

**EXECUTIVE SUMMARY  
OF THE  
OPTN/UNOS BOARD OF DIRECTORS MEETING  
June 11-12, 2018  
Richmond, VA**

Yolanda Becker, MD, OPTN/UNOS President, called the meeting to order at 1:15 p.m. on June 11, 2018. A quorum was present, and 41 of the Board members attended in person or by electronic means of communications.

In the first order of business, the Board approved changes to Bylaws Article 1.1 (Membership Guidelines), and Appendices A.1 (General Membership Requirements), A.2 (Designated Transplant Program Requirement), A.3 (Applying for Membership in the OPTN), B.1 (OPO Compliance), B.2 (OPO Performance Requirements), B.4 (Facilities and Services), B.5 (OPO Personnel), C.1 (Histocompatibility Laboratory Compliance), C.5 (Changes in Key Laboratory Personnel), C.6 (Histocompatibility Laboratory Policies and Procedures), D.1 (Transplant Hospital Compliance), D.2 (Geographic Requirements for Transplant Hospitals), D.8 (Changes in Key Transplant Program Personnel), D.10 (Investigation of Transplant Personnel), D.11 (Review of Transplant Program Functional Activity), D.12 (Additional Transplant Program Requirements), G.2 (Primary Pancreas Transplant Surgeon Requirements), G.3 (Primary Pancreas Transplant Physician Requirements), I.2 (Primary Lung Transplant Surgeon Requirements), I.3 (Primary Lung Transplant Physician Requirements), L (Reviews, Actions, and Due Process), and Appendix M (Definitions), that improve the OPTN review process and describes the process in a way that is more detailed and easier for members to understand.

The Board approved Policies 5.5.B (Host OPO and Transplant Hospital Requirements for Positive Hepatitis B, Hepatitis C, or Cytomegalovirus (CMV) Infectious Disease Results), 15.3 (Informed Consent of Transmissible Disease Risk), 15.3.A (Donors with Additional Risk Identified Pre-Transplant), and 15.3.B (Donors at Increased Risk for Transmission of Blood-borne Pathogens) that clarify informed consent policies for transmittable conditions.

The Board approved changes to Policies 1.2 (Definitions), 6.6.F (Allocation of Heart-Lungs), 10.2.A (Allocation Exception for Sensitized Patients), and 10.4 (Lung Allocation Classifications and Rankings) that improve equity in access to transplantation regardless of a candidate's location. The Board amended the original proposal, which contained a "sunset" provision for these modifications to remove the expiration date thereby making these modifications permanent until otherwise amended by the Board of Directors.

The Board approved updates to the *Heart Review Board (HRB) Guidelines* that reflect recent changes to adult heart allocation policy.

The Board approved changes to Policies 11.3.B (Kidney-Pancreas Waiting Time Criteria for Candidates At Least 18 Years Old) and 11.3.D (Waiting Time Assignments for Kidney, Kidney-Pancreas, Pancreas, and Islet Candidates) that improve how waiting time is assigned to kidney-pancreas candidates.

The Board approved the following Principles of Organ Distribution, as recommended by the Ad Hoc Geography Committee:

### **Principles of Organ Distribution**

Deceased donor organs are a national resource to be distributed as broadly as feasible. Any geographic constraints pertaining to the principles of organ distribution must be rationally determined and consistently applied.

Geographic distribution may be constrained in order to:

1. Reduce inherent differences in the ratio of donor supply and demand across the country
2. Reduce travel time expected to have a clinically significant effect on ischemic time and organ quality
3. Increase organ utilization and prevent organ wastage
4. Increase efficiencies of donation and transplant system resources

The Board approved the following Recommendations from the Ad Hoc Geography Committee:

1. Request community feedback on the recommended distribution frameworks with a goal of identifying a single, preferred distribution framework to be used across organ types.
2. Perform a policy analysis of current organ distribution policies in reference to the proposed principles of organ distribution.
3. Maintain the Ad Hoc Geography Committee through the remainder of 2018 to receive and respond to community feedback and to facilitate conversations among organ-specific committee leadership about policy analysis.

In the first order of business for the second day of the meeting, Dr. Becker gave a report of the Executive Committee.

The Board approved several resolutions contained in the Consent Agenda in a single vote. The subject of the individual resolutions approved in the Consent Agenda follows here:

1. The Board approved the 2017 fiscal year audit report.
2. The Board approved the minutes of recent Board of Directors meetings and conference calls.
3. The Board approved the appointment of OPTN/UNOS Committee Chairs.
4. The Board approved the guidance document entitled *Guidance on Optimizing VCA Recovery from Deceased Donors*.
5. The Board approved clarifications to Policies 6.1 (Adult Status Assignments and Update Requirements), 6.1.B (Adult Heart Status 2 Requirements), 6.1.B.iii (Mechanical Circulatory Support Device (MCSD) with Malfunction), 6.1.B.iv (Percutaneous Endovascular Mechanical Circulatory Support Device), 6.1.C (Adult Heart Status 3 Requirements), 6.1.C.v (Mechanical Circulatory Support Device (MCSD) with Right Heart Failure), 6.1.C.vi (Mechanical Circulatory Support Device (MCSD) with Device Infection), 6.1.C.x (Non-Dischargeable, Surgically Implanted, Non-Endovascular Left Ventricular Assist Device (LVAD)), 6.1.C.xi (Percutaneous Endovascular Circulatory Support Device after 14 Days), 6.2 (Pediatric Status Assignments and Update

Requirements), and Policy 6.6.E (Allocation of Hearts from Donors Less Than 18 Years Old).

6. The Board approved the guidance document entitled *Review Board Guidance for Hypertrophic and Restrictive Cardiomyopathy Exception Requests*.
7. The Board approved the white paper entitled *Manipulation of the Organ Allocation System Waitlist Priority through the Escalation of Medical Therapies*.
8. The Board approved changes to the Lung Transplant Recipient Follow-up Form (TRF) to better characterize longitudinal change in lung function following transplantation.
9. The Board approved changes to Bylaws Appendix D (Membership Requirements for Transplant Hospitals and Transplant Programs) and Appendix J (Membership and Personnel Requirements for Vascularized Composite Allograft (VCA) Transplant Programs) that better align VCA membership requirements with the requirements of other organ transplant programs.
10. The Board approved changes to Policies 1.2 (Definitions), 2.7.A (Exceptions to HIV Screening Requirement), 2.14.C (Organ Procurement Procedures) 2.14.D (Required Tissue Typing and Blood Type Verification Materials), 2.14.E (Authorization Requirement), 5.4.B (Order of Allocation), 5.5.C (OPO Requirements for Positive HIV Results), 5.8.C (Additional Pre-Transplant Verification Requirements for Extra Vessels), 5.9 (Released Organs), 9.8.A (Segmental Transplant and Allocation of Liver Segments), 14.8 (Packaging, Labeling, and Transporting of Living Donor Organs, Vessels, and Tissue Typing Materials), 14.8.A (Living Donor Vessel Recovery and Transplant), 14.8.B (Living Donors Vessel Storage), 15.3 (Informed Consent of Transmissible Disease Risk), 15.4.B (Host OPO Requirements for Reporting Post-Procurement Discovery of Recipient Disease or Malignancy), 16.1 (Packaging and Labeling Requirements for Living Donor Organs and Vessels), 16.2 (Packaging and Labeling Responsibilities), 16.3 (Packaging and Labeling), 16.3.A (Internal Packaging), 16.3.D (Internal Labeling of Vessels Packaged Separately from Other Organs), 16.3.E.i (Disposable Shipping Box), 16.3.E.iii (Cooler), 16.4 (Documentation Accompanying the Organ or Vessel), 16.4.A (Organ Packaging Documentation Requirements), 16.4.B (Vessel Documentation), 16.5 (Verification and Recording of Information before Shipping), 16.6 (Vessel Recovery, Transplant, and Storage), 16.6.A (Deceased Donor Vessel Recovery and Transplant Use), 16.6.B (Vessel Storage), 16.6.C (Blood Type Verification Prior to Transplant of Deceased Donor Vessels), 16.6.D (Recovery and Storage of Vessels from Living Donors), and 16.6.E (Blood Type Verification Prior to Transplant of Living Donor Vessels) that reduce reporting burdens and clarify policies regarding extra vessels.
11. The Board approved the guidance document entitled *Guidance for ABO Subtyping of Organ Donors for Blood Types A and AB*.
12. The Board approved the guidance document entitled *Guidance on Requested Deceased Donor Information*.
13. The Board rescinded a previously approved guidance document entitled *Guidance Regarding Adult Heart Status 1A(b) Device-Related Complications*.

14. The Board approved modifications to Policies 2.11.A (Required Information for Deceased Kidney Donors) and 2.11.D (Required Information for Deceased Lung Donors) to clarify organ laterality reporting requirements.

Following passage of the consent agenda, Brian Shepard, UNOS CEO and OPTN Executive Director gave the Executive Director's report to the Board.

Dr. David Reich, Treasurer, gave a report of the Finance Committee and presented one recommended action for consideration by the Board. Thereafter, the Board approved the 2019 OPTN Operating Budget.

Dr. Becker presented the OPTN Strategic Plan, which had been developed by the Board over the past year with input from the many stakeholders in the OPTN, which was then unanimously approved by the Board.

In the final order of business for the meeting, Dr. Becker gave her Presidential Address to the Board.

The meeting adjourned at 10:45 a.m. on June 12, 2018.