

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 1871 of the Social Security Act (42 U.S.C. 1302, 1306, 1320b–8 and 1395hh); and section 301 of the National Organ Transplant Act, as amended (42 U.S.C. 274e).

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

§ 121.1 Applicability.

(a) The provisions of this part, with the exception of § 121.13, apply to the operation of the Organ Procurement and Transplantation Network (OPTN) and to the Scientific Registry.

(b) The provisions of § 121.13 apply to the prohibition set forth in section 301 of the National Organ Transplant Act, as amended.

(c) 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 the Social Security Act, and organ procurement organizations designated under section 1138(b) of the Social Security Act, are subject to the requirements of this part.

[63 FR 16332, Apr. 2, 1998, as amended at 64 FR 56658, Oct. 20, 1999; 72 FR 10618, Mar. 9, 2007]

§ 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.

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 waiting 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, pancreas, intestine (including the esophagus, stomach, small and/or large intestine, or any portion of the gastrointestinal tract) or vascularized composite allograft (defined in this section). Blood vessels recovered from an organ donor during the recovery of such organ(s) are considered part of an organ with which they are procured for purposes of this part if the vessels are intended for use in organ transplantation and labeled “For use in organ transplantation only.”

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 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.

Vascularized composite allograft means a body part:

- (1) That is vascularized and requires blood flow by surgical connection of blood vessels to function after transplantation;
- (2) Containing multiple tissue types;
- (3) Recovered from a human donor as an anatomical/structural unit;
- (4) Transplanted into a human recipient as an anatomical/structural unit;
- (5) Minimally manipulated (i.e., processing that does not alter the original relevant characteristics of the organ relating to the organ's utility for reconstruction, repair, or replacement);
- (6) For homologous use (the replacement or supplementation of a recipient's organ with an organ that performs the same basic function or functions in the recipient as in the donor);
- (7) Not combined with another article such as a device;
- (8) Susceptible to ischemia and, therefore, only stored temporarily and not cryopreserved; and
- (9) Susceptible to allograft rejection, generally requiring immunosuppression that may increase infectious disease risk to the recipient.

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; 78 FR 40042, July 3, 2013]

§ 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 professionals; 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