients before and after transplant.

*Transplant program* means a component within a transplant hospital which provides transplantation of a particular type of organ.

*Transplant recipient* means a person who has received an organ transplant.

*Transplant surgeon* means a physician who provides surgical care and treatment to transplant recipients.

*Waiting list* means the OPTN computer-based list of transplant candidates.

[63 FR 16332, Apr. 2, 1998, as amended at 64 FR 56658, Oct. 20, 1999; 72 FR 10619, Mar. 9, 2007; 72 FR 10925, Mar. 12, 2007]

**§ 121.3 The OPTN.**

(a) *Organization of the OPTN.* (1) The OPTN shall establish a Board of Directors of whatever size the OPTN determines appropriate. The Board of Directors shall include:

(i) Approximately 50 percent transplant surgeons or transplant physicians;

(ii) At least 25 percent transplant candidates, transplant recipients, organ donors and family members. These members should represent the diversity of the population of transplant candidates, transplant recipients, organ donors and family members served by the OPTN including, to the extent practicable, the minority and gender diversity of this population. These members shall not be employees of, or have a similar relationship with OPOs, transplant centers, voluntary health organizations, transplant coordinators, histocompatibility experts, or other non-physician transplant profes-

sionals; however, the Board may waive this requirement for not more than 50 percent of these members; and

(iii) Representatives of OPOs, transplant hospitals, voluntary health associations, transplant coordinators, histocompatibility experts, non-physician transplant professionals, and the general public.

(2) The Board of Directors shall elect an Executive Committee from the membership of the Board. The Executive Committee shall include at least one general public member, one OPO representative, approximately 50 percent transplant surgeons and transplant physicians, and at least 25 percent transplant candidates, transplant recipients, organ donors, and family members.

(3) The Board of Directors shall appoint an Executive Director of the OPTN. The Executive Director may be reappointed upon the Board's determination that the responsibilities of this position have been accomplished successfully.

(4) The Board of Directors shall establish such other committees as are necessary to perform the duties of the OPTN. Committees established by the Board of Directors shall include:

(i) Representation by transplant coordinators, organ procurement organizations, and transplant hospitals, and at least one transplant candidate, transplant recipient, organ donor or family member; and

(ii) To the extent practicable, minority and gender representation reflecting the diversity of the population of transplant candidates, transplant recipients, organ donors and family members served by the OPTN.

(b) *Membership of the OPTN.* (1) The OPTN shall admit and retain as members the following:

(i) All organ procurement organizations;

(ii) Transplant hospitals participating in the Medicare or Medicaid programs; and

(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.

(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