

**OPTN/UNOS PATIENT AFFAIRS COMMITTEE
INTERIM REPORT**

November 3, 2011

The primary purpose for this call was to receive presentations on public comment proposals and document votes from the Committee.

- I. Thoracic Organ Transplantation Committee:
Plain Language Modifications to the Adult and Pediatric Heart Allocation Policies, Including the Requirement of Transplant Programs to Report in UNet a Change in Criterion or Status within Twenty-Four Hours of that Change

The Committee received the proposal and voted without discussion. Yes – 14, No – 0, Abstain – 0

- II. Ad Hoc International Relations and Ethics Committees:
Proposed Revisions to and Reorganization of Policy 6.0 (Transplantation of Non-Resident Aliens), Which Include Changes to the Non-Resident Alien Transplant Audit Trigger Policy and Related Definitions

The Committee strongly supported review of all transplants of non-US citizens/non-residents. The Committee cited this as a means to better ascertain the true extent of non-resident transplant in the US. Individual Committee members raised strong concerns regarding the use of self-reporting of residency status for transplant. The concerns were based upon the issue of fairness to US Citizens if non-citizens/non-residents are allowed to have priority over US Citizens in allocation. This was further seen as having the potential to undermine the public trust in the OPTN and the allocation system.

Transplant Center staff emphasized the ability to ascertain residency status with a fair amount of accuracy during the assessment process. A thorough and thoughtful assessment significantly limits the ability of individuals to misrepresent themselves in regard to residency. It was also noted that non-residents donate in approximately the same proportion that they receive organs from the system; about 1% in both instances.

After significant discussion the Committee voted as follows:
Yes – 14, No – 0, Abstain - 0

- III. Organ Procurement Organization (OPO) Committee:
Proposal to Eliminate the Use of an "Alternate" Label when Transporting Organs on Mechanical Preservation Machines and to Require the OPTN Distributed Standardized Label Organ Procurement Organization (OPO) Committee

The Committee received the proposal and voted without discussion. Yes – 14, No – 0-14, Abstain – 0

IV. Organ Procurement Organization (OPO) Committee:
Proposal to Change the Term "Consent" to "Authorization" Throughout Policy When
Used in Reference to Organ Donation “

The Committee received this proposal. A Committee member who voted via email raised concerns that the proposal would allow OPO's to diminish or 'dumb down' the information that is required to be shared with families. The proposal stressed that the changes reflect language and not process changes.

The Committee voted in support of the proposal: Yes – 13, No – 0, Abstain – 1

V. Organ Procurement Organization (OPO) Committee:
Proposal to Modify the Imminent and Eligible (I & E) Neurological Death Data
Reporting Definitions”

The Committee received the proposal and voted without discussion: Yes – 14, No – 0,
Abstain – 0

The Committee received a brief update on the status of *What Every Patient Needs to Know*. Committee members voiced concern over the amount of time Astellas is taking to approve the product.

PAC responses to the USPHS Proposal have been submitted for inclusion in the comprehensive OPTN statement. The OPTN statement will be forwarded to the Committee when it is available for public review.

The Committee was reminded to complete the UNOS Member Survey.

The Committee received updates on upcoming meetings:

- Conference Call 12-1-2011, 3:00 – 5:00 EST to complete Public Comment Reviews
- Conference Call 1-5-2012; 3-5 PM EST, Draft Bylaw Rewrite Special Public Comment
- Due Process Special Public Comment 2/2012