

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR PART 121

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ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

Docket Number: 97-HRSA-01

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

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

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

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

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

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

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

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

In order to bring about substantial increases in the number of organ donors and the number of transplants performed each year, a new National Organ and Tissue Donation Initiative has been launched. Working in partnership with national and local organizations, the Department of Health and Human Services (HHS) seeks to increase donation through encouraging more individuals to choose to be organ donors and that share that decision with their families; through improved performance by hospitals and organ procurement organizations toward ensuring that the families of potential donors are given the opportunity to allow donation; through higher consent rates by families, especially by encouraging those who elect to be organ

donors to inform their families of their decision; and through new research on enhancing donation. Proposed regulations affecting hospitals and organ procurement organizations were published December 19, 1997 (62 FR 66725). The Department expects that the supply of organs may be raised by about 20 percent through this initiative, which would greatly alleviate organ shortages.

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

The goals include:

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

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

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

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

The OPTN is required to develop proposals for the new allocation policies (except for livers) within a year of the effective date of the final rule. In the case of liver allocation policies,

where policy development work has been underway for several years, the OPTN is required to develop a new proposed allocation policy within 60 days of the effective date.

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

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

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

DATES: These regulations are effective (insert 90 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 § 121.6(c), which contains information collection requirements.

Comments on this final rule are invited. To ensure 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 Jon L. Nelson, Associate Director, Office of Special Programs, 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: Jon L. Nelson, Associate Director, Office of Special Programs, Room 7-29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857; telephone (301) 443-7577.

SUPPLEMENTARY INFORMATION: 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, and to hear ideas regarding increasing organ donation and the controversial and difficult problems surrounding organ allocation generally and liver allocation policies in particular. From December 10 to 12, 1996, that hearing was held. As under the proposed regulations, the final rule provides for Federal oversight of the processes by which the OPTN allocates organs for transplantation. It focuses the Federal role on ensuring that those processes and resulting policies are equitable, provides for broader public participation and Secretarial review, and includes access to information for patients and their families and physicians.

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

The Secretary has also announced an initiative to increase organ and tissue donation, most of whose components do not require regulatory action and are not included in this rule.

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I. Background

A. Overview

The National Organ Transplant Act of 1984 (NOTA) created the Organ Procurement and Transplantation Network (OPTN). The Act has been the subject of two major sets of amendments. In each instance, the Congress acted to encourage the development of a fair, national system of organ allocation. The original statute (P.L. 98-507, title II, § 201, formerly codified at 42 U.S.C. § 274(b)(2)(C)) required the OPTN to "assist organ procurement organizations in the distribution of organs which cannot be placed within the service areas of the organizations." (Emphasis supplied.) However, the underscored language was removed in a 1988 amendment to the NOTA (P.L. 100-607, title IV, § 403, formerly codified at 42 U.S.C. § 274(b)(2)(D)), according to the Senate "so as to remove any statutory bias respecting the

important question of criteria for the proper distribution of organs among patients.” S. Rep. No. 100-310 at 14-15 (1988). In 1990, this language was again rewritten, this time to require that the OPTN “assist organ procurement organizations in the nationwide distribution of organs equitably among transplant patients.” (Emphasis supplied.) P.L. 101-616, title II, § 202, now codified at 42 U.S.C. 274(b)(2)(D). The Senate explained that “[b]ecause the demand for transplantable organs is expected to continue to be considerably greater than the supply, a fair and equitable organ sharing system is critical to the future of a national transplant program that the public will support.” S. Rep. No. 101-530 at 7 (1990) (The 1990 amendments also required that the OPTN report on comparative costs and patient outcomes at all transplant centers). As discussed in more detail below, in 1986 the Congress also amended the Social Security Act to make OPTN membership, and compliance with allocation policies approved by the Secretary, mandatory rather than voluntary for Medicare-participating hospitals and all organ procurement organizations.

Thus, the Congress envisioned an equitable national system that would be operated by the transplant community -- including physicians and officials of transplant facilities as well as other specialists and individuals representing transplant patients, their families, and the general public - with oversight by HHS.

Human organs that are donated for transplantation are a public trust. These regulations are intended to ensure that donated organs are equitably allocated among all patients, with priority to those most in need in accordance with sound medical judgment. These regulations also complement the recently announced National Organ and Tissue Donation Initiative. The initiative addresses the fact that organ donation has not kept pace with the need. Only about a

third of potential cadaveric donations are made; and, when families are asked, only about half give consent. The initiative seeks to improve the number of potential donors identified and asked to donate organs. This improvement would be accomplished through proposed rules, published in the Federal Register on December 19, 1997, which would require Medicare-participating hospitals to work more closely with local organ procurement organizations. A similar approach was adopted by the Commonwealth of Pennsylvania, effective March 1995. By 1997, a 40 percent increase in organ donors and a 49 percent increase in organ transplants had taken place in southeastern Pennsylvania.

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

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

In addition, technological advances have made broader geographic sharing possible. For example, the use of the Belzer UW solution, developed in the 1980s, has dramatically increased

both graft survival rates and the time in which the organ survives out of the body. This “cold ischemic time” is used to transport an organ to a potential recipient.

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

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

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

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

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

The HHS Office of Inspector General reached similar conclusions, finding that “current organ distribution practices fall short of congressional and professional expectations,” and that “[t]here has been substantial progress in developing a national organ distribution system grounded in uniform policies and standards. However, organ distribution remains ... confined primarily within the individual service areas of the ... Organ Procurement Organizations.” The Distribution of Organs for Transplantation: Expectations and Practices at 8,13 (Office of Inspector General, March 1991).

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

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

The principle that donated cadaveric organs are a national resource implies that,

In principle, and to the extent technically and practically achievable, any citizen or resident of the United States in need of a transplant should be considered as a

potential recipient of each retrieved organ on a basis equal to that of a patient who lives in the area where the organs or tissues are retrieved. Organs and tissues ought to be distributed on the basis of objective priority criteria, and not on the basis of accidents of geography.

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

Another flaw in current OPTN policies pertains to disclosure of information. The statute requires the Secretary to provide information to patients, their families, and physicians about transplantation. Current policies in this area do not give patients, their families, and physicians the timely information they need to help in selecting a transplant hospital. For example, one-year survival rates of patients and organ grafts are valuable information in comparing the relative effectiveness of transplant programs. However, today a patient seeking this information would have to rely on four year old OPTN data released in 1997. Moreover, these data are contained in nine volumes with 3,200 pages. A patient seeking to compare centers would find these data difficult to use. In addition, access to accurate, timely data will enable the Department to monitor the effectiveness of organ transplantation and provide the general public with information on how well the transplantation network is performing.

The National Organ Transplant Act vested in the Secretary oversight of the OPTN and responsibility for ensuring public benefit. Amendments to the Social Security Act in 1986 underscored the Secretary's role. Working in partnership with the transplant community, the Secretary has final authority over OPTN policies and procedures. In particular, the Secretary has a statutory mandate not only to ensure that the OPTN distributes organs "equitably" and fulfills other statutory requirements but also to obtain and act upon "critical comments relating to the manner in which (the OPTN) is carrying out the duties of the Network." The Secretary has chosen to issue regulations for the purpose of

ensuring that the system evolves to keep pace with improvements in technology and medical science (such as improvements in organ preservation technology and reductions in the disparities in survival rates among more sick and less sick patients) and is operating effectively and efficiently to meet its statutory goals.

Six principles underlie this regulation:

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

- potential conflicts of interest should be minimized for those who are responsible for operation of the OPTN.

B. Legislative and Regulatory History

The OPTN was established under section 372 of the PHS Act, as enacted by the National Organ Transplant Act of 1984 (Pub. L. 98-507), and amended by Pub. L. 100-607 and Pub. L. 101-616.

Section 372 requires the Secretary to provide by contract for the establishment and operation of the OPTN to manage the organ allocation system, to increase the supply of donated organs, and to perform related and other activities.

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

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

Reconciliation Act of 1987 (Pub. L. 100-203) further delayed the effective date of § 1138(b) of the Act concerning OPOs to April 1, 1988.

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

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

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

The 1994 proposed regulations 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 was developed after consideration of comments from all elements of the transplant community on the entire range of issues. Comments were received not only during the original comment period but also during the last two years and attendant to the public hearing held in December 1996. Although the Secretary believes that this rule addresses all of the major issues and questions that had

been identified, the Department remains open to suggestions for further improvements. The Department has provided for additional public comments on these regulations to be submitted during the next 60 days. The Department will also provide for public input on OPTN proposals for policies to implement these regulations.

C. DHHS and OPTN Relationships

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

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

As a private organization, UNOS has by-laws, operating procedures, and membership requirements. They apply only to UNOS members and not to OPTN members. Membership in UNOS

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

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

The process adopted in this rule strikes a balance among these important principles. When the OPTN develops policies, or when complaints are raised concerning OPTN policies, the regulation allows a number of options. The Secretary may approve an OPTN-proposed policy or find that the complaint has no merit. The Secretary also may take another approach depending on the issues presented. For

example, the Secretary: may seek broader public input on the issue; may determine whether violations of OPTN-proposed policies should carry any one of a range of consequences--no consequence, loss of membership in the OPTN, or loss of a hospital's ability to participate in Medicare and Medicaid; may provide comments for the OPTN's consideration; may direct the OPTN to adopt a policy; or, may develop a policy that the OPTN must follow. An example of this last option is this regulation's provisions prescribing who the OPTN must admit as members. Instead of an exhaustive listing of these and other options, the regulation, at sections 121.4 (b) (2) and (d) simply provides that the Secretary may "take such other action as the Secretary determines appropriate."

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

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

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

D. Enforcement

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

1. Section 1138 of the Social Security Act

As discussed above, section 1138 requires Medicare and Medicaid participating hospitals that perform transplants to be members of the OPTN and abide by its rules and requirements. Section 1138

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

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

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

that allocation policy is not approved by the Secretary as enforceable policy. Therefore, policies of the OPTN that are not articulated in these or subsequent OPTN regulations or elsewhere approved by the Secretary are not enforceable under § 121.10.

2. OPTN Policies

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

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

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

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

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

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

Secretary considered other materials including, for example, correspondence from Members of Congress and a number of recent newspaper articles which focused on organ transplantation issues and controversies.

The testimony and comments received in connection with the public hearing contain a total of 541 documents, with 667 signatures. Of these, 180 signatories are identifiable as transplant recipients or candidates or their families and friends, 327 as physicians, and 43 as other health personnel such as nurses, hospital administrators, and directors of organ procurement organizations. National organizations submitted 30 documents. Twenty-two petition letters contain a total of 5,462 signatures. No attempt has been made to identify the signatories of the petition by type.

Among the documents in the docket room at 5600 Fishers Lane, Room 7-29, Rockville, MD 20857 and available for review or copying are the actual comments as well as a summary and analysis of all of the comments received in response to the NPRM and the December 1996 public hearing, the 1996 Annual Report of the OPTN and Scientific Registry, the 1996 Code of Medical Ethics of the Council on Ethical and Judicial Affairs of the American Medical Association, the 1993 white paper "The Principles of Equitable Organ Allocation" of the OPTN Ad Hoc Committee on Organ Allocation, the materials prepared for the OPTN Board of Directors before each Board Meeting over the last several years, the 1991 report of the HHS Inspector General entitled "The Distribution of Organs for Transplantation: Expectations and Practices," the 1993 report of the General Accounting Office entitled "Organ Transplants: Increased Effort Needed to Boost Supply and Ensure Equitable Distribution of Organs," the OPTN's multi-volume "Report of Center Specific Graft and Patient Survival Rates" for both 1994 and 1997, a 1995 report from the CONSAD Research Corporation providing "An Analysis of Alternative National Policies for Allocating Donor Livers for Transplantation," a number of computer simulations

on liver allocation policy prepared by the Pritsker Corporation in 1996 and 1997 (most included in the OPTN Board materials listed above), a number of computer simulations on liver allocation policy prepared by CONSAD in 1996 and 1997, a series of investigative articles on organ transplantation and allocation issues that appeared in the *Cleveland Plain Dealer* in early 1997, other newspaper articles, and a GAO report, "Organ Procurement Organizations, Alternatives Being Developed to More Accurately Assess Performance", published in November, 1997.

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

A. Summary of Original Public Comments

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

All but two of the 61 letters commenting on specific sections of the NPRM other than allocation policy were from individuals identified with organizations. National groups included the Ad Hoc Coalition on Organ Transplantation, the American Association of Kidney Patients, the American Center for Transplant Resources, the American Society of Histocompatibility and Immunogenetics, the American Society of Transplant Physicians, the American Society of Transplant Surgeons, the Association of Organ Procurement Organizations, the National Kidney Foundation, the North American

Transplant Coordinators Organization, and the United Network for Organ Sharing. Thirty-two letters were from individuals affiliated with hospitals, ten from organ procurement organizations, one from a law firm representing a hospital, two from members of the U.S. House of Representatives, one from a former member of Congress, and two from individuals who identified themselves as organ transplant recipients.

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

B. Summary of Public Hearing

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

1. What role should the Federal government have in organ allocation policy?

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

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

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

2. Are the liver allocation policies that the OPTN adopted in November 1996 fair?

The OPTN Board had approved a new liver allocation policy shortly before the public hearing. At the public hearing and in the comments received, many patients with chronic liver disease opposed the new policy; most physicians supported it. Table 1 presents the pertinent data.

Table 1
Opinions by Type of Respondent (Excluding Petitions)

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

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

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

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

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

3. Should transplantation be centralized in a few centers that meet more stringent criteria, or are there advantages to the present geographic distribution of programs?

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

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

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

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

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

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

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

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

Some argued that the feasibility of national organ sharing is limited by the cold ischemic time (the time after procurement that an organ remains viable for successful transplantation). Witnesses said that this time ranges from 12 to 18 hours for livers and that, for livers transplanted in less than this time, there is little difference in graft survival attributed to cold ischemic time. (Compared to livers, the cold ischemic time is much shorter for hearts and much longer for kidneys.) Some commenters argued that

travel times to and from large cities, where most transplant hospitals are located, readily permits a national allocation scheme for livers. However, others argued, travel times from small communities (the locale of many donors) to large cities or to other small communities are not always predictable and that estimates of travel time are not always reliable.

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

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

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

where the organ is used, believing that donor families want only that their loved one's organs help individuals most in need.

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

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

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

also essentially equal to those of acute patients, who were gaining preference. They questioned how reducing their chance of living, when both urgency and outcome were essentially equal, could meet any reasonable ethical standard.

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

6. How much "game playing" exists in the present system?

A number of witnesses asserted that the current system of organ allocation and listing can be manipulated by hospitals, physicians, and payers. Practices discussed included excluding high risk patients from the list, listing patients early to gain waiting time points, listing patients at more than one transplant hospital to increase the chance of getting an organ, and referring high risk patients to other hospitals to avoid adverse performance outcomes. No data were presented in support of these assertions, but they came from a cross-section of witnesses. Some commented that the present debate evinces

distrust among transplant professionals--local hospitals work together and with the local OPO, whereas non-local hospitals may be "gaming" the system to advantage their patients. Presenters suggested modifications to the system to minimize these tactics. Most supported the development of objective medical criteria for listing and classifying candidates as a specific reform that would increase fairness.

7. How can HHS promote and facilitate an increase in organ donation?

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

Toward that end, HHS is conducting a broad organ and tissue donation initiative that implements many of the suggestions made at the hearing, and others. Included as part of this initiative is a Notice of Proposed Rulemaking published in the Federal Register on December 19, 1997 (62 FR 66725), which would require that hospitals refer all appropriate deaths to OPOs, and that OPOs determine the criteria for these mandatory referrals. In cooperation with other Federal agencies, we are undertaking a major campaign to encourage Federal employees and their families to volunteer to become potential organ donors. We also encourage the transplant community to strengthen its various efforts to increase organ and tissue donation, and to review whether transplant hospitals are taking all reasonable steps to procure

organs (a recent review of OPTN data showed that about one-fourth of transplant hospitals produced no donors in 1995). Finally, the Department will host a conference to exchange information on identifying best practices and promising innovations.

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

8. What is the responsibility to provide access to transplantation services to all Americans, regardless of economic status?

Access to transplantation services was described as being dependent on a person's ability to pay, which virtually always requires health insurance. A few State-supported hospitals testified that they accept all patients regardless of ability to pay, but the preponderance of the testimony was that most

transplant hospitals require that the patient demonstrate an ability to pay. As a result, commenters argued, the promise to honor the altruistic gift of an organ to whoever needs it most is being violated.

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

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

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

1. § 121.2 - Definitions

"National list": Two commenters said that the proposed definition is misleading in that it implies a single, nationwide list for allocating organs whereas the OPTN policies for allocating organs give considerable weight to local and regional geographical considerations. The Department agrees that the term "national list" has been used in conjunction with allocation criteria that involve geographic factors.

However, all recipients of organs are selected from a set of national databases; and even the current allocation criteria have important national elements for some organs. Therefore, the Department has retained the term "national list."

"OPTN computer match program": The Department received two comments on this definition and has modified it to provide a better description of the matching process. The new definition states that the "OPTN computer match program" means a set of computer-based instructions that compares data on a cadaveric organ donor with data on transplant candidates on the national list and ranks the candidates according to OPTN policies to determine the priority for allocating the donor organ(s).

"Organ": The proposed rule defines "organ" as a human kidney, liver, heart, lung, or pancreas. Four commenters suggested that the definition be broadened to include parts of organs and other organs. The inclusion of other organs, such as the stomach and intestines, not only would have an impact on other requirements in these regulations such as the development of allocation policies, certification of designated transplant programs, and establishment of training requirements but also would affect OPO requirements to procure these organs in accordance with rules of the Health Care Financing Administration (HCFA). Thus, the Department believes it would be premature for this rule to specify other organs in addition to those already named. Instead, the Department will direct the OPTN contractor to consider which organs or parts of organs, if any, should be subject to OPTN policies, and to submit recommendations to the Secretary. The Department has added a reference to bone marrow to the definition, because section 374(d)(1) of the Act provides that the term includes bone marrow for purposes of the Scientific Registry.

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

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

"Transplant candidate": One commenter suggested a broader definition that the Department has accepted. It now defines "transplant candidate" as an individual who has been identified as medically suited to benefit from an organ transplant and has been placed on the national list by the individual's transplant program.

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

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

2. § 121.3 - The OPTN

This section of the proposed rule (originally titled "composition") elicited the most written comments, the majority of which discussed representation on the OPTN Board of Directors and committees. In addition, the public hearing identified the governance of the OPTN, including the

composition of the OPTN Board of Directors and committees, as a significant area of concern. OPTN membership is summarized in Table 2 below.

Table 2
OPTN Membership, 1996

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

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.

Both in the written comments and at the public hearings, numerous witnesses who disagreed on particular organ allocation issues nonetheless agreed that there is a potential conflict of interest if transplant professionals, representing particular programs that provide them employment, vote on matters that may substantially affect the financial viability of those programs. Others argued that disagreements among transplant professionals overwhelmingly reflect honest differences of opinion and the natural desire of physicians and others to ensure the best possible outcomes for their own patients.

Additionally, the Department received comments regarding the independence of the process for selecting members of the OPTN Board of Directors. Some members are currently elected from lists of persons selected by the nominating committee of the Board of Directors, not through independent nomination or election by sponsoring organizations. Regardless of the precise procedures and categories, many people believe that the OPTN Board of Directors would be more effective and have enhanced credibility if a greater percentage of its members were persons who broadly represent the public interest and persons who directly represent patient interests, without direct employment or similar ties to the field of transplantation.

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

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

transplant surgeons. Fourth, at least 25 percent of the Board members must be transplant candidates, transplant recipients, organ donors, and family members of any of these categories.

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

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

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

Several commenters suggested that patient groups should be permitted to select their own representatives to the Board and that the interests of patients and families of patients should be better represented on the Board and on its Executive Committee. The Department agrees with the comments

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

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

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

Another individual commented that the Board should include more minority representation. Proposed § 121.3(a)(2)(I) requires that the Board of Directors include individuals representing the diversity of the population of organ donors and recipients served by the OPTN, including minority and

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

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

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

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

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

participation and appeals processes required for policies, and the regulatory language of proposed § 121.10 on review and appeal of policies.

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

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

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

With respect to the proposed requirements for OPTN membership, several commenters suggested that the rules establish voting and non-voting membership categories or otherwise set out membership voting privileges. The Department believes this is appropriate for the OPTN's policy

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

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

3. § 121.5 - Listing requirements (formerly § 121.4)

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

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

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

Several commenters said that a time limit should apply when the OPTN submits to the Secretary a request for approval of the registration (listing) fee. The Department agrees in principle that such

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

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

4. § 121.6 - Organ procurement (formerly § 121.5)

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

expect such a decision, as well as the criteria themselves, to be developed through § 121.4, discussed above.

5. § 121.7 - Identification of Organ Recipient (formerly § 121.6)

This section of the proposed regulations (formerly § 121.6) prompted a number of editorial suggestions, as well as concerns about financial responsibility for the transport of donated organs and protecting the confidentiality of organ donor records. The Department has accepted the editorial suggestions. One commenter said that proposed § 121.6(a)(4) should include a requirement that the OPTN be advised of the reasons for a transplant hospital's refusal of an offered organ. The Department agrees with this suggestion, which is consistent with current practice, and has included it. This notice is to go to the hospital's affiliated OPO as well. See, § 121.7(b)(4).

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

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

Medicare and Medicaid, are within the purview of HCFA and its regulations related to organ acquisition costs.

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

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

6. § 121.4--Policies: Secretarial Review (formerly § 121.7(b) Public Participation)

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

The Secretary does not prescribe specific steps, but requires the OPTN to consider possible policies to reduce inequities. For example, the Secretary expects the OPTN to consider methods of

waiving or financing listing fees for patients unable to pay, through some form of cross-subsidy or by requiring that member hospitals absorb such fees.

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

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

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