

(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:

(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 § 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;

§ 121.11

42 CFR Ch. I (10–1–10 Edition)

(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.

(2) *Organ procurement organizations and transplant programs—(i) Maintenance of records.* All OPOs and transplant programs shall maintain such records pertaining to each potential donor identified, each organ retrieved, each recipient transplanted and such other transplantation-related matters as the Secretary deems necessary to carry out her/his responsibilities under the Act. The OPO or transplant program shall maintain these records for seven years.

(ii) *Access to facilities and records.* OPOs and transplant hospitals shall permit the Secretary and the Comptroller General, or their designees, to inspect facilities and records pertaining to any aspect of services per-

formed related to organ donation and transplantation.

(b) *Reporting requirements.* (1) The OPTN and the Scientific Registry, as appropriate, shall:

(i) In addition to special reports which the Secretary may require, submit to the Secretary a report not less than once every fiscal year on a schedule prescribed by the Secretary. The report shall include the following information in a form prescribed by the Secretary:

(A) Information that the Secretary prescribes as necessary to assess the effectiveness of the Nation's organ donation, procurement and transplantation system;

(B) Information that the Secretary deems necessary for the report to Congress required by Section 376 of the Act; and,

(C) Any other information that the Secretary prescribes.

(ii) Provide to the Scientific Registry data on transplant candidates and recipients, and other information that the Secretary deems appropriate. The information shall be provided in the form and on the schedule prescribed by the Secretary;

(iii) Provide to the Secretary any data that the Secretary requests;

(iv) Make available to the public timely and accurate program-specific information on the performance of transplant programs. This shall include free dissemination over the Internet, and shall be presented, explained, and organized as necessary to understand, interpret, and use the information accurately and efficiently. These data shall be updated no less frequently than every six months (or such longer period as the Secretary determines would provide more useful information to patients, their families, and their physicians), and shall include risk-adjusted probabilities of receiving a transplant or dying while awaiting a transplant, risk-adjusted graft and patient survival following the transplant, and risk-adjusted overall survival following listing for such intervals as the Secretary shall prescribe. These data shall include confidence intervals or other measures that provide information on the extent to which chance