

**OPTN/UNOS Executive Committee  
Meeting Summary  
August 12, 2016  
Web Conference**

**Stuart Sweet, MD, PhD, Chair**

*Discussions of the full committee on August 12, 2016 are summarized below. All committee meeting summaries are available at <https://optn.transplant.hrsa.gov>.*

**Committee Projects**

**1. Approval of public comment proposals**

Before each public comment period, the Executive Committee reviews and approves which committee proposals will be distributed for community and public input. The Policy Oversight Committee (POC) performs an extensive review of the proposals and presents a recommendation to the Executive Committee prior to the vote.

The Executive Committee considered 16 public comment proposals being requested by OPTN/UNOS standing/ad hoc committees. The Committee first voted unanimously (8-Yes, 0-No, 0-Abstentions) to approve 13 proposals as part of a non-discussion agenda:

1. Adult MELD exception guidance (Liver and Intestinal Organ Transplantation Committee)
2. Changes to HCC criteria for auto approval (Liver and Intestinal Organ Transplantation Committee)
3. Ethics of deceased donor organ recovery without requirement for explicit consent or authorization (Ethics Committee)
4. Split versus whole liver transplantation (Ethics Committee)
5. Ethical implications of imminent death donation (Ethics Committee)
6. Modifications of requirements for the informed consent of potential living donors (Living Donor Committee)
7. Consider primary transplant surgeon requirement-primary or first assistant on transplant cases (MPSC)
8. Proposal to modify the adult heart allocation system (Thoracic Transplantation Committee)
9. Subspecialty boards for primary liver transplant physicians (MPSC)
10. Updating primary kidney transplant physician requirements (MPSC)
11. Updating the OPTN definition of transplant hospital (MPSC)
12. Transplant program performance measures (MPSC)
13. Proposed changes to the OPTN transplant program outcomes review system (MPSC)

The Committee then discussed and voted on three proposals individually:

1. *Infectious disease verification (IDV) for patient safety (Operations and Safety Committee)*

The POC recommended that this proposal not be approved for public comment at this time. The POC was concerned that 1) some members disagreed with the complexity of the proposed verification system so soon after implementing the ABO verification proposal; 2) an identified stakeholder, the Living Donor

Committee, was not included in the policy development; and 3) the proposal primarily aligns with the strategic goal to promote patient and living donor safety and staff/committee resources are already over-allocated for that goal.

The Executive Committee discussed that HRSA staff had directed the Operations and Safety Committee to work on this project when several incidents were reported to the patient safety proposal and also that the safety issues involved were urgent when considering recent implementation of the HIV Organ Policy Equity (HOPE) Act. The Committee considered the POC's first concern to be one of substance on the policy and something that members should have the opportunity to comment on as part of the public comment process. They also considered that moving this project along was a step toward addressing the fact that a substantial amount of resources were allocated to the strategic goal regarding safety (UNOS staff reviewed portfolio projections with the committee, allowing a visual for the overall portfolio if this and other projects were approved by the Board in December). The Committee voted unanimously (8-Approve, 0-Delay, 0-Abstain) to approve the proposal for public comment, directing the Operations and Safety Committee to reach out to the Living Donor Committee during the public comment process.

2. *Elimination of OPTN Bylaws regarding the approval of transplant fellowship programs (MPSC)*

Although the POC recommended that this proposal be approved, several members of the Executive Committee requested that it be discussed due to correspondence from the American Society of Transplant Surgeons (ASTS) expressing concern. UNOS staff explained that the proposal had been reviewed by a Joint Societies Working Group (JSWG), which is comprised of representatives from the ASTS, the American Society of Transplantation (AST), and the North American Transplant Coordinators Organization (NATCO). The MPSC had discussed concerns expressed by ASTS and had settled on the final proposal before the Committee. HRSA staff weighed in that the sponsoring committee is required to consider the JSWG recommendations, but the committee is not required to adopt them if they agree on a different solution. There was also some discussion about whether ASTS had made their concerns known in a timely manner. Ultimately, the Executive Committee decided unanimously (0-Approve, 8-Delay, 0-Abstention) that the proposal not be approved for public comment. The Committee did agree that the JSWG process needs to be improved so that the societies weigh in on a timely manner.

3. *Redesigning liver distribution (Liver and Intestinal Organ Transplantation Committee)*

The POC unanimously recommended that this proposal move forward for public comment. UNOS staff had presented it to the Committee for discussion only to be certain that members of the Board understood the estimated timeline for the proposal (another round of public comment is planned for Spring 2017) and allow committee members to ask questions. The Committee unanimously approved the proposal for public comment (8-Approve, 0-Delay, 0-Abstentions).

## Policy Clarifications

### 2. Clarification to Policy 15.6.A

The Committee unanimously approved a change to Policy 15.6.A *Living Donor Recovery Hospital Requirements for Reporting Post-Donation Discovery of Living Donor Disease or Malignancy*. The change requires living donor recovery hospitals to report information about a potential disease transmission to the OPTN no more than seven days after receipt of the new information.

### 3. Clarification to Policy 14.5.B

The Committee unanimously approved a clarification to Policy 14.5.B *Living Donor Blood Subtype Determination*. The change adds the word “cell” in one line of the policy to make it consistent with the policy for deceased donor subtype determination.

## Response to Federal Rulemaking

4. UNOS has an established plan for review of federal issues, as outlined in the OPTN contract. Under this process, the relevant OPTN committees review the proposed rule and develop a recommended response for the Executive Committee to review and endorse. In July, CMS published proposed rules impacting OPOs and transplant centers. The OPO, Ops and Safety, and Membership and Professional Standards Committees reviewed the changes and drafted a proposed response. There are 4 major areas of change:

OPOs:

- Changing the imminent/eligible definition
- Removing requirement for paper documentation and changes to align with new ABO policy
- Moving toward yield metric for measuring performance

Transplant centers:

- Modifying the regulation to change the threshold for outcome performance

The Committee unanimously endorsed (8-Yes, 0-No, 0-Abstentions) the recommended response to be posted in the Federal Register.

## Upcoming Meeting(s)

- September 12, 2016
- October 5, 2016
- November 14, 2016
- December 5, 2016