

However, it would not necessarily reduce disparities in waiting times. Only more equitable organ sharing policies can directly reduce such disparities.

D. Alternatives Considered

Throughout this preamble, we have presented and analyzed alternatives that the Department considered. Many of those selected have an importance unrelated to regulatory impact as such, or have little or no economic effect. There were, however, two broad strategic options that we elected not to pursue at this time.

First, we could have required volume or performance standards for transplant programs. The possibility of such standards was presented at the public hearings, even though we had never proposed specific standards for consideration. A great deal of research evidence exists on differences among transplant programs in survival rates (the most common measure), and on how volume correlates with those rates. Nonetheless, we rejected that approach for a number of reasons. There are a number of technical problems with such standards that could have been overcome to varying degrees. For example, a volume standard would require an exception for new programs during a transition period or it would forever preclude new programs either in the many areas of the country that do not have such programs, or to compete with established programs where those now exist. More difficult to solve, a quality standard would have to deal with the variance introduced by small programs. For example, assuming a particular program had a "true" performance rate of 50 percent for a particular procedure, and performed the first four procedures with two successes and two failures, the fifth procedure would result either in a 60 percent or 40 percent cumulative rate, making it look very much better or worse than its true performance. Two or three favorable or unfavorable results in a row would not be statistically unusual. Lucky or unlucky runs that

would substantially affect potential error in apparent versus “real” results are likely in some low volume transplant programs. Further, the need to “case mix adjust” adds significant complexity, and more variance. Yet another problem arises because standards imply “pass-fail” rates which do not necessarily push better programs to even higher performance. And still another arises because a standard set today may be obsolete a year from now as performance generally improves. Not unimportantly, virtually the consensus view of the testimony on this subject at our public hearings opposed volume and even quality standards, and favored more and better information. Using better information, patients and physicians can and will reward better transplant programs by their choices, and exert pressure on all hospitals to improve. For these and other reasons, we elected to require instead improved information on transplant program performance. We believe that better information can equal or exceed the benefits of “pass-fail” standards without their potentially arbitrary and disruptive effects.

Nothing in this volume/quality position related to minimum volume is intended to discourage large payers and prudent purchasers from setting their own standards. There is a big difference between a single national standard that every program must meet or be terminated, and elective payer standards. We encourage payers to explore and set such standards, which can even focus on levels of excellence that could not reasonably be set as nationally uniform minimum levels. We also expect the OPTN to explore setting standards of excellence, and to continue both research and modeling on such standards.

A second set of strategic options revolved around the possibility of imposing directly, at this time, specific allocation standards focusing on geographic equity. Such options would have the advantage of reducing known inequities, and could rest substantially on the very competent work already performed both by the OPTN itself and other entities. For example, without any change in medical criteria, an “inpatient first” allocation policy could be introduced for liver allocation. A “time and distance weighted” allocation

policy, with high weight given to health status, could also greatly improve equity without increasing average travel times for donor livers as much as other options (see Table 13).

Table 13
Estimated Average Miles Transported of Donated Livers
Under Alternative Liver Allocation Policies

Option for Liver Allocation	Average Distance in Miles
1996 Policy	161
National Sharing	1,072
Time and Distance Proposal	242

Source: CONSAD Modeling run provided to Dr. John Roberts December 11, 1996. This particular Time and Distance Proposal gives only medium weight to health status directly but substantial weight to waiting time, which is correlated.

We have not adopted this family of options because we believe that the performance goal approach we have crafted is likely to produce superior results quickly and maintain its relevance as technology changes. With the cooperation of the OPTN in bringing its expertise to bear, there is no reason why policies better than any yet proposed cannot be developed. In this regard, improved listing criteria and medical status criteria will both reduce the need for broader sharing and increase the professional trust and confidence needed to make that sharing work. Not only can most transplant programs expect to gain as many organs for their patients as they lose, but their own most urgent cases will benefit.

A third option would have been to take no action at this time, as urged by some. Under this option, we would defer absolutely to the OPTN's judgment in the operation of the network. We rejected it for a number of reasons. These include the demonstrated need for improvements in the equitable allocation of organs, the Secretary's vital oversight role, and the need for a system to carry out the Department's legal obligations, including decisions on what binding standards will be used to determine whether hospitals can participate in the Medicare and Medicaid programs.

E. Effects on Transplant Programs

A great deal of fear and concern was evidenced at the public hearing over effects on transplant programs, particularly smaller programs, if broader sharing were to occur. Many witnesses feared the possibility that patients would select, and organs follow to, the largest programs (some of these witnesses asserted, and others denied, that the largest programs had the best outcomes). The Department believes that such fears are exaggerated, for many reasons. Perhaps most important of these is that any such effects will depend on the policies that the OPTN itself will devise. We expect that the OPTN can identify policies that achieve equity and medical goals for patients without harming medical care institutions.

In the discussion that follows, we note again that the majority of transplant hospitals are “small entities” under the Regulatory Flexibility Act simply by virtue of their non-profit status, and that there is no known correlation of size of transplant program with size of parent institution (beyond the fact that most small hospitals do not conduct transplant programs at all).

For the most part, the smaller transplant programs already compete directly with larger programs, even within the “local first” allocation schemes, or have the only program in their metropolitan area. As shown selectively in Table 14 below (covering one-fourth of the States in alphabetical order), and graphically on the map below, the approximately 112 liver transplant programs active in 1995 were concentrated in a far smaller number of cities. In fact, about a dozen States had no liver transplantation program at all.

Table 14

Number of Small, Medium and Large Volume Liver Programs in Selected States

State	City	No. Small (<12)	No. Medium (12-34)	No. Large (35>)	Total
AL	Birmingham	0	0	1	1
AK	None in Alaska	0	0	0	0
AR	None in Arkansas	0	0	0	0
AZ	Phoenix	1	0	0	1
	Tucson	0	1	0	1
CA	Los Angeles area	1	2	2	5
	Sacramento	1	0	0	1
	San Diego area	0	2	0	2
	San Francisco Bay area	0	0	3	3
CO	Denver	2	0	1	3
CT	Hartford	1	0	0	1
	New Haven	0	1	0	1
DC	Washington area	1	0	1	2
FL	Gainesville	0	0	1	1
	Miami	0	0	1	1
GA	Atlanta	1	0	1	2
HI	Honolulu	1	0	0	1
IL	Chicago	0	2	2	4
IN	Indianapolis	0	1	1	2
Total	17 Cities	9	9	14	32

Source: OPTN and Scientific Registry data supplied to the Department, through 1995, dated March 1, 1996.

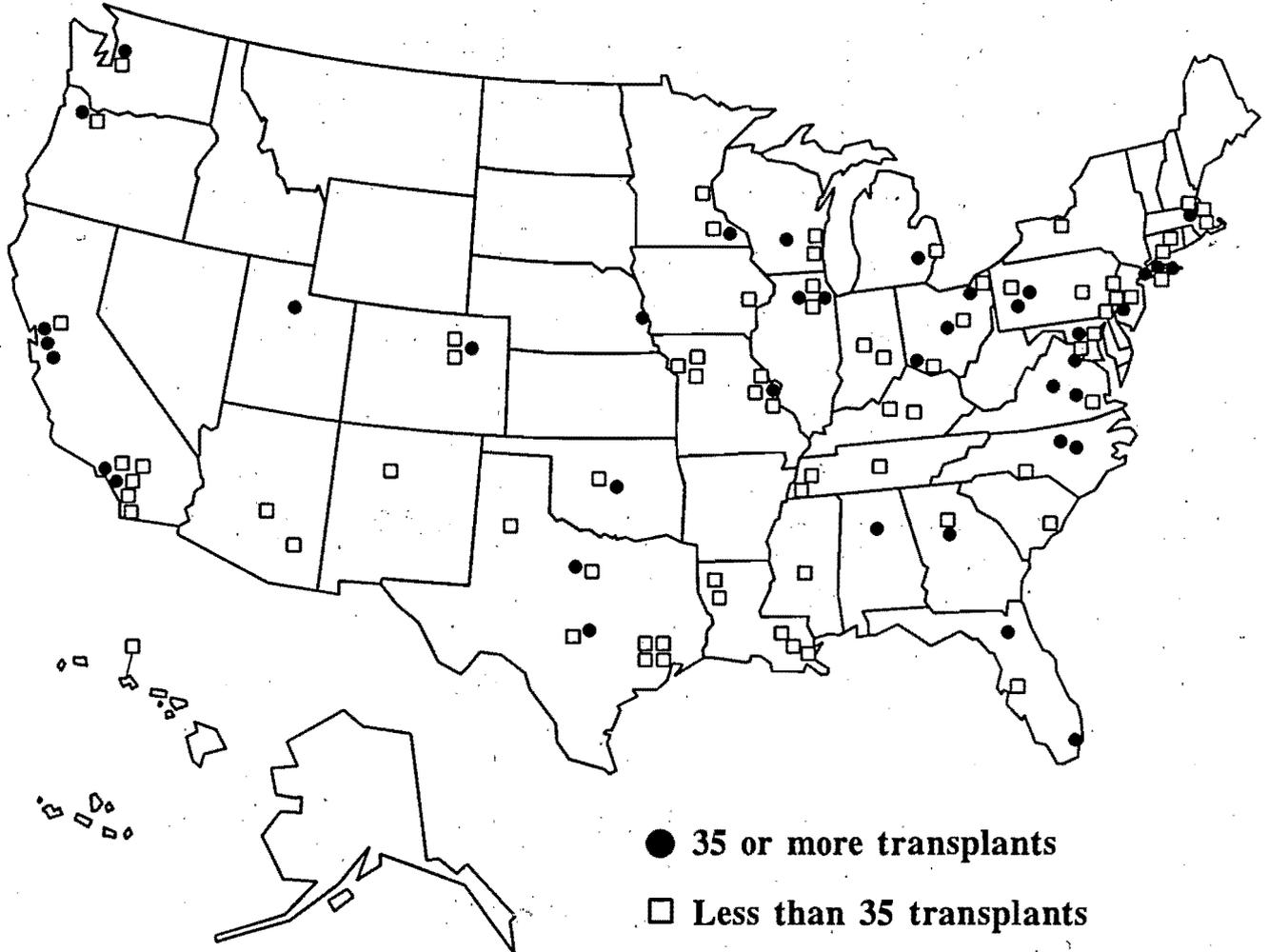
These 13 States and 17 metropolitan areas contain 32 liver transplant programs (the hundreds of remaining metropolitan areas, smaller cities, and rural areas in these States have no local transplant programs--their patients must travel). Of the nine small (fewer than 12 transplants annually) programs,

four have no local competitors. These four have effective local monopolies for those patients (undoubtedly a majority) who would prefer local transplantation if given a choice. The five with competitors are already surviving strong competition in their own health market. Thus, with or without changes in allocation policy that favor broader sharing, these transplant hospitals have substantial advantages or a demonstrated capacity to withstand competition for patients.

The map below shows the pattern of choice for the entire nation, grouping all transplant hospitals into small and medium (less than 35 transplants) or large (35 or more transplants). It shows that most

Distribution of All Current Liver Transplant Programs

by 1995 Volume



transplant hospitals already share cities or are located in closely adjacent cities.

Another potential concern arises from the fact that on average, smaller transplant hospitals serve relatively less sick patients and larger transplant hospitals tend to handle more hospitalized patients (Status 1 and 2) (there are numerous exceptions to these average tendencies). If nothing else changed

but the relative ability of the sickest patients to obtain organs, smaller transplant hospitals would be expected to lose transplant volume. One of the modeling firms, CONSAD, addressed this issue. As summarized in Table 15, its modeling shows the following percentage shares of patients transplanted at medium and large transplant hospitals under the alternative policies modeled, assuming no behavioral responses by the programs.

Table 15

Liver Transplants	1996 Policy	Allocation Committee	Inpatient First	National
Large programs (>35)	40%	45%	51%	52%
Medium programs (12-34)	37%	34%	30%	30%
Smaller programs (<12)	24%	21%	19%	18%

Source: CONSAD modeling run, dated March 24, 1997

This result assumes that programs continue their current policies as to which patients they tend to transplant, e.g., that smaller transplant hospitals do not more aggressively seek to retain the sickest patients. That seems extremely unlikely. Why would a program that is worried about volume not change its practices to improve its volume? But even in this “worst” case for smaller centers, they still perform 18 percent of total liver transplantation, and the medium programs still perform 30 percent of total liver transplantation. Far more likely, “threatened” programs will strengthen their programs and attract as many or more patients than they do at this time.

Finally, all of these computer simulations assume that the number of available organs remains unchanged. We believe that improved use of OPOs in identifying candidates for donation and in contacting families of potential donors to request permission can alone significantly improve organ supply. Data suggest that the Pennsylvania mandatory referral program has increased by about 40

percent the number of organ donors. The other actions that the Department will take can also have significant effects in increasing donation. Thus, it is quite likely that transplant programs of all sizes will see volume increases from the entire package of reforms. Our expectation that on average donations can be raised by about 20% over two years would allow all centers to increase the number of patients they transplant.

In sum, nothing in the available data nor reasonable expectations as to future business strategies by transplantation programs suggest either that smaller transplant hospitals will be driven out of business or that patients in cities served by smaller centers will be deprived of local service. However, the Department will monitor and review OPTN practices and policies as to their potential impacts on transplant institutions.

IV. Paperwork Reduction Act of 1995

This final rule contains information collections which have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 and assigned control number 0915-0184 with an expiration date June 30, 1998. In addition, there are reporting and disclosure requirements that have not yet been approved (as noted in the table). The title, description, and respondent description of all information collections are shown below with an estimate of the annual reporting and record keeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: Organ Procurement and Transplantation Network.

Description: Information will be collected from transplant hospitals, organ procurement organizations, and histocompatibility laboratories for the purpose of matching donor organs with potential recipients, monitoring compliance of member organizations with system rules, conducting statistical analyses, and developing policies relating to organ procurement and transplantation.

The practical utility of the data collection is further enhanced by requirements that the OPTN must report a variety of data to the Secretary, including data on performance by organ and status category, including program-specific data, OPO specific data, data by program size, and data aggregated by organ procurement area, OPTN region, the nation as a whole, and other geographic areas (§ 121.8(a)(4)(iv)). The OPTN must also transmit proposed allocation policies and performance indicators which will be used to assess the likely effects of policy changes and to ensure that the proposed policies are consistent with these rules.

The OPTN and Scientific Registry must make available to the public timely and accurate information the performance of transplant programs, and must respond to requests from the public for data needed for bona fide research or analysis purposes or to assess the performance of the OPTN or Scientific Registry, to assess individual transplant programs, or for other purposes (§ 121.11(b)(1)(C)).

The OPTN must provide to each member OPO and transplant hospital the plans and procedures for reviewing applications and for monitoring compliance with these rules and OPTN policies. The OPTN must also report to the Secretary on OPOs and transplant hospitals that may not be in compliance with these rules or OPTN policies, and on their progress toward compliance.

The OPTN and Scientific Registry are required to maintain and manage the information on candidates, donors, and recipients.

Description of Respondents: Non-profit institutions and small organizations.

ESTIMATED ANNUAL REPORTING AND RECORD KEEPING BURDEN:

Section	Activity	Annual Number	Annual Frequency of Respondents	Average Burden Per Response	Annual Burden Hours
121.3(c)(2)	OPTN membership application requirements for OPOs, hospitals, histo-compatibility laboratories	30	1***	40	1,200
121.6(c)** (Reporting)	Submitting criteria for organ accept.	900	1	0.1	90
121.6(c)** (Disclosure)	Sending criteria to OPOs	900	1	0.1	90
121.7(b)(4)	Reasons for refusal	900	38	0.1	3,400
121.7(e)*	Transplant to prevent organ wastage	900	.5	0.1	42
121.9(b)	Certification application requirements for transplant programs	10	1***	2.0	20
121.11(b)(2)*	Transplant candidate registration	900	33	0.1	3,000
121.11(b)(2)*	Donor registration	63	159	0.2	2,000

121.11(b)(2)* Potential Recipient	63	476	0.1	3,000
121.11(b)(2)* Donor Histocompatibility	56	143	0.1	800
121.11(b)(2)* Transplant Recipient Histocom.	56	321	0.1	1,800
121.11(b)(2)* Transplant Recipient Registration	900	23	0.25	5,250
121.11(b)(2)* Transplant Recipient Follow-up	<u>900</u>	<u>128</u>	<u>0.2</u>	<u>23,000</u>
Total	1,059			43,692

* The data collection forms for these activities have been approved by the Office of Management and Budget under the Paperwork Reduction Act (OMB No. 0915-0157).

** These requirements have been submitted for OMB approval. These requirements will not be effective until the Department obtains OMB approval.

*** Current members of the OPTN and currently certified transplant programs will not have to re-apply for membership and certification following promulgation of the new regulation. Only new applicants will be required to apply, one time.

The final rules also require OPOs and transplant hospitals to maintain records, as follows:

<u>Section</u>	<u>Requirement</u>
121.7(b)(4)	Documentation of reason for refusal
121.7(c)(2)	Documentation of suitability tests
121.11(a)(2)	Maintain records on organ donors and recipients

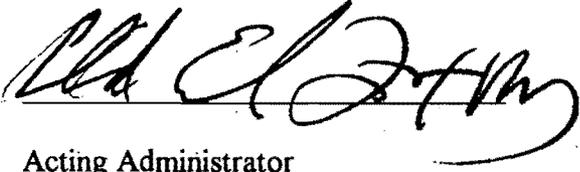
According to staff of OPOs and transplant hospitals, such record keeping is integral to the operation of these facilities. Therefore, these record keeping requirements impose no additional burden. In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104-13), comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Written comments and recommendations concerning the proposed information collection should be sent to: Patricia Royston, HRSA Reports Clearance Officer, Room 14-36, Parklawn Building, 5600 Fishers Lane, Rockville, MD, 20857. Comments should be received within 60 days after publication of this document in the Federal Register.

List of Subjects in 42 CFR Part 121

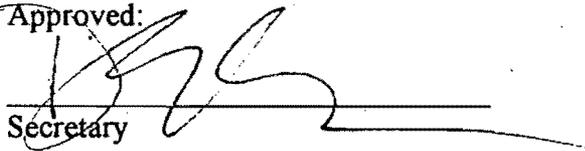
Organs-human, Organ procurement and transplantation network, Organ transplantation, Hospitals.

Dated:



Acting Administrator
Health Resources and Services
Administration

Approved:


Secretary

REGULATION TEXT

Accordingly, 42 CFR Part 121 is added to Subchapter K to read as follows:

Part 121-Organ Procurement and Transplantation Network

Sec.

121.1 Applicability.

121.2 Definitions.

121.3 The OPTN.

121.4 OPTN Policies; Secretarial Review and Appeals.

121.5 Listing requirements.

121.6 Organ procurement.

121.7 Identification of organ recipient.

121.8 Allocation of organs.

121.9 Designated transplant program requirements.

121.10 Reviews, evaluation, and enforcement.

121.11 Record maintenance and reporting requirements.

121.12 Preemption.

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).

§ 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) 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 practicable, 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

(iii) Other organizations, institutions, and individuals that have an interest in the fields of

organ donation or transplantation.

(2) To apply for membership in the OPTN:

(i) an OPO shall provide to the OPTN the name and address of the OPO, and the latest year of designation under section 1138(b) of the Social Security Act;

(ii) a transplant hospital shall provide to the OPTN the name and address of the hospital, a list of its transplant programs by type of organ; and

(iii) any other organization, institution, or individual eligible under paragraph (c)(1)(iii) of this section shall demonstrate to the OPTN an interest in the fields of organ donation or transplantation.

(3) The OPTN shall accept or reject as members entities or individuals described in paragraph (c)(1)(iii) of this section within 90 days.

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

(i) deny the appeal; or

(ii) direct the OPTN to take action consistent with the Secretary's response to the appeal.

(d) Corporate Status of the OPTN

(1) The OPTN shall be a private, not-for-profit entity.

(2) The requirements of this section do not apply to any parent, sponsoring, or affiliated organization of the OPTN, or to any activities of the contracting organization that are not integral to the operation of the OPTN. Such an organization is free to establish its own corporate procedures.

(3) No OPTN member is required to become a member of any organization that is a parent, sponsor, contractor, or affiliated organization of the OPTN, to comply with the by-laws of any such organization, or to assume any corporate duties or obligations of any such organization.

(e) Effective Date

The organization designated by the Secretary as the OPTN shall have six months from (insert the effective date of this regulation), or six months from its initial designation as the OPTN, whichever is later, to meet the board composition requirements of paragraph (a) of this section. The organization designated by the Secretary as the OPTN shall have six months from (insert effective date of this regulation), or six months from initial designation as the OPTN, whichever is later, to meet any other requirements of this section, except that the Secretary may extend such period for good cause.

§ 121.4 OPTN Policies: Secretarial Review and Appeals.

(a) The OPTN Board of Directors shall be responsible for developing, with the advice of the OPTN membership and other interested parties, policies within the mission of the OPTN as set forth in section 372 of the Act and the Secretary's contract for the operation of the OPTN, including:

- (1) policies for the equitable allocation of cadaveric organs in accordance with § 121.8;
- (2) policies, consistent with recommendations of the Centers for Disease Control and Prevention, for the testing of organ donors and follow-up of transplant recipients to prevent the spread of infectious diseases;
- (3) policies that reduce inequities resulting from socioeconomic status, including, but not

limited to:

(i) ensuring that patients in need of a transplant are listed without regard to ability to pay or source of payment;

(ii) procedures for transplant hospitals to make reasonable efforts to make available from their own resources, or obtain from other sources, financial resources for patients unable to pay such that these patients have an opportunity to obtain a transplant and necessary follow-up care;

(iii) recommendations to private and public payers and service providers on ways to improve coverage of organ transplantation and necessary follow-up care; and

(iv) reform of allocation policies based on assessment of their cumulative effect on socioeconomic inequities;

(4) policies regarding the training and experience of transplant surgeons and transplant physicians in designated transplant programs as required by § 121.9;

(5) policies for nominating officers and members of the Board of Directors; and

(6) policies on such other matters as the Secretary directs.

(b) The Board of Directors shall:

(1) provide opportunity for the OPTN membership and other interested parties to comment on proposed policies and shall take into account the comments received in developing and adopting policies for implementation by the OPTN; and

(2) provide, at least 30 days prior to their proposed implementation, proposed policies to the Secretary, who may provide comments and/or objections within a reasonable time, or may publish the policies in the Federal Register to obtain comments from the public. The Board of Directors shall indicate which of the proposed policies it recommends be enforceable under §

121.10. If the Secretary seeks public comments, these comments will be considered and may affect subsequent response to the OPTN. The OPTN shall take into account any comments the Secretary may provide. If the Secretary objects to a policy, the OPTN may be directed to revise the policy consistent with the Secretary's direction. If the OPTN does not revise the policy in a timely manner or if the Secretary otherwise disagrees with its content, the Secretary may take such other action as the Secretary determines appropriate.

(c) The OPTN Board of Directors shall provide the membership and the Secretary with copies of the policies as they are adopted, and make them available to the public upon request. The Secretary will publish lists of these documents in the Federal Register, indicating which ones are subject to the special compliance requirements and potential sanctions of section 1138 of the Social Security Act. The OPTN shall also continuously maintain OPTN policies for public access on the Internet, including current and proposed policies.

(d) The OPTN, or its members, or other individuals, or entities objecting to policies developed by the OPTN or the Secretary may submit appeals to the Secretary in writing. Any such appeal shall include a statement of the basis for the appeal. The Secretary will seek the comments of the OPTN on the issues raised in the appeal of an OPTN-developed policy.

Policies remain in effect during the appeal. The Secretary may:

(1) deny the appeal;

(2) direct the OPTN to revise the policies consistent with the Secretary's response to the appeal, or

(3) take such other action as the Secretary determines appropriate.

(e) The OPTN shall implement policies and:

(1) provide information to OPTN members about these policies and the rationale for them.

(2) update policies developed in accordance with this section to accommodate scientific and technological advances.

§ 121.5 Listing requirements.

(a) A transplant hospital which is an OPTN member may list individuals only for a designated transplant program.

(b) Transplant hospitals shall assure that individuals are placed on the national list as soon as they are determined to be candidates for transplantation. The OPTN shall advise transplant hospitals of the information needed for such listing.

(c) An OPTN member shall pay a registration fee to the OPTN for each transplant candidate it places on the national list. The amount of such fee shall be determined by the OPTN with the approval of the Secretary. No less often than annually, and whether or not a change is proposed, the OPTN shall submit to the Secretary a statement of its proposed registration fee, together with such supporting information as the Secretary finds necessary to determine the reasonableness or adequacy of the fee schedule and projected revenues. This submission is due at least three months before the beginning of the OPTN's fiscal year. The Secretary will approve, modify, or disapprove the amount of the fee within a reasonable time of receiving the OPTN's submission.

§ 121.6 Organ procurement. The suitability of organs donated for transplantation shall be

determined as follows:

(a) Tests. An OPTN member procuring an organ shall assure that laboratory tests and clinical examinations of potential organ donors are performed to determine any contraindications for donor acceptance, in accordance with policies established by the OPTN.

(b) HIV. Organs from individuals known to be infected with human immunodeficiency virus shall not be procured for transplantation.

(c) Acceptance criteria. Transplant programs shall establish criteria for organ acceptance, and shall provide such criteria to the OPTN and the OPOs with which they are affiliated.

§ 121.7 Identification of organ recipient.

(a) List of potential transplant recipients.

(1) An OPTN member procuring an organ shall operate the OPTN computer match program within such time as the OPTN may prescribe to identify and rank potential recipients for each cadaveric organ procured.

(2) The rank order of potential recipients shall be determined for each cadaveric organ using the organ specific allocation criteria established in accordance with § 121.8.

(3) When a donor or donor organ does not meet a transplant program's donor acceptance criteria, as established under § 121.6(c), transplant candidates of that program shall not be ranked among potential recipients of that organ and shall not appear on a roster of potential recipients of that organ.

(b) Offer of organ for potential recipients.

(1) Organs shall be offered for potential recipients in accordance with policies developed under § 121.8 and implemented under § 121.4.

(2) Organs may be offered only to potential recipients listed with transplant programs having designated transplant programs of the same type as the organ procured.

(3) An organ offer is made when all information necessary to determine whether to transplant the organ into the potential recipient has been given to the transplant hospital.

(4) A transplant program shall either accept or refuse the offered organ for the designated potential recipient within such time as the OPTN may prescribe. A transplant program shall document and provide to the OPO and to the OPTN the reasons for refusal and shall maintain this document for one year.

(c) Transportation of organ to potential recipient.

(1) Transportation. The OPTN member that procures a donated organ shall arrange for transportation of the organ to the transplant hospital.

(2) Documentation. The OPTN member that is transporting an organ shall assure that it is accompanied by written documentation of activities conducted to determine the suitability of the organ donor and shall maintain this document for one year.

(3) Packaging. The OPTN member that is transporting an organ shall assure that it is packaged in a manner that is designed to maintain the viability of the organ.

(d) Receipt of an organ. Upon receipt of an organ, the transplant hospital responsible for the potential recipient's care shall determine whether to proceed with the transplant. In the event that an organ is not transplanted into the potential recipient, the OPO which has a written agreement with the transplant hospital must offer the organ for another potential recipient in

accordance with paragraph (b) of this section.

(e) Wastage. Nothing in this section shall prohibit a transplant program from transplanting an organ into any medically suitable candidate if to do otherwise would result in the organ not being used for transplantation. The transplant program shall notify the OPTN and the OPO which made the organ offer of the circumstances justifying each such action within such time as the OPTN may prescribe.

§ 121.8 Allocation of organs.

(a) Policy development. The Board of Directors established under § 121.3 shall develop, in accordance with the policy development process under § 121.4, organ-specific policies (including combinations of organs, such as for heart-lung transplants) for the equitable allocation of cadaveric organs among potential recipients. Such policies shall meet the requirements in paragraphs (1), (2), (3), (4) and (5) below. Such policies shall be reviewed periodically and revised as appropriate.

(1) Minimum listing criteria for including transplant candidates on the national list shall be standardized and, to the extent possible, shall contain explicit thresholds for listing a patient and be expressed through objective and measurable medical criteria.

(2) Transplant candidates shall be grouped by status categories ordered from most to least medically urgent, with a sufficient number of categories to avoid grouping together persons with substantially different medical urgency. Criteria for status designations shall contain explicit thresholds for differentiating among patients and shall be expressed, to the extent possible, through objective and measurable medical criteria.

(3) Organ allocation policies and procedures shall be in accordance with sound medical judgment and shall be designed and implemented:

(i) to allocate organs among transplant candidates in order of decreasing medical urgency status, with waiting time in status used to break ties within status groups. Neither place of residence nor place of listing shall be a major determinant of access to a transplant. For each status category, inter-transplant program variance in the performance indicator "waiting time in status" shall be as small as can reasonably be achieved, consistent with paragraph (a)(3)(ii). Priority shall be given to reducing the waiting time variance in the most medically urgent status categories before reducing the waiting time variance in less urgent status categories, if equivalent reductions cannot be achieved in all status categories; and

(ii) to avoid futile transplantation, to avoid wasting organs, and to promote efficient management of organ placement.

(4) The OPTN shall:

(i) develop mechanisms to promote and review compliance with each of these goals;

(ii) develop performance indicators to facilitate assessment of how well current and proposed policies will accomplish these goals;

(iii) use performance indicators, including indicators described in subparagraph (iv) below, to establish baseline data on how closely the results of current policies approach these goals and to establish the projected amount of improvement to result from proposed policies; and

(iv) timely report data to the Secretary on performance by organ and status category, including program-specific data, OPO specific data, data by program size, and data aggregated by

organ procurement area, OPTN region, the nation as a whole, and such other geographic areas as the Secretary may designate. Such data shall include inter-transplant program variation in waiting time in status, total life years pre- and post-transplant, patient and graft survival rates following transplantation, patients mis-classified by status, and number of patients who die waiting for a transplant. Such data shall cover such intervals of time, and be presented using confidence intervals or other measures of variance, as appropriate to avoid spurious results or erroneous interpretation due to small numbers of patients covered.

(5) Transition.

(i) General. When the OPTN revises organ allocation policies under this section, it shall consider whether to adopt transition procedures that would treat people on the national list and awaiting transplantation prior to the adoption or effective date of the revised policies no less favorably than they would have been treated under the previous policies. The transition procedures shall be transmitted to the Secretary for review together with the revised allocation policies.

(ii) Special rule for initial revision of liver allocation policies. When the OPTN transmits to the Secretary its initial revision of the liver allocation policies, as directed by paragraph (c)(2) of this Section, it shall include transition procedures that, to the extent feasible, treat each individual on the national list and awaiting transplantation on (insert date of publication in the Federal Register) no less favorably than he or she would have been treated had the revised liver allocation policies not become effective. These transition procedures may be limited in duration or applied only to individuals with greater than average medical urgency if this would significantly improve administration of the list or if such limitations would be applied only after

accommodating a substantial preponderance of those disadvantaged by the change in the policies.

(b) Secretarial Review of Policies and Performance Indicators. The OPTN's transmittal to the Secretary of proposed allocation policies and performance indicators shall include such supporting 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 paragraph (a) of this section.

(c) Deadlines for Initial Reviews.

(1) The OPTN shall conduct an initial review of existing allocation policies and, except as provided in paragraph (c)(2) of this section, no later than (insert date one year after the effective date of this regulation) transmit initial revised policies to meet the requirements of § 121.8 (a), together with supporting documentation to the Secretary for review in accordance with § 121.4.

(2) No later than (insert date 60 days after the effective date of this regulation) the OPTN shall transmit revised policies and supporting documentation for liver allocation to meet the requirements of § 121.8 (a) to the Secretary for review in accordance with § 121.4. The OPTN may transmit these materials without seeking further public comment under § 121.4(b) or (c).

(d) Variations. The OPTN may develop 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.

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

§ 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 and Medicaid; 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 hospital which is a Dean's Committee hospital which shares a common university-based transplant team of a transplant program which meets the requirements of § 121.9(a)(1) or (2).

(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.

§ 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, or 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.

(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.

§ 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 national 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 performed 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 and shall include three month, one year, three year and five year graft and patient survival rates, both actual and statistically expected, and shall be presented no more than six months later than the period to which they apply. Data presented shall include confidence

intervals or other measures that provide information on the extent to which chance may influence transplant program-specific results. Such data shall also include such other cost or performance information as the Secretary may specify, including but not limited to transplant program-specific information on waiting time within medical status, organ wastage, and refusal of organ offers. These data shall also be presented no more than six months later than the period to which they apply;

(v) respond to reasonable requests from the public for data needed for *bona fide* research or analysis purposes, to the extent that the OPTN's or Scientific Registry's resources permit, or as directed by the Secretary. The OPTN or the Scientific Registry may impose reasonable charges for the separable costs of responding to such requests. Patient-identified data may be made available to *bona fide* researchers upon a showing that the research design requires such data for matching or other purposes, and that appropriate confidentiality protections, including destruction of patient identifiers upon completion of matching, will be followed. All requests shall be processed expeditiously, with data normally made available within 30 days from the date of request;

(vi) respond to reasonable requests from the public for data needed to assess the performance of the OPTN or Scientific Registry, to assess individual transplant programs, or for other purposes. The OPTN or Scientific Registry may impose charges for the separable costs of responding to such requests. An estimate of such charges shall be provided to the requester before processing the request. All requests should be processed expeditiously, with data normally made available within 30 days from the date of request; and

(vii) provide data to an OPTN member, without charge, that has been assembled, stored,

or transformed from data originally supplied by that member.

(2) An organ procurement organization or transplant hospital shall, as specified from time to time by the Secretary, submit to the OPTN, to the Scientific Registry, as appropriate, and to the Secretary information regarding transplantation candidates, transplant recipients, donors of organs, transplant program performance, and other information that the Secretary deems appropriate. Such information shall be in the form required and shall be submitted in accordance with the schedule prescribed. No restrictions on subsequent redisclosure may be imposed by any organ procurement organization or transplant hospital.

(c) Public access to data. The Secretary may release to the public information collected under this section when the Secretary determines that the public interest will be served by such release. The information which may be released includes, but is not limited to, information on the comparative costs and patient outcomes at each transplant program affiliated with the OPTN, transplant program personnel, information regarding instances in which transplant programs refuse offers of organs to their patients, information regarding characteristics of individual transplant programs, information regarding waiting time at individual transplant programs, and such other data as the Secretary determines will provide information to patients, their families, and their physicians that will assist them in making decisions regarding transplantation.

§121.12 Preemption.

No State or local governing entity shall establish or continue in effect any law, rule, regulation, or other requirement that would restrict in any way the ability of any transplant hospital, OPO, or

other party to comply with organ allocation policies of the OPTN or other policies of the OPTN that have been approved by the Secretary under this Part.