

the Secretary may require to assess the likely effects of policy changes and as are necessary to demonstrate that the proposed policies comply with the performance indicators and transition procedures of paragraphs (c) and (d) of this section.

(g) *Variations*. The OPTN may develop, in accordance with §121.4, experimental policies that test methods of improving allocation. All such experimental policies shall be accompanied by a research design and include data collection and analysis plans. Such variations shall be time limited. Entities or individuals objecting to variations may appeal to the Secretary under the procedures of §121.4.

(h) *Directed donation*. Nothing in this section shall prohibit the allocation of an organ to a recipient named by those authorized to make the donation.

[64 FR 56659, Oct. 20, 1999, as amended at 64 FR 71626, Dec. 21, 1999]

§ 121.9 Designated transplant program requirements.

(a) To receive organs for transplantation, a transplant program in a hospital that is a member of the OPTN shall abide by these rules and shall:

(1) Be a transplant program approved by the Secretary for reimbursement under Medicare; or

(2) Be an organ transplant program which has adequate resources to provide transplant services to its patients and agrees promptly to notify the OPTN and patients awaiting transplants if it becomes inactive and which:

(i) Has letters of agreement or contracts with an OPO;

(ii) Has on site a transplant surgeon qualified in accordance with policies developed under §121.4;

(iii) Has on site a transplant physician qualified in accordance with policies developed under §121.4;

(iv) Has available operating and recovery room resources, intensive care resources and surgical beds and transplant program personnel;

(v) Shows evidence of collaborative involvement with experts in the fields of radiology, infectious disease, pathology, immunology, anesthesiology, physical therapy and rehabilitation medicine, histocompatibility, and

immunogenetics and, as appropriate, hepatology, pediatrics, nephrology with dialysis capability, and pulmonary medicine with respiratory therapy support;

(vi) Has immediate access to microbiology, clinical chemistry, histocompatibility testing, radiology, and blood banking services, as well as the capacity to monitor treatment with immunosuppressive drugs; and

(vii) Makes available psychiatric and social support services for transplant candidates, transplant recipients, and their families; or

(3) Be a transplant program in a Department of Veterans Affairs, Department of Defense, or other Federal hospital.

(b) To apply to be a designated transplant program, transplant programs shall provide to the OPTN such documents as the OPTN may require which show that they meet the requirements of §121.9(a) (1), (2), or (3).

(c) The OPTN shall, within 90 days, accept or reject applications to be a designated transplant program.

(d) Applicants rejected for designation may appeal to the Secretary. Appeals shall be submitted in writing within 30 days of rejection of the application. The Secretary may:

(1) Deny the appeal; or

(2) Direct the OPTN to take action consistent with the Secretary's response to the appeal.

[63 FR 16332, Apr. 2, 1998, as amended at 64 FR 56660, Oct. 20, 1999]

§ 121.10 Reviews, evaluation, and enforcement.

(a) *Review and evaluation by the Secretary*. The Secretary or her/his designee may perform any reviews and evaluations of member OPOs and transplant programs which the Secretary deems necessary to carry out her/his responsibilities under the Public Health Service Act and the Social Security Act.

(b) *Review and evaluation by the OPTN*. (1) The OPTN shall design appropriate plans and procedures, including survey instruments, a peer review process, and data systems, for purposes of:

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(i) Reviewing applications submitted under § 121.3(c) for membership in the OPTN;

(ii) Reviewing applications submitted under § 121.9(b) to be a designated transplant program; and

(iii) Conducting ongoing and periodic reviews and evaluations of each member OPO and transplant hospital for compliance with these rules and OPTN policies.

(2) Upon the approval of the Secretary, the OPTN shall furnish review plans and procedures, including survey instruments and a description of data systems, to each member OPO and transplant hospital. The OPTN shall furnish any revisions of these documents to member OPOs and hospitals, after approval by the Secretary, prior to their implementation.

(3) At the request of the Secretary, the OPTN shall conduct special reviews of OPOs and transplant programs, where the Secretary has reason to believe that such entities may not be in compliance with these rules or OPTN policies or may be acting in a manner which poses a risk to the health of patients or to public safety. The OPTN shall conduct these reviews in accordance with such schedules as the Secretary specifies and shall make periodic reports to the Secretary of progress on such reviews and on other reviews conducted under the requirements of this paragraph.

(4) The OPTN shall notify the Secretary in a manner prescribed by the Secretary within 3 days of all committee and Board of Directors meetings in which transplant hospital and OPO compliance with these regulations or OPTN policies is considered.

(c) *Enforcement of OPTN rules*—(1) *OPTN recommendations.* The Board of Directors shall advise the Secretary of the results of any reviews and evaluations conducted under paragraph (b)(1)(iii) or paragraph (b)(3) of this section which, in the opinion of the Board, indicate noncompliance with these rules or OPTN policies, or indicate a risk to the health of patients or to the public safety, and shall provide any recommendations for appropriate action by the Secretary. Appropriate action may include removal of designation as a transplant program under

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§ 121.9, termination of a transplant hospital's participation in Medicare or Medicaid, termination of a transplant hospital's reimbursement under Medicare and Medicaid, termination of an OPO's reimbursement under Medicare and Medicaid, if the noncompliance is with a policy designated by the Secretary as covered by section 1138 of the Social Security Act, or such other compliance or enforcement measures contained in policies developed under § 121.4.

(2) *Secretary's action on recommendations.* Upon the Secretary's review of the Board of Directors' recommendations, the Secretary may:

(i) Request further information from the Board of Directors or the alleged violator, or both;

(ii) Decline to accept the recommendation;

(iii) Accept the recommendation, and notify the alleged violator of the Secretary's decision; or

(iv) Take such other action as the Secretary deems necessary.

[63 FR 16332, Apr. 2, 1998, as amended at 64 FR 56661, Oct. 20, 1999]

§ 121.11 Record maintenance and reporting requirements.

(a) *Record maintenance.* Records shall be maintained and made available subject to OPTN policies and applicable limitations based on personal privacy as follows:

(1) The OPTN and the Scientific Registry, as appropriate, shall:

(i) Maintain and operate an automated system for managing information about transplant candidates, transplant recipients, and organ donors, including a computerized list of individuals waiting for transplants;

(ii) Maintain records of all transplant candidates, all organ donors and all transplant recipients;

(iii) Operate, maintain, receive, publish, and transmit such records and information electronically, to the extent feasible, except when hard copy is requested; and

(iv) In making information available, provide manuals, forms, flow charts, operating instructions, or other explanatory materials as necessary to understand, interpret, and use the information accurately and efficiently.