

**OPTN/UNOS Operations and Safety Committee**  
**Meeting Summary**  
**October 28, 2014**  
**Conference Call**

**Theresa Daly, Chair**  
**David Marshman, Vice Chair**

*Discussions of the full committee on October 28, 2014 are summarized below and will be reflected in the committee's next report to the OPTN/UNOS Board of Directors. Meeting summaries and reports to the Board are available at <http://optn.transplant.hrsa.gov>.*

**Review of Public Comment Proposals**

**1. Vascularized Composite Allograft (VCA) Implementation**

The Committee requested a list of all exemptions for VCA in policy. Committee members did not have any opposing comments. The Committee supports this proposal.

**2. Quality Assurance Process Improvement Initiatives**

The Committee asked for and received clarifying comments that this proposal did not add any further requirements than what Centers for Medicaid and Medicare Services (CMS) currently requires. A crosswalk between the proposed OPTN and current CMS requirements was done to ensure that no new requirements would be added. It was further discussed that quality assurance requests would not be part of routine site surveying but would be used where the MPSC had concerns about ability to self-correct based on previous issues. The Committee asked if this proposal had been considered for only non-CMS programs, however it was clarified that the intent was for all programs.

No members expressed opposition to the proposal. The Committee supports this proposal.

**3. HIV Organ Policy Equity Act**

One Committee member clarified that this current proposal would only permit HIV positive to HIV positive transplantation among deceased donors and under an approved research protocol consistent with the Final Rule.

The Committee did discuss possible inclusion of living donors based upon draft NIH protocols discussed at the World Transplant Congress. It was noted that kidney surgeons and the physician with international experience in this type of transplant expressed vocal opposition to the possible inclusion of living donation.

The HOPE Act Work Group and the OPO Committee may consider addressing living donation in a second forthcoming proposal. Safety concerns such as HIV associated nephropathy were brought up with concerns that a living donor may give up an organ that they may later need. Another member expressed that with active retroviral therapy and good medical management that this concern may not be valid. Other medical concerns such as cardiomyopathy and metabolic syndrome were mentioned. One member shared that HIV-positive couples do present with one requesting the ability to

donate to their partner with some regularity and that it would be beneficial to be able to meet these requests at some point in the future. Other members offered that patient safety was paramount and this may not be supported in the interest of safety.

Committee members did not express opposing comments, however, for the proposal under consideration. The Committee does support this current proposal.

#### **4. Improving OPTN Policy Development Process**

The Committee did ask how often it was anticipated that alternative processes might be used. Previous examples were shared. It was stated that while this may not be a frequent occurrence some routine items might apply if their language is approved to have an expedited option. One member also shared comments from their regional meeting where one person may anonymously submit four or five comments against a proposal and then stop a possible expedited process.

The Committee did not have any opposing comments. The OSC supports this proposal.

#### **5. Clarify Definition of Organ Transplant and Transplant Date**

The Committee questioned if the OPTN would make requests to update data retrospectively if this proposal passes. A definitive answer will be researched and provided. It was noted that it would not be likely as policy typically applies starting with its implementation date.

The Committee did not have any opposing comments. The OSC supports this proposal.

#### **6. Clarification of Multi Organ Policies**

The Committee did not have any opposing comments. The OSC supports this proposal.

### **Other Significant Items**

#### **7. Domino Donor Draft Policy**

The Living Donor Committee requested Operations and Safety Committee feedback on a potential domino donor proposal. Domino donors are not common. In the past three years, there have been approximately 10-12 domino liver donors each year.

One member shared their experience with a recent domino donor experience. Meeting both donor and recipient requirements can be difficult. Domino donors are treated via two different paths that requires a lot of information. It was difficult to explain all of the verifications to staff. Some questions were raised such as is there anyway a transplant hospital can run their own match and can you document rationale for recipient choice without judgment? This member had one heart patient listed as domino donor although it was not performed. It was requested that options not be limited. It was also noted that completing forms for both recipients and donors was time consuming. It was requested, if possible, to have program data to cascade between the required forms.

### **Upcoming Meeting**

- December 2, 2014 (teleconference meeting)