UNOS DONATE LIFE
UNITED NETWORK FOR ORGAN SHARING

United Network for Organ Sharing
1100 Boulders Parkway, Suite 500
P.O. Box 13770
Richmond, Virginia 23225-8770
(804)330-8500 *fax* (804)330-8517

www.unos.org

Walter Graham, Executive Director

PUBLIC COMMENT NOTICE

To: OPTN/UNOS members and other interested persons

From: Douglas A. Heiney, Director
Department of Membership Services and Policy Development

Re: OPTN/UNOS policy proposals for public comment

Date: August 21, 2002

Attached for your consideration are nine policy proposals that are being issued for public comment. The proposals address issues considered during recent meetings of the Patient Affairs Committee, Kidney and Pancreas Transplantation Committee, Liver and Intestinal Organ Transplantation Committee, Thoracic Organ Transplantation Committee, and the Histocompatiblity Committee.

These policy proposals are also available for review on the OPTN and UNOS Internet Web sites at www.optn.org and www.unos.org. Comments on these proposals may be submitted electronically at these sites.

Following public comment and reconsideration by the appropriate Committee(s), all proposals in this document may be offered for consideration by the OPTN/UNOS Board of Directors at its November 14-15, 2002 meeting in Alexandria, Virginia. Please mail, fax or email your comments on these proposals to UNOS by October 7, 2002. UNOS appreciates receiving your response to these important issues.

Attachment

UNITED NETWORK FOR ORGAN SHARING
POLICY PROPOSALS

Page

Background

The United Network for Organ Sharing (UNOS) is a tax-exempt medical, scientific, and educational organization. On October 1, 2000, UNOS received a federal contract to continue operation of the national Organ Procurement and Transplantation Network (OPTN) and development of an equitable, scientific and medically-sound organ allocation system. The OPTN is charged with developing by-laws and policies that maximize utilization of organs donated for transplantation, assuring the quality of care for transplant patients, and addressing other complex medical issues related to organ transplantation in the United States. All by-laws and policies receive broad input from numerous constituencies including transplant patients, patient and donor families, the OPTN membership, and concerned individuals and organizations throughout the United States.

By-Laws and policies are adopted by the OPTN/UNOS Board of Directors pursuant to the UNOS contract with the United States Department of Health and Human Services (DHHS) and after circulation and discussion among organ transplant professionals and patient representatives. These by-laws and policies have been submitted to the Secretary of DHHS for review and are considered voluntary guidance to OPTN members until approved as OPTN rules and requirements by the Secretary of DHHS. UNOS is responsible for updating these by-laws and policies and for monitoring compliance by OPTN members. Instances of noncompliance with by-laws and policies may lead to disciplinary action and designation as a member-not-in-good-standing by the Board of Directors. In addition, instances of non-compliance are reported to the Secretary of DHHS.

The proposals that follow address issues considered during recent meetings of the Patient Affairs Committee, Kidney and Pancreas Transplantation Committee, Liver and Intestinal Organ Transplantation Committee, Thoracic Organ Transplantation Committee, and the Histocompatiblity Committee. Following public comment and reconsideration by the appropriate committee(s), all proposals in this document may be offered for consideration by the OPTN/UNOS Board of Directors at its November 14-15, 2002 meeting in Alexandria, Virginia.

These policy proposals are also available for review on the OPTN and UNOS Internet Web sites at www.optn.org **and** www.unos.org. **Comments on these proposals may be submitted electronically at these sites.**

Circulation of Notice

UNOS maintains a public comment distribution list for policy and by-law proposals. To be included on the distribution list, submit a written request to UNOS at the address below. All policy and by-law proposals issued for public comment are mailed to the distribution list. UNOS accepts comments from the public for at least 45 days after publication of the proposals and public hearings on the proposals are arranged if warranted.

Comment Deadline

The proposals in this document are being issued for public comment on **August 21, 2002**. To be considered, comments must be submitted in writing, or by completing the enclosed Public Comment Response Form, and sent to the UNOS contact person at the following address by **October 7, 2002**:

United Network for Organ Sharing
P.O. Box 13770
1100 Boulders Parkway, Suite 500
Richmond, VA 23225
FAX (804) 330-8596

UNOS Contact Persons

Inquiries regarding the policy proposals in this document should be made to the appropriate UNOS Regional Administrator at (804) 330-8500. The UNOS Regional Administrators are as follows:

Fred Geiger (geigerfr@unos.org)
Region 1 - Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont
Region 4 - Oklahoma, Texas
Region 9 - New York

Elizabeth Gans (gansel@unos.org)
Region 2 - Delaware, District of Columbia, Maryland, New Jersey, Pennsylvania, Northern Virginia, West Virginia
Region 5 - Arizona, California, Nevada, New Mexico, Utah
Region 6 - Alaska, Hawaii, Idaho, Montana, Oregon, Washington

Clifton McClenney (mcclence@unos.org)
Region 7 - Illinois, Minnesota, North Dakota, South Dakota, Wisconsin
Region 8 - Colorado, Iowa, Kansas, Missouri, Nebraska, Wyoming
Region 10 - Indiana, Michigan, Ohio

William Van Vleck (vanvlewh@unos.org)
Region 3 - Alabama, Arkansas, Florida, Georgia, Louisiana, Mississippi, Puerto Rico
Region 11 - Kentucky, North Carolina, South Carolina, Tennessee, Virginia

In the following proposals, new policy language is underlined. Language that will be deleted has a line through the text. For example, this is how proposed new language will appear ~~and this is how proposed deleted language will appear.~~

1. Proposed Modifications to OPTN/UNOS Policy 3.5.11.2 (Quality of Antigen Mismatch)

Summary

This proposal would eliminate from the national system of standard criteria donor kidney allocation points assigned for human leukocyte antigen (HLA) similarity between potential donor and recipient pairs at the B locus and modify points assigned for HLA similarity between potential donor and recipient pairs at the DR locus. It is intended to increase access to kidney transplantation for minority patients with minimal impact upon transplant outcomes for patients overall.

Please note that this is one of the first five proposals included in this document that would modify kidney allocation policy and were developed after considering recommendations from the National Conference to Analyze the Wait List for Kidney Transplantation held in Philadelphia, Pennsylvania, on March 4-5, 2002. Each proposal is presented separately. Therefore, cumulative or relative impacts of the proposals that might be expected upon combining the proposals have not been addressed. Comments in this regard are welcome.

Background

Current policies for allocating and distributing kidneys include provisions that determine the order in which available organs are offered to patients on the waiting list as well as governing the composition of the list at the time the offer is made. With certain exceptions, including priority for the best matched organs, kidneys are distributed initially to patients on the *local* list (generally defined as patients listed for transplantation at transplant centers served by the organ procurement organization that the donor hospital is affiliated with), then *regionally* (other non-local patients listed for transplantation at transplant centers within the UNOS region), and then *nationally* (other patients listed for transplantation at transplant centers in all of the other UNOS regions). For standard criteria donor kidneys, the allocation rank order of patients on the local, regional, or national lists is determined primarily by assigning points based on degree of HLA (human leukocyte antigen) similarity between potential donor and recipient pairs; degree of recipient anti-HLA antibody sensitization; for pediatric patients, age; and waiting time. Standard criteria donors are defined as all donors others than those identified by relative risk of graft failure according to the decision matrix and factors listed in Policy 3.5.1 (Definition of Expanded Criteria Donor and Standard Donor). Identity between donor and recipient ABO blood group for blood type O and blood type B kidneys is required for transplants other than those that are matched at the highest level (*i.e.,* zero antigen mismatched).

7. Proposed Modification to OPTN/UNOS Thoracic Policy 3.7.3 (Adult Patient Status)

Summary

The proposed modifications to OPTN/UNOS Policy 3.7.3 change the listing criteria and listing processes for exceptional cases of patients that have a similar clinical acuity and risk of mortality to a Status 1A patient but cannot otherwise be listed as Status 1A(a), (b), (c) or (d). The revised process requires prospective review and approval of a patient by the Regional Review Board prior to listing and prior to extension for Status 1A under this provision.

Background

In a continuing effort to refine heart allocation policy and adhere to the requirements of the OPTN Final Rule, the Thoracic Organ Transplantation Committee and the Heart Allocation Subcommittee have worked to review and revise current allocation criterion and processes, to promote greater objectivity and standardization in listing practices.

During the course of the July 26th Committee meeting, members discussed various issues and difficulties associated with Status 1A(e) patient listings and deliberated the necessity of maintaining a status category for exceptional cases.

Under the current criteria, a patient with exceptional clinical circumstances, who has a life expectancy of less than 7 days without a heart transplant, may be listed as Status 1A(e) for a period of 7 days and extended for an additional 7 day period by the attending physician. Additional extensions currently require a conference call with the Regional Review Board (RRB). In November 2001, the OPTN/UNOS Board of Directors passed a resolution developed by the Thoracic Committee that requires prospective review and approval by the RRBs, before a patient listed as Status 1A(e) can be extended for an additional term. Under this proposal, if RRB approval is not granted and the physician

continues to list the patient as a Status 1A(e), the case will be referred to the Thoracic Committee and the Membership Professional Standard Committee for review.

During the Thoracic Committee's May 14, 2002 meeting, in response to a request to clarify compliance and programming issues associated with the proposed prospective review process, members of the Committee recommended that an automated prospective review process be developed and modeled after the current MELD system for exceptional cases. Members suggested however that the system be designed to allow a telephone conference if requested by any of the parties, and to avoid automatically downgrading the patient if the extension request has been submitted in a timely manner but remains unresolved by the end of the previous extension. Additionally members agreed that, in the case of a negative vote, the center could either choose to submit a justification form and be automatically referred to the Thoracic Committee and MPSC, or be automatically downgraded if no form is submitted. This recommendation was submitted to and approved by, the OPTN/UNOS Board of Directors during their June 27-28th, 2002 meeting.

At the July 26th, 2002 meeting of the Committee, members reiterated concerns that the criteria for listing a patient as a Status 1A(e) is unrealistic and too subjective. Most members agreed that a pathway should be preserved to allow patients with exceptional circumstances to be listed as Status 1A and that the criteria should be refined in a manner that promotes greater objectivity and regional standardization in listing practices. Given the wide variations in clinical symptoms and unique circumstances of patients listed under the current criterion, and often the inherent difficulty for a physician to be able to predict a patients death within 7 days, members agreed to refine policy 3.7.3 to allow patients, with a similar clinical acuity and potential for benefit comparable to that of other Status 1A patients, to be listed as a Status 1A for a period of 14 days after prospective review and approval by the respective Regional Review Board. Equally members agreed that an extension of a patient past 14 days would require an additional prospective review and approval by the RRB, as originally approved by the OPTN/UNOS Board of Directors. Members agreed that this process would provide greater objectivity, promote regional standardization in listing practices, and ensure that those patients with a clinical acuity similar to that of other Status 1A patients get appropriately listed.

Policy Proposal

On the basis of their discussion, the Committee voted on the following resolution to go out for public comment. Following public comment and reconsideration by the Committee, the matter will be presented for consideration by the Board of Directors:

RESOLVED, that the amended language proposed below as UNOS policy 3.7.3 be approved for public comment:

3.7.3 Adult Patient Status. Each patient awaiting heart transplantation is assigned a status code which corresponds to how medically urgent it is that the patient receive a transplant. Medical urgency is assigned to a heart transplant patient who is greater than or equal to 18 years of age at the time of listing as follows:

Status	Definition
1A	A patient listed as Status 1A is admitted to the listing transplant center hospital and has at least one of the following devices or therapies in place:

(a) Mechanical circulatory support for acute hemodynamic decompensation that includes at least one of the following:
- (i) left and/or right ventricular assist device implanted for 30 days or less;
- (ii) total artificial heart;
- (iii) intra-aortic balloon pump; or
- (iv) extracorporeal membrane oxygenator (ECMO).

Qualification for Status 1A under this criterion is valid for 14 days and must be recertified by an attending physician every 14 days from the date of the patient's initial listing as Status 1A to extend the Status 1A listing.

(b) Mechanical circulatory support for more than 30 days with objective medical evidence of significant device-related complications such as thromboembolism, device infection, mechanical failure and/or life-threatening ventricular arrhythmias (Patient sensitization is not an appropriate device-related complication for qualification as Status 1A under this criterion. The applicability of sensitization to thoracic organ allocation is specified by UNOS Policy 3.7.1.1 (Exception for Sensitized Patients). Qualification for Status 1A under this criterion is valid for 14 days and must be recertified by an attending physician every 14 days from the date of the patient's initial listing as Status 1A to extend the Status 1A listing.

(c) Mechanical ventilation. Qualification for Status 1A under this criterion is valid for 14 days and must be recertified by an attending physician every 14 days from the date of the patient's initial listing as Status 1A to extend the Status 1A listing.

(d) Continuous infusion of a single high-dose intravenous inotrope (e.g., dobutamine >/= 7.5 mcg/kg/min, or milrinone >/= .50 mcg/kg/min), or multiple intravenous inotropes, in addition to continuous hemodynamic monitoring of left ventricular filling pressures; Qualification for Status 1A under this criterion is valid for 7 days and may be renewed for an additional 7 days for each occurrence of a Status 1A listing under this criterion for the same patient.

~~(e) A patient who does not meet the criteria specified in (a), (b), (c) or (d) may be listed as Status 1A if the patient is admitted to the listing transplant center hospital and has a life expectancy without a heart transplant of less than 7 days. Qualification for Status 1A under this criterion is valid for 7 days and may be recertified by an attending physician for one additional 7-day period.~~

A patient who does not meet the criteria for Status 1A may nevertheless be assigned to such status upon application by his/her transplant physician(s) and justification to the applicable Regional Review Board that the patient is considered, using accepted medical criteria, to have an urgency and potential for benefit comparable to that of other patients in this status as defined above. The justification must include a rationale for incorporating the exceptional case as part of the status criteria. The justification must be prospectively reviewed and approved by the Regional Review Board, before the patient can be listed as a Status 1A. A report of the decision of the Regional Review Board and the basis for it shall be forwarded to UNOS for review by the Thoracic Organ Transplantation and Membership and Professional Standards Committees to determine consistency in application among and within Regions and continued appropriateness of the patient status criteria. A patients listing under this exceptional provision is valid for 14 days. Any further extension of the Status 1A listing under this criterion requires prospective review and approval by a majority of the Regional

Review Board Members. If Regional Review Board approval is not given, the patient's transplant physician may list the patient as Status 1A, subject to automatic referral to the Thoracic Organ Transplantation and Membership and Professional Standards Committees.

For all adult patients listed as Status 1A, a completed Heart Status 1A Justification Form must be received by UNOS on UNet[sm] in order to list a patient as Status 1A, or extend their listing as Status 1A in accordance with the criteria listed above in policy 3.7.3. Patients listed as Status 1A will automatically revert back to Status 1B unless they are re-listed on UNet[sm] by an attending physician within the time frames described in the definitions of status 1A(a)-(e) above.

Status	Definition
1B	A patient listed as Status 1B has at least one of the following devices or therapies in place: (aa) left and/or right ventricular assist device implanted for more than 30 days; or (bb) continuous infusion of intravenous inotropes. For all adult patients listed as Status 1B, a completed Heart Status 1B Justification Form must be received by UNOS on UNet[sm] in order to list a patient as Status 1B. A patient who does not meet the criteria for Status 1B may nevertheless be assigned to such status upon application by his/her transplant physician(s) and justification to the applicable Regional Review Board that the patient is considered, using accepted medical criteria, to have an urgency and potential for benefit comparable to that of other patients in this status as defined above. The justification must include a rationale for incorporating the exceptional case as part of the status criteria. A report of the decision of the Regional Review Board and the basis for it shall be forwarded to UNOS for review by the Thoracic Organ Transplantation and Membership and Professional Standards Committees to determine consistency in application among and within Regions and continued appropriateness of the patient status criteria.
2	A patient who does not meet the criteria for Status 1A or 1B is listed as Status 2.
7	A patient listed as Status 7 is considered temporarily unsuitable to receive a thoracic organ transplant.

Prior to downgrading any patients upon expiration of any limited term for any listing category, UNOS shall notify a responsible member of the relevant transplant team.

[NO FURTHER CHANGES TO POLICY 3.7.3]

NOTE: Amendments to Policy 3.7.3 (Adult Patient Status) shall be implemented pending programming on the UNOS Computer System.