DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR PART 121

[Docket Number: 98–HRSA–01]

RIN 0906–AA32

Organ Procurement and Transplantation Network

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Final rule with comment period.

SUMMARY: This document sets forth the final rule governing the operation of the Organ Procurement and Transplantation Network (OPTN), which performs a variety of functions related to organ transplantation under contract with HHS. The document also offers a 60 day period for additional public comment. The rule will become effective 30 days following the close of the comment period. If the Department believes that additional time is required to review the comments, we will consider delaying the effective date. In combination with a new National Organ and Tissue Donation Initiative, this rule is intended to improve the effectiveness and equity of the Nation's transplantation system and to further the purposes of the National Organ Transplant Act of 1984, as amended. These purposes include: encouraging organ donation; developing an organ allocation system that functions as much as technologically feasible on a nationwide basis; providing the bases for effective Federal oversight of the OPTN (as well as for implementing related provisions in the Social Security Act); and, providing better information about transplantation to patients, families and health care providers.

DATES: These regulations are effective July 1, 1998.

Comments on this final rule are invited. To ensure consideration, comments must be received by June 1, 1998.

ADDRESSES: Written comments should be addressed to Jon L. Nelson, Associate Director, Office of Special Programs, Room 123, Park Building, 12420 Parklawn Drive, Rockville, MD 20857. All comments received will be available for public inspection and copying at the above address, weekdays (Federal holidays excepted) between the hours of 9:00 a.m. and 4:00 p.m. A copy of this rule, and selected background materials, will be posted on the Division of Transplantation Internet site at http://www.hrsa.dhhs.gov/bhrd/dot/dotmain.htm.

FOR FURTHER INFORMATION CONTACT: Jon L. Nelson, Associate Director, Office of Special Programs, Room 7–29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857; telephone (301) 443–7577.

SUPPLEMENTARY INFORMATION: Over the past two decades, the safety and survival rates for transplantation of human organs have improved markedly, and the number of transplants has increased. In 1996, about 20,000 transplants were performed in the United States. At the same time, the rapid development of transplant techniques and the growth of the Nation's transplant system present new challenges:

1. *The demand for organs for transplantation exceeds the supply, and this gap is growing.* About 4,000 persons died in 1996 while awaiting transplantation.

2. *The Nation's organ allocation system remains heavily weighted to the local use of organs instead of making organs available on a broader regional or national basis for patients with the greatest medical need consistent with sound medical judgment.* Technological advances have made it possible to preserve organs longer and share them more widely, but the allocation system does not yet take full advantage of this capacity. Instead, some patients with less urgent medical need receive transplants before other patients with greater medical need whether listed locally or away from home.

3. *The criteria used in listing those who need transplantation vary from one transplant center to another, as do the criteria used to determine the medical status of a patient.* This lack of uniform, medically objective criteria make it difficult to compare the medical need of patients in different centers.

4. *As a result of both the local preference in allocation and the lack of standard medical criteria, waiting times for organs are much longer in some geographic areas than in others.* The statute envisions a national allocation system, based on medial criteria, which results in the equitable treatment of transplant patients. But equitable treatment cannot be assured if medical criteria vary from one transplant center to another and if allocation policies prevent suitable organs from being offered first to those with the greatest medical need.

5. *Useful, current, transplant-center specific data for patients and health care providers are not available, despite information technology advances that make more current reporting feasible.*

Efforts are needed to address these challenges in the areas of both donation and allocation:

In order to bring about substantial increases in the number of organ donors and the number of transplants performed each year, a new National Organ and Tissue Donation Initiative has been launched. Working in partnership with national and local organizations, the Department of Health and Human Services (HHS) seeks to increase donation through encouraging more individuals to chose to be organ donors and that share that decision with their families; through improved performance by hospitals and organ procurement organizations toward ensuring that the families of potential donors are given the opportunity to allow donation; through higher consent rates by families, especially by encouraging those who elect to be organ donors to inform their families of their decision; and through new research on enhancing donation. Proposed regulations affecting hospitals and organ procurement organizations were published December 19, 1997 (62 FR 66725). The Department expects that the supply of organs may be raised by about 20 percent through this initiative, which would greatly alleviate organ shortages.

In order to improve allocation of organs for transplantation, this final rule establishes performance goals to be achieved by the OPTN. Actions already underway in the OPTN are consistent with several of these goals. The rule does not establish specific allocation policies, but instead looks to the organ transplant community to take action to meet the performance goals. The goals include:

- Minimum Listing Criteria—The OPTN is required to define objective and measurable medical criteria to be used by all transplant centers in determining whether a patient is appropriate to be listed for a transplant. In this way, patients with essentially the same medical need will be listed in the same way at all transplant centers.
- Status Categories—The OPTN is required to determine objective medical criteria to be used nationwide in determining the medical status of those awaiting transplantation. This will provide a common measurement for use by all transplant centers in determining the urgency of an individual's medical condition, and it will facilitate OPTN efforts to direct organs to those with greatest medical need, in accordance with sound medical judgment.
- Equitable Allocation—The OPTN is required to develop equitable allocation policies that provide organs to those with the greatest medical urgency, in accordance with sound medical judgment. This increases the likelihood of patients obtaining matching organs,

and gives all patients equal chances to obtain organs compared to other patients of equal medical status, wherever they live or list.

By requiring common criteria for listing eligibility and medical status, and by requiring that organs be directed so as to equalize waiting times, especially for those with greatest medical need, this rule is designed to provide patients awaiting transplants with equal access to organs and to provide organs to sickest patients first, consistent with sound medical judgment. While present OPTN policies give weight to medical need, the ''local first'' practice thwarts organ allocation over a broad area and thus prevents medical need from being the dominant factor in allocation decisions.

Under the provisions of this rule, it is intended that the area where a person lives or the transplant center where he or she is listed will not be primary factors in how quickly he or she receives a transplant. Instead, organs will be allocated according to objective standards of medical status and need. In this way, suitable organs will reach patients with the greatest medical need, both when they are procured locally and when they are procured outside the listed patients' areas. This objective reflects the views of many commenters on the proposed regulations, as well as the finding of the American Medical Association in its *Code of Medical Ethics:* ''Organs should be considered a national, rather than a local or regional resource. Geographical priorities in the allocation of organs should be prohibited except when transportation of organs would threaten their suitability for transplantation.''

The OPTN is required to develop proposals for the new allocation policies (except for livers) within a year of the effective date of the final rule. In the case of liver allocation policies, where policy development work has been underway for several years, the OPTN is required to develop a new proposed allocation policy within 60 days of the effective date.

Other provisions of this rule include requirements that the OPTN make more current data available for the public, including measures of performance of individually identified transplant centers. This information is needed by patients, families, physicians, and payers in choosing a course of action and is needed as a quality measurement instrument.

In addition, the rule defines the governing structure of the OPTN and outlines procedures for the establishment of policies by the OPTN that include appropriate participation by transplant professionals and families, with oversight by HHS. The rule also includes a requirement that the OPTN develop a ''grandfathering'' proposal for patients currently awaiting liver transplantation so that these patients are treated no less favorably under the new allocation policies than they would have been under current allocation policies. The OPTN also is required to develop proposed transition policies for the initial changes required by this rule to its allocation policies for other organs.

The National Organ and Tissue Donation Initiative and this final rule build on more than a decade of experience, including improving medical technology, to create a national community of organ sharing and to save and improve more lives through transplantation. The rule defines Federal expectations, based on the role given to the Secretary under the statute, but looks to the OPTN to propose policy choices that meet those expectations.

The remainder of this preamble is arranged under the following headings.

I. Background

A. Overview

The National Organ Transplant Act of 1984 (NOTA) created the Organ Procurement and Transplantation Network (OPTN). The Act has been the subject of two major sets of amendments. In each instance, the Congress acted to encourage the development of a fair, national system of organ allocation. The original statute (Pub. L. 98–507, title II, § 201, formerly codified at 42 U.S.C. 274(b)(2)(C)) required the OPTN to ''assist organ procurement organizations in the distribution of organs *which cannot be placed within the service areas of the organizations.*'' (Emphasis supplied.) However, the underscored language was removed in a 1988 amendment to the NOTA (Pub .L. 100–607, title IV, § 403, formerly codified at 42 U.S.C. 274(b)(2)(D)), according to the Senate ''so as to remove any statutory bias respecting the important question of criteria for the proper distribution of organs among patients.'' S. Rep. No. 100–310 at 14–15 (1988). In 1990, this language was again rewritten, this time to require that the OPTN ''assist organ procurement organizations in the *nationwide* distribution of organs *equitably among transplant patients.*'' (Emphasis supplied.) Pub. L. 101–616, title II, § 202, now codified at 42 U.S.C. 274(b)(2)(D). The Senate explained that ''[b]ecause the demand for transplantable organs is expected to continue to be considerably greater than the supply, a fair and equitable organ sharing system is critical to the future of a national transplant program that the public will support.'' S. Rep. No. 101–530 at 7 (1990) (The 1990 amendments also required that the OPTN report on comparative costs and patient outcomes at all transplant centers). As discussed in more detail below, in 1986 the Congress also amended the Social Security Act to make OPTN membership, and compliance with allocation policies approved by the Secretary, mandatory rather than voluntary for Medicare-participating hospitals and all organ procurement organizations.

Thus, the Congress envisioned an equitable national system that would be

operated by the transplant community—including physicians and officials of transplant facilities as well as other specialists and individuals representing transplant patients, their families, and the general public—with oversight by HHS.

Human organs that are donated for transplantation are a public trust. These regulations are intended to ensure that donated organs are equitably allocated among all patients, with priority to those most in need in accordance with sound medical judgment. These regulations also complement the recently announced National Organ and Tissue Donation Initiative. The initiative addresses the fact that organ donation has not kept pace with the need. Only about a third of potential cadaveric donations are made; and, when families are asked, only about half give consent. The initiative seeks to improve the number of potential donors identified and asked to donate organs. This improvement would be accomplished through proposed rules, published in the **Federal Register** on December 19, 1997, which would require Medicare-participating hospitals to work more closely with local organ procurement organizations. A similar approach was adopted by the Commonwealth of Pennsylvania, effective March 1995. By 1997, a 40 percent increase in organ donors and a 49 percent increase in organ transplants had taken place in southeastern Pennsylvania.

The initiative also seeks to improve the percentage of donations when requests are made to donate. The initiative will accomplish this goal by working with a number of partners to eliminate barriers to donation, such as the failure of individuals wishing to donate organs to discuss their wishes with their families. The initiative also seeks to learn more about what works to increase organ donation and to disseminate that knowledge broadly.

Advances in medical science and technology have made organ transplantation an increasingly successful and common medical procedure. Experience performing transplants and the development of better immunosuppressive regimens have increased the survival rates for transplant recipients. Comparing data for transplants performed in 1988 with data for transplants performed in 1995, one year patient survival rates increased as follows: livers, from 81 percent to 87 percent; hearts, from 83 percent to 85 percent; and lungs from 50 percent to 77 percent.

In addition, technological advances have made broader geographic sharing possible. For example, the use of the Belzer UW solution, developed in the 1980s, has dramatically increased both graft survival rates and the time in which the organ survives out of the body. This ''cold ischemic time'' is used to transport an organ to a potential recipient.

This rule is intended to ensure that organ allocation policies are continuously reevaluated and revised to meet the statutory goal of equitable national allocation of organs in accordance with medical criteria.

This rule provides the framework for OPTN activity by clarifying how the essential functions of the OPTN should be conducted in order to better achieve an equitable national system.

Several evaluations of organ allocation have recommended a truly national waiting system for organ allocation. A 1990 evaluation of the OPTN conducted by Abt Associates recommended that the OPTN develop a national patient-focused system:

> Unless there is a clear disadvantage to patients or procurement in having a single national list for each organ, the OPTN should move towards a single national list and develop point schemes that minimize cold ischemic and transplant times.

Evaluation of the Organ Procurement and Transplantation Network, at 85 (Abt Associates, August 21, 1990)

The HHS Office of Inspector General reached similar conclusions, finding that ''current organ distribution practices fall short of congressional and professional expectations,'' and that ''[t]here has been substantial progress in developing a national organ distribution system grounded in uniform policies and standards. However, organ distribution remains * * * confined primarily within the individual service areas of the * * * Organ Procurement Organizations.'' *The Distribution of Organs for Transplantation: Expectations and Practices* at 8, 13 (Office of Inspector General, March 1991).

Current OPTN organ allocations policies still do not create the truly national system intended by the statute. Current OPTN allocation policies do not reflect the more equitable, broader sharing possible under current views of appropriate cold ischemic time. These policies nominally give priority to the life or death needs of the sickest patients, but the resulting allocation schemes fall short of that objective. By allocating organs primarily at the local level, OPTN policies give the sickest patients a substantially lower chance at being promptly matched to a suitable organ (and thereby receiving a potentially life-saving transplant) than would be the case with broader geographic sharing.

At the national level, these policies treat patients inequitably because they create enormous geographic disparities in the time patients must wait to receive transplants. This approach is inconsistent with the views of transplant candidates and the general public who, according to a 1994 OPTN-initiated survey, were likely to give top priority to the policy that ''makes waiting time about the same for all patients nationally.'' Page 8 of the United Network for Organ Sharing (UNOS) comments on the NPRM, December 6, 1994. In effect, these policies treat the sickest patients differently depending on where they live or which transplant hospital's waiting list they are on. This result also is inconsistent with the views of at least half of transplant recipients and candidates, who, according to the same survey, ''would give top priority to a patient who is the most critically ill and has the least time to live.'' Page 7 of UNOS comments. Finally, this approach is inconsistent with the views of a blue ribbon panel that examined a broad range of issues pertaining to organ transplantation, including the technical, practical, and ethical limitations on sharing organs. The panel noted:

> The principle that donated cadaveric organs are a national resource implies that,
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> In principle, and to the extent technically and practically achievable, any citizen or resident of the United States in need of a transplant should be considered as a potential recipient of each retrieved organ on a basis equal to that of a patient who lives in the area where the organs or tissues are retrieved. Organs and tissues ought to be distributed on the basis of objective priority criteria, and not on the basis of accidents of geography.

Report of the Task Force on Organ Transplantation, April 1986 at 91 (quoting Hunsicker, LG)

Another flaw in current OPTN policies pertains to disclosure of information. The statute requires the Secretary to provide information to patients, their families, and physicians about transplantation. Current policies in this area do not give patients, their families, and physicians the timely information they need to help in selecting a transplant hospital. For example, one-year survival rates of patients and organ grafts are valuable information in comparing the relative effectiveness of transplant programs. However, today a patient seeking this information would have to rely on four year old OPTN data released in 1997. Moreover, these data are contained in

nine volumes with 3,200 pages. A patient seeking to compare centers would find these data difficult to use. In addition, access to accurate, timely data will enable the Department to monitor the effectiveness of organ transplantation and provide the general public with information on how well the transplantation network is performing.

The National Organ Transplant Act vested in the Secretary oversight of the OPTN and responsibility for ensuring public benefit. Amendments to the Social Security Act in 1986 underscored the Secretary's role. Working in partnership with the transplant community, the Secretary has final authority over OPTN policies and procedures. In particular, the Secretary has a statutory mandate not only to ensure that the OPTN distributes organs ''equitably'' and fulfills other statutory requirements but also to obtain and act upon ''critical comments relating to the manner in which (the OPTN) is carrying out the duties of the Network.'' The Secretary has chosen to issue regulations for the purpose of ensuring that the system evolves to keep pace with improvements in technology and medical science (such as improvements in organ preservation technology and reductions in the disparities in survival rates among more sick and less sick patients) and is operating effectively and efficiently to meet its statutory goals.

Six principles underlie this regulation:

- Transplant patients are best served by an organ allocation system that functions equitably on a nationwide basis;
- The Secretary of Health and Human Services should represent the public interest by setting broad goals for the OPTN and by overseeing OPTN policy development and operations with a view toward ensuring that the goals are being addressed in a reasonable manner;
- The OPTN must exercise leadership in performing its responsibilities under the National Organ Transplant Act, in particular by devising the specific policies assigned under these regulations, and by adapting its policies and procedures to changes in medical science and technology;
- Organs should be equitably allocated to all patients, giving priority to those patients in most urgent medical need of transplantation, in accordance with sound medical judgment;
- Thorough, timely, and easy to use information about transplant centers, including center-specific performance data, is essential for measuring quality of care and should be readily available to help patients and physicians in choosing among transplant centers;
- Potential conflicts of interest should be minimized for those who are responsible for operation of the OPTN.

B. Legislative and Regulatory History

The OPTN was established under section 372 of the PHS Act, as enacted by the National Organ Transplant Act of 1984 (Pub. L. 98–507), and amended by Pub. L. 100–607 and Pub. L. 101–616. Section 372 requires the Secretary to provide by contract for the establishment and operation of the OPTN to manage the organ allocation system, to increase the supply of donated organs, and to perform related and other activities.

Until the enactment of the Omnibus Budget Reconciliation Act of 1986 (Pub. L. 99–509), membership in the OPTN was voluntary. Section 9318 of Public Law 99–509 added a new section 1138 to the Social Security Act. Section 1138(a)(1)(B) requires hospitals that perform organ transplants to be members of and abide by the rules and requirements of the OPTN as a condition for participation in the Medicare and Medicaid programs. This requirement places at risk the transplant hospitals' participation in these programs, not just payments for transplantation, and as a practical matter makes the hospitals' survival dependent on following such rules and requirements. Section 1138(b)(1)(D) requires that to be eligible for reimbursement of organ procurement costs by Medicare or Medicaid an OPO must be a member of and abide by the rules and requirements of the OPTN.

Section 102(c) of the Balanced Budget and Emergency Deficit Control and Reaffirmation Act of 1987 (Pub. L. 100–119) delayed the effective date of § 1138(a) of the Social Security Act concerning hospitals from October 1, 1987, to November 21, 1987, and § 4009(g) of the Omnibus Budget Reconciliation Act of 1987 (Pub. L. 100–203) further delayed the effective date of § 1138(b) of the Act concerning OPOs to April 1, 1988.

The Organ Transplant Amendments of 1988 (Title IV of Pub. L. 100–607) amended § 372 of the Public Health Service Act to require that the OPTN establish membership criteria and subject its policies to public review and comment.

On March 1, 1988 (53 FR 6526), the Department published final rules that included the requirement that Medicare/Medicaid participating hospitals that perform transplants, and designated OPOs, be members of and abide by the rules and requirements of the OPTN (42 CFR 485.305 (now 42 CFR 486.308) and 482.12(c)(5)(ii)) in order to qualify for Medicare or Medicaid payments.

On December 18, 1989, the Department published a **Federal Register** Notice (54 FR 51802) addressing the oversight of the OPTN. In that Notice, the Secretary stated that no OPTN policies would become legally binding ''rules or requirements'' of the OPTN for purposes of section 1138 until or unless they were approved by the Secretary.

The 1994 proposed regulations (59 FR 46482) were intended to implement that decision, as is this final rule with comment period. In those proposed regulations, the Secretary raised a wide range of issues, including procedures for joining the OPTN, the Federal review processes, procedures and standards for information collection and dissemination; membership requirements and compliance procedures; and the criteria for allocation of each of the solid organs. On November 13, 1996, the Secretary issued a **Federal Register** notice reopening the comment period and announcing a public hearing to be held in December 1996, to address issues raised by those proposed regulations, and to hear ideas regarding increasing organ donation and the controversial and difficult problems surrounding organ allocation generally and liver allocation policies in particular. From December 10 to 12, 1996, that hearing was held. As under the proposed regulations, the final rule provides for Federal oversight of the processes by which the OPTN allocates organs for transplantation. It focuses the Federal role on ensuring that those processes and resulting policies are equitable, provides for broader public participation and Secretarial review, and includes access to information for patients and their families and physicians.

Under the final regulations, the OPTN has responsibility for developing medical criteria for patient listing, medical urgency criteria (''status'' definitions), organ allocation policies, other policies governing organ transplantation, and policies for the day-to-day operation of the OPTN. The Secretary has responsibility for oversight of the OPTN, for establishing performance goals and indicators to guide the national system for distribution of organs, and for final approval of those OPTN policies that are to be enforceable. Both the OPTN and the Secretary have responsibility for dissemination of information to the

public, including patients, physicians, payers, and researchers.

This final rule was developed after consideration of comments from all elements of the transplant community on the entire range of issues. Comments were received not only during the original comment period but also during the last two years and attendant to the public hearing held in December 1996. Although the Secretary believes that this rule addresses all of the major issues and questions that had been identified, the Department remains open to suggestions for further improvements. The Department has provided for additional public comments on these regulations to be submitted during the next 60 days. The Department will also provide for public input on OPTN proposals for policies to implement these regulations.

C. DHHS and OPTN Relationships

The public comments indicate that many persons misunderstand the role of the OPTN. The OPTN is sometimes characterized as a voluntary system through which consensus decisions are reached as to how to allocate organs among patients (who may live or die based on these decisions). The underlying statutes, absent Secretarial oversight, give the OPTN authority from which individual patients, physicians, and hospitals have little recourse. If the OPTN changes organ allocation criteria, it may advantage some patients and disadvantage others because there are not enough organs donated to meet the need and no alternative organ allocation entity exists. The unique role of the OPTN thus gives rise to a fundamental question. To what process or remedy can patients, their families, physicians, or members of the general public turn if they wish to question policies, decisions, procedures, or practices of the OPTN? By providing a framework for OPTN policy development and describing the role of the Secretary therein, this rule addresses that question.

The United Network for Organ Sharing (UNOS), a private corporation, operates the OPTN under contract with the Department. The contract is subject to the competitive bidding process. Under recent Requests for Proposals, there have been no effective competitors to the current contractor. The current contract expires September 30, 1999.

As a private organization, UNOS has by-laws, operating procedures, and membership requirements. They apply only to UNOS members and not to OPTN members. Membership in UNOS is not a requirement for membership in the OPTN. Therefore, such procedures are not OPTN procedures, and because they do not bind OPTN members, they are not the subject of this regulation. Because OPTN members are not required to become UNOS members, UNOS procedures are subject to these regulations only if they conflict with OPTN requirements, or if they conflict with the terms of the contract for the operation of the OPTN, or these regulations. For example, UNOS may impose conditions for membership in UNOS, but those conditions may not be substituted for, or used to augment, the regulatory requirements for the UNOS-administered OPTN. In contrast, matters relating to the OPTN are encompassed by these regulations; and UNOS, as the OPTN contractor, is required to comply with these regulations and to issue policies consistent with the requirements of these regulations.

The Department believes that the transplantation network must be operated by professionals in the transplant community, and that both allocation and other policies of the OPTN should be developed by transplant professionals, in an open environment that includes the public, particularly transplant patients and donor families. It is not the desire or intention of the Department to interfere in the practice of medicine. This rule does not alter the role of the OPTN to use its judgment regarding appropriate medical criteria for organ allocation nor is it intended to circumscribe the discretion afforded to doctors who must make the difficult judgments that affect individual patients. At the same time, the Department has an important and constructive role to play, particularly on behalf of patients. Human organs that are given to save lives are a public resource and a public trust.

The process adopted in this rule strikes a balance among these important principles. When the OPTN develops policies, or when complaints are raised concerning OPTN policies, the regulation allows a number of options. The Secretary may approve an OPTN-proposed policy or find that the complaint has no merit. The Secretary also may take another approach depending on the issues presented. For example, the Secretary: may seek broader public input on the issue; may determine whether violations of OPTN-proposed policies should carry any one of a range of consequences—no consequence, loss of membership in the OPTN, or loss of a hospital's ability to participate in Medicare and Medicaid; may provide comments for the OPTN's consideration; may direct the OPTN to adopt a policy; or, may develop a policy that the OPTN must follow. An example of this last option is this regulation's provisions prescribing who the OPTN must admit as members. Instead of an exhaustive listing of these and other options, the regulation, at sections 121.4 (b)(2) and (d) simply provides that the Secretary may ''take such other action as the Secretary determines appropriate.''

Questions have also arisen about the relationship of OPTN policies to other standards and requirements. A number of Federal statutes, including those relating to Medicare and Medicaid, civil rights, fraud and abuse, clinical laboratories, organ procurement, control of infectious disease, and regulation of blood and blood products, have provisions that may affect, or be affected by, the policies of the OPTN. For example, several years ago the Department made decisions as to the required qualifications for clinical laboratory directors, after an extended public comment process. Those decisions did not impose the most stringent possible academic qualifications because the available evidence did not show that those levels were necessary for high performance. Any OPTN policy that directly or indirectly would require member hospitals to do business only with laboratories with directors meeting a higher qualification would conflict with the HHS regulation, and thus not be binding upon OPTN members unless the Secretary approved that policy as an OPTN requirement.

In order to prevent such problems, this regulation creates a system in which the OPTN has three options whenever it identifies a policy that it believes will contribute to high performance: the OPTN can recommend its use by members; the OPTN can request that HHS make it enforceable, or the OPTN can petition HHS to modify other regulations (such as clinical laboratory or blood regulations) to adopt that policy. What the OPTN cannot do is unilaterally impose a policy that has the effect of, or changes the terms of, a national policy already subject to the oversight of a cognizant Federal agency.

The Secretary will review the OPTN policies that may interact with other statutes or with rules promulgated through other Federal programs. To clarify the policy development and review process, we have added a new § 121.4, Policies: Secretarial Review, and Appeals, which consolidates regulatory requirements from proposed §§ 121.3, 121.7, and 121.10. The addition of new § 121.4 results in renumbering §§ 121.4–121.12. See the discussion at section II(C6), under **SUPPLEMENTARY INFORMATION**, below.

D. Enforcement

Some of the comments received in response to the Notice of Proposed Rulemaking or delivered at the public hearings indicate that there may be misunderstandings about the relationship between section 1138 of the Social Security Act and the OPTN regulations, and their respective enforcement provisions.

1. Section 1138 of the Social Security Act

As discussed above, section 1138 requires Medicare and Medicaid participating hospitals that perform transplants to be members of the OPTN and abide by its rules and requirements. Section 1138 also contains similar requirements for OPOs in order for organ procurement costs attributable to payments to an OPO to be paid by Medicare and Medicaid. These requirements are also found in final rules (42 CFR 485.305 (now 42 CFR 486.308) and 482.12(c)(5)(ii)) published on March 1, 1988 (53 FR 6526). Further, on December 18, 1989, the Department published a general notice in the **Federal Register** (54 FR 51802) announcing that, in order to be a rule or requirement of the OPTN and therefore mandatory or binding on OPOs and hospitals participating in Medicare or Medicaid, the Secretary must have given formal approval to the rule or requirement. Violations of section 1138 could result in withholding of reimbursement under Medicare or Medicaid.

Section 1138 and the final rules and general notice that followed pertain only to OPOs and hospitals participating in Medicare or Medicaid. In its general notice, the Department intended to define what is meant by a ''rule or requirement of the OPTN'' for the purposes of implementing section 1138. In applying the policy in the general notice, the Department considers a ''rule or requirement of the OPTN'' to be those rules developed as provided for in these regulations.

Two examples illustrate the significance of this provision. First, an OPO or transplant hospital participating in Medicare or Medicaid could be considered in violation of section 1138 if the Secretary found that it did not provide information to the OPTN as required specifically by § 121.11(b)(2) or that it procured for transplantation organs known to be infected with the human immunodeficiency virus, prohibited specifically by § 121.6(b). Conversely, these institutions would not be considered in violation of section 1138 if they were found by the Secretary to be acting contrary to a policy implemented by the OPTN but not formally approved by the Secretary as enforceable. Second, if an OPTN member procured and arranged for allocation of donor kidneys in a manner inconsistent with the OPTN's kidney allocation policy as in effect in 1996, it would not be considered in violation of section 1138, because that allocation policy is not approved by the Secretary as enforceable policy. Therefore, policies of the OPTN that are not articulated in these or subsequent OPTN regulations or elsewhere approved by the Secretary are not enforceable under § 121.10.

2. OPTN Policies

There has been discussion about whether all OPTN policies should be enforceable. The Secretary believes that compliance with existing voluntary policies has been excellent. Furthermore, some commenters at the public hearings expressed support for the current role of the OPTN in devising and issuing such policies. Finally, the field of organ transplantation is dynamic, yielding technological advances that the OPTN must accommodate as quickly as possible if patients are to receive their full benefits. It can do so efficiently under this tested approach. Therefore, the Secretary has decided to continue this approach.

The Secretary recognizes, however, that compliance with certain policies, such as those relating to organ allocation, are crucial to the success of the OPTN and expects the OPTN to monitor compliance with these policies closely under § 121.10. If violations are widespread, or if uniform compliance is essential, the Secretary will consider making such policies enforceable. The Secretary also recognizes the need for additional public participation in the development of some OPTN policies, such as fundamental revisions to organ allocation policies, and has included in this rule provisions that (1) require the OPTN Board to provide opportunity for the OPTN membership and other interested parties to comment on all of its proposed policies, (2) enable the Secretary to seek comment from the public and to direct the OPTN to revise policies if necessary, and (3) provide timely access to information for patients, the public, and payers. These provisions are discussed further in section II.

The requirements that are explicit in this final rule are subject to its enforcement provisions. For example, if a transplant program did not establish organ acceptance criteria and provide such criteria to the OPOs with which they are affiliated and to the OPTN, as required specifically by § 121.6(c), it could be found to be out of compliance with the OPTN regulations and subject to suspension of its designated status under § 121.9, as discussed further in section II.

II. Summary of Public Comments and Policies of the Final Rule

In addition to public comments directed specifically to the NPRM document, the Department has received other comments and recommendations directed at issues covered by this final rule, as well as additional documents described below. Much of this additional information was received during 1996 and 1997, subsequent to the original rulemaking dates. In particular, the Secretary determined in 1996 that there were sufficient controversies to justify reopening the comment period and scheduled a three-day public hearing, subsequently held on December 10–12, 1996.

The information received since the close of the original comment period falls into several broad categories. First, the OPTN itself has considered or adopted a substantial number of policy changes, each accompanied by supporting information presented to the OPTN Board of Directors and to the public. Second, the transplant community, including the OPTN, has created additional materials. Both the OPTN and the University of Pittsburgh sponsored the development of simulation modeling to estimate the likely effects of alternative liver allocation policies (the ''Pritsker'' and ''CONSAD'' models discussed later in this preamble). Third, approximately 110 persons individually or representing the OPTN, patients and patient organizations, transplant institutions, and professional associations testified at the December 1996 public hearing; and hundreds of others sent written comments. Finally, the Secretary considered other materials including, for example, correspondence from Members of Congress and a number of recent newspaper articles which focused on organ transplantation issues and controversies.

The testimony and comments received in connection with the public hearing contain a total of 541 documents, with 667 signatures. Of these, 180 signatories are identifiable as transplant recipients or candidates or their families and friends, 327 as physicians, and 43 as other health personnel such as nurses, hospital administrators, and directors of organ procurement organizations. National organizations submitted 30 documents.

Twenty-two petition letters contain a total of 5,462 signatures. No attempt has been made to identify the signatories of the petition by type.

Among the documents in the docket room at 12420 Parklawn Drive, Room 123, Rockville, MD and available for review or copying are the actual comments as well as a summary and analysis of all of the comments received in response to the NPRM and the December 1996 public hearing, the 1996 Annual Report of the OPTN and Scientific Registry, the 1996 Code of Medical Ethics of the Council on Ethical and Judicial Affairs of the American Medical Association, the 1993 white paper ''The Principles of Equitable Organ Allocation'' of the OPTN Ad Hoc Committee on Organ Allocation, the materials prepared for the OPTN Board of Directors before each Board Meeting over the last several years, the 1991 report of the HHS Inspector General entitled ''The Distribution of Organs for Transplantation: Expectations and Practices,'' the 1993 report of the General Accounting Office entitled ''Organ Transplants: Increased Effort Needed to Boost Supply and Ensure Equitable Distribution of Organs,'' the OPTN's multi-volume ''Report of Center Specific Graft and Patient Survival Rates'' for both 1994 and 1997, a 1995 report from the CONSAD Research Corporation providing ''An Analysis of Alternative National Policies for Allocating Donor Livers for Transplantation,'' a number of computer simulations on liver allocation policy prepared by the Pritsker Corporation in 1996 and 1997 (most included in the OPTN Board materials listed above), a number of computer simulations on liver allocation policy prepared by CONSAD in 1996 and 1997, a series of investigative articles on organ transplantation and allocation issues that appeared in the Cleveland Plain Dealer in early 1997, other newspaper articles, and a GAO report, *''Organ Procurement Organizations, Alternatives Being Developed to More Accurately Assess Performance''*, published in November, 1997.

In addition, this rule and some of the documents listed above—such as the transcript of the public hearings—are available on the HRSA Web site at http://www.hrsa.dhhs.gov/bhrd/dot/dotmain.htm.

A. Summary of Original Public Comments

The preamble to the Notice of Proposed Rulemaking (NPRM) asked the public to comment separately on the specific provisions of the proposed rule and on the individual policies then in effect voluntarily under which organs were being allocated to potential transplant recipients. Of the 121 letters received, 59 contained comments on specific sections of the NPRM, 60 on the allocation policies, and two commented on both. About half of the original comments are addressed in the discussion of public comments on allocation policies, below.

All but two of the 61 letters commenting on specific sections of the NPRM other than allocation policy were from individuals identified with organizations. National groups included the Ad Hoc Coalition on Organ Transplantation, the American Association of Kidney Patients, the American Center for Transplant Resources, the American Society of Histocompatibility and Immunogenetics, the American Society of Transplant Physicians, the American Society of Transplant Surgeons, the Association of Organ Procurement Organizations, the National Kidney Foundation, the North American Transplant Coordinators Organization, and the United Network for Organ Sharing. Thirty-two letters were from individuals affiliated with hospitals, ten from organ procurement organizations, one from a law firm representing a hospital, two from members of the U.S. House of Representatives, one from a former member of Congress, and two from individuals who identified themselves as organ transplant recipients.

The 61 letters presented a total of 210 comments on specific sections of the NPRM as follows: § 121.2—Definitions (17); § 121.3—Composition of the OPTN (41); § 121.4—Listing Requirements (18); § 121.5—Organ Procurement (6); § 121.6—Identification of Organ Recipient (24); § 121.7—Allocation of Organs (40); § 121.8—Designated Transplant Program Requirements (34); § 121.9—Review and Evaluation (2); § 121.10—Appeals of OPTN Policies and Procedures (2); § 121.11—Record Maintenance and Reporting Requirements (26). These comments are discussed below in the context of those specific sections.

B. Summary of Public Hearing

The public hearings demonstrated that there is considerable controversy over many aspects of organ allocation policy, along with many areas of agreement. A number of fundamental questions were addressed by multiple witnesses, and their comments on these and the Secretary's decisions are summarized below. The Department's **Federal Register** Notice establishing the agenda for the hearing focused on two issues: Increasing organ donation and liver allocation policy—but those who testified raised many additional issues.

1. What Role Should the Federal Government Have in Organ Allocation Policy?

Partly as a result of the controversy surrounding the new OPTN liver allocation policies proposed in 1996, some individuals questioned whether the private sector can or should set policy for a system that has such a profound effect on life and death decisions. The recurring view expressed in testimony, however, was to preserve the current contractual arrangements for the operation of the OPTN, but for HHS to exercise closer oversight, particularly in organ allocation policy. Others testified to the contrary, arguing that the OPTN was dominated by the self-interest of transplant physicians and surgeons (see discussion below) and that only the government could take an impartial role in a field so dominated by conflicting interests.

Despite support for the OPTN contract and the structure of the OPTN, a number of individuals and organizations argued that the approval of a flawed liver allocation policy in November 1996 (see below), and the failure to improve current policy in more fundamental ways illustrated systemic flaws in the current governance structure. One line of comments focused upon the structure of the OPTN Board of Directors, which was characterized (incorrectly) as giving each transplant hospital one vote, without regard to the number of patients on the waiting list or the number of individuals transplanted. Some patients, patient groups, and directors of the larger programs advocated models where patients' interests would have greater representation. Others argued that the OPTN is dominated by hospitals—large and small—and transplant surgeons and physicians and that the larger public interest, the altruistic interests of donors and donor families, and interests of potential recipients are neglected.

As discussed elsewhere in this preamble, the Secretary believes that the Department has an important and constructive role to play, particularly on behalf of patients.

2. Are the Liver Allocation Policies That the OPTN Adopted in November 1996 Fair?

The OPTN Board had approved a new liver allocation policy shortly before the public hearing. At the public hearing and in the comments received, many patients with chronic liver disease

opposed the new policy; most physicians supported it. Table 1 presents the pertinent data.

TABLE 1.—OPINIONS BY TYPE OF RESPONDENT (EXCLUDING PETITIONS)

Category	Pro new policy	Con new policy
Physicians	136	5
Other health personnel	13	3
Recipients/candidates and families	31	128
Totals	180	136

Patients and their advocates asserted that their chance to receive an organ had been decreased significantly by the new policy of transplanting patients with acute hepatic failure and primary non-function before chronic patients who were also in intensive care units and had equally short life expectancies. Moreover, patients and their advocates asserted that there was no significant medical argument favoring preference for the ''acute'' group. (OPTN data tend to confirm this assertion and show that the acute patients do not have an appreciably better post-transplant survival rate than the chronic patients, as discussed later in this preamble). They pointed out that, despite the prospect of imminent death, they were newly downgraded into a lower priority group of patients and that all chronic patients were being grouped together rather than differentiating among chronic patients and their varying medical conditions. Strong pleas were made by some medical personnel, patients, and patient advocacy groups for a system of classification based on objective and relevant medical criteria and for broader sharing of organs.

Most OPTN officials defended the new policies but based these arguments on the extensive and prolonged committee processes involved rather than medical data. However, the Chairman of the OPTN Patient Affairs Committee indicated that the needs of the chronic disease patients had not been considered carefully enough when the new policy was evaluated by his committee. He stated that the OPTN, while attempting to accomplish good purpose for one group of patients, had apparently disadvantaged another group with equally high medical urgency. He also promised to have his committee reconsider its position.

Some commenters urged that a moratorium be placed on the implementation of the new policy until the needs of the chronic patients could be properly considered. As a result of the airing of these issues at the hearing, the OPTN established this moratorium shortly after the hearing. In further response, in June 1997, the Board of Directors voted to implement a new policy that would reform the controversial policy to some degree. The newer policy places very sick chronic patients in a separate status subgroup and also assigns them a second priority—i.e., after the acute patients. However, as explained in greater detail below, it reduces, but does not eliminate, the disadvantage that had been imposed on chronic patients in 1996.

This rule requires the OPTN to promptly take a fresh look at its current policies in light of the rule's performance goals.

3. Should Transplantation Be Centralized in a Few Centers That Meet More Stringent Criteria, or Are There Advantages to the Present Geographic Distribution of Programs?

Although the Department had not identified establishing volume or performance criteria for individual hospitals as a hearing topic, some commenters raised this issue. This issue arises because, although patients are free (subject to insurance coverage) to select from among most transplant hospitals in the United States, under current OPTN policies, the number of organs available to a hospital in a particular area does not rise or fall as the number of patients increases or decreases but is largely dependent on the number of donors in that local area. As a consequence of a ''local first'' allocation policy, most organs leave the local area only if there are no local patients who could use the organ. (An exception is ''no mismatch'' kidneys, which are shared nationally.) As a result of hospitals drawing primarily from the local pool of donated organs, no hospital can expand its program beyond the local supply of organs without disadvantaging the patients who choose it. Representatives of some small-volume transplant programs argued that broader geographic sharing might result in local, smaller hospitals being forced to close their transplant programs.

The argument for wider sharing of organs was made vigorously by representatives of some large-volume transplant programs. They also argued that the quality of performance and outcome was related to the number of procedures performed. The contrary argument—to recognize the importance of the small-volume programs—was made vigorously on the basis of local and regional access to transplants and with testimony and data suggesting that many small programs have outcomes equal to or better than the larger hospitals. In addition, some patients expressed concern about losing their system of support (family and neighbors) if they had to leave their homes or communities to receive a transplant. Another concern was the extra expense incurred by patients having to move outside the home community for a transplant.

After the hearing, the Department determined, however, that this concern over local access and increased travel only affects a small number of patients. About half of liver patients must travel outside their local area to obtain a transplant simply because almost all rural areas, most cities, and about a dozen States have no liver transplant programs. Also, the great majority of small-volume programs are located in the same metropolitan area as large-volume programs. Thus, very few patients might have to face this potential problem.

Some argued that the more remote the large hospital may be from a needy patient, the greater the travel costs and the more likely those without insurance or those with lower income will be effectively excluded from the opportunity to receive an organ. On the other side, some argued that larger programs have been more willing to list the sicker patients and those with less ability to pay. The Department finds these arguments speculative. About half of all patients have to travel anyway, and nothing other than anecdotal evidence was presented regarding how many patients are taken as charity cases at hospitals, large or small.

It was argued that the Health Care Financing Administration and some other large payers such as managed care organizations refer their patients to higher volume programs and, thus, strain a system already under stress because of the shortage of organs. Others argued that the organ shortage is the same regardless of where payers direct their patients.

The Secretary concludes that there is no persuasive evidence that the provisions of this rule—equitable sharing of organs, based on objective criteria of medical urgency and free patient choice among transplant programs—will damage transplant institutions of any size. However, in this regard, the Department also will consider whether any demonstrable institutional impact will result from the policies to be developed by the OPTN.

4. Should Organs Be Shared Across Geographic Lines—Regionally or Nationally?

Many patients and patient advocates, and some hospital representatives, argued that organs should ''follow'' the patient. That is, regardless of where a patient lives or lists, he or she should have the same chance of receiving an organ as if living or listing elsewhere. Local preference prevents this result, and proponents of this view opposed local preference. Why should some patients who list in areas that, for whatever reason, obtain more organs in relation to local demand benefit over patients from other areas who have equal or greater medical need? Why should other patients in those same areas who are sicker nevertheless not receive a matching organ from another area? Another argument against local preference is that it limits the ability of patients to select the medical program and physician they prefer. The patients of large payers are also disadvantaged if organs are not allocated where the patient will get her or his care, unless the payer is willing to make special arrangements to move patients where waiting lists are shortest or to ''multiple list'' patients at more than one transplant hospital because of long local waiting times. Patients or payers who consider ''multiple listing'' are also, in effect, forced to choose between using local providers and, potentially, cross-continental travel simply to have a good chance of getting a organ.

Some argued that the feasibility of national organ sharing is limited by the cold ischemic time (the time after procurement that an organ remains viable for successful transplantation). Witnesses said that this time ranges from 12 to 18 hours for livers and that, for livers transplanted in less than this time, there is little difference in graft survival attributed to cold ischemic time. (Compared to livers, the cold ischemic time is much shorter for hearts and much longer for kidneys.) Some commenters argued that travel times to and from large cities, where most transplant hospitals are located, readily permits a national allocation scheme for livers. However, others argued, travel times from small communities (the locale of many donors) to large cities or to other small communities are not always predictable and that estimates of travel time are not always reliable.

Proponents of national sharing of livers pointed out that other organs—including hearts and kidneys—are successfully shared outside of the local area and that many livers were nationally shared for the sickest patients until 1991. These witnesses argued that the transportation argument was irrelevant since any sensible policy would be designed to ensure that organs would not be transported in cases where this would result in waste.

Some witnesses argued that sharing of organs across geographic lines would just ''switch the zip codes'' of those who died. This reflects the stark reality that, so long as the number of organs is insufficient to transplant all those in need, some persons are likely to die while awaiting a transplant. Proponents of broader sharing countered that the OPTN's own modeling showed that lives could be saved if organs went to the sickest patients first within broad geographic areas rather than giving preference to local patients who, though ill, were not in imminent danger of death.

Among the arguments made against broader sharing was that this could harm local procurement. Those taking this view emphasized the value of the relationships between the transplant hospitals and their local organ procurement organization and asserted that local allocation tends to promote organ donation and retrieval by local transplant surgeons. A related argument was advanced against broader sharing suggesting that, if referring physicians perceive organs are always ''shipped out'', they will be dissuaded from referring donors. However, those in favor of broader sharing argued that there was no evidence to support the local preference argument. They stated that donor families have no preference where the organ is used, believing that donor families want only that their loved one's organs help individuals most in need.

In this regard, a 1994 OPTN survey (reported in the *UNOS Update* of July 1994) shows that the overwhelming majority of donor families state as their preference that organs go to the neediest patients, regardless of geography, so long as organs are not wasted. That same survey showed very high support for equalizing waiting times. Many commenters noted that, even under the current system of local priority, some organs are shared regionally or nationally. HHS has seen no credible evidence that local preference encourages donation or that sharing organs regionally or nationally for the sickest patients will impact organ donation. Nor is there any evidence that transplant professionals perform differently when the retrieval is for a distant patient rather than a local patient.

5. Which Is Preferred, Transplanting the Sickest First or Transplanting Patients Who Are Most Likely To Survive the Greatest Number of Years?

Many witnesses at the public hearing agreed on two broad points: first, from the perspective of an individual patient who is at risk of imminent death, the ''sickest first'' policy is the only choice; and second, there are patients who are so likely to die that it would be futile to transplant them and waste an organ that could have saved someone else. Some argued that transplantation before a patient becomes ''sickest'' provides better outcomes and longer graft and patient survival, and increases the supply of organs by reducing the number of second transplants. However, to adopt a policy favoring transplantation of the least sick patients would mean that more hospitalized patients might die. Moreover, the chronic liver patients asserted that their expected survival rates were not only high, but also essentially equal to those of acute patients, who were gaining preference. They questioned how reducing their chance of living, when both urgency and outcome were essentially equal, could meet any reasonable ethical standard.

The available evidence shows that, for most patients, higher medical urgency does not reduce the likelihood of post-transplant survival to the extent that less ill patients should receive higher priority. Although current OPTN policies vary by organ, the predominant thrust of the OPTN policies is to give priority to greater medical need. (These regulations are not intended to preclude considerations underlying current allocation policies such as the judgment afforded surgeons in individual cases, the needs of children and sensitized patients, and the priority given to no antigen mismatches for kidney patients.) The Secretary therefore concludes that ethical considerations require that the most medically urgent patients—those who are very ill but who, in the judgment of their physicians, have a reasonable likelihood of post-transplant survival—receive preference in organ allocation over those who are less medically urgent.

6. How Much ''Game Playing'' Exists in the Present System?

A number of witnesses asserted that the current system of organ allocation and listing can be manipulated by hospitals, physicians, and payers. Practices discussed included excluding high risk patients from the list, listing patients early to gain waiting time points, listing patients at more than one

transplant hospital to increase the chance of getting an organ, and referring high risk patients to other hospitals to avoid adverse performance outcomes. No data were presented in support of these assertions, but they came from a cross-section of witnesses. Some commented that the present debate evinces distrust among transplant professionals—local hospitals work together and with the local OPO, whereas non-local hospitals may be ''gaming'' the system to advantage their patients. Presenters suggested modifications to the system to minimize these tactics. Most supported the development of objective medical criteria for listing and classifying candidates as a specific reform that would increase fairness.

7. How Can HHS Promote and Facilitate an Increase in Organ Donation?

A plea for vigorous involvement of and leadership by HHS in organ donation was almost unanimously supported. The diversity of experiences and effectiveness among OPOs and hospitals, and variation among State laws and practices, suggest a need for shared communication, education, and Federal action. Many suggestions were offered to minimize disincentives and maximize appropriate incentives for organ donation. Emerging research data provide information about factors that influence a donor family's decision to consent to offer a loved one's organs. Many specific ideas were suggested for how government could invigorate organ donation.

Toward that end, HHS is conducting a broad organ and tissue donation initiative that implements many of the suggestions made at the hearing, and others. Included as part of this initiative is a Notice of Proposed Rulemaking published in the **Federal Register** on December 19, 1997 (62 FR 66725), which would require that hospitals refer all appropriate deaths to OPOs, and that OPOs determine the criteria for these mandatory referrals. In cooperation with other Federal agencies, we are undertaking a major campaign to encourage Federal employees and their families to volunteer to become potential organ donors. We also encourage the transplant community to strengthen its various efforts to increase organ and tissue donation, and to review whether transplant hospitals are taking all reasonable steps to procure organs (a recent review of OPTN data showed that about one-fourth of transplant hospitals produced no donors in 1995). Finally, the Department will host a conference to exchange information on identifying best practices and promising innovations.

A number of surveys and studies have shown broad support for organ donation generally. The Secretary believes the policies that are contained in this rule will complement the initiative and build on this public support for organ donation. Allocating organs nationally to those most in need also will build on a broad base of public support. As noted above, according to a 1994 OPTN-initiated survey, at least half of transplant recipients and candidates ''would give top priority to the patient who is the most critically ill and has the least time to live.'' Page 7 of UNOS comments on NPRM, December 6, 1994. While some commenters suggested that locally based allocation increases donation, they did not offer any studies to support this suggestion. A 1991 HHS Inspector General report rejects the notion of local use increasing local donation. *The Distribution of Organs for Transplantation: Expectations and Practices* at 15–16 (Office of Inspector General, March 1991). The same OPTN-initiated survey also discounts this approach, concluding that ''Americans do not think that keeping an [donated] organ in a specific locality is an important goal in and of itself. * * *'' Page 8 of UNOS comments.

8. What Is the Responsibility To Provide Access to Transplantation Services to All Americans, Regardless of Economic Status?

Access to transplantation services was described as being dependent on a person's ability to pay, which virtually always requires health insurance. A few State-supported hospitals testified that they accept all patients regardless of ability to pay, but the preponderance of the testimony was that most transplant hospitals require that the patient demonstrate an ability to pay. As a result, commenters argued, the promise to honor the altruistic gift of an organ to whoever needs it most is being violated.

The Department cannot solve this problem under existing law or through this rule. Nor are problems with the ability to pay unique to transplantation. What is unique is the interest of the donor family in fair allocation. The Secretary concludes that the Department and the OPTN should give more emphasis to socio-economic equity in transplantation. Steps toward this end are described later in this preamble.

C. The Department's Response and Policies of the Final Rule

Because most of the original commenters referenced specific sections of the NPRM, these comments are generally identified in numerical terms, e.g., two commenters had suggestions regarding the definition of ''national list.'' Most subsequent comments, particularly those made in connection with the public hearing, did not reference the NPRM. However, most of the latter comments focused on specific issues (organ donation, organ allocation, liver allocation, and oversight procedures) and are addressed in the corresponding sections below.

1. Section 121.2—Definitions

''National list'': Two commenters said that the proposed definition is misleading in that it implies a single, nationwide list for allocating organs whereas the OPTN policies for allocating organs give considerable weight to local and regional geographical considerations. The Department agrees that the term ''national list'' has been used in conjunction with allocation criteria that involve geographic factors. However, all recipients of organs are selected from a set of national databases; and even the current allocation criteria have important national elements for some organs. Therefore, the Department has retained the term ''national list.''

''OPTN computer match program'': The Department received two comments on this definition and has modified it to provide a better description of the matching process. The new definition states that the ''OPTN computer match program'' means a set of computer-based instructions that 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'': The proposed rule defines ''organ'' as a human kidney, liver, heart, lung, or pancreas. Four commenters suggested that the definition be broadened to include parts of organs and other organs. The inclusion of other organs, such as the stomach and intestines, not only would have an impact on other requirements in these regulations such as the development of allocation policies, certification of designated transplant programs, and establishment of training requirements but also would affect OPO requirements to procure these organs in accordance with rules of the Health Care Financing Administration (HCFA). Thus, the Department believes it would be premature for this rule to specify other organs in addition to those already named. Instead, the Department will direct the OPTN contractor to consider

which organs or parts of organs, if any, should be subject to OPTN policies, and to submit recommendations to the Secretary. The Department has added a reference to bone marrow to the definition, because section 374(d)(1) of the Act provides that the term includes bone marrow for purposes of the Scientific Registry.

''Organ donor'': One commenter suggested the addition of a definition for this term. The Department has accepted the suggestion and has defined ''Organ donor'' as a human being who is the source of an organ for transplantation into another human being.

''Potential transplant recipient'': The Department has edited this definition in accordance with the two comments it received. The new definition more accurately describes the relationship of the individual to the OPTN computer match program.

''Transplant candidate'': One commenter suggested a broader definition that the Department has accepted. It now defines ''transplant candidate'' as 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 physician'' and ''transplant surgeon'': The Department has added definitions for these terms in response to a commenter's suggestion that they be included. The final rule defines ''transplant physician'' as a physician who provides non-surgical care and treatment to transplant patients before and after transplant, and ''transplant surgeon'' as a physician who actually does transplants and provides surgical care and treatment to transplant recipients.

''Transplant program'': As suggested by one commenter, the Department has made an editorial change in this definition.

2. Section 121.3—The OPTN

This section of the proposed rule (originally titled ''composition'') elicited the most written comments, the majority of which discussed representation on the OPTN Board of Directors and committees. In addition, the public hearing identified the governance of the OPTN, including the composition of the OPTN Board of Directors and committees, as a significant area of concern. OPTN membership is summarized in Table 2 below.

Table 2—OPTN Membership, 1996

Transplant Centers	281
Consortium Members	4
Organ Procurement Organizations	*54
Histocompatibility Laboratories	55
Voluntary Health Organizations	12
Medical/Scientific Organizations	29
General Public Members	8
TOTAL	443

*This only includes independent OPOs; the other 9 OPOs are represented through their hospitals.

Source: 1996 Annual Report of the OPTN, page C–2 Table C–2.

Both in the written comments and at the public hearings, numerous witnesses who disagreed on particular organ allocation issues nonetheless agreed that there is a potential conflict of interest if transplant professionals, representing particular programs that provide them employment, vote on matters that may substantially affect the financial viability of those programs. Others argued that disagreements among transplant professionals overwhelmingly reflect honest differences of opinion and the natural desire of physicians and others to ensure the best possible outcomes for their own patients. Additionally, the Department received comments regarding the independence of the process for selecting members of the OPTN Board of Directors. Some members are currently elected from lists of persons selected by the nominating committee of the Board of Directors, not through independent nomination or election by sponsoring organizations. Regardless of the precise procedures and categories, many people believe that the OPTN Board of Directors would be more effective and have enhanced credibility if a greater percentage of its members were persons who broadly represent the public interest and persons who directly represent patient interests, without direct employment or similar ties to the field of transplantation.

The Secretary believes none of the changes being made in the regulatory provisions describing the composition of the Board of Directors will jeopardize either the expertise or the continuity of leadership important to the functioning of the OPTN. Transplant professionals will continue to be strongly represented on the Board. However, the rule will foster a broader range of diverse and independent views.

Accordingly, the Secretary is requiring the following changes in the composition of the Board of Directors (all in the context of a Board membership of 30 or more persons, as determined by the OPTN itself): First, at least eight of the Board members are to be transplant candidates, transplant recipients, organ donors, or family members and none of these members or general public members may have an employment or similar relationship with the OPTN or with the categories of members listed in § 121.3(a)(1)(I) or (iii)—OPOs, transplant hospitals, etc. Second, at least six members of the Board of Directors are to represent the general public; these members must be free of an employment or similar relationship to the OPTN or institutions or individuals involved in transplantation. Third, not more than 50 percent of the Board members, and of the Executive Committee, may be transplant physicians and transplant surgeons. Fourth, at least 25 percent of the Board members must be transplant candidates, transplant recipients, organ donors, and family members of any of these categories.

To give the OPTN some flexibility in meeting this new requirement, the Secretary is eliminating the originally proposed requirement that every OPTN region be represented on the Board. The Department does not require even that the OPTN use a regional structure. Thus, no reason exists to impose regulatory requirements for regional membership on the Board even if the OPTN continues to use a regional structure on its own volition.

This will also give the OPTN more flexibility in determining Board size. Depending on the OPTN's decisions as to size of the Board and whether the OPTN wishes to have any other members serve in a dual capacity and represent regions, this could free up as many as 11 seats on the Board of Directors. For the same reason, the rule gives the OPTN flexibility in the size of the Board of Directors—making clear that the contracting organization is free to have its own governing board structure that is separate and distinct from the structure of the OPTN itself. The rule gives the OPTN six months from its effective date to make these changes.

Turning to the original written comments on specific regulatory language, two comments indicated that the regulatory language in proposed § 121.3(a)(1) was confusing with respect to the number of individuals comprising the Board of Directors. The Department agrees and has not set any requirements as to maximum board size (although the minimum numbers specified for required members add up to 30 persons). At present, the Board has 39 members.

Several commenters suggested that patient groups should be permitted to select their own representatives to the Board and that the interests of patients and families of patients should be better represented on the Board and on its

Executive Committee. The Department agrees with the comments on the need to ensure that the interests of patients and their families are represented; however, the Department believes the OPTN should have flexibility as to its nomination and selection process. Thus, § 121.3 now provides that eight transplant candidates, transplant recipients, organ donors, or family members shall be included on the Board.

In addition, the Department has added to § 121.3 a requirement that the Board include at least 25 percent transplant candidates, transplant recipients, organ donors, and family members. Over the last few years, these individuals have represented 20 to 33 percent of the Board; and the Secretary expects that a comparable representation will be maintained. Section 121.3(b)(1) now requires the Executive Committee to include at least one member who is a transplant candidate, transplant recipient, organ donor, or family member, one general public member, and one OPO representative. Section 121.3(b)(3) requires transplant candidate, transplant recipient, organ donor, or family member representation on all committees established by the OPTN and also requires representation by transplant coordinators, OPOs, and transplant hospitals, as suggested by several commenters. The Department expects the OPTN to determine the appropriate number of such representatives on each committee, based on the types of issues that the committee will address.

The American Society of Transplant Physicians (ASTP) commented that it should select its own Board representative. The Department disagrees that it would be useful to add such a requirement, because transplant physicians are otherwise well represented on the Board and those members are members of the ASTP.

Another individual commented that the Board should include more minority representation. Proposed § 121.3(a)(2)(i) requires that the Board of Directors include individuals representing the diversity of the population of organ donors and recipients served by the OPTN, including minority and gender representation reflecting that diversity. A similar requirement with respect to committees is proposed at § 121.3(b). The Department has reviewed these proposed requirements, considered the commenter's suggestion, and decided to clarify these requirements in the final rule. The Department believes that including individuals from groups under-represented in the transplant patient population would enhance the ability of the OPTN Board and its committees to address the critical health needs of these populations. However, because the Board is elected, its composition is not guaranteed to reflect minority and gender diversity. Moreover, the Department intended that the Board requirement parallel the requirement for committees, that is, that the OPTN should attempt to reflect such diversity ''to the extent practicable.'' In neither case, however, does the Department intend to impose requirements that it would enforce, although, the Department strongly urges the OPTN to consider appropriate and practicable ways to encourage participation by minorities and women on its Board and on its committees.

One commenter asked that the general public category be broadened to include ''pre-transplant'' patients. As proposed, § 121.3(a)(1)(ii)(F) lists examples of individuals who could be elected from the general public. Because the section also says that the general public category is not limited to the examples given, ''pre-transplant'' patients could be chosen. However, the Department has modified § 121.3(a)(1), as discussed above, by adding the category transplant candidates, transplant recipients, organ donors, and family members to § 121.3(a)(1)(ii). This addresses the interests of transplant patients and candidates (pre-transplant patients), and transplant recipients, as well as family members of individuals who have donated or received an organ. Also, transplant candidates now are included within the diversity requirements of §§ 121.3(a)(3)(i) and 121.3(b)(3)(ii).

Another commenter suggested that regional representatives to the Board be elected from OPOs rather than transplant hospitals. The NPRM does not identify an organizational affiliation for regional representatives, nor does the final rule. Thus, regional representatives, if the OPTN elects to continue this approach, may be individuals affiliated with OPOs. They could also include other individuals who are affiliated neither with OPOs nor with transplant hospitals.

Two other commenters recommended staggered terms for Board members. One commenter recommended that the Executive Committee be elected annually rather than every two years as proposed; and three commenters said that proposed § 121.3(a)(5), requiring the appointment of an Executive Director to serve a four-year term, was unnecessary. We agree and have deleted that requirement. The existing OPTN practice is to stagger the terms of Board members, and the Department believes that the OPTN will continue to manage this aspect of its operation without the need for Federal regulation. With respect to annual election of the Executive Committee, the Department sees no reason to impose this requirement. In sum, we have tried to specify only the most essential features of the OPTN governance structure and to give the OPTN maximum flexibility in making decisions on other aspects of governance.

Two commenters said that all of the policy development duties of the Board of Directors in proposed § 121.3(a)(6) should be subject to the public participation process in proposed § 121.7(b), requiring public comment on proposed organ allocation policies. As mentioned above, we have added a new § 121.4 to clarify the intent of the policy development processes in the proposed rule. New § 121.4 incorporates the regulatory language in proposed § 121.3(a)(6) concerning the development of policies by the OPTN Board of Directors, the regulatory language of proposed § 121.7(b) regarding the public participation and appeals processes required for policies, and the regulatory language of proposed § 121.10 on review and appeal of policies.

Proposed § 121.3(a)(6)(ii) requires that the OPTN provide to the Secretary copies of all policies as they are adopted and make them available to the public upon request. It also states that the Secretary will periodically publish lists of these documents in the **Federal Register**. The Department has retained these requirements in new § 121.4(c) and has added a requirement that the Board of Directors provide the OPTN membership with copies of the policies (as well as notification of upcoming Board meetings). In addition, the Secretary will publish a statement indicating which OPTN policies trigger the special compliance requirements and potential sanctions under section 1138 of the Social Security Act.

The Secretary also has added a requirement that copies of all OPTN policies be continuously maintained on the Internet, to provide access to OPTN members, patients, donor families, transplant professionals, and other persons interested in organ transplantation. (The OPTN already operates an extensive and valuable Web site that substantially meets this requirement, at http://www.unos.org.) All policies of the OPTN are subject to review by the Secretary at any time under § 121.4(b)(2) and policies may be appealed under § 121.4(d). The Secretary will determine which policies should be subject to the notice and

comment process of the Administrative Procedure Act.

An editorial change was suggested to delete from proposed § 121.3(a)(6)(i)(B) the words ''fair and'' from the phrase ''fair and equitable allocation of human donor organs.'' The Department agrees that the proposed language is redundant and has accepted the recommendation. See § 121.4(a)(1).

With respect to the proposed requirements for OPTN membership, several commenters suggested that the rules establish voting and non-voting membership categories or otherwise set out membership voting privileges. The Department believes this is appropriate for the OPTN's policy development process and expects the OPTN to submit to the Secretary for review policies it has already developed in this regard. Two commenters pointed out what they perceived to be a drafting error in proposed § 121.3(c), which states that the OPTN *shall* admit and retain as members organizations, institutions, or individuals that have an interest in organ transplantation. The commenters said that the word ''shall'' should be changed to ''may'' to give the OPTN discretion in granting membership under § 121.3(c)(3). The Department has retained the mandatory term ''shall'' because we believe that anyone with a documented interest in organ procurement and transplantation must be granted membership. Should the OPTN deny membership under § 121.3(c)(3), applicants may appeal to the Secretary under § 121.3(c)(4). In addition, we have added to § 121.3(c)(3) a requirement that the OPTN process membership applications within 90 days to establish in principle that the Secretary expects the process to be carried out as expeditiously as possible given the OPTN's operational constraints.

The Secretary has added a new subsection 121.3(d) on corporate status of the OPTN. That section recognizes that requirements as to composition of the Board of Directors and membership admission requirements could create some problems for the OPTN contractor. The current contractor, a Virginia corporation, has chosen to recognize OPTN membership as automatically creating a right to corporate membership. At some future time, this or some other contractor might wish to create different arrangements. The language in this rule allows for this and clarifies that OPTN members do not have to become (nor the contracting corporation to accept them as) members of the corporation. The Secretary has also added a provision at § 121.3(e) that allows current and future contractors six months to come into full compliance with regulatory requirements in this section.

3. Section 121.5—Listing Requirements (Formerly § 121.4)

Most of the original comments received on this section of the proposed rule were on the subject of multiple listing, either supporting or opposing it. The proposed rule, in keeping with existing policy, did not prohibit transplant candidates from being listed with more than one transplant hospital. The final rule adopts this policy despite the commenters' concerns that it may disadvantage individuals who lack the insurance coverage or resources to seek listing with more than one institution or may raise ethical issues.

The Department believes that multiple listing is one of the few avenues open to patients who wish to choose their own medical care providers or try to overcome the waiting time inequities produced by the current ''local first'' allocation policies. Moreover, under current allocation policies, multiple listing helps patients who prefer to use a nearby transplant hospital that falls outside the so-called ''local area'' instead of a distant hospital that falls within that boundary. In addition, very few patients select this option. Steps to reduce waiting time inequities are described later in this preamble. When waiting times have become substantially equivalent among programs, the Secretary may ask the OPTN contractor to revisit the issue through its policy development process and submit its recommendations to the Secretary.

Several commenters suggested replacing the term ''OPTN member'' in proposed § 121.4(a)(1) and (3) with ''transplant hospital.'' The Department has accepted the suggestion with respect to proposed § 121.4(a)(1). See, § 121.5(a). However, because registration fees may be paid by OPTN members other than transplant hospitals, we have not made the suggested change in proposed § 121.4(a)(3). See, § 121.5(c).

Several commenters said that a time limit should apply when the OPTN submits to the Secretary a request for approval of the registration (listing) fee. The Department agrees in principle that such requests should be handled promptly and has added a requirement that the Secretary will approve or disapprove the amount of the fee within ''a reasonable time'' of receiving a request for approval and such supporting information as will provide the Secretary an informed basis for that decision. See, § 121.5(c). This language allows for the Secretary's discretion to publish a notice requesting public comments on any change in the registration fee. If the necessary supporting information is provided, a ''reasonable time'' should not exceed 30 days, and the Department will make every effort to meet that deadline. We welcome suggestions as to whether additional steps are needed to ensure that OPTN revenues are properly used for OPTN purposes.

One commenter suggested adding a new section requiring transplant hospitals to provide patient acceptance criteria to all patients. The Department agrees that patients should have access to as much information as possible. However, such a requirement would be very difficult to craft and enforce and would involve providing detailed medical information, because acceptance criteria are based on the varying medical conditions associated with end stage organ failure. Instead of creating a specific provision, we are greatly strengthening various requirements (see below) related to disclosure of information of benefit to patients.

4. § 121.6—Organ Procurement (Formerly § 121.5)

All but one of the comments received on this section concerned the criteria for acceptance of donor organs. Proposed § 121.5(c) permits transplant programs to establish such criteria but does not require it. Suggestions ranged from requiring minimum acceptance criteria to establishing standardized or universal criteria. The Department agrees that criteria are necessary and has added a requirement for the establishment of criteria for organ acceptance. See, § 121.6(c). However, we defer to the OPTN on whether to establish standardized criteria. Should the OPTN decide that such criteria are desirable, we expect such a decision, as well as the criteria themselves, to be developed through § 121.4, discussed above.

5. Section 121.7—Identification of Organ Recipient (Formerly § 121.6)

This section of the proposed regulations (formerly § 121.6) prompted a number of editorial suggestions, as well as concerns about financial responsibility for the transport of donated organs and protecting the confidentiality of organ donor records. The Department has accepted the editorial suggestions. One commenter said that proposed § 121.6(a)(4) should include a requirement that the OPTN be advised of the reasons for a transplant hospital's refusal of an offered organ. The Department agrees with this

suggestion, which is consistent with current practice, and has included it. This notice is to go to the hospital's affiliated OPO as well. See, § 121.7(b)(4).

Several commenters expressed concern about protection of confidentiality of donor records required by proposed § 121.6(c)(2). The Department agrees that such records must be protected and is confident that adequate safeguards exist in Federal and State legislation. No specific provisions are required in this regulation.

According to two commenters, proposed § 121.6(c)(1) should be amended to indicate that either a transplant hospital or an OPO is responsible for transporting a donated organ. Another suggested setting limits on, or otherwise accounting for, the financial implications of ''unreasonable'' transport requests. The Department intended that proposed § 121.6(c)(1) be broad enough to allow for a variety of situations that could arise in the transport of a donated organ. Moreover, proposed § 121.6(c) does not assign financial responsibility for such arrangements, which, with respect to transplants reimbursed by Medicare and Medicaid, are within the purview of HCFA and its regulations related to organ acquisition costs.

Three commenters said that OPOs cannot ensure the viability of transported organs, as indicated in proposed § 121.6(c)(3). The Department agrees and has modified this paragraph to require that the OPTN members transporting an organ ensure that it is packaged to enhance the probability that the organs will remain viable. See, § 121.7(c)(3).

Proposed § 121.6(d) elicited several comments pointing out that, in practice, OPOs make the offer of donor organs, not transplant hospitals. The Department agrees and has modified the language to delete the reference to transplant hospitals. See, § 121.7(b). We have also changed the term ''OPTN member'' in proposed § 121.6(e) to ''transplant hospital'', as suggested by one commenter. See, § 121.7(e).

6. Section 121.4—Policies: Secretarial Review (Formerly § 121.7(b) Public Participation)

Based primarily on the issues raised at the public hearing, this section has been expanded to include a new requirement (§ 121.4(a)(3)) that the OPTN modify or issue policies to reduce inequities resulting from socioeconomic status to help patients in need of a transplant be listed and obtain transplants without regard to ability to pay or source of payment. While such access is not guaranteed for other medical procedures, transplantation presents a special case. Donation is a valuable gift that is not conditioned on ability of recipients to pay nor do donors pass a ''means'' test. For these reasons, further efforts to facilitate access to the ''gift of life'' are necessary.

The Secretary does not prescribe specific steps, but requires the OPTN to consider possible policies to reduce inequities. For example, the Secretary expects the OPTN to consider methods of waiving or financing listing fees for patients unable to pay, through some form of cross-subsidy or by requiring that member hospitals absorb such fees.

The problem of paying for the transplant itself is much more complex, given the cost of these procedures, but a number of possibilities exist. Many member hospitals, for example, are obligated to provide uncompensated care under their charters or through the Hill-Burton requirements imposed as a condition of public grants and subsidized loans. The OPTN directly, or through member hospitals, could seek charitable contributions. Member hospitals could be obliged to provide a certain fraction of their transplants without charge to the patient, in recognition of the substantial value of the ''gift of life'' that the donors and families have provided for purely altruistic motives. Medicaid reimbursement could be sought more aggressively, for example, through the ''spend down'' provisions that enable many persons to qualify for insurance under that program. These and other options present difficult problems of policy and design; the Secretary simply requires here that the OPTN devote its energy to devising solutions and proposing policies to implement them. We are particularly interested in ideas that the OPTN could use to implement this provision.

As previously discussed, this general subject consumed a great deal of time and attention at the public hearings. Those hearings did not, however, focus on the details of the proposed rule or on how best to amend those.

With respect to proposed § 121.7(b), the Department received three comments during the original comment period about the process of adopting final allocation policies. Two commenters raised the issue of publishing proposed changes to allocation policies in the **Federal Register**. One said that the Secretary's decisions should be published; and the other suggested that, to meet the requirements of the Administrative Procedure Act, all proposed changes should be published with analyses before the Secretary makes a decision.

UNOS asked if the OPTN contractor would be required to submit to the Secretary for approval allocation policies in effect on the effective date of the final rule, pursuant to the process described in the final rule. For policies that the OPTN wants to be enforceable, the answer is yes. With the exception of particular policies established in this rule, all policies that have not been approved by the Secretary as enforceable remain voluntary, as explained in the 1989 **Federal Register** Notice. OPTN members that disagree with those policies may appeal them to the Secretary.

During the public hearing, a great many comments were directed to the question of the appropriate level of Federal oversight. While virtually all commenters agreed that the Department should have some role, opinions as to what that role should be varied from passive monitoring to taking very direct charge. Many of the particular suggestions made reflected the legal constraints that apply to organ transplantation. Some of these commenters also misunderstood the role and obligations of the Federal government for requirements that are established by law, even if implemented in part through private parties rather than by Federal staff. If the OPTN were a purely voluntary organization that happened to be a Federal contractor and if approved OPTN rules had no binding effect on patients or hospitals, then the appropriate level of oversight might be relatively low and limited primarily to efficient execution of the contract. But under the current law, patients have, as a practical matter, no choice but to use the system governed by the OPTN. Moreover, hospitals can lose the right to participate in Medicare and Medicaid and OPOs can lose reimbursement under Medicare and Medicaid for noncompliance with OPTN rules and requirements.

Both the genesis and wording of the National Organ Transplant Act (NOTA), as amended, obligate the Secretary to utilize the transplantation community substantially in both developing and executing transplantation policy. Under the statutory framework established by the Congress, however, the Department has oversight obligations, arising from the NOTA, as well as other laws and executive orders. For example, the Secretary has an affirmative obligation to make sure that policies and actions of the OPTN do not violate the civil rights of candidates for organ transplants. In this regard, however, most commenters stated, and the Secretary agrees, that

Departmental oversight should not micro-manage the development of purely medical criteria or routine day to day decision-making of attending medical professionals or the OPTN contractor.

The Department, in the preamble to the proposed rule (59 FR 46486), made clear its intention to provide the public with an opportunity to comment on organ allocation policies and proposed changes to them. While we believe that the comment process administered by the OPTN itself is invaluable in obtaining technical advice, it does not reach all of the affected public—including potential donors and interested persons who are not OPTN members and have no access to the OPTN—or otherwise provide the functions and protections accorded by the impartial review by the Secretary. These principles are carried forward in the final rule. To allow sufficient time for public comment on policies that the Secretary decides to publish, we have deleted from proposed § 121.7(b)(3) the 30-day time limitation and have substituted ''within a reasonable time.'' See, § 121.4(c)(2). The Secretary recognizes the importance of these issues, and expects the Department to act expeditiously on them. To ensure stability of the system, organ allocation policies, once implemented, continue to be in force during pending appeals or revisions.

New § 121.4 provides for an ongoing process of review that attempts to marry several goals: relying on the expert OPTN process to the maximum extent feasible; providing for independent review by the Department with additional opportunity for public comment; providing for cases where changes in policies may need to be made more rapidly than either process or both together would allow; and allowing the Secretary to take such other actions as the Secretary deems appropriate. Key to the effective functioning of this process is the acceptance by the transplant community of OPTN policies that have not been (and may never be) formally approved as enforceable requirements, but that most institutions choose to accept. A body of voluntary standards that can be rapidly revised, particularly for purely technical changes, is a crucial function of the OPTN system and one that the Secretary strongly supports. The Secretary believes that this rule puts in place an approach that accommodates all of the above goals.

7. Section 121.8—Allocation of organs

The majority of written comments received on proposed § 121.7 were opinions both for and against elements of the existing individual organ allocation policies, rather than comments on the content of this section of the proposed rule.

Several people discussed either the desirability or undesirability of permitting variances to current policies for allocating organs. Other commenters suggested broadening the geographic areas for organ allocation, localizing the areas for organ allocation, or allocating organs on a nationwide basis. One commenter said that allocation should be nationwide, because the current system is unfair to veterans. Under the medical coverage provided by the Department of Veterans Affairs (VA), veterans who need organ transplants are required by the VA to be listed with a transplant program with which the VA has contracted. Another commenter said that local allocation is an important incentive to organ procurement and that the relationship should be studied. Another commenter objected to disparities in waiting time among geographic areas.

The American Society of Transplant Physicians suggested a conference to determine the suitability of patients for transplant, the establishment of standardized criteria to determine when a patient should be placed on the waiting list, and to define standards for a patient to be retransplanted. The United Network for Organ Sharing (UNOS), the OPTN contractor, provided a list of factors to be considered by the OPTN Board of Directors in developing organ allocation policies. All of these issues are addressed in this preamble. The Secretary notes that since the publication of the NPRM, some of these suggestions have been adopted.

The Secretary originally received 62 letters commenting on organ allocation policies, of which 50 were about the lung allocation policy (many of those concerning lungs were form letters from patients at a single institution). These commenters, most of whom were individuals identifying themselves as organ transplant recipients, potential recipients, and friends or relatives of potential recipients, urged that geographic areas for lung allocation be broadened to permit more organs to be allocated to a particular medical program.

Comments on other organ allocation policies were also received from individuals affiliated with hospitals, from the American Society of Transplant Physicians, from the Cystic Fibrosis Foundation, from a law firm representing a hospital, and from a member of Congress on behalf of a constituent. Two comments were on the kidney allocation policy, one supporting local allocation and the other providing a copy of technical comments sent to the OPTN on revising the point system. One comment was on the heart allocation policy, suggesting that the geographic boundaries for allocation under the current policy be made more flexible. Two comments were not specific with respect to a particular organ, but recommended that allocation be nationwide based on time on the waiting list.

The Secretary also received letters urging action on liver allocation with emphasis on wider sharing. These comments, and many others on related allocation issues, arising both in the original comment period and at the public hearing, are addressed below in our proposed performance goals.

When the proposed rule was issued in 1994, the Department posed several open-ended questions about allocation policy, with the expectation that public response would help us decide how best to handle allocation policy and the extent to which we would seek to establish such policy in this final rule or in policy-by-policy reviews. Both in the initial set of public comments and in the months surrounding the public hearing, the Department received a great deal of information about, and many criticisms of, current allocation policies. For example, we learned that current allocation policies, by allowing local geographic boundaries to override patient needs, do not follow an ethical opinion addressing this very issue, promulgated through the Code of Medical Ethics of the Council on Ethical and Judicial Affairs of the American Medical Association. Second, we received the early results of computer modeling sponsored independently by UNOS and the University of Pittsburgh Medical Center (UPMC). These modeling efforts provided quantitative estimates of a great many variables—lives saved both pre-and post-transplant, time on waiting list, graft survival rates, etc.—that had previously been difficult to address systematically when alternative allocation policies were compared. Third, the OPTN itself continued to study, debate, and consider major revisions to its policies. Building on this new information, a primary purpose of the December hearings was to obtain even more information and opinions on organ allocation policies, particularly those affecting livers. That purpose was achieved.

Based on these sources and much other information, the Department has determined that the original proposal in the NPRM was insufficient. The

transplantation community is very divided, on allocation policy in general and specifically on liver allocation, and the existing policy development process is unlikely to bridge those divisions. Medical issues, ethical issues, and matters of trust and actual practice are substantially intertwined. Yet, the Department is unwilling, at this time, to issue a prescriptive allocation policy. We believe the OPTN must be primarily responsible for establishing medical criteria for patient listing and status categories, and for developing equitable allocation policies that reflect the Secretary's policies, as expressed in this regulation.

The Secretary decided, therefore, to approach the issue in terms of performance goals. The basic idea of a performance goal is to set a target, allow the operating entity (in this case the OPTN) to determine how best to meet that goal, and then measure performance against that goal. This model is widely used in business and in public programs. It is the model for this Department's Healthy People 2000 goals and other initiatives as well as the recently enacted Government Performance and Results Act. Quite apart from its other advantages, it promises to clarify and strengthen the Department's review and approval process for OPTN policies.

Based on the detailed and helpful dialogue at the hearing, and the clearly expressed preferences of commenters on both sides of specific issues, the Secretary has determined that three broad performance goals for organ allocation are needed. The topics of these goals are: (1) minimum listing criteria, (2) patient status, and (3) priority for patients with the highest medical urgency. The Secretary has also added a requirement, discussed below, for the OPTN to assess the cumulative effect of its policies, and develop new policies as appropriate, regarding socioeconomic equity. All of these goals are subject to sound medical judgment, both as to specific patients and as to overall standards, in order to avoid organ wastage, reflect advances in technology, and otherwise operate an effective and efficient allocation system.

Listing (§ 121.8(a)(1)). Many commenters at the hearings pointed out that current allocation policies (which give substantial weight to overall waiting time without regard to status) encourage aggressive physicians to list patients for transplants as early as possible, in some cases years before they will need or want a transplant. Other physicians are more conservative, and some patients do not come to the attention of transplant professionals until later in the course of their underlying condition. As a result, persons with equal waiting times may have very different medical urgency. This means that overall waiting time as a ''tie-breaker'' is unfair, encourages ''gaming'' behaviors and distrust within the transplant community, and discourages sharing of organs across geographic areas (because a less needy patient in one local area may obtain preference over a more needy patient in another local area simply by virtue of aggressive early listing). We have determined, therefore, to require that the OPTN develop listing criteria that are based on objective medical criteria pertinent to each organ, and to update these criteria to reflect increasing medical knowledge. The OPTN already has efforts underway that go a long way toward achieving this objective, and the Secretary applauds those. As explained below, overall waiting time will also be replaced by waiting time in status as a ''tie breaker.''

Patient Status (§ 121.8(a)(2)). Another set of themes emerging from the hearings is the recognition that current liver allocation criteria fail to differentiate adequately among different degrees of medical urgency and the desire for substantial improvements in the use of objective medical criteria for the classification of patients. In some cases, existing criteria are based on situational factors, such as whether a person is hospitalized, which are neither medical criteria nor necessarily good proxies for underlying medical condition or urgency. They can also encourage choices on the part of managing physicians to make sure that their own patients are not disadvantaged relative to other persons. At the same time, we know that advances in transplantation medicine and the OPTN's extensive investment in patient information systems have made possible improvements in the classification of patients. The ever-improving knowledge base about the medical factors that correlate with transplant outcomes, combined with the use of computer technology and statistical analysis, allow sophisticated ranking of patients, without the need to group disparate patients into relatively few and crude categories. The Secretary has decided to endorse the requested reforms and require improved categorization of patients, based on objective medical criteria that distinguish among different levels of urgency in sufficient detail as to reduce discriminatory effects.

Priority for the Most Urgent and Geographic Equity (§ 121.8(a)(3)). By far the most controversial aspect of current allocation policies is that the ''local first'' feature creates inequities in access for organs among patients of equal medical urgency, making where they live or list a more important factor than objective measures of medical status in obtaining an organ. All patients are affected by these inequities, but the consequences fall most heavily on those whose medical need is greatest and who are most likely to die before receiving an organ. As shown in tables 3a and 3b below, there are vast differences in median waiting times for kidneys among different transplant programs and different organ procurement areas (table 3a addresses transplant hospitals and is adapted from OPTN data printed in the Cleveland Plain Dealer on February 5, 1997; table 3b addresses organ procurement areas and is adapted from OPTN data on waiting times that will shortly be published):

TABLE 3a.—SHORTEST AND LONGEST WAITING TIMES BY KIDNEY TRANSPLANT PROGRAM 1994–1995

	Median [1]
Shortest Hospital Waiting Times:	
Harris Methodist, Fort Worth, TX	54
Presbyterian-University, Pittsburgh, PA	79
Southwest Florida, Fort Myers, FL	114
Henrietta Egleston, Atlanta, GA	144
Oregon Health Sciences, Portland, OR	147
Longest Hospital Waiting Times:	
University of Pennsylvania, Philadelphia, PA	822
Northwestern Memorial, Chicago, IL	828
Lehigh Valley, Allentown, PA	838
William Beaumont, Royal Oak, MI	850
Milton Hershey, Hershey, PA	858

[1] Median waiting times (days).

Source: *Cleveland Plain Dealer,* February 5, 1997, reporting UNOS data.

TABLE 3b.—SHORTEST AND LONGEST KIDNEY TRANSPLANT WAITING TIMES BY LOCAL ALLOCATION (OPO) AREA, 1993–1995 FOR BLOOD TYPE O

	Median [1]
Shortest OPO Waiting Times:	
Oregon Health Sciences University Hospital	107
Lifelink of Southern Florida	143
Lifelink of Florida	161
Life Connection of Ohio	204
Longest OPO Waiting Times:	
Carolina Organ Procurement Agency	1,423

TABLE 3B.—SHORTEST AND LONGEST KIDNEY TRANSPLANT WAITING TIMES BY LOCAL ALLOCATION (OPO) AREA, 1993–1995 FOR BLOOD TYPE O—Continued

	Median [1]
Regional OPA of Southern California	1,501
California Transplant Donor Network	1,513
New York Organ Donor Network	1,680

[1] Waiting times (days).

Source: UNOS data, soon to be published in report on waiting times. The OPO waiting times are longer than hospital waiting times mainly because type O patients wait longer than most other blood types.

Unfortunately these data, although the best available, do not isolate the differences in patient condition or in transplant centers listing practices that underlie some of the observed disparity. For example, as discussed previously, some doctors aggressively list patients very early in the course of their disease to give them more waiting time and raise their chance of obtaining an organ. Such a practice artificially inflates waiting times in some areas. However, the differences in waiting times by area far exceed the differences in medical status by area.

These differences exist throughout the United States. As shown in Table 4, each OPTN region has many local OPO allocation areas with relatively short and relatively long waiting times:

TABLE 4.—RANGE OF KIDNEY TRANSPLANT WAITING TIMES AMONG OPOS BY OPTN REGION MEDIAN WAITING TIME IN DAYS, 1994 FOR BLOOD TYPE O

Median waiting times for kidneys	Days (shortest–longest)
Region 1 (New England)	413–1,360
Region 2 (DC, DE, MD, NJ, PA, WV)	702–1,378
Region 3 (Southeast)	143–761
Region 4 (OK, TX)	386–655
Region 5 (California & Southwest)	374–1,513
Region 6 (Northwest)	107–1,061
Region 7 (Upper Midwest)	794–1,176
Region 8 (CO, IA, KS, MO, NE, WY)	287–754
Region 9 (NY)	228–1,680
Region 10 (IN, MI, OH)	204–1,422
Region 11 (KY, NC, SC, TN, VA)	231–1,423

Source: UNOS data, soon to be published in report on waiting times.

Similar waiting time differences exist for other organs. To some degree, these differences in waiting times result from the current absence of standardized listing criteria, as discussed above. Hence, these are imperfect measures of differentials. They also reflect, however, the fact that current patients who happen to list in areas with either higher incidence of end stage organ disease, or less ability to generate organ donors, are systematically disadvantaged by policies that do not permit the organs to go to the patients who need them the most. They also work to the disadvantage of prudent purchasers who wish to designate or contract with particularly high quality (or low cost) transplant hospitals to serve their patients. Under current allocation policies, neither individual patients nor concerned payers have the freedom to select their preferred medical provider without, in many cases, increasing the chance that the patient will wait longer and die while waiting for an organ.

Individual patients are directly affected, regardless of medical need. Although the Department is mindful that anecdotes can be misleading, the following example illustrates the inherent effects of establishing unduly restrictive geographic barriers to equitable organ allocation. In a recent case reported in the press (Sunday World Herald of Omaha, Nebraska, May 25, 1997), a patient was forced to choose between listing with a ''local'' hospital 250 miles away but in an organ procurement area that covered his State and had access to relatively more organs, or with his strongly preferred and truly local hospital just 20 minutes across a river and in another State that had access to relatively fewer organs. Cases such as this are inherent in a system that established defined areas for the purposes of administering organ procurement, but whose boundaries also have been used to limit organ allocation. Reliance on boundaries that make sense for administrative convenience may lead to inequities in organ allocation criteria. For example, in a number of States one OPO is surrounded by another; and in Texas there is an OPO that is composed of four non-contiguous areas separated by other OPOs. Some OPOs are based on the service area of a single hospital; some follow the boundaries of a single State; and others serve four or more States. These and other vagaries of this system are shown in the following map. Because of the differences in OPO size, geography, and population, the Secretary has decided that OPO areas should not be the primary vehicle for organ allocation.

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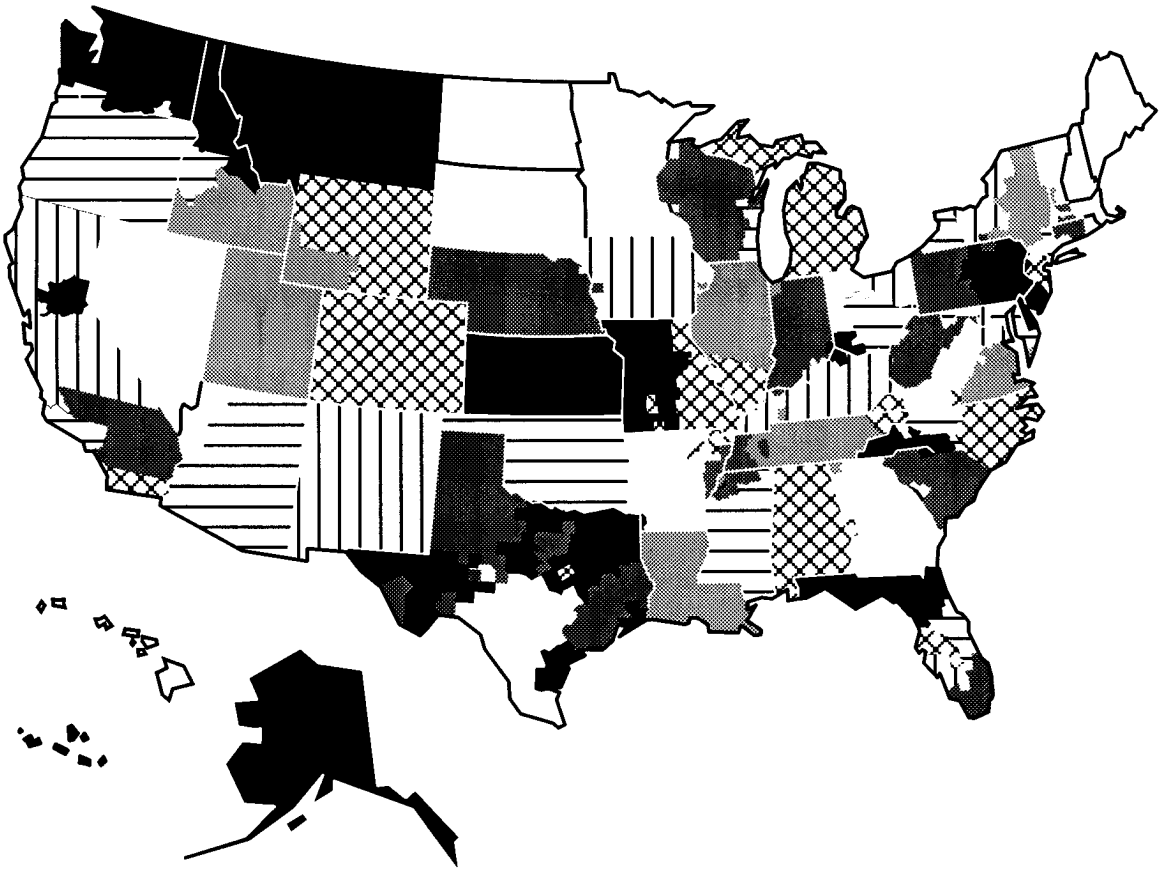
Organ Procurement Organization Service Areas, 1997



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Payers are also directly affected. Their ability to select transplant hospitals for their patients is hampered if listing patients solely at those hospitals forces them to compete with local patients for the limited supply of local organs, even though this listing frees up organs in the areas in which the patient would otherwise be listed. Some large payers have tools at their disposal to ameliorate this problem, such as listing some patients at more than one center (multiple listing), listing some patients at centers with shorter waiting lists, or accelerating hospitalization to put patients in a preferred status. However, most payers do not use such techniques and only a minority of patients benefit from such ''gaming.''

Perhaps the greatest inequity that the current system of local priority creates is that it particularly disadvantages those who face imminent death through unusually rapid deterioration. The chance that an organ that will match one's physiology will be available in the local area within the next week is very small. Yet, the chance that an appropriate organ will be available somewhere in the country and that it can be transported without risking wastage is much higher.

The transplant community has differing opinions over the issue of broader sharing. According to some commenters, this is in part because some hospitals and their patients reap the benefits of a highly productive OPO and they are concerned that they may receive fewer organs under a national system. Many commenters have pointed out that local preference draws upon, and reinforces, close bonds among local organ procurement organizations and local hospitals and physicians. Almost all agree that there are logistical and practical reasons why organs cannot be shipped back and forth across the country in response to the daily needs of every individual patient.

As shown below in Table 5, there are great disparities among OPOs in the production of donor organs, and under the current system, the productivity of the local OPO directly impacts on the number of transplants done in the OPO service area.

TABLE 5.—DONORS PER MILLION POPULATION 1995

Donors per million pop.	Percentage of OPOs
<15.00	19.4
15.00–20.00	22.4
20.01–25.00	37.3
25.01>	20.9

Note: The range of OPO donors per million population is 6.4 to 31.6.

Source: Calculation by the Division of Transplantation using UNOS Data.

Major review agencies, including the Inspector General of this Department and the Congress' General Accounting Office, have reviewed allocation issues and issued reports concluding there are major inequities and that major reform is needed to make the allocation system a truly ''national'' system as intended by the Congress.

The American Medical Association has studied organ allocation through a panel of experts. In its 1996 Code of Medical Ethics it states that: ''Organs should be considered a national, rather than a local or regional, resource. Geographical priorities in the allocation of organs should be prohibited except when transportation of organs would threaten their suitability for transplantation.'' In reaching this conclusion, the AMA panel reviewed the evidence concerning several organ types, and a wide range of alternative formulations. Of particular importance was their finding that current organ allocation policies were, in some cases, seeking to favor patients of lesser urgency but more likely to benefit, but that in actual practice these benefit differences were far too small to justify differential priority.

Taking all of these arguments into account, the Secretary has determined that a national performance goal is needed to encourage the OPTN to take advantage of advances in technology and survival rates, and to bring policies in line with the intent of the National Organ Transplant Act. That goal would reduce geographic inequities by requiring that persons with equal medical urgency (i.e., in the same status as defined under the second performance goal) have essentially equal waiting times regardless of where they list. This standard emphasizes, however, that the sickest categories of patients should receive as much benefit as feasible under this standard, in accordance with sound medical judgment. This is a significant departure from current policies, not only in making geography less important for allocation purposes, but also in its approach to waiting time disparities. The relevant ''tie-breaker'' will no longer be total waiting time, perhaps years, but will become waiting time within a group of patients with equal medical urgency.

We are mindful that there are practicalities involved, including especially transportation. The problem is not occasional cross-continental shipping from one large city to another, which is relatively straightforward. Instead, however, there can be severe logistical problems with frequent shipping of organs (often preceded by a special team that travels to retrieve the organ and return with it), or with moving organs among relatively transportation-disadvantaged areas, even within the same State. The performance goals are designed to allow (and require) the OPTN to craft policies tailored to each organ transplant type that are workable, feasible, and avoid organ wastage.

Many commenters urged that the Secretary require national sharing of organs, without any role for geographic factors. Others urged regional sharing. We prefer the performance goal approach. Achieving the goal will certainly require greater geographic sharing and will probably require national sharing for some organs for patients with specified medical conditions. Indeed, regional sharing is already a prominent feature of heart allocation, and national sharing a prominent feature of kidney allocation. However, we believe that any simple formulation would inhibit the ability of the OPTN to craft the most sensible policies that achieve practical as well as ethical results, and we wish to encourage change over time as medical science and medical criteria improve. Therefore, we are at this time using the performance goal approach for all organs (with an accelerated schedule for the initial revision of policies for liver allocation).

Implicit in the requirement that patients with equal medical urgency and waiting time in status have an equal chance of receiving an organ is reform of policies that encourage organs to be diverted from patients of blood type O, the ''universal donor,'' in favor of patients of other blood types, if that would preclude equalization of waiting times in status. One of the inequities of present organ allocation policies is that patients of blood type O wait much longer for organs than other patients. For example, according to recently calculated data from the OPTN, the median waiting time for primary kidney transplants in 1994 was 824 days overall, but 1,007 days for patients of blood type O. For hearts, the median waiting time was 224 days overall, but 353 days for patients of blood type O in

1996. Blood type is not an indicator of medical urgency, although it is a key determinant in organ matching.

The Secretary appreciates that there are many factors that can contribute to achieving the geographic equity goal. For example, if the Department's organ donation initiative were to achieve a high rate of success, then fewer organs would need to be shared. Improved listing criteria and medical status categories will reduce measured inequities. Nonetheless, within foreseeable parameters, we see no basis to expect that inequities can be eliminated for any major organ category without broader geographic organ sharing, on at least a broad regional basis for all patients with high levels of urgency.

We also require the OPTN to take into account key constraints on organ allocation. There are patients with urgent need for whom transplantation is futile. Organs cannot be used without an assessment of the immune system and other physical conditions of patients. Broad geographic sharing should not come at the expense of wasting organs through excessive transportation times. Efficient management of organ allocation will sometimes dictate less transportation when the highest ranking patient can wait a day or two for the next available organ. Sound medical judgment must be exercised before a final decision on whether to transplant a particular organ into a particular patient. Our goals allow for these factors to affect transplantation outcomes. For example, current OPTN policies take into account the special medical needs of children. The Secretary endorses this approach and expects that the OPTN will continue to take these needs into account as it develops new medical criteria and allocation policies.

Transition Protections (§ 121.8 (a)(5)) Finally, we have added a requirement that transition protections (sometimes termed ''grandfather'' rights) be considered whenever a change in policy disadvantages an identifiable set of patients already waiting on the national list of transplant candidates.

To implement these protections, the OPTN would determine whether a change disadvantaged some patients, and if so, consider developing a transition policy to eliminate that disadvantage. The transition policy would be submitted to the Department for review along with the new policy, together with estimates of the likely effects of each. Because a transition policy complicates organ allocation, and because the Secretary wants to preserve OPTN flexibility to develop and implement minor improvements with no consequential effect on existing patients' priorities, the transition provision allows the OPTN some flexibility as to whether, for how long, and for which patients the transition procedure would be developed. Of course, the OPTN would be free to devise particular approaches that would be most efficient and effective for a particular patient population. As with all other allocation policies, the Department would review each proposed transition procedure.

In addition, the Secretary has adopted a special transition provision for the first revision of the liver allocation policy. The OPTN is directed to develop a transition proposal for the Secretary's review which would, to the extent feasible, treat each individual on the national list and awaiting transplantation on the date of the publication of this regulation in the **Federal Register** no less favorably than he or she would have been treated had the revised policy not become effective. The transition procedures for this initial revision of the liver allocation policy 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 disadvantages by the change in the policy. See § 121.8(a)(5)(ii).

Kidneys pose potential problems because, unlike other organs, a significant fraction of patients have already spent years on the national list and turnover is much lower. On the other hand, transition procedures may be particularly important for kidney patients for the same reason. We request comments on the transition procedure generally and specifically as to its suitability for kidney patients.

(a) *Indicator Data* (§ 121.8 (a)(4) and 121.8 (b)) In order to assess how well the OPTN's current or proposed allocation policies achieve the performance goals previously stated, the Secretary requires the OPTN to collect and report indicator data on outcomes, and to compare alternative policies against estimated or projected outcomes. It is primarily against these indicators that the Secretary will determine whether the OPTN's proposed revisions to organ allocation policies will be approved. The Secretary expects the OPTN to develop appropriate indicators, but has specified several of central concern. These are: disparities in waiting times in status among transplant programs (especially disparities among the sickest categories of patient); life-years lost (both pre-and post-transplant); the number of patients who die while waiting for a transplant, and the number of patients mis-classified. Our requirements for performance indicators are presented in § 121.8(a)(4). See also, § 121.8 (a)(3), discussed earlier, for the allocation policies themselves.

Over the past year, a great deal of the debate and analysis of alternative allocation policies has benefitted from the results of computer-based modeling of liver allocation. While current modeling has some limitations, it is nonetheless useful today and holds great promise of assisting the OPTN in devising, as well as assessing, policies. The Secretary expects the OPTN to develop and use such models for all organs and to present results to the Department.

(b) *Deadlines for Initial Reviews* (§ 121.8(c)) The Secretary expects the achievement of these goals to be an ongoing process as medical technology, experience, and our understanding of transplantation improve over time. Therefore, we have provided for periodic policy revisions. However, for all organs other than livers, the Secretary is requiring that the OPTN develop initial revised policies to meet the goals, and to submit these within one year from the effective date of this rule. For livers, the Secretary is requiring development of policies that will meet these goals, to be submitted by 60 days from the effective date of this rule.

Shortly after this deadline the Secretary will take action with respect to the OPTN liver allocation proposal, depending on the information available to us as to which option best meets the performance goals set out in this rule. During consideration, the Secretary is committed to using a process allowing for effective comment and presentation of alternatives. In order to minimize the time needed to develop approved policies, the Secretary will follow carefully the OPTN's progress in developing the new liver allocation policies.

(c) *Liver Allocation Policies* The OPTN has wrestled with liver allocation issues for a decade. A brief summary of this history helps in understanding both the current OPTN policy and the Department's approach in this regulation. One of the two main purposes of the December hearing was to obtain additional information and views on liver allocation.

UNOS adopted a liver allocation policy in 1986, the first year of OPTN operations. The allocation policy featured a point system assigning relative weights for medical urgency, blood group compatibility and waiting

time to patients within distinct distribution units. This initial system allocated organs first among all patients locally (with ''local'' waiting lists meaning the OPO procurement area, ranging from a single transplant hospital's list to the combined lists of all transplant hospitals in an entire State), then to patients in the OPTN region. At the time this policy was adopted, the country was divided into nine regions. Eventually, the number of regions was expanded to the current eleven to reduce differences in population size among the regions. Major differences still remain, however.

The liver allocation policy also included an informal emergency voluntary sharing practice known as ''UNOS STAT'' whereby a transplant hospital would notify the UNOS Organ Center (the 24-hour organ placement operation maintained by UNOS) that a patient was critically ill and expected to die within 24 hours without a transplant. The Organ Center, in turn, would immediately notify all OPOs and transplant programs of the urgent need. Should a liver become available, the OPO could bypass the usual allocation process and the liver could be directed to the UNOS STAT patient's hospital. In effect, UNOS STAT was a system for sharing livers nationally, but only for the medically neediest patients. Between 1987 and 1990, it is estimated that 15 percent of the patients who received transplants were designated as UNOS STAT.

Objections were raised about the use of UNOS STAT, citing a lack of formal, uniform rules governing its use, and a concern that it was being used excessively or inappropriately. It was abolished by the OPTN in 1991. In addition to eliminating the UNOS STAT category, the liver allocation policy modified in 1991 expanded significantly the definition of the most urgent category by redefining it to mean death within seven days without a transplant (rather than 24 hours as in UNOS STAT). The rationale for the change was to provide greater opportunity within the formal allocation system for transplantation of chronically ill patients as well as those with acute fulminant liver failure.

Waiting time accrual under the liver allocation criteria was also modified to give greater priority to the most urgent patients. Status 1 (originally Status 4; in the discussion the sickest patients will always be referred to as Status 1, the current definition) patients were assigned the highest priority within the same distribution unit by only allowing waiting time accrued by a patient while listed as Status 1 to count for liver allocation. The Status 1 criteria specified until recently that such patients have a life expectancy of less than 7 days without a liver transplant. Patients who are listed as Status 1 automatically revert to Status 2 after 7 days unless they are relisted as Status 1 by an attending physician. Prior to this policy change, it was possible for a patient who had been waiting a long time in a lower status to accumulate enough waiting time points to give that patient enough total points to be ranked higher than a patient who was a Status 1. The definitions of Status 2, 3, and 4 patients were, until changed, as described below:

Status 2: Patients are continuously hospitalized in an acute care bed for at least 5 days, or are in the intensive care unit. Continuous hospitalization is required.

Status 3: Patients require continuous medical care but may be followed at home or near the transplant hospital.

Status 4: Patients at home, functioning normally.

However, because the system allocates organs first locally, then regionally or nationally only if no local patients are a good match for the organ, and because at any time it is likely that the relatively few (or no) local patients in Status 1 will match, many organs go to Status 2 and 3 patients despite their being ranked lower in medical priority. In the mid 1990s, about two thirds of liver transplants were received by patients waiting in the ''local'' area, about one fifth by patients in the region and outside of the ''local'' area, and about one eighth by patients outside the region. Therefore, the preference for ''local'' plays a significant role in determining a patient's likelihood of receiving an organ. Under the current system, there is a wide range among OPOs and the OPTN regions in the number of patients on the waiting list, the number of donor livers available, and the ratio of patients per donor. Consequently, patients in different locations have disproportionate probabilities of being offered a liver under this arrangement. Further, because fixed boundaries are used in local and regional distribution, some patients nearest the site of the donor who are otherwise highly ranked according to urgency or waiting time continue to wait while less sick patients in the ''local'' region are transplanted. As a result, some patients with higher medical urgency die waiting for a liver while other patients with less medical urgency receive a transplant.

Between 1990 and 1996, the number of liver transplant hospitals performing at least one liver transplant increased from 75 to 110, and the number of liver transplant programs performing 35 or more liver transplants per year increased from 18 to 41. Liver transplants increased from 2,676 to 4,012. Thus, patients have more transplant hospitals from which to choose, but at the same time competition among liver transplant programs for available livers has increased. During 1996, there were 8,026 registrations for a liver transplant.

Some people criticize this policy because livers are allocated ''local first'' to whomever is highest ranked in the local area of procurement. Thus, less sick patients can be transplanted before sicker patients in other local allocation areas. They believe that the sickest patients should always be transplanted first regardless of their location, because their lives are most at risk. In 1996, about 21 percent of liver patients transplanted were Status 1 and about 30 percent were Status 2. Almost 48 percent of transplanted patients were Status 3, and less than 1 percent were Status 4.

The counter argument to this criticism is that, if sickest patients are always given preference, there is a less efficient use of the available livers, because the sickest patients (Status 1) have lower survival rates than transplant recipients with other statuses. Others say that if less sick patients receive lower preference than under the current policy, more of them will become sicker while waiting and then will have lower survival rates when they are eventually transplanted. Optimally, patients should be transplanted at a time when they are sick enough to benefit from a transplant, but not so sick that the risk of losing the graft is heightened. OPTN data show, however, that at one year after transplant there is about an 11 percentage point difference in patient survival rates and 13 percentage point difference in graft survival rates between former Status 1 and 2. Some argue that part of this difference is due to a side effect of local preference rather than greater risk of graft loss: Status 1 patients, they assert, often get an inferior organ that was made available only after it was turned down for use for any patient in another local procurement area.

Table 6, taken from pages 143 and 149 of the *1997 Annual Report of the OPTN and Scientific Registry* shows graft and patient survival rates of liver transplant patients, by status:

TABLE 6.—THREE MONTH AND ONE YEAR GRAFT AND PATIENT SURVIVAL RATES OF LIVER TRANSPLANT PATIENTS BY STATUS

Waiting list status at transplant	N	3 Month survival rate		One year survival rate	
		Graft (percent)	Patient (percent)	Graft (percent)	Patient (percent)
Status 1	1,019	74.6	81.9	67.7	76.3
Status 2	1,562	84.0	89.8	77.1	83.6
Status 3	3,437	90.0	95.1	84.0	91.4
Status 4	91	87.8	97.6	82.2	93.7
Unknown	162	n.c.	n.c.	n.c.	n.c.
Overall	6,271	85.4	91.6	79.1	87.0

NOTE: Covers patients transplanted 1994–95 for which a survival time could be determined.
n.c.=not calculated

Another frequent criticism of the current policy is that there is wide variation in waiting times from one geographic area to another. A counter argument is that this variation cannot be attributed entirely to the allocation policy, because it may also be a function of patient selection decisions and the number of organs procured locally. However, the allocation policy, particularly as it relates to the size of the initial allocation area, is a major determinant of variation in waiting times. For livers, waiting time differentials among transplant hospitals and among organ allocation areas vary by a factor of five or more.

A third criticism of the ''local first'' policy is that it greatly limits patient choice. If some non-local transplant hospitals do a better job and attract more patients, these patients come to those hospitals only at the price of a reduced chance for a transplant and compete with each other for the limited supply of organs available locally. A counter argument is that some patients prefer to list at local hospitals and that an assured supply of local organs facilitates this particular choice.

Consideration of Alternative Policies

Following discussions with the Department, which suggested that computer modeling be undertaken, UNOS contracted with the Pritsker Corporation in 1995 to develop a computer simulation model for liver allocation. The model presents the hypothetical outcomes resulting from the application of a number of alternative allocation policies. Among the many outcomes measured were: patients transplanted, percentages of patients transplanted by status, number of pre- and post-transplant deaths, median waiting times, and distance from donor location to transplant location.

The Liver/Intestinal Transplantation Committee of the OPTN considered seven policies that were most representative of all those modeled, including a policy for national sharing proposed by the University of Pittsburgh Medical Center (UPMC). The UPMC proposal and the other options had also been modeled by the CONSAD Research Corporation under contract with the UPMC. The Committee's subsequent recommendations were reviewed by the OPTN Patient Affairs Committee and by its Allocation Advisory Committee which put forth an alternate proposal. This proposal included a modest component of regional sharing of organs, but rejected major regional sharing as well as the national sharing advocated by UPMC.

At its meeting in June 1996, the Board of Directors considered the policies proposed by the Liver/Intestinal Committee and the Allocation Advisory Committee, as well as the existing liver allocation policy. The Board decided to change the existing policy in several ways, including redefining Status 1 to include only patients with ''acute'' failure, placing other patients in intensive care into the broader Status 2 group along with other patients of lesser urgency, eliminating Status 4 as an urgency category for prioritizing liver transplant candidates, and mandating regional rather than local sharing for the newly defined Status 1 group (region for Status 1 allocation would be the area encompassing the 20 percent of the total number of Status 1 and 2 candidates on the national list who are nearest to the available organ). The Board of Directors then sent this proposal into an OPTN public hearing process held in the fall. In November 1996, the Board voted to adopt the new Status definitions, but to drop regional sharing. This change was scheduled to take place in January 1997. However, for the reasons described below, the Board suspended the new Status definitions (except for dropping Status 4) and the previous allocation system remained in place with little change.

At the Department's public hearing in December 1996, these system revisions became a major issue. The de facto effect of the Board's vote, as presented by many witnesses and uncontradicted by any evidence, was substantially to disadvantage the group called ''chronic crashers'', which had previously had a high priority as the predominant group within Status 1. In effect, the Board had increased the priority for ''acute'' patients with high medical urgency and little waiting time at the expense of another group with almost equally high medical urgency. While the Board did not present a formal rationale for the change in the record of its meeting, the change appears to be premised on the Board's belief that acute patients have a higher survival rate if transplanted promptly, and were disadvantaged under the current system, as well as its belief that some types of chronic liver disease, for example liver disease caused by alcoholism (alcoholic liver disease or ALD), had substantially lower survival rates.

As to the survival rate issue, the Department agrees with the approach taken by the American Medical Association in its report that supported the 1996 Code of Medical Ethics provisions discussed earlier. The report noted, ''only very substantial differences in the likelihood of benefit among patients are relevant to allocation decisions.'' In fact, as reported in the *UNOS Update* magazine of September/October 1996, the ''acute'' category of fulminant liver failure actually has a lower survival rate after transplant than most types of chronic liver disease.

With respect to ALD, the Department notes that data presented at a National Institutes of Health Workshop indicated, ''[r]ates of graft and patient survival after liver transplant for ALD are excellent and are similar to those for other chronic liver diseases. * * *''

As a result of the airing of these matters at the HHS hearing, the OPTN Board of Directors rescinded its decision and placed the new policy on hold (while allowing, however, limited

experimentation with broader sharing for ''acute'' patients in two OPTN regions). The net effect was temporarily to restore the prior system. At its meeting of June 25–26, 1997, the OPTN Board approved another policy, which would favor ''acute'' over ''chronic crasher'' patients. This revised policy puts the ''acute'' group first, the ''chronic crasher'' group second, and less urgent patients lower. Whatever the merits of giving preference to ''acute'' or ''chronic'' patients, these changes do little to reduce the fundamental inequities affecting patients across the country, the vast majority of whom have ''chronic'' liver disease. On the other hand, the new preference for ''acute'' patients exhibits a commendable understanding of the crucial argument in favor of this group: medical urgency.

All of these policy priorities, ranging from STAT to ''acute'', represent OPTN attempts to favor the most urgent needs. In its performance goals, the Department retains and emphasizes this recurring theme of OPTN policies regarding allocation of livers as well as other organs.

In light of the extensive deliberative process within the OPTN, the many policies that have been considered, the substantial technical information available, the availability of two modeling tools that provide approximate quantitative estimates of the differing effects of alternative policies, and above all the demonstrated inequity of the current liver allocation policies, the Department is not providing the OPTN the same period of time to reform liver allocation policy that it is providing for other organs. For all organs other than livers, the OPTN has one year from the effective date of these regulations to develop and submit to the Department allocation policies that meet the aforementioned performance standards. For livers, the Secretary is allowing 60 days from the effective date of these regulations. The Secretary appreciates that this time is far shorter than normal OPTN time frames, which include an opportunity for public comment. However, lengthy deliberations have already occurred and a great deal of information is available that will facilitate rapid reform. Moreover, the regulation specifies that no further public comment need be solicited by the OPTN before the deadline, although the OPTN may choose to do so. Similarly, the OPTN may choose to begin this process immediately if it believes that more time is required.

The final rule requires that the OPTN submit proposed transition procedures at the same time that it submits the proposed new allocation policy, together with supporting data. The Department will review these materials expeditiously, along with alternative proposals and public comments. The Department's plan is to obtain public input immediately following the deadline for the OPTN proposal. Commenters may propose alterations or alternatives. We ask that all proposals, whether from the OPTN or commenters, identify likely effects on inequalities in waiting times for patients of like medical urgency, on mortality, on life-years, on likelihood of organ wastage, and on other outcomes of importance.

The Secretary anticipates that similar procedures will be followed for other organs. In assessing these reforms for both livers and other organs, the Secretary will take into account that increased donation, more objective listing standards, and objective medical criteria for status categories all have significant potential for reducing geographic inequities. However, the Secretary has seen no evidence suggesting that fundamental inequities can be removed in the near future without broader geographic sharing of organs.

This final rule has not established specific quantitative measures that an OPTN liver allocation policy must attain to receive Secretarial approval. We expect the OPTN to use its medical expertise and consultative process to develop an appropriate policy. However, based on the use of the performance goals as a regulatory framework, it is unlikely that the Secretary would approve a policy that did not achieve a significant reduction in the disparity of waiting times, particularly for the most urgent patients.

(d) *Directed Donation* (§ 121.8(e)) Proposed § 121.7(d) on directed donation elicited several comments. Suggestions were made to delete the section on the basis that it would be misconstrued, and to refine it to take into account varying State laws. One commenter said that it contradicts the intent of the National Organ Transplant Act, and another said that directed donation should be discouraged but not prohibited. The existing OPTN policy discourages directed donation to designated groups or classes of people, but permits directed donation to named individuals. This policy is consistent with provisions of the Uniform Anatomical Gift Act, a model law that has been adopted by all States. The Department has retained in the final rule the language of proposed § 121.7(d) permitting directed donation of organs to named individuals. See, § 121.8(e). It should be pointed out that the final rule permits directed donation of an organ to named individuals only.

8. Section 121.9—Designated Transplant Program Requirements

Section 1138 of the Social Security Act creates an extraordinarily severe sanction for failure to comply with approved OPTN rules and requirements. This, in turn, would make it unfair and impossible to create standards higher than a threshold that any competent hospital might attain. In the proposed rule, the Department suggested the idea of ''designated transplant programs'' as a way around this dilemma.

Under this approach, failure to meet certain OPTN standards could result in an inability to receive organs, without necessarily jeopardizing either other transplant programs at the same institution or all Medicare and Medicaid reimbursement. No commenters objected to this approach, and no controversy over this approach surfaced at the public hearing. Accordingly, the Department has decided to retain the proposed approach, while improving it to reflect useful suggestions from commenters.

Most of the commenters on this section of the proposed rule recommended that the standards for the training and experience of transplant surgeons and transplant physicians, required for designation under proposed § 121.8(a)(2), apply also to Medicare-approved transplant programs designated under proposed § 121.8(a)(1). Three commenters suggested that transplant programs be designated on the basis of a minimum volume of transplant procedures and on patient survival standards, criteria now used in approving certain transplant programs for reimbursement under Medicare. Another commenter said that the NPRM was contradictory in admitting as OPTN members all Medicare-approved transplant hospitals, while expressing concern about proliferation of transplant hospitals and emphasizing that the Department did not wish to exclude hospitals from entering the field of transplantation. In the preamble to the proposed rule, the Department stated that the criteria for designation under proposed § 121.8(a)(1) and (2) are complementary, providing designated transplant program status to programs that meet Medicare standards, as well as to non-Medicare-approved programs which meet other requirements established by the OPTN. The Department's concern about the number of transplant hospitals was expressed in the context of ''uncontrolled proliferation of transplant facilities,'' that is, permitting designated status

without a method of ensuring the quality of care. See 59 FR 46488.

The Department sees the merit in having uniform standards for designated transplant programs, but believes that it would be disruptive to impose them unilaterally at this time. Instead, the Secretary will consider this issue in the context of revising the OPTN and Medicare standards. In that light, the Department has asked the OPTN contractor to consider developing standards regarding risk-adjusted graft and patient survival rates, and possibly volume of transplant procedures, if the latest scientific evidence supports such standards. If appropriate, such standards could supplement the requirements for designated transplant programs under § 121.9, following the notice and comment provisions of the Administrative Procedure Act.

The OPTN contractor, UNOS, said that the OPTN would not be able to provide patients with information about key personnel in Medicare-approved transplant programs, because it would have such information only for transplant programs designated under proposed § 121.8(a)(2). In addition, UNOS suggested that the OPTN be given authority to collect, maintain, and distribute data on key personnel for all transplant programs. The Department believes that the OPTN should define such a role through its Board of Directors' policy development process under § 121.4, and has asked the contractor to do so. Thus, explicit regulatory language is not required. In the meantime, to the extent that information is not readily available from the OPTN, we expect individuals to obtain it from the transplant programs themselves.

Two commenters suggested that a conflict exists between proposed § 121.8(c) and proposed § 121.3(d)(2) with respect to designation of transplant programs and membership of transplant hospitals. Under proposed § 121.3(d)(2), the OPTN is directed to accept as members of the OPTN transplant hospitals which meet the requirements of proposed § 121.3(c)(1) or (2). Under proposed § 121.8(c), (now § 121.9(c)), the OPTN may accept or reject applications from transplant programs for designated status. There is no conflict, because membership under § 121.3 does not confer designated status under § 121.9. One commenter said that proposed § 121.8(a) should indicate that designated transplant programs are also OPTN members. The Department has edited that paragraph in accordance with the suggestion. See, § 121.9(a). We have also added to § 121.9(c) a requirement that the OPTN act ''within 90 days'' on requests for designated status, making it comparable to the change made in § 121.3(c)(3), discussed above.

With respect to the disciplines listed in proposed § 121.8(a)(2)(v) as areas for collaborative involvement for designated transplant programs, two commenters suggested adding histocompatibility and immunogenetics. The Department has done so. See, § 121.9(a)(2)(v). The commenters also suggested that the term ''tissue typing'' in proposed § 121.8(a)(2)(vi) be changed to ''histocompatibility testing.'' The change has been made. See, § 121.9(a)(2)(vi).

The Department also has added a provision at § 121.9(a)(2) requiring transplant programs to have adequate resources to provide transplant services to their patients and promptly to notify the OPTN and patients listed for transplantation if the program becomes inactive. We are aware of at least one instance in which a transplant program became inactive, yet did not advise its patients of its inability to perform transplants. Such a situation also could lead to use of the enforcement provisions of § 121.10.

9. Section 121.10—Reviews, Evaluation, and Enforcement

Two comments were received on this section of the proposed rule. In response to one comment, an editorial suggestion, the Department has clarified proposed § 121.9(b)(1)(iii) to indicate that compliance by member OPOs and transplant hospitals with OPTN policies, as well as regulations, is covered in reviews and evaluations carried out by the OPTN. See, § 121.10(b)(1)(iii).

The other comment was an expression of concern about patients listed at transplant programs whose designated status to receive organs for transplantation may be suspended. The Department wishes to assure all who share this concern that the enforcement provisions of § 121.10(c) allow for an orderly phase-out and transition period should such a situation occur. Under § 121.10, the OPTN is required to monitor the compliance of individual transplant programs, to report to the Secretary the results of any reviews or evaluations that indicate noncompliance, and to make recommendations for appropriate action by the Secretary. The Secretary expects the OPTN to pay particular attention to programs experiencing difficulty. The rule further permits the Secretary to request more information from the OPTN or from the alleged violator, or both, before accepting or rejecting the OPTN's recommendations, or to take any other action the Secretary deems necessary. We expect that enforcement of these provisions will follow the pattern established by UNOS and member transplant hospitals in seeking voluntary compliance with OPTN policies in the past. That is, through a dialogue between the OPTN (and the Secretary, if necessary) and the transplant hospital alleged to be in violation of the rules, every effort will be made to reach a resolution before a decision is made to suspend a transplant program's designated status. It is the Secretary's intention that the OPTN develop a policy which minimizes disruption and cost to patients, and keeps them informed. The best interests of patient care will be paramount in monitoring and enforcement of compliance with this rule. In this regard, we have also elaborated on the procedures for OPTN reviews of transplant hospitals and OPOs. The OPTN shall conduct those reviews in accordance with the schedule specified by the Secretary and shall report progress on those reviews to the Secretary. See § 121.10 (b)(3) and § 121.10(b)(4).

10. Proposed Section 121.10—Appeals of OPTN Policies and Procedures

The Department received two comments on this section of the proposed rule. One commenter pointed out that appeals submitted to the Secretary must be sufficiently clear and substantiated. We agree that the Secretary must have appropriate information on which to base a decision, and believe that the language of the proposed rule provides the latitude needed for the Secretary to obtain such information. See, § 121.4(d). The other commenter expressed an opinion that the Secretary's role in approving policies and deciding appeals could lead to arbitrary and capricious actions, and suggested that the Secretary's decisions be published in the **Federal Register**. Similar points were raised in comments about proposed §§ 121.3 and 121.7 regarding publication of the Secretary's decisions on allocation and other policies of the OPTN, discussed above.

The Secretary's authority under proposed § 121.10(b) is not dependent on appeal and may be exercised at any time. We have moved the language of proposed § 121.10(a) to § 121.4(d). Because proposed § 121.10(b) is redundant in light of § 121.4(b)(2) and (d), we have deleted this section from the final rule.

11. Section 121.11—Record Maintenance and Reporting Requirements

Most of the comments on this section expressed concern that the proposed rule falls short of needed protections of confidentiality, and suggested as a model the protections delineated in MEDPAR, a Medicare data system used by HCFA. We agree with the need to ensure protection of confidentiality and believe that the protocols in MEDPAR may lend themselves appropriately to the records falling within the purview of § 121.11. We also believe, however, that the design of a system to protect the confidentiality of OPTN records should be left to the OPTN, subject to the Secretary's review and the data release provisions of this final rule. We expect the OPTN to submit for the Secretary's consideration a policy which will protect the confidentiality of OPTN records, but at the same time permit access by researchers to the OPTN and Scientific Registry data bases. Thus, we have amended proposed § 121.11(a) to reflect that records must be maintained and made available subject to policies of the OPTN and this final rule, as well as to applicable limitations based on personal privacy. We have also amended this section from the original proposal to clarify that the OPTN must follow such standard practices as making its information transactions and dissemination electronic to the extent feasible (unless requested in hard copy), and in disseminating information to include manuals and other explanatory materials as necessary to assure that the material is easily and accurately understood and used. We have also emphasized in § 121.11(b) and elsewhere that the OPTN should use rapidly advancing Internet technology to make information swiftly, conveniently, and inexpensively available throughout the nation.

Two commenters suggested adding a requirement that member transplant hospitals submit data to the Scientific Registry, a repository of data on transplant recipients that is operated under contract with the Department. Proposed § 121.11(b)(1) requires that the OPTN submit data to the Scientific Registry. We agree that a parallel requirement for transplant hospitals and OPOs is also appropriate, and have added it. See, § 121.11(b)(2). Another commenter suggested establishing a 90-day time limit for the submission of data under proposed § 121.11(b)(2). Such an explicit provision is not necessary because proposed § 121.11(b)(2) requires that information be provided on a prescribed schedule. In addition, UNOS suggested requiring the submission of cost data to the OPTN. Although we believe the language of the proposed rule is broad enough to permit the OPTN to request submission of such data, we have added to the final rule the phrase ''and other information that the Secretary deems appropriate.'' We have also corrected omissions in proposed § 121.11(b) by including the Secretary as a recipient of the information. We have added to the reporting requirements the phrase ''the OPTN and the Scientific Registry as appropriate. . . .'' This reflects the fact that some data which are to be reported or otherwise made available to the public are held by the contractor operating the Scientific Registry, while other data are held by the OPTN contractor.

The OPTN and the Scientific Registry are often asked by researchers, payers, the press, patients, and others for data. We appreciate the importance of the contractors' obligation to maintain the confidentiality of patient-identified data. However, we also recognize that data, collected as a consequence of Federally funded contracts and of official designation as a contractor of the Federal government, generally should be in the public domain. Even patient-identified data can be shared with researchers who provide appropriate protections against redisclosure. It is vitally important that *bona fide* researchers and modelers have ready and timely access to detailed data in order to explore ways to improve organ transplantation and allocation. Therefore, information should be made available to the public while protecting patient confidentiality. To correct the oversight of omitting this activity from the proposed rule, we have added § 121.11(b)(1)(v) which requires the OPTN and the Scientific Registry to respond promptly (normally within 30 days) and favorably to requests from the public for data to be used for *bona fide* research or analysis purposes, to the extent that the contractors' resources permit, or as directed by the Secretary. The contractors may impose reasonable charges for responding to such requests. Pursuant to Federal government-wide policy under OMB Circular No. A–130, charges should reflect only the marginal cost of preparing the data for dissemination, not the cost of collecting or maintaining it.

We have also added language in paragraph § 121.11(b)(1)(vi) saying that the contractors must respond similarly to reasonable requests from the public. The regulation does not require the contractors to satisfy every request; however, the ability to charge for data requests should enable the contractors to accommodate most requests. In addition, the contractors would have to provide ready access to data that it originally received from transplant hospitals and OPOs, to these same institutions. See, § 121.11(b)(1)(vii).

The Secretary has added language to § 121.11(b)(2) making clear that hospitals and OPOs must provide data directly to the Department upon request, and must authorize the OPTN and Scientific Registry to release data to the Department or others as provided in the regulation. The OPTN has informed us of difficulties it has in complying with both instructions from the Department and its perceived obligation to these institutions not to disclose data that might be made public by the Department. While we do not believe this to be a serious dilemma, we have drafted the final rule to make it clear that any hospital or OPO must, as a condition of its OPTN membership, make data available without restriction for use by the OPTN, by the Scientific Registry, by the Department, and in many circumstances by others, for evaluation, research, patient information, and other important purposes. In this regard, we particularly emphasize that we are requiring that current, institution-specific performance data be made available so that patients, payers, referring physicians, the press, and others can appraise the quality of transplantation programs. The Congress made this an obligation of the OPTN.

We have added language in § 121.11(b)(1)(I)(B) stating that the OPTN and the Scientific Registry shall submit to the Secretary information the Secretary deems necessary to prepare the Report to Congress required by section 376 of the Act, in order to clarify the contractors' responsibility in this area.

To complete the articulation of this policy, we have added a new paragraph (c) to § 121.11, ''Public access to data.'' This paragraph provides that the Secretary may release to the public information upon determining that the release will serve the public interest. For example, data on comparative costs and outcomes at different transplant programs, information on waiting list time, and information on the frequency with which transplant hospitals refuse offers of organs for their listed patients, will assist patients and their families and advisors in deciding where they wish to be transplanted. This release of data is consistent with section 375 of the Act, 42 U.S.C. 274c, which directs the Department to provide information to patients, their families, and their physicians about transplantation resources and about the comparative

costs and patient outcomes at each transplant hospital affiliated with the OPTN, in particular. It is also consistent with the Department's practice of having the contractor include in its published reports extensive data, including transplant hospital-specific survival data.

The provisions of § 121.11(c) were not included in the NPRM of September 8, 1994. To delay the implementation of this paragraph would be contrary to the public interest in that the decision-making of these parties regarding this life-saving procedure should be fully informed as soon as possible. The release of data is essential to allow patients, their families, and their physicians to make the most informed decisions possible about transplantation. Furthermore, the release of these data is consistent with the above-cited section of law and with the well-established practice of publishing center-specific outcome data, and thus public comment prior to publication is unnecessary.

The Secretary specifically requests comments on whether the above provisions sufficiently achieve the several important purposes served by provision of information to the OPTN, the Department, and the public, while protecting patient privacy.

12. Section 121.12—Preemption

A new section regarding preemption has been added to the final rule. This section does not require notice and comment rulemaking by the agency, as it does not alter the rights and responsibilities of any party. Instead, it simply applies the preemption principles derived from the Supremacy Clause of the United States Constitution. The Secretary is directed by section 372 to oversee a national system for distribution of organs, and the policies of the OPTN currently require organ sharing across State lines. The performance goals and indicators articulated by these rules are almost certain to increase interstate sharing.

At least one State has passed a law that appears to limit organ sharing policies. A national organ sharing system based primarily on medical need, with geographic considerations having less weight than at present as an allocation criterion, would be thwarted if a State required that, prior to sharing an organ with any other State, there be a written agreement with that other State or a requirement that the hospital or OPO first attempt to match the organ with an eligible transplant candidate within the State, regardless of status.

Similarly, a State enforcing such a law would almost certainly render impossible the compliance of transplant hospitals and OPOs within that State with rules and requirements of the OPTN, and thus would jeopardize their ability to obtain Medicare and Medicaid reimbursement. This too would thwart the Federal scheme created by Congress.

A further negative effect would flow from the enactment by additional States of such restrictive laws. If more States were to enact such laws, greater disruption in the allocation of organs under the OPTN's policies would occur. Patients registered for transplants in such States would almost certainly die as a result of the restrictions on organ sharing, while other patients would receive organs even though their transplants would not be approved until later under the OPTN's policies. Accordingly, for policy as well as legal reasons, the Department has added the preemption statement to the regulation.

The preceding discussion constitutes a Federalism Assessment, as required by Executive Order 12612, and we certify that this rule was assessed in light of the principles, criteria, and requirements of that Order.

III. Economic and Regulatory Impact

A. Legal Requirements

A number of statutes and executive orders require us to analyze the economic impacts of final rules.

Executive Order (E.O.) 12866 requires that all regulations reflect consideration of alternatives, of costs, of benefits, of incentives, of equity, and of available information. Regulations must meet certain standards, such as avoiding unnecessary burden. Special analysis is required for regulations which are ''significant'' because they create economic effects of $100 million or more; create adverse effects on the economy, public health, or other named categories; create serious inconsistency with actions of another agency; or materially alter the budgetary impact of entitlements and other programs or the rights and obligations of recipients thereof; or raise novel legal or policy issues.

The Regulatory Flexibility Act requires that we analyze regulations to determine whether they create a significant impact on a substantial number of small entities (for purposes of the Act, all not-for-profit hospitals and all OPOs are categorized as small entities), and if so to prepare a Regulatory Flexibility Analysis exploring ways to mitigate adverse impact.

Executive Orders 12875 and 12612 (dealing, respectively, with ''Enhancing the Intergovernmental Partnership'' and ''Federalism'') require that we review regulations to determine if they unduly burden States, localities, or Indian tribes, or if they inappropriately infringe upon the powers and responsibilities of States.

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that we determine whether regulations may result in the expenditure of $100 million either by State, local, and tribal governments, or by the private sector.

The Congressional review procedure of section 801(a)(2)(A) of title 5, United States Code, enacted in 1996, requires that rules with an economic effect of $100 million or more or other comparable effects be classified as ''major'', and that these rules may not take effect until the Congress has had 60 days to review them.

We have determined that this rule will not have consequential effects on States, local governments, or tribal governments, because it affects primarily the operation of private sector OPTN functions and the allocation of organs among patients based on their medical condition. It will not require an expenditure of $100 million or more by the private sector. Therefore, it does not meet the special consultative requirements of the Unfunded Mandates Reform Act. We have determined that it will not have a significant impact on a substantial number of small entities, and so certify under the provisions of the Regulatory Flexibility Act. However, because there is significant concern over the effects of changes in allocation policies on smaller hospitals, and because we considered as an alternative the possibility of imposing quality standards on transplant hospitals, we have prepared a voluntary Regulatory Flexibility Analysis (RFA). The analysis which follows, together with the remainder of this preamble, constitutes an RFA. We have also determined that this is an economically ''significant'' rule under E.O. 12866 and a ''major'' rule for purposes of Congressional review of agency rulemaking. (This rule is also ''significant'' under E.O. 12866 because it ''materially alters'' the rights of recipients—patients—of entitlement and grant programs). The analysis that follows, together with the remainder of this preamble, constitutes a Regulatory Impact Analysis (RIA) meeting these requirements.

This combined Regulatory Impact Analysis and Regulatory Flexibility Analysis also serves to analyze the effects of policies that we expect to approve under the procedures put in place under this rule, and that are assessed in this preamble, including all organ allocation policies necessary to

implement the performance goals and indicators that we establish.

At the time of the proposed rule, we stated that it would be premature to analyze alternatives because of the procedural emphasis of the NPRM. We stated that we would analyze comparatively the range of options that we considered, including the existing OPTN policies, based on the comments and information we later received. Subsequent events explained earlier in this preamble, and the information that we have subsequently received, have made it both desirable and possible to analyze qualitatively, and in part to quantify, the effects of the substantive, non-procedural policies promulgated under this final rule. We are far better able to quantify the effects of changes in liver allocation policy than of changes in allocation policy for other organs. However, we expect those changes to be qualitatively similar, and this analysis covers all allocation policies.

B. Effects of Organ Transplantation

Industry Structure and Size. As indicated in Table 7 below, covering selected organs, transplantation services are a very substantial set of medical procedures, although only a very small fraction of the trillion dollar health care sector.

TABLE 7.—ESTIMATED BILLED CHARGES FOR TRANSPLANTS, 1996

Major organ	No. programs 1996	No. transplants 1996	Average billed charges per transplant 1996 ($1000s)	Total program billed charges 1996 ($1000s)	Average program billed charges 1996 ($1000s)
Kidney	253	11,099	$94	$1,043,306	$4,124
Liver	120	4,058	290	1,176,820	9,807
Pancreas	120	1,022	110	112,420	937
Heart	166	2,342	228	533,976	3,217
Lung	94	805	241	194,005	2,064
Total programs	753	19,366		3,060,527	
Total hospitals	281	19,366		3,060,527	10,892

Sources: Data on numbers of programs and hospitals 1996 Annual Report of the OPTN, page 20 and C–2. Data on transplants performed from Facts About Transplantation in the U.S., UNOS, July 23, 1997. Data on billed charges per transplant from ''Cost Implications of Human Organ and Tissue Transplantations, an Update: 1996,'' by Richard H. Hauboldt, F.S.A., of Milliman & Robertson, page 30, excluding OPO charges.

These data show that on average, transplant programs generate revenues in the millions of dollars. Since most transplant hospitals operate several programs, the unduplicated revenue average across the 281 transplant hospitals that are OPTN members is about $11 million annually. This includes not just the cost of the transplant procedure itself, but also pre- and post-transplant charges such as time in the hospital waiting for a transplant. Because the source of these data uses billed rather than negotiated charges, actual receipts may be somewhat lower than shown above.

The range of revenues is much broader than these averages convey because the number of transplants performed varies so widely. Table 8 below, taken from OPTN and Scientific Registry data, shows the dozen highest volume programs for liver transplants performed in 1995 and 1996. These dozen programs performed one fourth of all liver transplants. Taken together, the two dozen lowest volume programs of those that performed transplants in 1996 only performed about 80 transplants, 2 percent of the total. Among active liver programs, the median program performed about 30 transplants, while the average was about 36.

TABLE 8.—12 OF THE HIGHEST VOLUME LIVER TRANSPLANT PROGRAMS, 1995–1996

Transplant program	1995 Volume	1996 Volume
UCLA Hospital Center, Los Angeles, CA	230	245
Presbyterian-University Hospital, Pittsburgh, PA	209	179
Mount Sinai Medical Center, New York, NY	209	180
Jackson Memorial Hospital, Miami, FL	194	179
Baylor University Medical Center, Dallas, TX	140	118
University of Chicago Medical Center, Chicago, IL	132	130
University of California, San Francisco, CA	106	100
University of Nebraska Medical Center, Omaha, NE	94	81
Rochester Methodist Hospital, Rochester, MN	91	89
University of Alabama Hospital, Birmingham, AL	82	86
Shands Teaching Hospital & Clinics, Gainesville, FL	81	102
University of Michigan Hospital, Ann Arbor, MI	78	59
Total	1,646	1,548

Source: 1997 Annual Report of the OPTN, pp. 391–396

Thus transplant volumes, and revenues, are highly skewed, with the average much higher than the median.

The billing cost data in Table 7 focus primarily on hospitals, and do not include procurement charges, which average approximately $24,000 per major organ in 1996, for a total of approximately one-half billion dollars

per year in addition to the $3 billion spent at transplant hospitals. Procurement charges are paid through organ procurement organizations. OPOs are by law given local (in some cases state-wide or larger) monopolies through a review and designation system administered directly by the Federal government. Currently, there are 63 of them, averaging some $8 million annually in revenues. Most of the revenues of both transplant programs and OPOs are paid by Federally funded health programs, primarily Medicare and Medicaid, but also Federal Employees Health Benefits Program (FEHBP), CHAMPUS, the Uniformed Services and the VA. In total, the government is by far the largest single payer for transplantation.

Included in the data above, but not separately identified, are laboratory costs. These can be very substantial, as a wide range of condition-related tests are necessary to monitor patient urgency, and both donors and recipients must have a broad range of laboratory tests.

The data above also include follow-up charges for one year, but not subsequent follow-up charges for immunosuppressive therapy and other costs. These average, according to Milliman & Robertson, about $7,000 for pancreas, $16,000 for kidneys, and between $21,000 and $29,000 for the other major organs in 1996. Adjusted for survival, Milliman & Roberts estimate the five-year cost of major organ transplants including follow-up costs as follows: heart, $317,000; liver, $394,00; kidney, $172,000; lung, $312,000; and pancreas, $149,000.

There are other sources of data on these categories of costs, each using somewhat different estimating techniques. Their estimates are generally comparable though sometimes lower. We note that such figures do not generally estimate the marginal cost of transplantation, after subtracting other costs that would be incurred if the patient did not receive an organ. Marginal costs are much lower. In the case of kidneys, a number of studies have estimated that transplantation costs are more than offset by reductions in other medical costs such as dialysis costs.

For purposes of the Regulatory Flexibility Act, an entity is considered ''small'' if it has revenues below a certain size threshold, or operates as a not-for-profit entity that is not dominant in its field. For health care providers, such as hospitals, the threshold amount is $5 million in annual revenues. Taking into account total hospital revenues and not just transplant revenues, few or no transplant hospitals fall below this threshold. However, the great majority of these institutions are not-for-profit entities, and hence qualify as ''small entities'' despite their substantial revenues.

Patient Effects. Table 9 below provides dramatic evidence of the importance both of increasing organ donation and of reducing unnecessary deaths while waiting for organs. Unlike growth in the waiting list, which in part reflects factors such as earlier and more aggressive listing, these data on deaths while waiting for organs provide clear evidence of the need for transplantation.

TABLE 9.—REPORTED DEATHS ON THE WAITING LIST 1988–1996

Year	Organ								
	1988	1989	1990	1991	1992	1993	1994	1995	1996
Kidney	739	759	917	975	1052	1285	1361	1510	1814
Kidney-Pancreas	0	0	0	0	15	61	71	86	91
Pancreas	6	23	21	37	33	3	13	4	5
Liver	195	284	316	435	495	562	657	799	954
Heart	494	518	612	779	780	763	724	769	746
Heart-Lung	61	77	68	45	44	51	48	28	48
Lung	16	38	50	139	219	252	286	340	385
Intestine	0	0	0	0	0	3	15	19	22
Overall	1,502	1,666	1,962	2,360	2,580	2,902	3,055	3,421	4,065

Source: UNOS web site at http://www.UNOS.org/sta—dol.htm, data as of January 13, 1997.

The approximately 20,000 annual transplants of major organs fall into two broad groups. More than half are kidneys. In the case of kidneys, dialysis is an alternative to transplantation for extended periods of time. Therefore, for most patients transplantation is not a matter of immediate survival. Instead, the benefits of transplantation fall largely (though not exclusively) in the domain of improved quality of life. These improvements can be very substantial, as physical health while on dialysis is significantly impaired, and dialysis imposes major stresses and substantial inconveniences in carrying out normal activities. In sum, dialysis sustains life but not well-being whereas a transplant can and often does restore well-being. For other organs, a transplant is in most cases a matter of survival. There are life-prolonging technologies that work for some patients (e.g., left ventricular assist devices for hearts) but for most awaiting extrarenal organs, a transplant is literally essential to survival. Thus, in round numbers the annual benefits of organ transplantation include about eleven thousand lives vastly improved by kidney transplantation, and another eight thousand lives both vastly improved and prolonged by transplantation of other major organs.

It is common, in benefit cost analysis, to use a concept termed ''value of a statistical life'' to estimate in monetary terms the benefits from lives saved. Estimates of this value can be derived from information on the preferences of individuals for reduction in the risk of death, and their willingness to pay for such reductions. In this case, however, it is important to take into account two major factors that reduce the usefulness of a statistical life as a measure: (a) most organ transplant recipients are much older than average and hence gain fewer years than would average beneficiaries of other life-saving interventions, and (b) an organ transplant carries a substantial risk of either the graft or the patient not surviving. For example, according to historical data from the 1997 Annual Report of the OPTN (page 23), only 62 percent of cadaveric kidney grafts survive 5 years, and only 81 percent of these patients survive 5 years (patient survival is substantially higher because dialysis is usually an option if the organ fails). Five year patient survival rates for livers 72 percent, for hearts 67 percent, and for lungs 43 percent. As each year passes, additional patients die, though at lower rates than in the first year or two. Survival rates

have improved in recent years, but the statistical expectation of increased longevity and/or graft survival from a transplant is on the order of a dozen years (a rough estimate since we do not yet know what the long-term experience will become), not the 40 years (half a lifetime) that underlies most estimates of statistical lives. Using the more conservative concept of a ''statistical life-year'' saved, then, the benefit from each year's cohort of approximately eight thousand non-renal transplant recipients approximates one hundred thousand life years. In a recent rule-making on tobacco, HHS estimated the value of a statistical life-year at about $116,000 (see **Federal Register** of August 28, 1996, at page 44576). This was a conservative estimate that would reasonably apply to organ transplantation (though a figure several times as high could equally reasonably be used). Applying the conservative $116,000 value to statistical life-years saved by non-renal organ transplants, the social benefit from each annual cohort of recipients is on the order of $12 billion. (Additional benefits could be calculated for quality of life improvements for kidney recipients.) Thus, whether one counts lives saved, life-years extended, or improved quality of life, and whether or not expressed as dollars, the social benefits of transplantation far exceed the admittedly expensive costs of transplantation.

C. Effects of This Rule

This rule creates three major effects. First, it establishes terms of public oversight and accountability for the entire organ transplantation system, and the OPTN in particular. We believe that this reform creates major public benefits in the categories of ''good government,'' preserving public trust and confidence in organ allocation, and assuring the rule of law. The Secretary does not believe that such oversight creates any consequential costs. Its benefits are substantial, but intangible. They may well lie primarily in future problems avoided (e.g., reduction in organ donation if the public were to lose confidence in the fairness of the OPTN in allocating organs) rather than in specific current problems solved.

Second, this rule requires creation of a system of patient-oriented information on transplant program performance. At present, the fundamentals of such a system exist through the efforts of the OPTN. The OPTN collects, validates, and analyzes a great deal of important information. It publishes, in collaboration with this Department, a *Report of Center Specific Graft and Patient Survival Rates*. This report consists of 9 volumes and 3,200 pages, and contains valuable information. However, from a patient perspective it is not up-to-date or easy to use. The most recent version was the 1997 report, but the data were current only up through April, 1994. The primary limitations of the Report are that the survival rates are for patients transplanted several years earlier and that there is no information regarding the waiting list at individual transplant centers. We believe the data should be more current. In addition, we believe center specific waiting times and numbers and percentages of transplant center organ turndowns of organs for non-medical reasons should be made available to the patients. Finally, versions are needed that are easy to use for patients, physicians, and families who wish to compare center performance on any or all of these dimensions.

Third, this rule will improve equity by creating performance goals against which the OPTN can reform current allocation policies. Such a reform has important benefits—though benefits virtually impossible to quantify—in their own right. We note that ''equity'' is an important goal under Executive Order 12866. Unfortunately, improved equity is an extraordinarily difficult concept to quantify. It is a goal and as it is achieved, benefits accrue to members of society at large, to donor families, to transplant candidates, and to transplant recipients. We do have some measures of additional benefits arising in part from improved equity, such as life-years saved, but these are a separate category of benefit. We believe that a system that allocates organs to those most in need in accordance with sound medical judgment, but with as little regard to geography as reasonable, has profound benefits quite apart from those that are life saving.

Table 10 below summarizes a number of measures of the effects of alternative approaches to improved equity in organ allocation, for livers. Comparable data are not readily available for other organs, and for a number of reasons liver transplants are particularly susceptible to improvement (hearts, for example, are already shared regionally and kidney patients have dialysis options). However, these liver data suggest the kinds of improvements that can be made for other organs.

TABLE 10.—SUMMARY OF MEASURES OF ALTERNATIVE APPROACHES TO LIVER ALLOCATION

	1996 Policy	Allocation committee	Inpatient first	National
Percent transplanted by hospitalization:				
Inpatient	59%	73%	96%	97%
Outpatient	41%	27%	4%	3%
Share of organs:				
Local	78%	44%	38%	20%
Regional	18%	28%	31%	6%
National	4%	28%	31%	74%
Number transplants:				
Initial	10,992	10,998	10,451	10,231
Repeat	1,663	1,659	2,189	2,425
Total	12,655	12,657	12,640	12,656
Number on waiting list at end	11,534	11,788	12,729	13,050
One year survival rate	80%	81%	76%	73%
Deaths:				
Pre-transplant	3,704	3,599	3,168	2,963
Post-transplant	2,539	2,555	2,967	3,144
Total	6,243	6,154	6,135	6,107
Life-years:				
Pre-transplant	26,600	27,193	29,443	29,915

TABLE 10.—SUMMARY OF MEASURES OF ALTERNATIVE APPROACHES TO LIVER ALLOCATION—Continued

	1996 Policy	Allocation committee	Inpatient first	National
Post-transplant	24,712	24,840	22,759	21,765
Total	51,312	52,033	52,202	51,680

Source: These estimates all come from modeling runs created by the Pritsker Corporation for the OPTN. Most of those results were included in information provided at OPTN Board of Directors meetings. All data cover a three year period, and are not annual estimates. Actual data for 1996 do not necessarily agree with these modeling estimates, which apply to future years.

These data show, in broad outline, the effects of several alternative policies for liver allocation. We emphasize that none of the alternatives modeled included the effects of improved listing and status standards, and for that and other reasons discussed below, these results cannot be taken as precise predictions of the effects of changes.

These data also omit a large number of alternative policies that have been modeled, in the interest of economy of presentation. Of particular interest are a set of policies that deal with a family of options that have been termed ''time and distance weighted.'' This family of options seeks to minimize transportation of organs while achieving equity based on medical urgency and waiting time. In effect, organs are transported long distances only when there is no alternative for patients with high priority. Organs are kept locally when only very small differences in patient benefit could be achieved by regional or national transportation. Depending on the precise weights given to medical status, waiting time, and distance, inequities due to waiting time disparities can be greatly reduced. (See testimony of Dr. John P. Roberts of the University of California, San Francisco, presented at the public hearing and two letters from Dr. Roberts included as Exhibit L in the Liver and Intestinal Organ Transplantation Committee Report presented to the OPTN Board of Directors for its meeting on June 25, 1997) .

In Table 10, some of the most studied options are presented. These options focus increasingly on broader geographical sharing, and on greater reliance on medical urgency, from left to right. The first column simply presents the predicted results of 1996 policy. The ''Allocation Committee'' column shows the results of an option reviewed and subsequently rejected by the OPTN Board in 1996, that would have allocated organs to Status 1 (most urgent) patients across regions comprising 20 percent of the eligible hospitalized patients. Other patients would have received either a slightly improved or no chance at organs from out of the local area. Thus, this represents a very modest change towards regional sharing from current policy. The third column, ''Inpatient First'', shows the results of an option that would have allocated organs first nationally to hospitalized patients, and only then to Status 3 patients. The ''National'' column shows the results of an option proposed by the University of Pittsburgh Medical Center that would have allocated organs by status, primarily on a national basis, from most to least urgent (even the ''National'' proposal preserved a substantial role for local allocation, by allocating first to a local patient in Status 1, then nationally, then to a local patient in Status 2, then nationally, etc.).

One very striking result is that even a modest policy change can very substantially change the kinds and places of patients receiving organs. The Allocation Committee option decreases the share of livers allocated to non-hospitalized patients (Status 3 and 4) from 41 percent to 27 percent, and decreases the number of organs shared locally from 78 percent to 44 percent.

Taking the remainder of the rows in order, broader sharing has no consequential effect on the number of transplants, but raises the number of repeat transplants, thereby reducing the number of individuals transplanted. This is a consequence of transplanting very sick patients who are more likely to reject an organ graft after transplantation. The number on the waiting list rises when organs go first to more urgent patients. This is both a good and bad outcome—longer waiting is ''bad'' but not if the alternative for other patients is death. Survival rates decrease with a priority to the most urgent because the most urgent patients tend to have more advanced disease and additional co-morbidities (as discussed below, we do not believe that current simulation results accurately measure likely survival rates). However, as shown in the estimate of deaths, the net effect of these changes is to reduce premature death, despite the decrease in survival rates. Of importance is that the net total change in deaths masks a very pronounced difference in direction for deaths pre-transplant (which are substantially reduced), and deaths post-transplant (which in the Pritsker model increase almost enough to offset pre-transplant lives saved—but see discussion below of the CONSAD model). Life-years exhibit a similar pattern to deaths, but are arguably a better measure of real effects. Over a longer period of years, the total number of people dying under all options will approach equality—but only if there is no increase in transplant survival rates through medical progress. But a life-year lived is never ''lost'' and represents an unambiguous gain for the patients who benefit. Unfortunately, the post-transplant life-years increase very little or decrease under broader sharing (as estimated by Pritsker), whereas the years on the waiting list, not dying but not well, increase dramatically.

As shown both in the Pritsker results and in the CONSAD results presented below, no organ allocation gains are free. Taking as an example deaths under a National policy, the Pritsker model estimates that over a three year period some 700 fewer people would die pre-transplant, and some 600 more people would die post-transplant. These are changes of one-fifth or more in the number dying in each group. Both costs and benefits are very high, thus reducing the net benefit substantially.

The CONSAD model produces generally similar results, but shows a distinct difference in the magnitude of deaths and life-years (as shown in Table 11):

TABLE 11.—NUMBERS OF PRE- AND POST-TRANSPLANT DEATHS AND LIFE YEARS UNDER ALTERNATIVE LIVER ALLOCATION POLICIES

	1996 Policy	Allocation committee	Inpatient first	National
Deaths:				
Pre-transplant	4,571	4,394	4,060	4,216
Post-transplant	2,468	2,487	2,734	2,527
Total	7,039	6,881	6,794	6,743
Life-years:				
Pre-transplant	15,093	17,837	19,580	18,683
Post-transplant	38,107	38,096	35,537	36,465
Total	51,200	53,933	55,117	55,148

Source: CONSAD model run dated March 24, 1997.

As shown, under the CONSAD model the net life saving and life-year saving effects of broader sharing are much more pronounced, as well as more favorable to post-transplant experience. CONSAD shows National allocation preventing a net of over 300 deaths and saving a net of almost 4,000 life-years, in contrast to Pritsker's estimate of about 140 deaths and about 400 life-years (though 900 life-years for Inpatient First). These are not small differences. Under the Pritsker model, deaths would decrease, and life-years would rise, only about 2 percent from current levels under the most favorable result for broader sharing. Under the CONSAD model, deaths would decrease about 4 percent and life-years would rise about 8 percent. Realistically, in view of the modeling issues discussed below, a 2 percent difference may represent less than the possible error in the model, though an 8 percent difference is much more robust—if the model parameters and assumptions are accurate. But even the CONSAD results indicate that improved allocation policies have at best a limited potential to improve outcomes. In contrast, improved organ donation represents an unambiguous and potentially much larger gain.

There are known differences in model assumptions and approaches that illustrate the strengths and weakness of both efforts. The Pritsker model results ''throw away'' the first of the four years modeled, to show more clearly the long-term rather than transitional effect of change. In contrast, the CONSAD model cumulates the results of years one, two, and three, rather than two, three, and four. Since many life-years and deaths occur in the transition year, totals vary for this reason. Second, the Pritsker model assumes that all transplant programs operate at the same effectiveness as in the early 1990's, all through the modeling years. The CONSAD model, in contrast, assumes a slow but steady increase in transplant program performance and patient survival. This assumption naturally results in fewer deaths and more life-years gained in CONSAD runs, differentially in favor of those who would otherwise die but could now expect to survive.

One difficulty shared by both models is that the OPTN has not released current data on transplant outcomes. Thus, these modeling results rely on data centering around 1990 and 1991 (including several years before and after) rather than on the latest outcome data. Because current graft and patient survival rates are known to be higher, this makes certain outputs, particularly graft survival rates, deaths, and life-years, inaccurate. CONSAD attempts to estimate recent progress, but this is not a complete substitute for better baseline data.

Showing the importance of progress over time, UNOS data show that between 1990 and 1995, one year patient survival for liver transplant recipients increased from 83 to 87 percent.

Neither model completely captures a variety of real world nuances. For example, under current policies survival rates for the sickest patients who receive organs from outside their local area may be influenced adversely by the sometimes lower quality of the organs they receive that have been turned down elsewhere. But no hard data exist, and neither model attempts to estimate such an effect. Neither model attempts to deal with a hypothetical breakthrough in technology. Neither model deals with the ''friction'' involved in transporting organs over broader geographic areas (although they do produce estimates of increased organ travel); both assume no wastage or reduced graft survival results. None of these differences or commonalities imply a fatal weakness in either or both of these models, but simply a recognition that simulation modeling is by its very nature a partial and incomplete attempt to predict results with any number of assumptions potentially affecting outcomes.

From the Department's perspective, what is most important about these modeling results is that despite the somewhat different interests of their sponsors and the potential bias that might result, and the infant efforts that they represent, these two independent efforts agree almost completely on the qualitative effects to be expected from changes in allocation policies, and substantially on the magnitudes involved as well.

More complex to display are measures that capture likely effects of improved policies on disparities in waiting times. As discussed earlier in this preamble, program-specific, area-specific, and region-specific results look very different, because aggregation masks disparities. However, even regional differences are substantial. Table 12 below follows shows the disparities under the 1996 policy, the Allocation Committee (regional) proposal, the Inpatient First proposal, and the National (local first, then national) proposal, as measured in average days waiting for a liver transplant:

TABLE 12.— ANALYSIS AVERAGE DAYS WAITING FOR A LIVER TRANSPLANT UNDER ALTERNATIVE LIVER ALLOCATION POLICIES

OPTN region	1996 Policy	Allocation committee	Inpatient first	National
Region 1	102	123	110	105
Region 2	126	120	121	124
Region 3	23	70	81	109
Region 4	91	91	100	113
Region 5	121	113	109	119
Region 6	56	107	94	107
Region 7	118	113	105	110
Region 8	110	116	106	122
Region 9	119	99	107	115
Region 10	88	92	93	110
Region 11	70	76	88	123
Standard Deviation	32.24	17.93	11.55	6.81

Source: CONSAD model run dated March 24, 1997.

In this table, the standard deviation entry measures the extent to which Regional averages differ. The standard deviation is a statistical measuring tool. In this context, it means that under the current system about two-thirds of the regions are within 32.24 days of the average (both longer and shorter), and the remaining one-third are more than that many days longer or shorter than the average. As these results show, even modest geographic sharing based on a proxy for medical need greatly reduces disparities in waiting time, from a standard deviation of 32.24 days under current policy to as few as 6.81 days under a national system of distribution. (Of course, as discussed previously, current measures of waiting time disparities are weak because the lack of listing standards does not create uniform, status-related measures that would be truly fair as tie-breaking criteria.)

Another dimension of improved equity arises from reducing the role of ethically irrelevant characteristics such as race or insurance coverage in organ allocation. We already know, from prior studies, that racial minorities—particularly African Americans—may not benefit to the extent that their medical need warrants. In the final rule, as noted previously, we have tasked the OPTN to develop policies to reduce socio-economic inequities. No data from the modeling efforts or other sources enable us to predict precise effects, even if the full potential of such policies were clear. However, to the extent that improved allocation policies reduce the ability of patients, payers, or physicians to ''game'' the system, it will necessarily benefit the more disadvantaged patients.

The performance goals created by this rule do not directly mandate any of the allocation options just discussed. Instead, we require the OPTN to craft new policies that achieve those goals. To the extent that the modeling results capture our expectations, we expect those reformed policies to show results much more similar to the rightmost two columns in tables above than to the leftmost two columns. But neither precise policy nor expected results have been modeled yet. And neither modeling effort purports to measure directly equity, except insofar as reduced disparities in waiting time in status capture this goal.

One final effect of the Department's overall initiative is extremely important, though not attributable to this regulation. Increases in organ donation are an unambiguous benefit. If, as seems possible, the package of initiatives proposed by the Department could increase organ donation by 20 percent or more, the benefits in lives saved and life-years increased would both dwarf the estimates of these effects as calculated by the simulation models. Increased donation would also reduce waiting times. 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

TABLE 14—NUMBER OF SMALL, MEDIUM AND LARGE VOLUME LIVER PROGRAMS IN SELECTED STATES—Continued

State	City	No. small (<12)	No. medium (12–34)	No. large (35>)	Total
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.

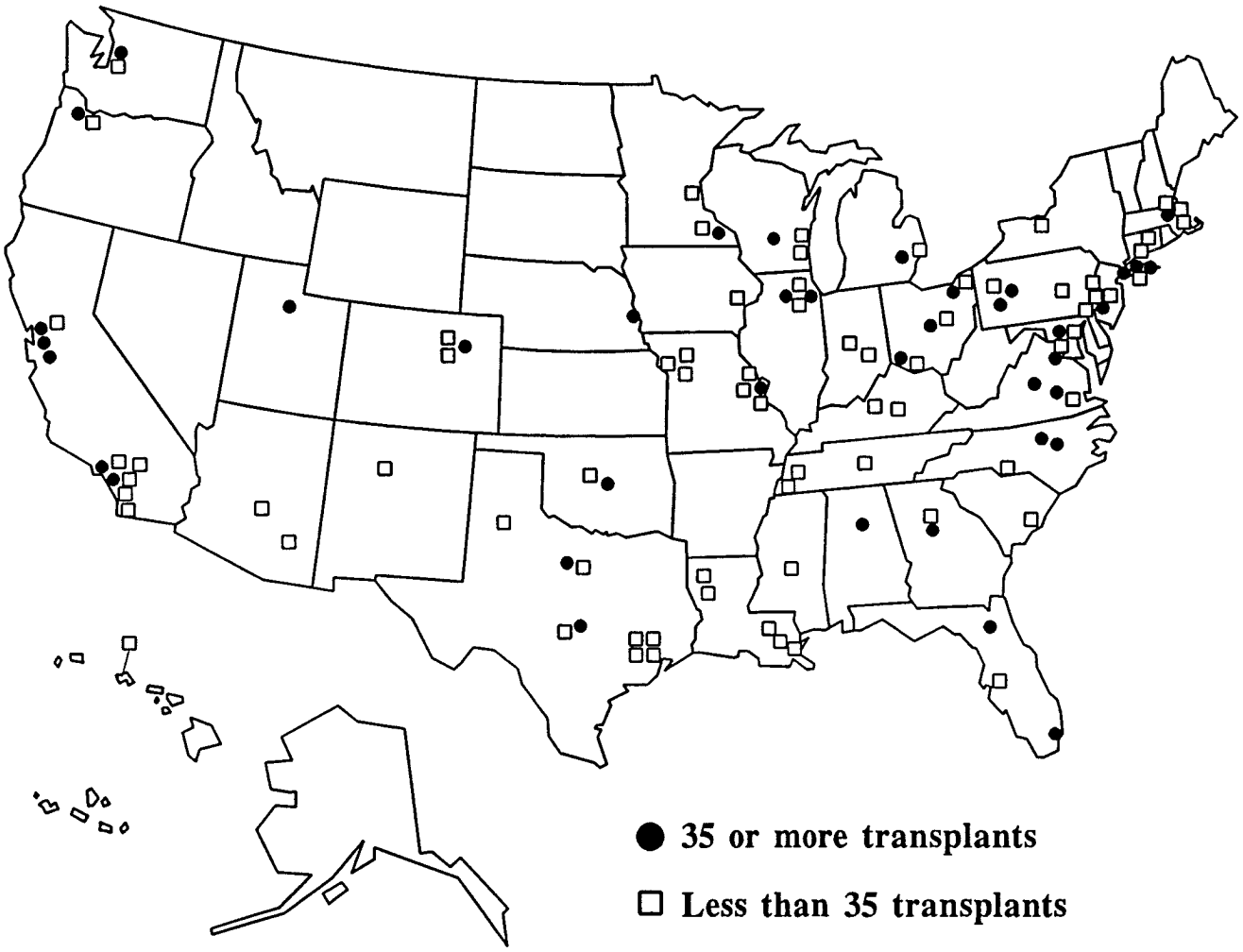
These 13 States and 17 metropolitan areas contain 32 liver transplant programs (the hundreds of remaining metropolitan areas, smaller cities, and rural areas in these States have no local transplant programs—their patients must travel). Of the nine small (fewer than 12 transplants annually) programs,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

BILLING CODE 4160–15–P

Distribution of All Current Liver Transplant Programs

by 1995 Volume



BILLING CODE 4160–15–C

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 (percent)	Allocation committee (percent)	Inpatient first (percent)	National (percent)
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 No.	Annual frequency of respondents	Average burden per response	Annual burden hours
121.3(c)(2)	OPTN membership application requirements for OPOs, hospitals, histocompatibility 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 Histocompitability	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	900	128	0.2	23,000
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:

Section	Requirement
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.

A separate announcement will be published in the **Federal Register** when the Department obtains Office of Management and Budget approval for § 121.6(c), which contains information collection requirements. 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

Organ transplantation, Hospitals.

Dated: March 20, 1998.

Claude Earl Fox,

Acting Administrator, Health Resources and Services Administration.

Approved:

Donna E. Shalala,

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.

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) of this section 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 July 1, 1998, 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 July 1, 1998, 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 (a)(1), (2), (3), (4) and (5) of this section. 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) of this section. 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 paragraph (a)(4)(iv) of this section, 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 April 2, 1998 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 July 1, 1999 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 August 31, 1998 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) *Variances.* 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 variances shall be time limited. Entities or individuals objecting to variances 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.

[FR Doc. 98–8191 Filed 3–26–98; 8:45 am]

BILLING CODE 4160–15–P