

**OPTN/UNOS Ad Hoc International Relations
Committee Meeting**

**October 14, 2008
Teleconference and Live Meeting**

INTERIM REPORT

**Gloria Garcia Bohrer – Chair
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The OPTN/UNOS Ad Hoc International Relations Committee met via telephone and Live Meeting on October 14, 2008. The following is a summary of the Committee's discussions.

1. Orientation

UNOS provided an orientation to the Committee members on the following topics:

- OPTN Regulatory and Contractual Framework
- Role of the Research Department
- Policy Development Process
- Policy Implementation – Technology Considerations

UNOS staff will review the HHS Program Goals and the Score card during the January, 2009 Committee meeting.

2. Proposal to Verify that Foreign Agencies Importing Organs to the United States (US), or Receiving Organs Exported from the US, are Legitimate and Test Organs for Transplant Safety

UNOS staff presented themes in the responses to the Committee's proposal to modify Policies 6.4.2 (Developmental Protocols in International Organ Exchange) and 6.4.3 (Ad Hoc Organ Exchange). The committee submitted this proposal for public comment during the June 30, 2008 through September 24, 2008 public comment cycle. The Committee discussed the responses, and suggested modifications to the proposed policy language based on public comment feedback.

Listed below are the primary concerns expressed by the public about the Committee's proposal:

- The OPTN, not its members, should certify foreign agencies that export organs to a US OPO or transplant center;
- The OPTN should certify Canadian OPOs;
- Impact these modifications will have on the export of organs to and import of organs from Canada;
- Modifications place an unfair burden on members by asking them to verify the legitimacy of foreign agencies, who are exporting organs to said members; and,
- There is general concern about the existing language in Policies 6.4.2 and 6.4.3 that require documentation from OPTN members regarding verification of the legitimacy of foreign agencies that export deceased donor organs for transplant in the US.

The Committee opined that it is not within the purview of the OPTN contractor to legitimize foreign agencies. The Committee decided to enhance the language about ethics. The Committee opined that the requirements outlined in existing and proposed policy language for organ exchanges (ad hoc or via protocol) necessitate that centers and OPOs allow time to collect the required documentation. As such, OPTN members should take the time to collect the relevant documentation in order to adhere to the existing and proposed policy modifications.

Actions

- UNOS staff will draft the briefing paper for this proposal.
- UNOS staff will modify the proposed language as requested by the Committee, and distribute the revised language, via email, for voting.

3. Review of Audit Letters

The Committee reviewed responses, to its audit letters, from transplant centers that exceeded the 5% non-resident alien transplant rate in the following years: 2005-2006, and 2007. Five transplant centers received audit letters for exceeding the 5% non-resident alien transplant rate in 2005-2006. Three transplant centers received audit letters for exceeding the 5% non-resident alien transplant rate in 2007. These latter three centers also received audit letters (for the same organ transplant programs) for 2005-2006. The Committee received responses to its letters, i.e., all centers audited responded. The Committee accepted the justification provided by each center for its transplant rate. A common reason for exceeding the 5% non-resident alien transplant rate, as reported by several centers, were due to misclassification of transplant recipients. Some of the centers had reported children who qualified for health care entitle funds from their state of residence, but whose parents were non-resident aliens, as non-resident aliens. Per Policy 6.1.2 (Domestic, American Candidate or Resident Alien), the centers should have entered these children as resident aliens. The Committee discussed pro-active measures, such as an article in the UNOS Update, to educate transplant centers in correctly classifying the citizenship status of pediatric candidates.

Actions

- UNOS staff will inform each center about the Committee's review of the center's response to the audit letter.
- UNOS staff will prepare a draft of the educational material regarding Policy 6.1.2.

4. Review of an Ad-Hoc Organ Exchange

Policy 6.4.3 (Ad Hoc Organ Exchange) tasks the Committee to review each ad hoc organ exchange. The Committee reviewed documentation on the US import of a liver from Panama. A representative of the OPO that imported the organ, for directed donation, serves on the Committee and questions of Committee members. The Committee reviewed the documentation and found no issue with the characteristics of the organ exchange. This organ exchange was the first that the Committee had reviewed since at least August, 2006.

Action

- UNOS staff will inform the OPO about the Committee's review of the ad hoc organ exchange.

5. Transplant Tourism

The Committee discussed the issue of transplant tourism in the context of what further actions to take to safeguard the American transplant candidate who opts to travel overseas for an organ transplant. The Committee discussed two cases of American transplant tourism that resulted in very sick recipients. The Committee expressed interest in developing a position paper and educational materials to alert Americans to the public health risks with transplant tourism as practiced today.

Action

- UNOS staff will draft this position paper and circulate it to the Committee for review.