

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.

§ 121.3 The OPTN.

(a) *Composition of the Board.* (1) The OPTN shall establish a Board of Directors of whatever size the OPTN determines appropriate, provided that it includes at least the following members:

(i) Six members representing the following categories (two members from each category):

(A) Transplant coordinators;
(B) Organ procurement organizations;

(C) Histocompatibility experts;
(ii) Eight individuals representing transplant candidates, transplant recipients, organ donors, and family members;

(iii) Ten members from the following categories (two members each):

(A) Transplant surgeons;
(B) Transplant physicians;
(C) Transplant hospitals;
(D) Voluntary health associations;

and
(E) Other experts from related fields including medical examiners, hospital administration, or donor hospital personnel in such fields as trauma, emergency medical services, critical care, neurology, or neurosurgery; and

(iv) Six members from the general public from fields such as behavioral science, computer science, economics, ethics, health care financing, law, policy analysis, sociology, statistics, or theology. These members need not have technical expertise in organ donation or allocation.

(2) None of the members who are transplant recipients, transplant candidates, organ donors, family members, or general public members under paragraph (a)(1) of this section shall be employees of, or have a similar relationship with, the categories of members listed in paragraph (a)(1)(i) or paragraph (a)(1)(iii) or the OPTN.

(3) The Board of Directors shall include:

(i) Individuals representing the diversity of the population of transplant candidates and recipients served by the OPTN, including, to the extent prac-

ticable, minority and gender representation reflecting the population of potential transplant candidates served by the OPTN;

(ii) No more than 50 percent transplant surgeons or transplant physicians; and

(iii) At least 25 percent transplant candidates, transplant recipients, organ donors and family members.

(4) Individuals on the Board shall be elected for a two-year term.

(b) *Duties of the OPTN Board of Directors—*(1) *Executive Committee.* The Board of Directors shall elect an Executive Committee from the membership of the Board. The Executive Committee shall include at least one member who is a transplant candidate, transplant recipient, organ donor, or family member; one general public member, one OPO representative, and not more than 50 percent transplant surgeons and transplant physicians.

(2) *Executive Director.* 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.

(3) *Committees.* 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 potential transplant candidates served by the OPTN.

(4) The Board of Directors shall develop and propose policies for the equitable allocation of organs, as described in § 121.8.

(c) *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

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(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