OPTN/UNOS Membership and Professional Standards Committee (MPSC) Meeting Minutes July 17, 2018 Chicago, Illinois

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Introduction

The Membership and Professional Standards Committee met in Chicago, Illinois, on July 17, 2018, to discuss the following agenda items:

- 1. Member Related Actions
- 2. Living Donor Events
- 3. Geographic Organ Distribution Principles and Models Recommendations
- 4. Directed Donation Requirements
- 5. Committee Training and Updates
- 6. Committee Actions

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

1. Member Related Actions

The Committee is charged with determining whether member clinical transplant programs, organ procurement organizations, histocompatibility laboratories, and non-institutional members meet and remain in compliance with membership criteria. During each meeting, it considers actions regarding the status of current members and new applicants.

The Committee reviewed the applications and status changes listed below and will recommend that the Board of Directors take the following actions when it meets in December:

- Fully approve renewal of 2 non-institutional members for two year terms
- Fully approve 2 new transplant hospitals
- Fully approve 6 new transplant programs
- Fully approve reactivation of 1 program
- Fully approve reactivation with personnel changes of 5 programs and 1 living donor component
- Fully approve 1 conditional extension (12 months)
- Conditionally approve (12 months) 2 new living donor components
- Conditionally approve (12 months) 1 reactivation with personnel change

In addition, the Committee also reviewed and approved the following actions:

- 76 Changes in transplant program and living donor component personnel
- 16 Changes in histocompatibility lab personnel

The Committee also received notice of the following membership changes:

- 6 Transplant programs and 2 living donor components inactivated
- 3 Transplant programs, 3 living donor components, and 1 histocompatibility lab withdrew
- 4 Changes in organ procurement organization (OPO) personnel

The full Committee reviewed the membership consent agenda and passed the following resolution:

RESOLVED, that the Membership and Professional Standards Committee approves the membership consent agenda.

The Committee voted 34 Yes, 0 No, 0 Abstentions

2. Living Donor Events

The Committee reviewed 11 items that were placed on the consent agenda, which included eight aborted procedures and three living donor deaths, all of which were closed with no action. The Committee approved the consent agenda by a vote of 35 Yes, 0 No, 0 Abstentions.

The Committee also reviewed one item on discussion, which involved an aborted nephrectomy. The Committee decided to request an informal discussion with the hospital.

3. Geographic Organ Distribution Principles and Models Recommendations

The OPTN Executive Director provided an overview of the Geography in Organ Allocation project and asked the MPSC to provide feedback before the concept paper goes out for public comment in the fall.

He informed the Committee that the Ad Hoc Geography Committee, comprised of board members, committee, and representatives from the societies was formed in December 2017. This Committee is charged with

- Establishing defined guiding principles for the use of geographic constraints in organ allocation
- Reviewing and recommending models for incorporating geographic principles into allocation policies
- Identifying uniform concepts for organ specific allocation policies in light of the requirements of the OPTN Final Rule

The plan is to distribute a concept paper for public comment in the fall that will describe three framework options: fixed distance units, mathematically optimized areas, and borderless distribution. The goal is to identify a single framework to be used across organs. Policy work will continue within the organ specific committees. Following the presentation, committee members raised the following questions or concerns.

- How do you balance traveling further and higher procurement costs? Is it possible that access could be impacted because the costs become prohibitive for some patients?
- OPO productivity and incentives
- Will circles take into consideration the total area available? For example, are boundaries with oceans or foreign countries being considered in the models?
- Is the location of recipient being taken into consideration?
- Modeling logistics is difficult because of practical limitations in the availability of commercial flights around the clock and the costs of charters (additional 20-30K). What may appear to work on paper may not functionally be possible without exceeding the cold ischemia time.
- Patient access is part of the equation. The charges will go up due to logistics and preservation expenses and that may affect patient access due to the increase costs. It could in turn influence the survivability of transplant programs, which could further impact patient access.
- Access for vulnerable populations, such as the rural South.
- Compressed timeframe for proposal development.

- A concern about the composition of the committee was expressed.
- Need to be able to evaluate the distribution system based on its effect on communities, which are specifically discussed in the Final Rule.

4. Directed Donation Requirements

UNOS General Counsel gave a brief presentation to the Committee regarding the existing requirements applicable to directed donation. This was in response to questions regarding directed donation that arose during a prior meeting of the full Committee, including whether an organ can be directed to a category of potential recipients including residents of a particular state.

Several authorities touch on directed donation. "Directed donation" is defined in the OPTN/UNOS policies as the allocation of a living or deceased donor organ to a specific named candidate by a person authorized to make the donation. The named candidate must be medically suitable for the donated organ. The OPTN Final Rule states that nothing in the rule "shall prohibit the allocation of an organ to a recipient named by those authorized to make the donation." 42 CFR §121.8(h). In commentary accompanying the OPTN Final Rule in 1999, Department of Health and Human Services (HHS) stated, "[t] "The existing OPTN policy discourages directed donation to designated groups or classes of people, but permits directed donation to named individuals...It should be pointed out that the final rule permits directed donations to named individuals only. 63 Fed. Reg. 16318 (April 2, 1999). Additionally, the Uniform Anatomical Gift Act (UAGA), a variation of which has been adopted in every state, lists the persons who may receive an anatomical gift and describes a directed donation as "an individual designated by the person making the anatomical gift if the individual is the recipient of the part." In November 1994, the OPTN/UNOS Board of Directors approved the following reference statement: "Donation of organs in a manner which discriminates for or against a class of people based on race, national origin, religion, gender, or similar characteristics is unethical and may not ethically be accepted by UNOS member or transplant professionals."

These authorities consistently state that an organ may only be directed to a named individual, and may not be directed in a manner that would permit discrimination against classes of candidates. Members should continue to honor all directed donation requests that name a specific medically compatible transplant candidate.

5. Committee Training and Updates

New committee members received training in a special session on July 17. This training supplemented the MPSC courses on UNOS Connect and a conference call held in June. Additionally, the full committee received training on the changes that were approved to Appendix L during the June Board of Director's Meeting.

Educational Referrals: There were no specific education topics identified by members during the meeting, however, the staff asked the Committee to submit any ideas that occur to them later. The goal is to provide 20 educational referrals annually.

Changes to Hospital-based OPO Voting Privileges: Staff reminded the Committee that this MPSC sponsored proposal would be distributed for public comment on August 3. The proposal has been placed on the non-discussion agenda and will be presented during a webinar on August 6. It will not be discussed at the regional meetings unless it is moved to the discussion agenda by the individual regions.

6. Committee Actions

The Committee unanimously agreed that actions regarding Bylaws, Policy, and programspecific decisions made during the OPTN session would be accepted as UNOS actions.

RESOLVED, that the Committee accepts those program specific determinations made during the meeting as UNOS recommendations.

FURTHER RESOLVED, that the Committee also accepts the recommendations made relative to Bylaw and Policy changes.

The Committee voted 35 Yes, 0 No, 0 Abstentions

Upcoming Meetings

- August 31, 2018, 3:00-5:00pm ET, conference call
- September 20, 2018, 3:00-5:00pm ET, conference call
- October 16-18, 2018, Chicago
- February 26-28, 2019, Chicago
- July 16-18, 2019, Chicago
- November 5-7, 2019, Chicago