EXECUTIVE SUMMARY OF THE OPTN/UNOS BOARD OF DIRECTORS MEETING

December 1-2, 2015 Richmond, Virginia

Betsy Walsh, JD, OPTN/UNOS President, called the meeting to order at 4:00 p.m. on December 1, 2015. A quorum was present, and 40 of the Board members were in attendance in person or by electronic means of communications.

During the first day of the meeting, the Board approved several resolutions contained in the Consent Agenda in a single vote. Two items were removed from the consent agenda to permit amendments to the effective dates of those proposals. The subject of the individual resolutions approved in the Consent Agenda follows here:

- 1. The Board approved the minutes of the June 1-2, 2015, meeting of the Board of Directors held in Atlanta, GA.
- 2. The Board approved several routine actions for new members and changes in membership status for existing members.
- 3. The Board approved changes to Policies 1.2 (Definitions), 13.7 (OPTN KPD Screening Criteria), 13.8 (Two- and Three-Way Matches), and 13.9 (Donor Chains) that revise the OPTN Kidney Paired Donation (KPD) Pilot Program's priority points system.
- 4. The Board approved changes to Policies 11.6 (Administrative Rules), 11.6 A (Facilitated Pancreas Allocation), and 11.6.B. (Facilitated Pancreas Offers) that update the procedures and requirements of facilitated pancreas allocation.
- 5. The Board approved changes to Policies 5.3.E (Pediatric Heart Acceptance Criteria to Receive Intended Blood Group Incompatible Hearts), 6.5.A (Allocation of Hearts by Blood Type), 6.5.B (Eligibility for Intended Blood Group Incompatible),10.1.F (The LAS Calculation), 10.4.B (Allocation of Lungs by Blood Type), 10.4.C (Allocation of Lungs from Deceased Donors at Least 18 Years Old), 10.4.D (Allocation of Lungs from Deceased Donors 12 to Less Than 18 Years Old), and 10.4.E (Allocation of Lungs from Deceased Donors Less than 12 Years Old) that give candidates less than 18 years old better access to properly sized donors, establishes eligibility criteria for candidates registered prior to their second birthday to receive offers for deceased donor lungs of any blood type, establishes the use of the term "intended blood group incompatible" to refer to ABOi transplants in the pediatric lung proposal, and resolves the language in the pediatric heart policy to match the language in the lung policies, as amended.
- The Board approved changes to Policy 2.11.A (Required Information for Deceased Kidney Donors), Policy 2.11.B (Required Information for Deceased Liver Donors), Policy 4.1 (HLA Typing) through Policy 4.11 (Reference Tables of HLA Antigen Values and Split Equivalences), 13.5.A (HLA Typing Requirements for OPTN KPD Candidates), and

- 13.5.C (HLA Typing Requirements for OPTN KPD Donors) that add alleles to the Human Leukocyte Antigen (HLA) dropdown options in UNetSM to increase access to transplants for sensitized candidates and update the HLA Equivalency Tables as required annually by Policy 4.7.
- 7. The Board approved revisions to the white paper entitled "Living Non-Directed Donation."
- 8. The Board approved changes to Policy 19 (Data Release) that align current data release policies with the OPTN Final Rule.
- 9. The Board approved changes to the Bylaws Appendixes E.3.G (Conditional Approval for Primary Transplant Physician), F.3.G (Conditional Approval for Primary Transplant Physician), F.7.F (Rejection of Conditional Approval), F.12.B. (Rejection of Conditional Approval), G.3.D (Conditional Approval for Primary Transplant Physician), H.3.D (Conditional Approval for Primary Transplant Physician), and I.3.D (Conditional Approval for Primary Transplant Physician) that clarify the time frames for program inactivation after a period of conditional approval.
- 10. The Board approved changes to Policy 1.2 (Definitions) that change the effective date to January 1, 2017, for the new imminent and eligible death data definitions.
- 11. The Board approved changes to OPTN Bylaws Article VII, Sections 7.2 (Standing Committee Chairs), 7.3 (Terms of Standing Committee Members), and 7.5 (The Policy Oversight Committee (POC)) that increase the majority of OPTN/UNOS committee terms to three years.

Following passage of the consent agenda, the Board considered the following two proposals that were removed from the consent agenda solely to change the effective date of those proposals. The Board approved changes to Bylaws Appendices E.2. (Primary Kidney Transplant Surgeon Requirements), E.2.A (Formal 2-year Transplant Fellowship Pathway), E.2.B (Clinical Experience Pathway), E.3 (Primary Kidney Transplant Physician Requirements), E.3.A (Twelve-month Transplant Nephrology Fellowship Pathway), E.3.B (Clinical Experience Pathway), E.3.C (Three-year Pediatric Nephrology Fellowship Pathway), E.3.D (Twelve-month Pediatric Transplant Nephrology Fellowship Pathway), E.3.E (Combined Pediatric Nephrology Training and Experience Pathway), E.3.G (Conditional Approval for Primary Transplant Physician), F.2 (Primary Liver Transplant Surgeon Requirements), F.2.A (Formal 2-year Transplant Fellowship Pathway), F.2.B (Clinical Experience Pathway), F.3 (Primary Liver Transplant Physician Requirements), F.3.B (Clinical Experience Pathway), F.3.C (Three-year Pediatric Gastroenterology Fellowship Pathway), F.3.D (Pediatric Transplant Hepatology Fellowship Pathway), F.3.E (Combined Pediatric Gastroenterology/Transplant Hepatology Training and Experience Pathway), F.3.G (Conditional Approval for Primary Transplant Physician), F.4 (Requirements for Director of Liver Transplant Anesthesia), F.9 (Primary Intestine Transplant Surgeon Requirements), F.9.A (Full Intestine Surgeon Approval Pathway). F.9.B (Conditional Intestine Surgeon Approval Pathway), F.10 (Primary Intestine Transplant Physician Requirements), F.10.B (Conditional Intestine Physician Approval Pathway) G.2 (Primary Pancreas Transplant Surgeon Requirements), G.2.A (Formal 2-year Transplant Fellowship Pathway), G.2.B (Clinical Experience Pathway), G.3 (Primary Pancreas Transplant Physician Requirements), G.3.D (Conditional Approval for Primary Transplant Physician), H.2 (Primary Heart Transplant Surgeon Requirements), H.2.A (Cardiothoracic Surgery Residency Pathway), H.2.B (Twelve-month Heart Transplant Fellowship Pathway), H.2.C (Clinical

Experience Pathway), H.3 (Primary Heart Transplant Physician Requirements), H.3.A (Twelvemonth Transplant Cardiology Fellowship Pathway), H.3.B (Clinical Experience Pathway), H.3.D (Conditional Approval for Primary Transplant Physician), I.2 (Primary Lung Transplant Surgeon Requirements), I.2.A (Cardiothoracic Surgery Residency Pathway), I.2.B (Twelve-month Lung Transplant Fellowship Pathway), I.2.C (Clinical Experience Pathway), I.3 (Primary Lung Transplant Physician Requirements), I.3.A (Twelve-month Transplant Pulmonary Fellowship Pathway), I.3.B (Clinical Experience Pathway), and I.3.D (Conditional Approval for Primary Transplant Physician) that clarify required qualifications for key personnel who do not possess American board certification. These modifications will be effective pending implementation and notice to the membership.

With amendment to the effective date, the Board approved changes to the Bylaws Appendices E.2.A (Formal 2-year Transplant Fellowship Pathway), E.2.B (Clinical Experience Pathway). E.3.A (Twelve-month Transplant Nephrology Fellowship Pathway), E.3.B (Clinical Experience Pathway), E.3.C (Three-year Pediatric Nephrology Fellowship Pathway), E.3.D (Twelve-month Pediatric Transplant Nephrology Fellowship Pathway), E.3.E (Combined Pediatric Nephrology Training and Experience Pathway), E.3.G (Conditional Approval for Primary Transplant Physician), F.2.A (Formal 2-year Transplant Fellowship Pathway), F.2.B (Clinical Experience Pathway), F.3.A (12-month Transplant Hepatology Fellowship Pathway), F.3.B (Clinical Experience Pathway), F.3.C (Three-year Pediatric Gastroenterology Fellowship Pathway), F.3.D (Pediatric Transplant Hepatology Fellowship Pathway), F.3.E (Combined Pediatric Gastroenterology/Transplant Hepatology Training and Experience Pathway), F.3.G (Conditional Approval for Primary Transplant Physician), F.9.A (Full Intestine Surgeon Approval Pathway), F.9.B (Conditional Intestine Surgeon Approval Pathway), G.2.A (Formal 2-year Transplant Fellowship Pathway), G.3.A (Twelve-month Transplant Medicine Fellowship Pathway), G.3.B (Clinical Experience Pathway), G.3.D (Conditional Approval for Primary Transplant Physician), H.2.A (Cardiothoracic Surgery Residency Pathway), H.2.B (Twelve-month Heart Transplant Fellowship Pathway, H.3.A (Twelve-month Transplant Cardiology Fellowship Pathway), H.3.B (Clinical Experience Pathway), H.3.D (Conditional Approval for Primary Transplant Physician). I.2.A (Cardiothoracic Surgery Residency Pathway), I.2.B (Twelve-month Lung Transplant Fellowship Pathway), I.3.A (Twelve-month Transplant Pulmonary Fellowship Pathway), I.3.B (Clinical Experience Pathway), I.3.D (Conditional Approval for Primary Transplant Physician) that update the requirements for organ procurement experience. These modifications will be effective pending implementation and notice to the membership.

The Board approved the slate of nominees for the election of members of the Board of Directors for terms beginning July 1, 2016.

Ms. Walsh gave a report from the Executive Committee.

The Board approved the transfer of \$1,100,000 from the OPTN Primary Account to the OPTN Reserve Account.

The Board approved the modified 2016 OPTN Budget, which was updated to reflect additional federal funding for additional tasks, which were added to the OPTN Contract.

The Board directed the MPSC over the next 6 months to provide the Board with a proposal for an improved program specific reporting system that identifies substantive clinical differences in patient and graft outcomes. The OPTN/UNOS President will appoint a working group consisting of 10 members; 3 from the OPTN/UNOS Board, 3 from the societies of the AAAU, and 3 from the MPSC, and 1 ad hoc member from CMS - this working group will, over a three month

period, identify objective measures that define clinically relevant outcome differences - this work group will then submit their findings to the MPSC for approval, and present that proposal to the Board for action at its June 2016 meeting.

In the second day of the meeting, the Board met in closed session to consider two member adverse actions recommended by the Membership and Professional Standards Committee. The Board declared an OPO a Member Not in Good Standing, and placed a transplant hospital on Probation.

The Board received a presentation from the UNOS Information Technology Advisory Committee.

The Board approved changes to the Bylaws Appendices E.2.C (Alternative Pathway for Predominantly Pediatric Programs), E.3.F (Alternative Pathway for Predominantly Pediatric Programs), E.5 (Kidney Transplant Programs that Perform Transplants in Patients Less than 18 Years Old), F.2 (Primary Liver Transplant Surgeon Requirements), F.3.C (Alternative Pathway for Predominantly Pediatric Programs), F.4.F (Alternative Pathway for Predominantly Pediatric Programs) F.7 (Liver Transplant Programs that Register Candidates Less than 18 Years Old), G.8 (Pancreas Transplant Programs that Perform Transplants in Patients Less than 18 Years Old), H.2.D (Alternative Pathway for Predominantly Pediatric Programs), H.4 (Heart Transplant Programs that Perform Transplants in Patients Less than 18 Years Old), I.4 (Lung Transplant Programs that Perform Transplants in Patients Less than 18 Years Old), L.17 (Interviews), and L.18 (Hearings) that establish requirements for pediatric components of kidney, liver, and heart transplant programs.

The Board approved changes to Policies 1.2 (Definitions), 6.5.F (Allocation of Domino Donor Hearts), 14.1.A (Living Donor Psychosocial Evaluation Requirements), 14.2.A ILDA Requirements for Living Donor Recovery Hospitals, 14.3 (Informed Consent Requirements), 14.4.B (Living Donor Medical Evaluation Requirements), 14.6.B (Placement of Non-directed Living Donor Kidneys), 14.6.C (Transplant Hospital Acceptance of Living Donor Organs), 14.9 (Requirements for Therapeutic Living Donation, 14.9.A (Informed Consent Requirements for Therapeutic Donors), 14.9.B (Psychosocial and Medical Evaluation Requirements for Therapeutic Donorion), 14.9.C (Recovery of Therapeutic Donor Organs), 14.6.D (Acceptance of Therapeutic Donor Organs), 14.9.E (Reporting and Data Submission Requirements for Therapeutic Donors), and 18.1 (Data Submission Requirements) that establish and clarify requirements for domino and non-domino therapeutic donors.

The Board approved changes to Policies 2.2 (OPO Responsibilities), 16.1 (Organs Recovered by Living Donor Recovery Hospitals), and 16.4.A (Organ Documentation) that reduce the amount of paper documentation that must be shipped with organs.

The Board received presentations on the discussions of three breakout sessions attended by the Directors on the prior day.

The Board received a presentation on the status of implementation of the revised Kidney Allocation System (KAS).

In the final item of the meeting, the Board received and discussed a presentation describing the work of the Liver and Intestinal Organ Transplantation Committee on potential liver allocation redistricting. No actions were taken on these issues following the discussions.