

**EXECUTIVE SUMMARY  
OF THE MINUTES**

**OPTN/UNOS**

**BOARD OF DIRECTORS MEETING**

**November 15-16, 2001**

**Alexandria, Virginia**

Dr. Turcotte called the meeting to order at 10:00 a.m. on November 15, 2001. A quorum was present, and 31 of the Board members were in attendance during the meeting.

The Board appointed Lloyd H. Jordan, Jr., CPA to fill the vacancy created by the resignation of Susan Gunderson, MHA representing the Organ Procurement Organizations on the Board of Directors and appointed Douglas E. Wood, M.D. to fill the vacancy created by the resignation of Michael S. Seely, RN, MS, CPTC representing Region 6 on the Board of Directors, effective November 15, 2001.

The Board approved several resolutions contained in the Consent Agenda in a series of three votes. The subject of the various individual resolutions follows here:

- 1) The Board approved the recommendation to modify Policy 9.0 (Release of Information to the Public) deleting the inclusion of Center and OPO specific data submission compliance rates and allowing the release of information and data that had not previously been made available to the public.
- 2) The Board approved modifications to Policy 7.5 (Submission of Feedback Information) to provide that PTR forms must be submitted within 30 days of the match run date and that after 45 days from the date of the offer the refusal reason will be considered accurate and validated.
- 3) The Board approved modifications to Policy 3.7.8.1 (Heart Allocation to Pediatric Candidates Registered Under Blood Type "A") to create a "Z" blood type designation for *in utero* candidates and pediatric candidates.
- 4) The Board approved the recommendation providing for the on-line submission of Patient Justification Forms.
- 5) The Board approved the recommendation to remove the Cadaver Donor Referral Form as an OPTN/UNOS data collection form.
- 6) The Board approved the recommendation to program Unet<sup>sm</sup> to allow the entry of HLA-A, B, C, DR, DQ antigens, and DR51, 52, 53, Bw4 and Bw6 for all potential transplant candidates of all organs, and for all potential organ donors and further, to program UNet<sup>sm</sup> to allow the entry of unacceptable antigens to HLA-A, B, C, DR, DQ antigens, and DR51, 52, 53, Bw4 and Bw6.
- 7) The Board approved Appendix 3A(HLA-A, B, and DR Matching Equivalencies and Unacceptable Antigen Equivalencies Tables), as amended, to more clearly define the table headings and to give the users better examples of how the tables work.

- 8) The Board approved three requests for waiting time modification, as recommended by the Kidney and Pancreas Transplantation Committee.
- 9) The Board approved the recommendation that OPTN/UNOS policy establishing rules for owing and being owed a payback kidney only after accumulation of two such debts/credits of the same blood type shall not be applied when kidneys are offered in satisfaction of long-term kidney payback debt. Further, that an OPO that retains only a single long-term payback debt in a particular blood group (with no short term debt in the blood group) shall have the option of offering kidneys in satisfaction of this payback debt but shall not be required to do so unless this would result in failure to meet the OPO's long-term debt threshold.
- 10) The Board approved the recommendation to modify Policy 3.6.4.1 (Adult Patient Status) and Policy 3.6.4.2 (Pediatric Patient Status) that will allow urgent Status Justification Forms for patients whose listing/upgrade occurs over a weekend or holiday to be due for submission the following business day.
- 11) The Board approved the recommendation of the Membership and Professional Standards Committee to approve new transplant programs, new public members and program status changes.
- 12) The Board approved the recommendation to approve the proposed modifications of Policy 3.7.3 (Adult Patient Status) and Policy 3.7.4 (Pediatric Patient Status) and the Heart Status Justification Forms for Status 1A and 1B patients, to allow for submission of the forms on the following business day.
- 13) The Board approved the Florida Alternative Local Unit (ALU) application for lungs to operate for a period of 18 months commencing at the date of the original ALU's termination.

The Board approved modifications to Policy 3.5 (Allocation of Cadaveric Kidneys) defining expanded criteria donor kidneys; limiting offers of expanded donor kidneys to potential recipients of the expanded donor kidneys for a period of two hours from the time the first offer is made; and requiring OPOs to identify potential recipients within six hours post cross clamp or offer the organs for eligible patients listed regionally and then nationally.

The Board tabled further discussion of a proposed amendment to UNOS Policy 3.5.9.2 which would remove points for HLA matching from the system for kidney allocation.

The Board approved a modification to Region 1's alternative distribution/allocation system for kidneys to allow an exemption from the standard protocol for sharing kidneys for zero antigen mismatched patients for kidneys procured from non-heartbeating donors with a condition for annual reporting of transplant outcomes to the Kidney and Pancreas Transplantation Committee.

The Board declined to approve a request to exempt Region 1 from the standard protocol for sharing kidneys for zero antigen mismatched patients for kidneys procured from donors age  $\geq$  60.

The Board approved the proposal from Ohio Valley LifeCenter for a pancreas allocation variance to allocate pancreases for islet transplantation locally before offering the pancreases for whole organ transplantation regionally and nationally.

The proposal from the Ohio Valley LifeCenter to allocate kidneys using the proposed paired kidney exchange program was withdrawn.

The Board approved amendments to OPTN/UNOS Policy 3.7.3 and Policy 3.7.4 providing that heart patients listed as Status 1A will automatically revert back to Status 1B unless they are relisted within the prescribed time frame by an attending physician.

The Board approved modifications to Policy 3.2.1.7 to distinguish between neonatal and *in utero* candidates and to list neonatal candidates for first preference from neonatal donors and directed that the UNOS computer algorithm be modified to reflect this revision to Policy 3.2.1.7.

The Board approved modifications to Appendix B – Attachment 1-A of the Bylaws (Standards for Histocompatibility Testing) to add additional sections due to advances in clinical testing knowledge and to comply with all relevant CLIA requirements. The Board specifically amended the proposal to leave the words “as applicable” in section 11.000 of the proposed standards that had been stricken.

The Board approved modifications to Policy 3.6 (Allocation of Livers) incorporating the MELD/PELD mortality risk scoring system including Policy 3.6.4.3 (Liver Candidates with Hepatocellular Carcinoma (HCC)) and with two friendly amendments to Policy 3.6.2.1 which was amended to state that “. . . blood type O donors may only be allocated to blood type O patients, or B patients with a MELD/PELD score greater than or equal to 20” and that “patients who do not send in the laboratory date shall be given a MELD score of 6.” The Board also approved the recommendation that the liver allocation policy remains flexible to timely modification to avoid harm to patients.

In a single vote, the Board approved the continuation of UNOS-approved variances and/or sharing agreements currently in place in Regions 4, 5, 7, and 8; and the states of Ohio and Hawaii as modified to incorporate the MELD/PELD scoring system. The Board also approved the continuation of the existing UNOS-approved Status 1 sharing agreements currently in place in Regions 1 and 10 and the state of Florida, and the statewide sharing agreements for all statuses in place in New York (Region 9) and Tennessee. In the same vote, the Board approved the discontinuation of the existing OPTN/UNOS liver allocation variances currently approved for Region 10 and the New England Organ Bank upon implementation of the MELD/PELD system.

The Board approved a resolution to forward to the Department of Health and Human Services the current allocation policies as of November 16, 2001 and recommends that all organ allocation policies remain flexible to timely modification to avoid harm to patients.

The Board approved a resolution providing for the Minority Affairs Committee and the Ethics Committee to convene on a regular basis four times per year using one-day meetings. In the same vote, the Board approved a resolution providing for the Patient Affairs Committee to meet four times per year with two of the meetings to be two-day meetings.

The Board approved the recommendation to refer to the OPO Committee for its review, a draft resolution affirming an ethical duty for OPOs to follow the wishes of a decedent regarding organ donation.

The Board resolved that all programs identified to be a statistically significant outlier in regards to their listing of Status 1A(e) patients will be site audited with their records reviewed by a non-local physician who will report to the Thoracic Organ Transplantation Committee.

The Board approved a modification to Policy 3.7.3 requiring that for any further extension of Status 1A(e) listing, prospective review and approval by a majority of the Regional Review Board Members and if Regional Review Board approval is not given, the patient's transplant physician may list the patient as Status 1A subject to immediate review by the Thoracic Organ Transplantation and the Membership and Professional Standards Committees.

The Board approved three requests for wait time modification as recommended by the Thoracic Organ Transplantation Committee.

The Board approved a resolution reaffirming the importance of informed consent of donors and donor families and stressing the necessity of maintaining trust and accountability in the systems of both organ and tissue donation.

The Board approved modifications to Policy 7.8.1 requiring each OPO, Transplant Center and Histocompatibility Laboratory to meet the following standard for submission of data collected on all forms and donor referral information to the UNOS Transplant Registries: 95% of expected forms complete within three months of the due date and 100% of expected forms complete within six months of the due date. 100% of the potential recipient refusal code data must be submitted within 30 days of the match run date, effective June 30, 2002.

The Board adopted the slate of nominees for election of members to the UNOS Board of Directors as recommended by the Nominating Committee.

The Board amended Article II, Section 2.1 of the Bylaws to extend the directorial term of the Director elected to serve as the Vice-President of Patient and Donor Affairs to a term of four years.

The Board amended Article IV, Section 4.1 of the Bylaws to extend the term of office for the Vice-President of Patient and Donor Affairs to a term of two years.