

**OPTN Policy Oversight Committee
Meeting Minutes
May 28, 2019
Conference Call**

**Jennifer Milton, BSN, CCTC, MBA, Chair
Alexandra Glazier, JD, MPH, Vice Chair**

Introduction

The Policy Oversight Committee (POC) met via teleconference on 05/28/2019 to discuss the following agenda items:

1. Committee Projects Review
2. OPTN Updates

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

1. Committee Projects Review

The POC reviewed one project. The project was sponsored by the Liver and Intestinal Transplantation Committee and was titled, "Clarification of Pre-existing Liver Disease".

Summary of discussion:

The proposed project intends to clarify the definition of pre-existing liver disease in OPTN policy. Patients meeting specific criteria for fulminant hepatic failure are eligible for listing as Status 1A when they are "without pre-existing liver disease". Current policy is ambiguous regarding whether or not receipt of a prior liver transplantation constitutes a "pre-existing liver disease". The Liver and Intestinal Transplantation Committee is seeking to clarify the definition of pre-existing liver disease so that it does not include the receipt of a prior liver transplant.

UNOS staff asked if the POC had any questions on the proposed project. The POC had no questions.

A formal vote was taken regarding: do you object to recommending that the OPTN Executive Committee approve the project?

Results were as follows: 0 Yes (0%); 14 No (100%); 0 Abstain (0%)

Next steps:

The project will move forward for consideration by the OPTN Executive Committee.

2. OPTN Updates

UNOS staff provided an update on OPTN activities.

Summary of Discussion:

UNOS staff presented a timeline of the current liver litigation. Currently, liver allocation is by donation service areas (DSAs) and regions. The National Liver Review Board (NLRB) is in place and the median model for end-stage liver disease (MELD) at transplant (MMaT) is being calculated by the DSA. The precise path forward is still to be determined, but the court should provide more clarity in approximately five weeks.

The Chair asked if there could be similar litigation for the organ systems that have already moved to broader allocation (thoracic). UNOS staff could not say for certain, but noted that it would be different to challenge a policy that is already in place as opposed to a policy that has

not yet been implemented. UNOS staff also commented that much of the litigation is surrounding the administrative processes outlined in the Final Rule.

A POC member asked if the court ordered implementation efforts to be stopped for all organ allocation changes or just for liver. UNOS staff stated that the order was specific to liver. UNOS staff did note that the outcome of the litigation could have an impact on the other organs, but this case is specific to liver.

A POC member noted that he did not see much advertisement for the recently convened Advisory Committee on Organ Transplantation (ACOT) meeting. The POC member asked if the meeting had been planned in advance or was a result of the current litigation. UNOS staff stated that the meeting was planned in advance of the litigation. HRSA staff also noted that the ACOT meeting was planned unrelated to the litigation.

UNOS staff also clarified that the initial court order was a denial of a temporary restraining order. The plaintiffs then appealed that decision and the court granted an injunction pending that appeal.

A POC member asked if the OPTN will examine the data from the time when Acuity Circles was implemented. UNOS staff said that it was still too early to know if any significant conclusions will come from those data, but UNOS research staff will examine them. A POC member stated that it would be interesting to see if the number of split liver transplantations changed during the time that Acuity Circles was implemented.

UNOS Staff then informed the POC of some of the agenda items at the upcoming OPTN Board of Directors (BOD) meeting. Those items were:

- Ethical Implications of Multi-Organ Transplantation*
- Split Liver Variance*
- Eliminate the Use of DSAs in Thoracic Distribution*
- Eliminate the Use of Regions in VCA Distribution*
- Clarifications on Reporting Maintenance Dialysis*
- Modify HOPE Act Variance to Include Other Organs*
- Effective Practices in Broader Organ Sharing*
- Kidney-Pancreas Update
- POC Presentation
- Committee Chair Breakfast

The asterisks denote voting items. UNOS staff noted that the public comment proposal titled, “Expedited Placement of Livers” is not going to the June BOD meeting, but will go out for another round of public comment. UNOS staff reminded the group that the POC is now an operating committee of the BOD, so they are required to give an annual update to the BOD.

UNOS staff then presented a list of proposals slated to go out for public comment in the fall:

- Modify Data Submission Policies
- Expedited Organ Placement
- Eliminate the Use of DSAs and Regions in Kidney Allocation
- Eliminate the Use of DSAs and Regions in Pancreas and Kidney-Pancreas Allocation
- Modify Appointment Process for the Histocompatibility Vice Chair
- Data Collection to Evaluate the Logistical Impact of Broader Distribution
- Clarification of Pre-Existing Liver Disease
- Continuous Distribution of Lungs Concept Paper

UNOS staff then noted that the new committee term starts on July 1, 2019. UNOS staff will work with incoming POC members to schedule meetings after July 1, 2019. UNOS staff also reminded the POC that during an upcoming call they will be reviewing the slate of projects scheduled to go out for public comment in the fall. They will also keep discussing the ongoing geography efforts.

Next Steps:

UNOS staff will keep the POC informed of the liver litigation, policy development process, and geography discussion.

Upcoming Meeting

- June 25, 2019 – Teleconference