# OPTN/UNOS Executive Committee Meeting Summary September 12, 2016 Web Conference

# Stuart Sweet, MD, Chair Yolanda Becker, MD, Vice-Chair

Discussions of the full committee on September 12, 2016 are summarized below. All committee meeting summaries are available at <a href="https://optn.transplant.hrsa.gov">https://optn.transplant.hrsa.gov</a>.

## **Committee Requests**

### 1. Requests for approval of new committee projects

The Committee approved two new committee projects:

a) OPTN Bylaws Revisions, Appendix L (Membership and Professional Standards Committee)

Appendix L of the OPTN Bylaws details actions that the OPTN may take when members fail to comply with OPTN obligations. Appendix L also outlines members' due process rights when the MPSC or Board of Directors is considering taking certain actions. Since the implementation of the Bylaws rewrite in 2012, UNOS staff, the MPSC and the Board of Directors have identified a number of conflicting and sometimes unclear due process requirements. In addition, staff have recognized that some of the timelines and other operational requirements within Appendix L are not reasonable or efficient and that there are gaps in the process that could be more fully described and provide greater transparency to the membership such as the specific standard of review and burden of proof at each stage of the multiple review pathways.

It is expected that the most significant revisions will include changes to the Imminent Threat Pathway, which outlines due process procedures and timelines when an urgent and severe risk to patient health or public safety is identified. This project is intended to primarily impact the strategic goal to promote living donor and transplant recipient safety.

#### Maximum Allowable BMI for KP Waiting Time (Pancreas Transplantation Committee)

Current policy requires kidney-pancreas candidates who are on insulin, and with a C-peptide greater than 2 ng/mL, have a body mass index (BMI) less than or equal to the maximum allowable BMI to accrue waiting time. With the implementation of the new Pancreas Allocation System (PAS) in 2014, the maximum allowable BMI is reviewed every 6 months to determine if it should be modified. The determination to either increase or lower the maximum allowable BMI is based on the percentage of active kidney-pancreas candidates that meet the waiting time criteria. The maximum allowable BMI at implementation of PAS was 28, and subsequently after 6 months it was raised to 30. Subsequent 6 month analyses have indicated the maximum BMI should be raised further however, current policy states that the maximum allowable BMI cannot be modified to exceed 30.

The Pancreas Committee intends to develop a proposal to increase the maximum allowable BMI. This project is intended to primarily impact the strategic goal to increase the number of transplants.

The Committee approved but delayed further committee work on the below Pediatric Committee project due to the number of complex liver allocation projects already in the project portfolio. The Executive Committee will re-assess this project once resources become available.

Reduce pediatric liver waiting list mortality (Pediatric Transplantation Committee)

This project will further investigate mortality rates and waiting time for pediatric liver candidates on the waiting list and whether higher allocation sequences are appropriate in certain circumstances.

The Committee did *not* approve the following two committee project requests:

b) <u>Informing potential donors about eligibility criteria and KPD options (Living Donor Committee)</u>

The POC recommended that this project be cancelled. After further discussing the goals of the project, it was decided that it might be more appropriate as an educational effort rather than Board endorsed guidance. The Executive Committee agreed.

c) <u>Ethical Considerations of Experimental Manipulations of Organs Recovered from</u> Deceased Donors (Ethics Committee)

The Executive Committee did not approve this project due to the fact that the Institute of Medicine (IOM) has convened a working group to discuss it and these committee efforts could be duplicative or contradictory to those efforts.

# Other Significant Items

#### 2. Review of strategic goal definitions and guidance

As the POC discusses new committee projects and alignment with the 2015-2018 OPTN strategic plan, several questions have come up about the scope of the content that belongs under each strategic goal. The Committee reviewed proposed definitions and guidance to assist the POC in its review going forward. The Committee requested additional time to review the definitions and offer feedback.

#### 3. Update from the Board Governance Subcommittee

Dr. Sweet provided an update from the Board Governance Subcommittee. The subcommittee has been meeting monthly to look at the Board's structure and recruitment process and has made several recommendations regarding improving diversity on the Board. Dr. Sweet relayed that the subcommittee will be providing at least quarterly updates on the group's progress.

#### **Upcoming Meetings**

- November 14, 2016
- December 5, 2016