FOIA Number: 2008-1524-F

FOIA MARKER

This is not a textual record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

Collection/Record Group: Clinton Presidential Records

Subgroup/Office of Origin: Office of Science and Technology Policy

Series/Staff Member: Jerold Mande

Subseries:

OA/ID Number: 13034

FolderID:

Folder Title:
Organ Procurement and Transplantation Network (OPTN): [Correspondence] [3]

Stack:	Row:	Section:	Shelf:	Position:
S	66	4	3	2

Billing Code: 4160-15

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR PART 121

RIN: 0906-AA32

ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Final rule with comment period.

SUMMARY: This notice sets forth the final rule governing the operation of the Organ Procurement and Transplantation Network (OPTN), and requests comments on possible changes to that rule. The regulations establish requirements and procedures for oversight of the OPTN, for membership in the OPTN, for listing transplant candidates on a nationwide computer network, for allocating organs, and for maintaining records and reporting by Organ Procurement Organizations (OPOs) and transplant hospitals. They also establish certain OPTN standards; establish procedures for future Secretarial approval of OPTN policies; and require the OPTN to develop and propose policies to improve organ allocation. These regulations provide the oversight framework within which the OPTN, its members, and other participants in organ donation and transplantation must operate; clarify lines of authority and responsibility for data reporting; establish requirements for providing patients and payers information on the performance of

transplantation programs; and also establish performance standards for organ allocation. The Department is also providing an additional opportunity for public comment and will consider revising this rule based on those comments.

These rules have three primary purposes. First, they establish HHS oversight procedures, but link these to the OPTN's policy development process in ways that rely initially on medical expertise and the collaborative processes of the OPTN, while protecting patients, donors, and the public interest through HHS oversight. Second, they establish performance goals for organ allocation that focus OPTN energies on creating allocation standards that will direct organs on the basis of objective medical criteria to those patients in most urgent need, wherever they live. The OPTN is directed to revise its current organ allocation policies to achieve these goals, with prompt reform of liver policies. Third, they provide the basis for a substantial improvement in the availability of data for the public that will help patients, and their families and physicians, decide which transplant programs are most or least likely to serve them well.

These rules solicit the medical and operational expertise of the transplant professionals and provide a general framework for the OPTN. They also provide for Secretarial oversight and increase information available to the public, to payers, and to HHS. The Secretary will review significant OPTN policies, including those for organ allocation, to assure that they are equitable, and to assure that policies do not frustrate the goal of establishing a national organ allocation system, unreasonably discriminate against some patients, burden payers or providers, or unreasonably deny hospitals' participation in Medicare and Medicaid or organ procurement organizations' reimbursement. The

Secretary is ultimately accountable for making such public policy choices fairly and properly.

DATES: These regulations are effective (insert 60 days after publication in the Federal Register). A separate announcement will be published in the Federal Register when the Department obtains Office of Management and Budget approval for Sections 121.4(a)(2) and 121.6(c), which contain information collection requirements.[Add Congressional Review language]

Comments on this final rule are invited. To assure consideration, comments must be received by (insert date 60 days after date of publication in the Federal Register).

ADDRESSES: Written comments should be addressed to Judith B. Braslow, Director, Division of Transplantation, Room 7-29, Parklawn Building, 5600 Fishers Lane, 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 8:30 a.m. and 5:00 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: Judith B. Braslow, Director, Division of Transplantation, Room 7-29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857; telephone (301) 443-7577.

SUPPLEMENTARY INFORMATION: On September 8, 1994, the Secretary of Health and Human Services published proposed regulations to establish a framework for the operation of the OPTN. (59 FR 46482-99). 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, 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 and organ allocation, 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 broad national goals and performance standards to guide the national system for distribution of organs, and for final approval of those standards that become binding Federal rules rather than voluntary private practices. Both the OPTN and the Secretary have responsibility for dissemination of information to the public, including patients, physicians, payers, researchers, and the press.

The Secretary is simultaneously announcing a donation initiative, most of whose components do not require regulatory action, and are not included in this rule.

The remainder of this preamble is arranged under the following headings. [Page numbers are approximate and to be removed in Federal Register version. Suggest headings in both contents and text be reworded so that new section numbers are primary with previous numbers parenthetical or omitted.]

I. Background

A. Overview

Human organs which are donated for transplantation are a public trust. Advances in medical technology have made organ transplantation an increasingly successful and common medical procedure. Under the National Organ Transplant Act of 1984 and the Social Security Act, it is the responsibility of the Secretary of Health and Human Services to ensure that this system distributes organs "equitably" and meets other statutory purposes, to obtain and act upon "critical comments relating to the manner in which the Organ Procurement and Transplantation Network is carrying out the duties of the Network," and to issue regulations that assure that the system is operating efficiently to meet its goals.

In creating the Organ Procurement and Transplantation Network (OPTN), Congress envisioned a system that would be managed by the transplant community, including physicians and transplant facilities, as well as other specialists and those representing transplant patients and the general public. In this way, technical demands and changes, as well as professional and patient perspectives, can be quickly and appropriately accommodated. At the same time, oversight of the system and responsibility for the public benefit are assigned to the Secretary of Health and Human Services. Working in partnership with the transplant community, the Secretary has final authority over policies and procedures of the OPTN, thus encompassing organ donation and transplantation as one part of the Secretary's public trust responsibilities.

This final regulation defines the procedures to be followed by the Secretary in carrying out that responsibility. It embodies the original purposes of the Act, and it

reflects the growth and maturing of the OPTN as a nationwide system in the years since passage of the Act. The final regulation is designed to assure (1) that the benefit of transplant patients is paramount in the operation of the OPTN; (2) that allocation of organs be equitable nationwide; and (3) that transplant professionals, patients and the public be provided the most accurate, timely and useful information possible concerning transplantation options and the performance of transplant facilities.

In addition, the Secretary is taking steps to increase organ donation. Under this organ donation initiative, a wide range of actions are being taken. Only with a substantial increase in donation can the extremely difficult choices among patient priorities be made easier. These steps include a wide range of partnering activities to encourage organ donation, educating families about organ donation; research and evaluation on alternative approaches to encouraging donation; and some regulatory proposals. In particular, in a separate regulation being issued by the Health Care Financing Administration on Medicare Conditions of Participation for Hospitals we are proposing to require that hospitals utilize OPO staff in their work with donor families, and that hospitals refer all appropriate deaths to the OPO giving the OPO the opportunity to decide which cases may be appropriate for organ donation.

Several principles are reflected in this final regulation:

- transplant patients and professionals are best served by an organ allocation system that functions equitably on a nationwide basis;
- the Secretary of Health and Human Services should outline both broad goals of public benefit as well as more specific performance goals for the OPTN and should

determine whether these goals have been achieved;

- the transplant system must respond quickly and appropriately to changes in medical technology;
- allocation of human organs should be made to those who are in most urgent medical need of transplantation, without regard to geographical location, except as limited by the time period of the usefulness of the organ or patient ability to benefit;
- thorough, timely, and well-presented information is essential for measuring quality of care and should be available to patients and physicians making choices among transplant facilities; and
- potential conflicts of interest should be minimized for those who are responsible for operation of the OPTN.

To achieve these purposes and principles, the final regulation establishes organizational requirements for the leadership of the OPTN; provides for Secretarial oversight of the OPTN and for review of its policies; creates performance standards in specific areas; and provides for availability of transplant hospital-specific performance information for patients and physicians.

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 coordinative 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 transpiants 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 for organ procurement costs attributable to payments to an OPO to be paid by Medicare or Medicaid, the 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 Section 1138(a) of the Social Security Act concerning hospitals from October 1, 1987, to November 21, 1987, and Section 4009(g) of the Omnibus Budget Reconciliation Act of 1987 (Pub. L. 100-203) further delayed the effective date of Section 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 Section 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 (HHS) published final rules that included the requirement that hospitals participating in Medicare and Medicaid which perform transplants and designated OPOs be members of and abide by the rules and requirements of the OPTN (42 CFR 485.305 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 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.

This final rule reflects comments from all elements of the transplant community on the entire range of issues, received not only during the original comment period, but also during the last two years and attendant to the special public hearing held last December. 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 improvements. The Secretary is particularly interested in the comments of the OPTN, and others, on any implementation problems that might need regulatory clarification despite the flexibility that this rule provides.

C. DHHS and OPTN Relationships

We have found 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). However, from the perspective of patients awaiting transplantation, the OPTN operates a difficult to understand, centralized system that determines in mandatory fashion which persons, as categorized by the OPTN, may receive a transplant. Individual patients or transplant programs have no effective way to escape those decisions. The underlying statutes give that system authority from which individual patients, physicians, and hospitals have little or no recourse. If the OPTN changes allocation criteria, it necessarily advantages some patients and disadvantages others--simply because there are not enough organs donated to meet the need. Those changes carry virtually the force of law, because patients and hospitals cannot turn to an alternative organ allocation entity. Further, to what process or remedy can the disadvantaged patient or the public at large turn if the OPTN or its contractor makes a mistake, uses allocation criteria that are inequitable, contradicts other government policies, refuses to make information available, or exceeds its authority? These concerns have been raised about the

relationships between the OPTN and the current contractor, the United Network for Organ Sharing (UNOS), the Department, and the affected public. These regulations seek to address those questions.

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

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. 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 Organ Procurement and Transplantation Network 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. Under this process, the Secretary may offer the public opportunity to participate at the Federal level and may direct the OPTN to revise policies

at any time. The Secretary may approve OPTN-drafted policies or standards as binding rules or requirements, may decline to approve them (in which case they may not be used as a basis for expulsion from the OPTN or denial of Medicare and Medicaid participation or reimbursement), may approve them with changes, or may direct the OPTN to issue an HHS-authored policy as OPTN requirements. The Department intends to rely on the OPTN to develop policies, and will review those policies as appropriate both to determine their reasonableness and to determine whether they will become binding rules and requirements pursuant to section 1138.

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, anti-trust, 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 sought to create a standard that would require member hospitals to do business only with laboratories with directors meeting a higher qualification would conflict with the HHS regulation, if the OPTN policy had any status other than as a recommendation for voluntary action, or unless the Secretary approved that policy as a requirement. In order to prevent such problems, this regulation creates a system through which the OPTN can

identify a substantive standard which it believes will contribute to high performance and recommend its voluntary use by members, request that HHS make it a binding policy pursuant to section 1138 of the Social Security Act, or ask HHS to modify other regulations (such as clinical laboratory or blood regulations) to adopt that standard. What the OPTN cannot do is unilaterally impose a standard that has the effect of, or changes the terms of, a national policy already subject to the oversight of a cognizant Federal agency. Allocation policies, of course, fall uniquely within the scope of the OPTN and do not raise such jurisdictional issues.

To ensure appropriate interagency coordination and that the requirements of the Administrative Procedure Act are met, the Secretary will review not only allocation policies, but also 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, which consolidates regulatory requirements from proposed §§ 121.3, 121.7, and 121.10. The addition of new § 121.4 results in renumbering §§ 121.4 - 121.10. See the discussion at section II, (B2), under Supplementary Information, below.

D. Enforcement

From some of the comments received in response to the Notice of Proposed Rulemaking or delivered at the public hearings, we believe 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 and abide by the rules and requirements of the OPTN. It 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 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.

It should be pointed out that Section 1138, and the final rules and general notice that followed, pertain only to OPOs and hospitals participating in Medicare or Medicaid. These institutions make up only a portion of the membership of the OPTN. Thus, 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, that is, issued by the Secretary in accordance with Section 372 of the PHS Act. With respect to the OPTN regulations, it means those specific provisions of the final rule, approved by the Secretary and published in the Federal Register, that delineate requirements applicable to Medicare or Medicaid

hospitals and OPOs. For example, 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 binding on them. For example, 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, unless that allocation policy had been enunciated specifically in these OPTN regulations or approved by the Secretary. Therefore, policies of the OPTN that are not articulated in these or subsequent OPTN regulations or approved by the Secretary are not enforceable as potential section 1138 violations.

2. OPTN Policies

There has been much discussion about whether all OPTN voluntary policies should be mandatory, i.e., incorporated specifically into the OPTN regulations and published in the Federal Register. The Department believes that compliance with existing voluntary policies has been excellent. Furthermore, the public hearings demonstrated strong support for the current role of the OPTN in devising and issuing such policies. Therefore, the Secretary has decided to continue this approach. The field of organ transplantation is

dynamic, with technological advances that the OPTN must accommodate as quickly as possible. It can do so efficiently under this tested approach. However, the Secretary recognizes 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 voluntary policies mandatory. The Secretary also recognizes the need for additional public participation in the development of some significant OPTN policies, as noted above, and has retained in the final 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, and (2) enable the Secretary to seek comment from the public and to direct the OPTN to revise policies at any time. (See the discussion below).

The requirements that are explicit in this final rule are mandatory for all members of the OPTN, as appropriate, and 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. (See the discussion below.)

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 factual information. 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 factual, scientific, and related information. For example, both the OPTN and the University of Pittsburgh sponsored the development of simulation modeling to predict the likely effects of alternative organ allocation policies (the so-called "Pritsker" and "CONSAD" models discussed later in this preamble). Third, approximately 110 persons representing the OPTN, patients and patient organizations, transplant institutions, professional associations, and others testified at the December 1996 public hearing, and hundreds of others sent written comments. Finally, a number of recent newspaper articles have focused in depth on OPTN 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 are represented by

30 documents. The 22 petition letters contain a total of 5,462 signatures. No attempt has been made to identify the petition signatories by type.

We have placed much of the above information in the docket room at 5600 Fishers Lane, Room 7-29, Rockville, MD 20857. Among the documents in the docket room 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, 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 UNOS Ad Hoc Committee on Organ Allocation, the materials prepared for the OPTN Board of Directors before each Board Meeting over the last several years, a 1991 report of the HHS Inspector General on "The Distribution of Organs for Transplantation: Expectations and Practices," a 1993 report of the General Accounting Office on "Organ Transplants: Increased Effort Needed to Boost Supply and Ensure Equitable Distribution of Organs," the OPTN's multi-volume 1994 Report of Center Specific Graft and Patient Survival Rates, 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 prepared by the Pritsker Corporation in 1996 and 1997 (most included in the OPTN Board materials listed above), a number of computer simulations prepared by CONSAD in 1996 and 1997, and a series of investigative articles on organ transplantation and allocation issues that appeared in the Cleveland Plain Dealer in early 1997.

In addition, this final 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 dominant 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 policy 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 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 a model 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 overlooked.

As discussed in detail later in this preamble, the Department has responded to these comments by substantially strengthening representation of patients and the general public in the OPTN, and by establishing performance goals and oversight mechanisms to

assure that organ allocation policies are designed to benefit patients rather than transplant hospitals.

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

Opinions by Type of Respondent (Excluding Petitions)

Category	Pro New Policy	Con New Policy
Physicians	136	5
Other Health Personnel	13	3
Recipients/Candidates & Families	31	128
Totals	180	136

Patients believed 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, and that there was no significant medical argument favoring preference for the "acute" group. (OPTN data confirm this criticism 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

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 any medical data. However, the Chairman of the OPTN Patient Affairs Committee admitted 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 urged that a moratorium be placed on the implementation of new policy until the needs of the chronic patients could be properly considered. (This moratorium was in fact established shortly after the hearing, but in June of 1997 the Board of Directors voted to implement a new policy similar to the controversial policy, though less disadvantageous to the very sick chronic patients because it placed them in a separate Status subgroup with second priority.)

The issue of liver allocation policy is discussed later in this preamble. The Department is requiring the OPTN to develop a policy within 90 days of the date of publication of this Final Rule that will achieve substantial progress toward the goals of

allocating organs preferentially to the most medically urgent patients, and eliminating artificial boundaries that prevent organs from reaching those patients wherever they live.

3. Should liver transplantation be centralized in "centers of excellence", 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 most patients are free to select from among most transplant hospitals in the United States, under current local preference policies, organs generally do not follow patients if they list at a hospital outside their local area. That is, 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" policy, most organs leave the local area only if there are no local patients who could use the organ, or, in the case of perfectly matched kidneys, which are shared nationally. As a result of hospitals drawing primarily from the local pool of donated organs, with little organ sharing, no hospital can expand its program significantly without disadvantaging the patients who choose it. Some smaller hospitals 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 some large transplant hospitals. These hospitals 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 smaller hospitals-- was made vigorously on the basis of local and regional access to transplants and with testimony and data that showed that many small hospitals 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 moving outside the home community for a transplant.

After the hearing the Department determined, however, that this concern over local access and increased travel only affected a small number of patients. About half of liver patients must travel outside their local area to obtain a transplant simply because rural areas, most cities, and many states have no liver transplant programs. Also, the great majority of smaller hospitals are located in the same metropolitan area as larger hospitals. Only about 4 percent of patients live in areas served only by smaller centers. Thus, very few might have to face this potential problem.

The following table summarizes an analysis provided shortly after the hearing by the CONSAD Corporation in response to these concerns. This analysis was based on percentage of the Medicare and Medicaid population in Consolidated Standard Metropolitan Statistical Areas (CMSA) but results would have been essentially the same if the entire population had been used. Using the smaller SMSA definition of urban area would have raised the percentage of patients without local access to liver transplantation from 47 percent to 58 percent.

Table 2

Percentage of Medicare and Medicaid Population in

Consolidated Standard Metropolitan Statistical Areas (CMSA)

Percentage of Population in a CMSA:	
With any large program (>35 transplants)	40%
With a medium or medium and small program only (12 to 35 transplants)	8%
With a small program only (<12 transplants)	4%
With any transplant program	53%
With no transplant program	47%

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 hospitals 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 very few 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 hospitals and, thus, add a stress to a system already under stress because of the shortage of organs.

Others argued that the organ shortage is the same regardless of where they payers direct their patients.

The Department concludes that there is no persuasive evidence that equitable sharing of organs based on objective criteria of medical urgency, free patient choice among transplant programs, and better information on transplant program performance will damage transplant institutions of any size.

4. Should organs be shared across geographic lines--regionally or nationally?

Many patients and patient advocates, and some hospitals, 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. One argument advanced for this position is that local preference is simply a form of discrimination. Why should patients 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? Another argument is that local preference 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 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--both of which could compromise the quality of care. 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 a significant limit on the feasibility of national organ sharing is the cold ischemic time (the time after procurement that an organ remains viable enough for successful transplantation). Testifiers said that this time ranges from 12 to 18 hours for livers, and that among livers transplanted in less than this time there is little difference in graft survival based on 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 nor are estimates of travel time always reliable. The more time expended in travel, the less time is available to transplant the organ. This problem is compounded if, upon receipt, the organ proves unsuitable for the intended recipient and the program must transplant the organ into another patient. 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 assure 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 will have to die. Proponents of broader sharing countered that the OPTN's own modeling showed that lives could be saved if organs went to the sickest patients rather than 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 that local allocation tends to promote organ donation and retrieval by local transplant surgeons. 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. Another argument against broader sharing advanced by many was that if referring physicians perceive organs are always "shipped out" they will be dissuaded from referring donors. This argument ignores that organs will "shipped out" will approximate the number of organs "shipped in." HHS

has seen no credible evidence that local preference encourages donation, or that sharing organs regionally or nationally with 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 than a local patient.

The Department believes that the evidence shows that local preference for organs brings no substantial benefits to either donation or transplantation, whereas it denies organs to patients whose medical urgency is greatest but who happen to live or list in the "wrong" place. The Secretary is therefore directing the OPTN to develop policies that eliminate such inequities without wasting organs. This decision is further discussed later in this preamble. In this regard, we point out that the OPTN already has policies in place that effectively provide broad geographic sharing for children who need organ transplants. We strongly endorse such arrangements and this role will have the effect of extending broader sharing to include adults as well.

5. Which is preferred, transplanting the sickest first or transplanting patients who are most likely to survive the greatest number of years?

Most witnesses at the public hearing agreed on two broad points. First, many argued that 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 a life. The issue then, is do the present OPTN voluntary policies strike the right balance.

Some argued that transplantation before a patient becomes "sickest" provides better outcomes and longer graft and patient survival. The chronic liver patients pointed out that their expected survival rates were not only high, but essentially equal to those of 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 consequentially reduce likelihood of post-transplant survival. The Department does not believe that organs should be wasted in cases where a physician's medical judgment is that the transplant would not be successful. The Department also believes that ethical considerations require that the sickest patients--those who are about to die but whose lives will likely be saved by a transplant--receive preference in organ allocation over those who are sick but can wait. This position is supported by medical, ethical, and public policy considerations.

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 ranged from excluding high risk patients from the list, to listing patients early to gain waiting time points, to listing patients at more than one transplant hospital to increase the chance of getting an organ, to referral of 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 patients. Some commented that the present debate reflects 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. The Department has decided to require the OPTN to develop policies that maximize the use of objective medical criteria for both listing and classification by medical urgency. These policies are desirable for many reasons, including reducing incentives and opportunities for manipulating the system.

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 launching a broad organ donation initiative that implements many of the suggestions made at the hearing, and others. Included as part of this initiative will be a Notice of Proposed Rulemaking that requires a form of mandatory referrals by hospitals to refer potential donors to OPOs and that OPOs determine the criteria for these mandatory referrals. We also encourage the transplant community to strengthen its various efforts to increase organ 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).

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 the bill, which virtually always requires insurance. Some 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 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. Thus, the Secretary is requiring that the OPTN make socio-economic equity in transplantation a major goal, assess the cumulative effects of its policies, and as appropriate develop new policies that use available avenues

to reduce current inequities. These policies are to include waiving listing fees for patients unable to pay.

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

Most of the original commenters referenced specific sections of the NPRM, and we have generally identified these in numerical terms, e.g., two commenters had suggestions regarding the definition of "national list." The great number of additional comments received, particularly at the public hearing, did not reference the NPRM. However, most of those comments focused on specific issues (organ donation, organ allocation, liver allocation, and oversight procedures) and are addressed in the corresponding sections below.

1. § 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 that does not take into account the geographical factors in the existing organ matching and allocation process. The Department agrees that the term "national list" has been used in conjunction with allocation criteria that involve geographic factors. As discussed elsewhere in this preamble, there will be substantial changes in these criteria. In addition, all recipients of organs are selected from a set of national databases, and even the current allocation

criteria have substantial 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 more comprehensive description of the matching process. The new definition states that the "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": 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, 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, and would also 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 to specify other organs in addition to those already named. Instead, we have asked the OPTN contractor to consider which organs or parts of organs should be regulated by the OPTN, and to submit its recommendations to the Secretary. The Secretary will then initiate a separate rulemaking in which the public will have an opportunity to comment.

"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 more comprehensive definition which 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 hospital.

"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. § 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 dispute.

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 assure the best possible outcomes for their own patients. Additionally, the Department received criticisms regarding the independence of the process for selecting members of the current OPTN Board of Directors. Some members are currently elected from lists of persons selected by the nominating committee of the Board of Directors, not by the independent nomination of sponsoring organizations. Regardless of the precise procedures and categories, it is apparent that the current OPTN Board of Directors under-represents persons who broadly represent the public interest and persons who directly represent patient interests, without direct economic ties to the field of transplantation.

Table 3

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

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

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

Accordingly, the Secretary is requiring several changes in the composition of the Board of Directors. The Secretary believes none of these will jeopardize either the expertise or the continuity of leadership so vital to the functioning of the OPTN. Transplant professionals will continue to be strongly represented on the Board. However, a broader range of diverse and independent views will be required. While the Secretary is adding some minimum requirements to assure improved public, patient, and independent representation, she is eliminating other requirements that had originally been proposed in the NPRM, and allowing the OPTN substantial flexibility.

These new requirements for the composition of the OPTN Board of Directors are as follows (all in the context of a Board membership of 30 or more persons, as determined by the OPTN itself). First, we are requiring that not fewer than eight of the Board members be elected by patient advocacy groups and that none of the patient advocate

members be employees of institutions that earn substantial revenues from performing transplantation services or receive significant emoluments from such institutions or the OPTN itself. Second, we are requiring that not fewer than six members of the Board of Directors represent the general public, that these members have substantial expertise in objective analysis of policies, and that these members likewise be free of substantial financial ties to institutions involved in transplantation. Third, we are requiring that not fewer than 14 Board members representing various associations and patient advocacy groups (including the eight patient advocacy members specified above) be selected by those organizations rather than by the OPTN itself. Fourth, we are specifying that not more than 50 per cent of the Board members, and of the Executive Committee, be transplant professionals, including transplant physicians and transplant surgeons.

To reduce requirements, we are eliminating the originally proposed requirement that every OPTN region be represented on the Board. We do not require even that the OPTN use a regional structure, and we see no reason to impose regulatory requirements for regional membership on the Board because the OPTN currently elects to use regions. This will also give the OPTN more flexibility in determining Board size. Depending on the OPTN's decisions as to reasonable 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, we are giving the OPTN substantial flexibility in the size of the Board of Directors and clarifying that the contracting organization is free to have a Board of Directors structure that is separate and distinct from the structure of the OPTN itself. We are also giving the OPTN six months

from the date of publication of this Rule to make these changes.

We request comment on these changes, and on whether there are other or similar requirements that we should consider imposing, or additional flexibility that we can reasonably provide to the OPTN. We particularly solicit the views of the OPTN itself, and its suggestions for modifications to improve these standards or for alternatives that will as well or better achieve the broad purposes and roles of the OPTN. Of course, nothing in these minimum requirements precludes the OPTN from making even more substantial changes. The OPTN is also free to propose an alternative Board structure, subject to the approval of the Secretary, but must have the above structure in place by the above deadline unless an alternative structure is approved by that date.

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 simply deleted any requirement as to minimum or 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 elect 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. Thus, § 121.3 now provides that eight associations representing transplant candidates, patients and donor families shall each select one Board

member. Should more than one organization exist in a category, the Department expects the OPTN, in carrying out the provisions of new § 121.4(a), to determine which organizations will be represented, with emphasis on selecting a range of organizations that bring distinct viewpoints or expertise. (That section requires that the Board of Directors develop policies for nominating Board officers and members). In addition, the Department has added to § 121.3 a requirement that the Board be comprised of a reasonable portion of transplant candidates or recipients or individuals who are part of the families of transplant candidates or recipients or organ donors. Over the last few years, these individuals have represented twenty to thirty-three percent of the Board, and the Secretary expects that a similar representation will be maintained. Section 121.3(b)(1) now requires the Executive Committee to include at least one transplant candidate or recipient or family member of a candidate, recipient or donor, one patient advocate member, one general public member, and one OPO representative. Section 121.3(b)(3) requires patient or donor family 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 elect 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. We are requiring, however, that

at least fourteen members--those from associations and patient advocacy groups--be selected by those organizations directly rather than by the OPTN itself.

Another individual commented that the Board should include more minority representation. Proposed § 121.3(a)(3)(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 at proposed § 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 donor or recipient populations 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 it cannot guarantee that its composition will necessarily 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 mandatory requirements that it would enforce. However, 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 "patient advocacy groups" to § 121.3(a)(1)(I) which will represent the interests of transplant candidates (pre-transplant patients), transplant recipients, as well as individuals who are part of the family of individuals who have donated or received an organ. We have also added transplant candidates to the diversity requirements of §§ 121.3(a)(3)(i) and 121.3(b)(2), and a requirement to § 121.3(a)(3) that the Board of Directors include a reasonable portion of transplant candidates or recipients or individuals from patient or donor families. See, § 121.3(a)(3)(iii).

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) (now §121.3(a)(6)), requiring the appointment of an Executive Director to serve a four-year term, was unnecessary. 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. The Department agrees that the proposed term limitation for the Executive Director is unnecessary and has deleted it. 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(a)(3) 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 of which OPTN policies trigger the special compliance requirements and potential sanctions under Section 1138 of the Social

Security Act. The Secretary has also 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(a)(2) and policies may be appealed under § 121.4(c). 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)(i).

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 that the OPTN will 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 transplantation must be granted membership. Should the OPTN deny membership under § 121.3(c)(3), applicants may appeal to the Secretary under § 121.3(d)(3)(??). In addition, we have added to § 121.3(d)(2) a requirement that the OPTN process membership applications "within a reasonable time" not to exceed 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 section 121.3(e) that allows the current contractor, and future contractors six months, to come into full compliance with regulatory requirements in this section.

3. § 121.5 - Listing Requirements

Based primarily on the issues raised at the public hearing, we have expanded this section to include a new requirement (section 121.4(a)(3) that the OPTN assess the

cumulative effect of transplantation policies and practices on patients with differing socioeconomic status, and modify or issue policies to reduce inequities resulting from socioeconomic status, such that to the extent reasonably feasible patients in need of a transplant are 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 represents 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 a wide range of possible policies to reduce inequities. For example, the Secretary would expect the OPTN to develop 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, 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 substantial energy to devising solutions and proposing policies to implement them. We are particularly interested in comments on ways to strengthen or implement this provision.

Most of the original comments received on this section of the proposed rule were on the subject of multiple listing, both supporting and opposing it. The proposed rule, in keeping with existing policy, does not prohibit transplant candidates from being listed with more than one transplant hospital. The final rule does not change this policy despite the Department's concern that it may disadvantage individuals who lack the financial resources to seek listing with more than one institution. There are many alternatives to the existing policy, ranging from outright prohibition of multiple listing to selective prohibition by organ type, and the Department believes it would be inappropriate to select an alternate policy without full public participation. We have instead asked the OPTN contractor to revisit the issue through its policy development process and submit its recommendations to the Secretary. The Department would then make that policy available for public comment. We are mindful that multiple listing raises serious ethical issues, but as practiced today it is one of the few avenues open to patients who wish to choose their own medical care providers without current "local first" allocation policies jeopardizing their ability to get a transplant. 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. Later in this preamble, we discuss reforms that will in the near future render multiple listing unnecessary or ethically unobjectionable. In addition, we are requiring that the contractor

make available to patients standardized information on transplant hospitals' waiting lists and survival data to help them select a transplant hospital with which they may choose to be listed.

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)(1). 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(a)(3). A similar suggestion was made with respect to proposed § 121.4(b) to replace the term "OPTN members" with "OPOs." The Department has made this change. See, § 121.5(b).

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(a)(3). This language parallels that in § 121.3(d)(2) and 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 request comments on whether we should take additional steps to assure 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. Moreover, we are requiring the OPTN to develop improved medical criteria for listing and assigning patients to urgency categories. The Secretary is open to considering other regulatory requirements at a future time and welcomes additional comments in this area.

4. § 121.5 (now § 121.6) - Organ Procurement

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 and has added a requirement for the establishment of criteria for organ acceptance. See, § 121.6(c). However, we also believe that it is inappropriate for Federal regulation to require establishment of 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.

One commenter suggested replacing the term "OPTN member" in proposed § 121.5(a) with "OPO", because OPOs are principally responsible for procuring organs. The Department agrees and has made the change. See, § 121.6(a). It should also be pointed out that this section is consistent with the OPO Conditions for Coverage under Medicare.

5. § 121.7 - Identification of Organ Recipient

This section of the proposed regulations 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. See, § 121.7(a)(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 points out that OPTN members are bound by the confidentiality requirements of § 121.11, which covers all records, including those relating to organ donors. This issue is discussed further below, under "Record Maintenance and Reporting Requirements."

According to two commenters, proposed § 121.6(c)(1) should be amended to

indicate that either a transplant hospital or 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 assure 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 assure 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 reflect current procedure. See, § 121.7(d). 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. § 121.4 (former §121.7(b))--Policies: Secretarial Review (former Allocation of Organs)

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 binding, the answer is yes. With the exception of substantial number of policies established in this rule all policies that have not been approved by the Secretary as binding remain voluntary, as explained in the 1989 Federal Register Notice. OPTN members that disagree with those policies should continue to comply while appealing to the Secretary for change, but may in some circumstances elect not to comply and risk an OPTN challenge to their membership (recognizing that the Secretary makes the final decision regarding expulsion).

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 would 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 and other entities can involuntarily lose all Federal reimbursement under Medicare and Medicaid for noncompliance with OPTN rules and requirements.

Under the statutory framework established by the Congress, the Department has certain legal obligations, arising from the Constitution's express language regarding the role of officers appointed by the President, the National Organ Transplantation Act (NOTA), section 1138 of the Social Security Act, and the Administrative Procedure Act, as well as many other laws and executive orders that influence how these are implemented. 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. At the same time, both the genesis and wording of NOTA obligate the Secretary to utilize the transplantation community very substantially in both developing and executing transplantation policy. In this regard, however, most commenters stated, and the Secretary agrees, that Departmental oversight should eschew any attempt to micro-manage purely medical criteria or day to day decision-making of 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 Administrative Procedure Act process--most importantly the impartial review of the Secretary on behalf of all Americans. 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(b). 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; and 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 act independently if she deems it 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 binding requirements, but that most institutions can accept voluntarily. 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, but welcomes comments on ways to further improve the system.

7. § 121.7 (now § 121.8(a)) - 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 in the time periods 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 standards.

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 giving a substantial preference to local allocation, do not follow an ethical opinion promulgated through the Code of Medical Ethics of the Council on Ethical and Judicial Affairs of the American Medical Association. 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. Thirdly, the OPTN itself continued to study, debate, and consider substantial revisions to its policies. Building on this new information, a primary purpose of the December hearings was to obtain even more information and opinion on organ allocation policies, particularly those affecting livers. That purpose was achieved.

Based on this input, 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 to interject itself needlessly into matters that are primarily medical, into which category many (but by no means all) allocation issues fall.

The Secretary decided, therefore, to approach the issue in terms of performance goals. The basic idea of a performance goal is to set a standard, 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 simplify and expedite the Department's review and approval process for OPTN standards.

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 standards for organ allocation are needed. The topics of these standards are: (1) listing, (2) patient status, and (3) priority to patients with the highest medical urgency without artificial geographic restrictions. The Secretary has also added a requirement, discussed above, for the OPTN to assess the cumulative effect of its policies, and develop new policies as appropriate, regarding socioeconomic equity.

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 in 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 under way 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 broad consensus theme that emerged from the hearings is that current liver allocation criteria fail to differentiate adequately among different degrees of medical urgency, and the desire of the entire transplant community to see 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 as such nor necessarily good proxies for underlying medical condition or urgency, and which 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 the OPTN's extensive investment in patient information systems has made possible significant improvements in the classification of patients. Computer technology allows very 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 opportunities for discriminatory effects.

Priority for the Most Urgent and Geographic Equity (§121.8(a)(3)). By far the most problematic feature of current allocation policies is that the "local first" feature implicity discriminates against needy patients, based on where they live or list. As shown in the table below, adapted from OPTN data printed in the Cleveland Plain Dealer on February 5, 1997, there are vast differences in median waiting times among different transplant hospitals and local areas for kidneys:

Table 4

Shortest and Longest Waiting Lists for Kidney Transplant Programs

by Median Waiting Time in Days

Shortest Waiting Times:	Median 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 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

These data do not take into account the substantial differences in patient condition and urgency that underlie much of the observed disparity. For example, as discussed previously many 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.

Similar but less dramatic differences--3 to 1 rather than 10 to 1--are observed when the data are aggregated by OPTN region:

Table 5

Median Kidney Waiting Times by OPTN Region 1992

Median Waiting Times for Kidneys, 1992	Days
Region 1 (New England)	1130
Region 2 (DC, DE, MD, NJ, PA, WV)	918
Region 3 (Southeast)	513
Region 4 (OK, TX)	449
Region 5 (California & Southwest)	1121
Region 6 (Northwest)	420
Region 7 (Upper Midwest)	872
Region 8 (CO, IA, KS, MO, NE, WY)	476
Region 9 (NY)	*
Region 10 (IN, MI, OH)	745
Region 11 (KY, NC, SC, TN, VA)	811

*Median waiting time cannot be determined because fewer than half of waiting list patients have been transplanted.

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 live (and list) in areas with either higher incidence of end stage organ disease, or lower 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 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. In one 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 relatively more organs, or with his strongly preferred and truly local hospital just 20 minutes across a river and in another State that had relatively fewer organs. Such cases are inherent in a system that was established for the purposes of encouraging organ donation, but over the years has increasingly been used for organ allocation. For example, in a number of States one OPO is surrounded by another; and in Texas there is an OPO which 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 map on the next page. Because of the differences in OPO size, geography, and population, the Secretary has decided that OPOs should not be the primary vehicle for organ allocation.

Organ Procurement Organization Service Areas, 1997