OPTN Membership and Professional Standards Committee Membership Requirements Revision Subcommittee Meeting Summary February 2, 2021 Conference Call

Clifford Miles, M.D., Chair

Introduction

The Membership Requirements Revision Subcommittee of the Membership and Professionals Standards Committee (MPSC) met via Citrix GoToTraining teleconference on 02/02/2021 to discuss the following agenda items:

- 1. Welcome
- 2. Inactivation, Reactivation, Functional Inactivity
- 3. Next Steps

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

1. Welcome

The Membership Requirements Revision Subcommittee Chair provided welcomed the Subcommittee to the call and discussed the objectives of the meeting. Staff explained that the goal for the meeting would be for the Subcommittee to discuss recommendations to provide to the MPSC for framework around program inactivation and reactivation. Staff advised that the Subcommittee would develop the proposal language that would go out in the summer 2021 public comment cycle.

2. Inactivation, Reactivation, Functional Activity

Staff noted that there is a focus on consistency with the Final Rule, and the final proposal would include an assessment the proposal's compliance with the Final Rule. The relevant section of the OPTN Final Rule was reviewed with the Subcommittee. The Final Rule requires that the "... transplant program ... shall ... be an organ transplant program which has adequate resources to provide transplant services to its patients and **agrees promptly to notify the OPTN and patients awaiting transplants if it becomes inactive**" The Subcommittee reviewed the current bylaw requirements for inactive waiting list, program inactivation, and functional inactivity, noting when notification to the OPTN and to patients is required. The Subcommittee reviewed inactive waiting list data from 2017-2019. Staff also advised the Subcommittee that current data for program inactivation showed 18 programs and components in inactive status, 10 programs and 8 components.

The Subcommittee was asked to consider the following questions:

For inactive waiting list:

- Are there circumstances that support a program being able to turn off entire waiting list without notification to OPTN & to individual patients?
 - For what time period or events?
 - What notice to OPTN and/or patients should be required, if any?

For program inactivation:

- When should program inactivation be expected?
- Is MPSC review of reactivation necessary in all circumstances?

Feedback by the Subcommittee:

The Subcommittee supported retaining the ability of programs to set their waiting lists to inactive and agreed that, if a program could not accept an organ for a short time period, the program should be encouraged to set their waiting list to inactive in order to increase the efficiency of organ allocation. The Subcommittee further discussed when it is appropriate for a program to set the waiting list to inactive and when patient and OPTN notification should be required.

- Patient Notification The Subcommittee discussed the importance of patient notification if a program should make its waiting list inactive. One subcommittee member raised concerns about urgent status patients not receiving notice that their surgeon is unavailable for as many as 14 consecutive days. Other subcommittee members agreed on the importance of notification to urgent status patients. They also mentioned the operational challenges for programs to notify patients every time a waiting list is inactivated and their concern regarding a slippery slope in that program's refuse organs all the time without notification to patients. If the OPTN was to require programs to notify patients every time the waiting list is set to inactive, it could discourage programs from setting the waiting list to inactive and as a result, negatively affect organ allocation by slowing it down with organ refusals. Another subcommittee member expressed interest in hearing from OPTN family and patient representatives on their thoughts about patient notification. The Subcommittee supported further consideration of various modalities for patient notification that could be less burdensome on the program, for example text, email, alerts from UNet or from the hospital's electronic medical record (EMR).
- **OPTN Notification** The Subcommittee also discussed notification to the OPTN should a program inactivate its waitlist. One subcommittee member recommended the inclusion of an automatic/computerized notification to the OPTN when programs set their waitlist to inactive. The Subcommittee also supported the ability for programs to set their waiting list to inactive and agreed that this could also improve allocation efficiency.
- Time Period and Events of Notification The Subcommittee discussed the time period and events for which programs should notify the OPTN and patients about inactivation of waitlists. One subcommittee member supported continued use of a time period rather than an enumerated list of events since it would be difficult to be inclusive of all events that would justify setting the waitlist to inactive. The Subcommittee agreed that programs should not have to notify patients of very short time frames of waiting list inactivity, and the notification requirements should also take into account whether the event is planned or unplanned (i.e. weather, disaster, etc.). Time periods suggested were 24 hours particularly for urgent status patients, and 3 5 days and flexibility if a disaster is involved.

3. Next Steps

Staff advised that considerations for the program inactivation topic would be discussed at the February MPSC meeting. The Subcommittee reviewed a timeline for upcoming subcommittee meetings and topics that will be discussed. Staff advised subcommittee members that they would receive a poll for availability to schedule a subcommittee meeting in early March. Staff also shared that the language for the proposal would be finalized during the May subcommittee meeting.

Upcoming Meeting(s)

- February 23-25, 2021: MPSC Meeting
- March 31, 2021: Membership Requirements Revisions Subcommittee –11:00 am- 1:00 PM ET

Attendance

- Committee Members
 - Clifford D. Miles (Subcommittee Chair)
 - Christina D. Bishop
 - o Theresa M. Daly
 - o Jonathan A. Fridell
 - o PJ Geraghty
 - o Edward F. Hollinger
 - o lan R. Jamieson
 - Heung Bae Kim
 - Jon A. Kobashigawa
 - o Anne M. Krueger
 - Saeed Mohammad
 - o Nicole A. Pilch
 - o Scott C. Silvestry
 - Lisa M. Stocks
 - Parsia A. Vagefi
 - o Gebhard Wagener

• HRSA Representatives

- o Marilyn E. Levi
- o Arjun U. Naik
- o Raelene Skerda

UNOS Staff

- o Sally Aungier
- o Nicole Benjamin
- o Tameka Bland
- o Demi Emmanouil
- o Amanda Gurin
- o Krissy Laurie
- Ann-Marie Leary
- Jacqueline O'Keefe
- o Liz Robins Callahan
- o Sharon Shepherd
- Leah Slife
- o Olivia Taylor
- Roger Vacovsky
- o Marta Waris

• Other Attendees

o Zoe Stewart Lewis