

**Report of the OPTN/UNOS Ad Hoc International Relations Committee Meeting  
August 9, 2011**

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The following is a summary of the Ad Hoc International Relations Committee's (AHIRC) discussion, which occurred via telephone and Internet, on the revisions to Policy 6.0 (Transplantation of Non-Resident Aliens): Proposed Revisions to and Reorganization of Policy 6.0, Which Include Changes to the Non-Resident Alien Transplant Audit Policy and Related Definitions. This proposal is sponsored by both the Ethics Committee and the AHIRC.

The proposed modifications to Policy 6 are:

1. Change in the title to state the concepts addressed by policy;
2. Revisions to the citizenship definitions, as described above;
3. Deletion of the following policies that cannot be measured or are no longer current:
  - Policies 6.2.2 (Transplant Centers), 6.2.5 (Community Participation), and 6.2.6 (Training Programs) cannot be monitored by the OPTN contractor as written. To re-write these policies so that that the OPTN contractor can monitor them would likely result in language that mandates transplant center behavior that is not related to organ allocation.
  - Policy 6.2.3 (Fees) need not be its own policy as its content aligns well with Policy 6.2.1 (Nondiscrimination/Organ Allocation).
4. Allow the Committee to audit any transplant program that adds to the wait list or transplants candidates who are in the "non-US citizen/non-US resident" category;
  - This audit of listings and transplants will enable the Committee to distinguish between non-US citizens/non-US residents who traveled to the US for transplant, and why, from those who are residents of the US.
5. Delete Policy 6.5 (Violation). This subsection is redundant because all policy violations are subject to review by the OPTN/UNOS Membership and Professional Standards Committee (MPSC);
6. Refocus the current organ exchange section to only organ imports;
  - Policy on deceased donor organ imports is necessary to assure that such organs are clinically safe for transplant; accompany documentation such as consent and type of death; and, are reported to the OPTN contractor.
  - Policy 6.4 (Exportation and Importation of Organs-Developmental Status) does not need to outline the recovery processes related to organ export, as these organs are recovered in the US and policies already address organ recovery requirements.
  - Retain the ability to export organs as stated currently but move the language to Policy 3.2.1.4 (Prohibition for Organ Offers to Non-Members), because exportation is an exception to the prohibition of sharing organs with non-members;

7. Retain the ability to import organs ad hoc and through a formal agreement;
8. Delete the requirement for a program to establish a formal agreement with a foreign agency if it imports more than six ad hoc organs from that foreign agency, because: a) six is an arbitrary number; and, b) the small number (85 transplants with imported deceased donor organs during the 2003 through 2009 time period – see Figure 1) of deceased donor organ imports that occur in a given year do not warrant a policy;

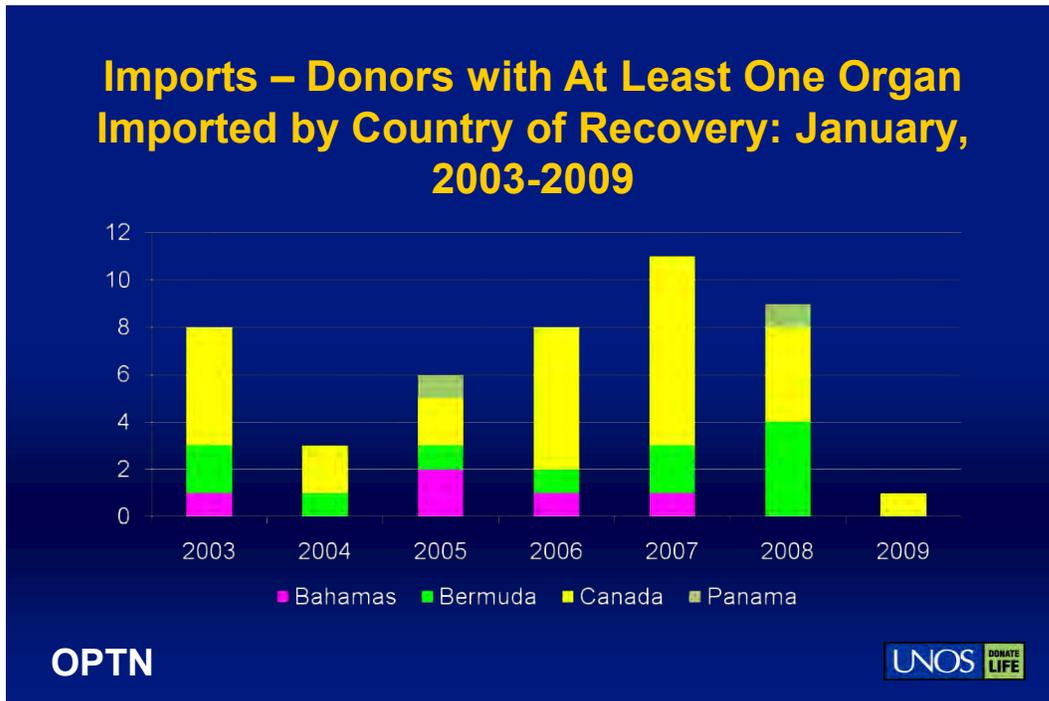


Figure 1: Imports – Donors with at Least One Organ Imported by Country of Recovery: January, 2003-2009 [OPTN Data as of September 8, 2010]<sup>1</sup>

From 2003 through 2009, there were 85 deceased donor organ transplants performed with organs imported from outside of the US. The number of transplants in any given year ranged from 2 in 2009 and 2004 to 22 in 2007. The number of centers performing these same transplants ranged from 2 to 14 during this period. The majority of these organs were recovered by OPOs with formal agreements to import organs.

9. Delete the policy on ethical practices (6.4.4), because defining the characteristics that constitute ethical practices are subjective and may not be applied consistently within and between professional eras; and,
10. Delete language about the import of an organ for valuable consideration, because to do so is a criminal offense that is under the purview of another federal agency.

<sup>1</sup> New England Organ Bank has a formal agreement to serve as the OPO for recovering deceased donor organs from Bermuda, and the Life Alliance Organ Recovery Agency has a formal agreement to serve as the OPO for recovering deceased donor organs from the Bahamas.

A HRSA representative requested that its legal opinion, which was provided to the AHIRC and the Ethics Committee prior to the April, 2011 joint meeting of these two committees, be included in the proposal. The final proposal includes that opinion, which is:

“The National Organ Transplant Act (NOTA) requires that OPTN match organs and individuals in accordance with "established medical criteria" and establish "medical criteria for allocating organs." 42 USC 274(b)(2). The plain language of the statute requires that the OPTN base organ allocation policies on medical criteria and does not provide any authority for basing such policy upon United States citizenship or residency status.

The OPTN final rule also does not provide any authority for basing such policy upon United States citizenship or residency status. The regulations specify the use of "objective and measureable medical criteria" and provide no basis for the use of citizenship or residency status in the allocation of organs. 42 CFR 121.8(b).”

On August 9, 2011, the Ad Hoc International Relations Committee voted in favor of the proposed policy language: 15-supported; 0-opposed; and, 0-abstained. As the proposal was jointly sponsored by the Ethics Committee, in August, 2011, the Ethics Committee’s leadership approved the policy and approved the submission of the revisions for public comment.

On August 16, 2011, the OPTN/UNOS Executive Committee approved the distribution of the proposal to revise Policy 6. UNOS will distribute this document on September 16, 2011.