

**EXECUTIVE SUMMARY
OF THE MINUTES**

OPTN/UNOS

BOARD OF DIRECTORS MEETING

June 27-28, 2002

Orlando, Florida

Dr. Turcotte called the meeting to order at 10:00 a.m. on June 27, 2002. A quorum was present, and 33 of the Board members were in attendance during the meeting.

The Board approved the recommendation to increase the Registration Fee for listing a potential recipient on the patient waiting list to \$415 from the previous Registration Fee amount of \$384 and approved the 2003 OPTN Operating Budget.

The Board approved the assessment of a 1.5% late fee on all accounts receivables balances over 120 days old to begin on October 1, 2002 and directed the UNOS staff to inform all members of the late fee policy.

The Board approved the recommendation to refer members who have failed to pay the late fee to the Membership and Professional Standards Committee to consider the recommendation of the Finance Committee to designate such member as a “member not in good standing.”

The Board directed the OPTN Membership and Professional Standards Committee to develop procedures for designating, with the OPTN Finance Committee’s referral, an OPTN member with accounts receivable greater than \$10,000 and more than 120 days old as an OPTN “member not in good standing.”

The Board approved the 2001 OPTN audited financial statements and the related OMB Circular A-133 compliance audit.

The Board approved several resolutions contained in the Consent Agenda in a single vote. The subject of the various individual resolutions follows here:

- 1) The Board approved the recommended amendments to By-Laws, Appendix B (Standards for Histocompatibility Testing), Sections H4.100 and H4.200, requiring prospective typing of donors and recipients for Bw4 and Bw6 antigens.
- 2) The Board approved modifications to Policy 3.8.1.1 (Regional Whole Pancreas Allocation); Policy 3.8.1.2 (National Whole Pancreas Allocation); and Policy 3.8.1.3 (Facilitated Pancreas Allocation) that would remove priority for HLA matching for the system for pancreas allocation, with the exception of priority assignment for zero antigen mismatches between donor and patient.

- 3) The Board approved the recommended amendments to By-Laws, Appendix B, Section III, C Section V (Proposed Modifications to the Transplant Surgeon and Physician Requirements) allowing some flexibility in applying the membership criteria to programs serving primarily pediatric patients that meet substantially all, but less than all, of the current criteria, pending development of requirements more specific to these programs.
- 4) The Board approved modifications to Policy 7.0-7.5 (Data Submission Requirements), to ensure the policy reflects current OPTN form name references and submission times in addition to reordering certain sections to provide a different structure.
- 5) The Board approved modifications to Appendix 3A (HLA A, B, and DR Matching Equivalences and Unacceptable Antigen Equivalences Tables).
- 6) The Board approved three requests for waiting time modification pending receipt of additional documentation and programming on the UNOS computer system as recommended by the Kidney and Pancreas Transplantation Committee.
- 7) The Board approved two requests for waiting time modification as recommended by the Kidney and Pancreas Transplantation Committee.
- 8) The Board declined a request for waiting time modification based on the Kidney and Pancreas Transplantation Committee's conclusion that it does not satisfy the requirements of Policy 3.2.1.8 (Waiting Time Modification).
- 9) The Board approved the recommendation that the elements necessary to determine a patient's Child-Turcotte-Pugh (CTP) score continue to be collected on the OPTN liver waiting list until February 27, 2003.
- 10) The Board approved the recommendation to waive the requirement for MELD/PELD data upon removal from the waiting list for those patients listed prior to February 27, 2002, with no MELD/PELD data entered into UNetsm at the time of removal.
- 11) The Board approved modifications to Policy 3.2.1.8.1 (Waiting Time Modification for Urgent Status Patients) which would delete reference to Status 2A.
- 12) The Board approved amendments to Policy 3.6.4.1 (Adult Patient Status) and Policy 3.6.4.2 (Pediatric Patient Status) to state that Status 1 listing must comply with the applicable recertification and reassessment schedule for adult or pediatric patients.
- 13) The Board approved amendments to Policy 3.6.4.2.1 (Pediatric Patient Recertification and Reassessment Schedule) to reflect negative PELD scores.
- 14) The Board approved amendments to Policy 3.6.4.5 (Liver Candidates with Exceptional Cases) such that patients whose MELD exceptions are not recertified will be assigned the patient's currently calculated MELD/PELD score.
- 15) The Board approved reinstatement of patient waiting time in eight cases reviewed by the Liver and Intestinal Organ Transplantation Committee.
- 16) The Board approved the on-line submission of Status 1 Justification Forms in UNetsm.
- 17) The Board approved new transplant programs, public members, organ procurement organizations, and tissue typing laboratories, as well as changes in program status.
- 18) The Board approved amendments to Policy 2.4 (Obtaining Consent), so that the Host OPO must document consent for donation according to applicable legal authority.
- 19) The Board approved the recommendation that the Patient Affairs Committee convene two-day meetings, three times per year, one of which would be held during the summer in between Board of Directors' meetings.

- 20) The Board approved the recommendation to modify the heart Status 1A and 1B online justification forms and the respective modifications to the language of Policy 3.7.3 (Adult Patient Status) and 3.7.4 (Pediatric Patient Status).
- 21) The Board approved the development of an online system for Regional Review Boards as an initial basis for implementing the prospective review process for patients listed as Status 1A(e) and seeking a second extension.
- 22) The Board approved the recommendation that B-Type Natriuretic Peptide (BNP) not be included in the list of intravenous drugs that are acceptable for upgrading a patient to Status 1A or 1B.
- 23) The Board approved LifeGift Organ Donation Center's request to use an alternative allocation system for pancreases, pending receipt of all necessary signatures for transplantation of 10 patients, after which the OPO would need to apply to the Committee for continuation of the alternative system.
- 24) The Board approved the University of Wisconsin and Clinics Heart Transplant Program (UWHC) and the William S. Middleton Veterans Affairs Medical Center variance application regarding Status 1A patients being admitted to the listing transplant center hospital.

Following passage of the consent agenda, the Board approved modifications to Policy 3.4.1 (Time Limit for Acceptance), Policy 3.5.3.5 (Mandatory Sharing of Zero Antigen Mismatched Kidneys – Time Limit) and Policy 3.8.1.6.1 (Mandatory Sharing of Zero Antigen Mismatched Pancreata – Time Limit), that would maintain strictly the time limits for making zero antigen mismatched organ offers even if this would allow less than the one hour typically permitted for organ acceptance.

The Board granted final approval for Policy 3.6.4.4 (Liver Transplant Candidates with Hepatocellular Carcinoma (HCC) and Policy 3.6.12.1 (Transition for Currently Listed Status 2B HCC Patients), to amend language addressing liver transplant candidates with HCC and that the policy be evaluated by the Liver and Intestinal Organ Transplant Committee six months after implementation.

The Board approved modifications to Policy 3.7.3 (Adult Patient Status) Status Criterion 1A(a)(i) (patients listed with ventricular assist devices) and the respective changes to Status Criterion 1B (aa), providing that patients listed under the criterion for ventricular assist devices may be listed for 30 days at any point after being implanted as Status 1A once the treating physician determines that they are clinically stable, and admittance to the listing transplant center hospital is not required.

The Board approved modifications to Policy 3.7.8 (ABO Typing for Heart Allocation) and Policy 3.7.8.1 (Heart Allocation to Pediatric Candidates Registered Under Blood Type “Z”) to create a “Z” type ABO designation to allow infants under one year of age, to accept hearts from an ABO incompatible donor.

The Board approved the recommendation to modify Policy 3.2.1.7 (Neonatal Thoracic Donor Organ) to clarify the placement of neonatal donor hearts in light of policy modifications allowing incompatible blood matching.

The Board resolved to communicate with the ASTS regarding the status of its efforts involving the credentialing of donor procurement professionals toward the end of bringing rapid closure to this matter.

The Board approved the Executive Committee's recommended Data Submission Amnesty Plan, effective June 30, 2002.

The Board resolved to support legislation to permit the initiation of demonstration projects to evaluate the impact of financial and other incentives on cadaveric organ donation.

The Board resolved for the President to establish a joint subcommittee of interested committees coordinated by the Organ Availability Committee to suggest guidelines and monitor the implementation and evaluation of such demonstration projects.

The Board approved the recommendation that a more extensive data collection instrument, utilizing existing structures, be incorporated in the UNOS Living Donor Registry in order to track the long-term results for living donation, and recommendation that the OPTN should develop mechanisms to improve compliance with this data reporting and that transplant centers should be required to report living donor transplants, as well as the donor name, date of birth, social security number, at a minimum.

The Board approved the recommendation to endorse legislation or regulation that will help fund long-term follow-up of live donor liver donors and recipients and to advocate that the OPTN be granted purview over living donor transplantation.

The Board declined to approve the recommendation that OPOs should include items on the donor questionnaire to identify individuals at risk for Chagas' Disease, and to notify prospective transplant centers if the answer to any of the items referenced is "yes."

In a single vote, the Board approved both the proposal from Donor Network of Arizona for an alternative system for kidney allocation pending agreement by the parties to defer acceptance of zero antigen mismatched kidneys procured from non-heartbeating donors outside the OPO, and OneLegacy's request for a modification to its alternative allocation system for kidneys.

The Board voted to reconsider Ohio Valley LifeCenter's request to allocate kidneys using the proposed paired kidney exchange program, which resolution had previously been tabled at the Board's November 15-16, 2001 meeting. Then in a single vote, the Board approved Ohio Valley LifeCenter's request to allocate kidneys using the proposed paired kidney exchange program; Mid-America Transplant Services' request to use an alternative allocation system for renal allocation/incompatible recipient pairs; FingerLakes Donor Recovery Network's request to use an alternative allocation system for renal allocation/incompatible recipient pairs; and California Transplant Donor Network for modification to alternative system for allocating/distributing kidneys.

The Board approved the UCLA heart allocation variance application.

The Board approved the recommendation that the current Region 7 Status 1 Liver Sharing Alternative System be modified to state that the MELD score to be used for the payback threshold is the actual calculated MELD score rather than the MELD score used by the match, pending receipt of necessary signatures.

The Board approved the recommendation that UNOS provide each liver transplant program with a list of its patients who are currently registered on the OPTN Liver waiting list but have been reported as deceased on the Social Security Death Master File.

The Board approved the State of Florida ALU application for lung allocation as recommended by the Thoracic Organ Transplantation Committee.

The Board approved the request from Tennessee Transplant Society to modify its alternative allocation/distribution system for pancreases shall be approved pending receipt of all necessary signatures as recommended by the Kidney and Pancreas Transplantation Committee.

The Board resolved to recognize that human cloning holds great potential for good but also engenders significant societal concerns and strongly recommends against legislation that would prohibit stem cell research or cellular replacement by nuclear transfer for therapeutic purposes a.k.a. therapeutic cloning as opposed to reproductive cloning, that could potentially impact organ and tissue transplantation.

The Board adopted the Ethics Committee statement regarding the “Allocation of Organs from Non-directed Living Donors.”

The Board rescinded the Ethics Committee resolution regarding informed consent, which was previously approved at the Board’s November 15-16, 2001 meeting pending appropriate review and further discussion between the OPO and Ethics Committees.

The Board approved modifications to Policy 7.0 (Data Submission Requirements) to require electronic submission of all OPTN data collection forms, effective January 1, 2003.

The Board resolved that staff should send materials and exhibits to Board members not less than fourteen days prior to scheduled meetings of the Board of Directors.