OPTN Executive Committee Meeting Minutes October 8, 2019 Conference Call Maryl Johnson, MD, FACC, Chair David Mulligan, MD, FACS Vice Chair

Introduction

The Executive Committee met via teleconferenceon October 8, 2019 to discuss the following agenda items:

- 1. OPTN Committee Charters review & updates
- 2. OPTN Policy Actions
 - a. Clarification to OPTN KPD Policy*
 - b. Region 8 Split Liver Special Public Comment*
- 3. Fall 2019 Public Comment review
- 4. Policy Oversight Committee actions
 - a. OPTN Project Strategic Themes*
 - b. New OPTN projects recommended for approval*

The following is a summary of the Committee's discussions.

1. OPTN Committee Charters review & updates

UNOS Staff presented the OPTN Committee Charters review and update project. The new OPTN contract requires the OPTN to review all committee charters and seek Board ratification in December 2019. The Executive Committee is the official sponsor of the action that will go to the Board.

Staff explained the process by which each committee is reviewing and updating its charter. The majority of committees are making nonsubstantive changes, but staff highlighted some that were making more strategic updates, like the Policy Oversight Committee. Several committee members supported the direction of the updated POC charge. The Committee Chair encouraged the Vascular Composite Allographs Committee to expand a bit further on its charge; staff noted they had relayed that feedback early on to the Committee. A committee member noted that the Patient Affairs Committee may need to consider a strategic directional change to give it more weight in the policy development process. Staff noted that the Ethics and Ad Hoc International Relations Committees are especially in need of directional feedback.

Next steps:

The Chair thanked the presenter and encouraged members to email staff or committee leadership if they think of think of any other feedback to offer the committees as they embark on their reviews during their fall in person meetings. Otherwise, they should expect to see the final charges at the Executive Committee for sponsorship for Board action in December.

2. OPTN Policy Actions

OPTN Kidney Paired Donation (KPD) Policy Clarification

UNOS Staff presented a clarification to OPTN Kidney Paired Donation policy. Board-approved policy language from 2015 is currently unclear as to how OPTN KPD priority points should be applied to candidates entering the program with more than one potential paired donor of different blood types. This change clarifies that the original intent of the policy was to award blood type points based on the paired donor whose blood type is associated with the *fewest* priority points. This was intended to enable harder-to-match blood types additional access to paired donation. The Kidney Committee reviewed and unanimously approved this clarification for the Executive Committee's action on October 7th.

There were no questions from the Committee. A motion was made and seconded. The motion passed with 11 in favor, 0 nays and 0 abstentions.

Region 8 Split Liver Variance Special Public Comment Period

UNOS staff presented a proposed special comment period for the *Region 8 Split Liver Variance* from the Liver Committee. This closed variance was approved by at the Board June Board meeting. The approved language allows participating programs in Region 8 to offer the second segment of a split liver to Status 1 and high MELD candidates within 500 NM. The variance is time-limited to three years. The Executive Committee approved a clarification on August 1, 2019 to align language with liver allocation based on DSA and region with the intention of reverting back to circles upon implementation of the "Acuity Circles" liver allocation policy (date as yet unknown). The Executive Committee is now asked to approve release of this change for special public comment (30 days) before implementation of the variance. The Vice Chair of the Executive Committee spoke in favor of this proposed special public comment period. There were no questions from the Committee.

A motion was made and seconded. The motion passed with 11 in favor, 0 nays and 0 abstentions.

3. Fall 2019 Public Comment Update

UNOS Staff presented an update on the seven proposals that were released for fall 2019 public comment. Based on the analysis performed on public comment received, the presumption is that all proposals will proceed substantively unchanged to the Board for action in December, with the exception of the Kidney and Pancreas proposals.

Sentiment analysis revealed that the 500 Nautical Mile (NM) proposals did not receive broad support at the regional meetings and through comments posted to the public comment page. The Committees have been checking in regularly to review comment received and are aware of this feedback. Many of the comments on the 500 NM proposals have surrounded potential operational challenges with this distance, to include concerns about:

- Increased flying and dependence on commercial flights
- Cross-matching concerns with increased distance
- Increased logistical complexity could lead to increased costs
- The potential for delays in transportation that would cause more cold ischemia time
- Operational challenges combined could lead to more discards than predicted

Other emerging themes from public comment include concerns about the KPSAM modeling and outcomes metrics in the modeling; concerns about variability in OPO operations and its impact on system performance; and questions about standards for medical urgency and import back-up.

Some regions have instead expressed support for a 250 NM circle for kidney and pancreas allocation and staff noted that the Kidney and Pancreas Committees have indicated they are considering offering this circle size to the Board, in lieu of 500 NM. The Committee is aware that any proposal they provide to the Board must include, at minimum, justification for the Final Rule. They are also considering developing

separate proposals for medical urgency and import back up for spring 2020 public comment; this is currently not expected to delay overall implementation of the final kidney and pancreas proposals.

4. Policy Oversight Committee (POC) Actions

Setting Strategic Policy Priorities

The Chair of the Policy Oversight Committee (POC) presented another update on the effort of setting strategic policy priorities for the policy governance committees. In setting these priorities, the following factors are considered:

- Impact multiple organ systems
- Impact multiple member types
- Require expertise from multiple committees and stakeholder organizations
- Require changes to multiple policies to provide consistent approach
- Result in large scale improvement to deliver the greatest benefit to the community
- Ripe for prioritized work
- Ability to address through OPTN policy

The identified policy priorities are:

- 1. More efficient donor/recipient matching to increase utilization
- 2. Continuous distribution
- 3. Improved equity for multiorgan and single organ candidates

The POC will also develop a work plan for the suite of strategic projects in this portfolio for the next few years. In terms of next steps, the POC will:

- Solicit project ideas at Fall in-person committee meetings
- Review project ideas in work groups and refine each priority
- Prioritize ideas and constructs project plan at October in-person meeting

Recommend approval of portfolio of projects and suggested timeframes aligned with priorities In addition to the three priorities above, there are two other priorities that the POC is interested in developing in the future: (1) a framework for incorporating longevity into organ allocation, and (2) improving equity for access to transplant registration.

The Chair opened the floor for questions. One member expressed appreciation for inclusion of the multiorgan equity priority. Hearing no other discussion, the Chair asked if the Committee was comfortable voting on the priorities in a bloc. Members expressed support for the bloc.

A motion was made and seconded. The motion passed with 11 in favor, 0 nays and 0 abstentions.

New Committee Projects for Approval

The Chair of the POC presented the following four projects recommended by her committee for approval by the Executive Committee.

- 1. Socio-economic status and access to transplant (MAC) Target Fall 2020 public comment
- 2. Considerations in ABO testing (Operations and Safety) Target Spring 2020 public comment
- 3. 2020 Update to Equivalency Tables (Histocompatibility) Target Spring 2020 public comment
- 4. NLRB Operational Guidelines Update (Liver) *Target Spring 2020 public comment*

The POC Chair noted that POC expressed some concerns about how the MAC would effectively address the problem as stated in their project charter. While acknowledging that there is additional work to be done in clarifying which data points would be required to address the issues called out in the project itself as well as within the community as a whole. The POC did vote, though non unanimously, to allow the MAC to continue to work on the project to further refine the concept.

The Executive Committee Chair opened the floor for discussion. The Vice Chair expressed support for moving these projects forward. Committee members were informed that they could recommend approval of each project; recommend not to approve at this time; or provide feedback to the sponsoring committee and request more information. A motion was made and sconded to approve the projects. The motion passed with 11 in favor, 0 nays and 0 abstentions.

The Chair adjourned the meeting.

Upcoming Meetings

- December 2, 2019 @ Dallas, TX
- Monday, April 20, 2020 @ Chicago, IL