

material, including the results of model-based computer simulations, as 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) *Variances.* 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 variances shall be time limited. Entities or individuals objecting to variances 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: