

SUBCHAPTER K—HEALTH RESOURCES DEVELOPMENT

PART 121—ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

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AUTHORITY: Sections 215, 371-376 of the Public Health Service Act (42 U.S.C. 216, 273-274d); Sections 1102, 1106, 1138 and 1872 of the Social Security Act (42 U.S.C. 1302, 1306, 1320b-8 and 1395ii).

SOURCE: 63 FR 16332, Apr. 2, 1998, unless otherwise noted.

§ 121.1 Applicability.

(a) The provisions of this part apply to the operation of the Organ Procurement and Transplantation Network (OPTN) and to the Scientific Registry.

(b) In accordance with Section 1138 of the Social Security Act, hospitals in which organ transplants are performed and which participate in the programs under titles XVIII or XIX of that Act, and organ procurement organizations designated under Section 1138(b)(1)(F) of the Social Security Act, are subject to the requirements of this part.

§ 121.2 Definitions.

As used in this part—

Act means the Public Health Service Act, as amended.

Designated transplant program means a transplant program that has been found to meet the requirements of § 121.9.

Family member means a family member of a transplant candidate, transplant recipient, or organ donor.

National list means the OPTN computer-based list of transplant candidates nationwide.

OPTN computer match program means a set of computer-based instructions which compares data on a cadaveric organ donor with data on transplant candidates on the national list and ranks the candidates according to OPTN policies to determine the priority for allocating the donor organ(s).

Organ means a human kidney, liver, heart, lung, or pancreas, and for purposes of the Scientific Registry, the term also includes bone marrow.

Organ donor means a human being who is the source of an organ for transplantation into another human being.

Organ procurement organization or *OPO* means an entity so designated by the Secretary under Section 1138(b) of the Social Security Act.

Organ procurement and transplantation network or *OPTN* means the network established pursuant to Section 372 of the Act.

Potential transplant recipient or *potential recipient* means a transplant candidate who has been ranked by the OPTN computer match program as the person to whom an organ from a specific cadaveric organ donor is to be offered.

Scientific Registry means the registry of information on transplant recipients established pursuant to Section 373 of the Act.

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 national 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.

§ 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