

**OPTN/UNOS Policy Oversight Committee (POC)
Meeting Minutes
March 26, 2019
Conference Call**

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

Introduction

The Policy Oversight Committee met via Citrix GoToTraining teleconference on March 26, 2019 to discuss the following agenda items:

1. New Project Review
2. Update on Critical Comment
3. Public Comment Updates

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

1. New Project Review

The Policy Oversight Committee reviewed three new project ideas. Members voted on whether these projects should be recommended for approval to the Executive Committee.

Data summary (as applicable):

Initial Survey Votes:

- Project 1: 11-Yes, 2- No, 1- Maybe.
- Project 2: 11- Yes, 1- No, 2- Maybe.
- Project 3: 13- Yes, 0- N, 1- Maybe.

Summary of discussion:

Project 1: Continuous Distribution of Lungs, Thoracic Committee.

Strategic Goal: Provide equity in access to transplants.

- A member asked about plans for monitoring the impact of continuous distribution after the project has been implemented.
 - The committee was told that the new project would be closely and regularly monitored in order to evaluate changes that result from continuous distribution.
- Members voted to recommend project approval to the Executive Committee:
 - **Vote: 12 - Y**

Project 2: Guidance for Transplant Hospitals on Transplant Candidate Use of Social Media to Find Living Donors, Living Donor Committee.

Strategic Goal: Increase the number of transplants.

- A member asked if there was a planned approach for working with living donors and the ethical situations that can occur during the donation process.
 - The committee was told that the current plan is to reach out to transplant hospitals in order to identify and investigate the real-life experiences of living donors. The purpose behind this plan is to understand and prepare for some ethical dilemmas that could arise.
- Members voted to recommend project approval to the Executive Committee:
 - **Vote: 12- Y, 1- Request for more information**

Project 3: Modify Appointment Process for the Histocompatibility Vice Chair, Histocompatibility Committee.

Strategic Goal: Promote efficiency in donation and transplantation.

- A member commented that it is important to keep a consistent approach on committee leadership.
- Members voted to recommend project approval to the Executive Committee:
 - **Vote: 12- Y**

Next steps:

These projects will move forward be presented to the Executive Committee.

2. Update on Critical Comment

The UNOS CEO gave a critical comment update on the new liver policy:

UNOS received a critical comment on the new liver policy. This comment was sent to the United States Department of Health and Human Services (HHS) and written by Jones Day law firm on the behalf of 10 transplant hospitals. This comment claims that the new liver policy is inconsistent with the Final Rule. The OPTN described their process and defended the development of their liver policy. The Health Resources and Services Administration (HRSA) also responded to certain criticized aspects of the policy.

Summary of discussion:

- UNOS staff stated that they believe the liver committee had done its due diligence in answering questions, releasing data, and being as transparent as possible thorough this process. The policy is still scheduled for implementation on April 30, 2019.
- A member commented that re-education of the community will be important with the changes the policy will being about.
- A member was concerned that the rejection of the response may result in a lawsuit, counter lawsuit, and the eventual federal regulation of liver allocation.
 - The POC was told that the Liver Committee was very deliberate under the Final Rule when creating this policy and have solid ground to stand on in its defense.
- A member asked how UNOS plans to prevent law and liver issues in the future. How will UNOS get back to its mission and reunify the organization with its members?
 - UNOS staff responded that evidence based policy development is the key to defending any potential lawsuits. These projects are core to the organization's mission and NOTA's founding principles to allocate organs based upon medical priority as much as feasible. We'll continue to educate the community about the benefits of these principles while continuing to address the urgent needs of the transplant community.
- The conversation among members turned to focus on the policy development process. They inquired as to what could make it the most trustworthy.
 - UNOS staff responded that everything will not always be unanimous, but that it is important to ensure that we are using the resources we have in the most efficient ways possible. The POC plays an important role in identifying and prioritizing the projects for the committees.
- A member suggested that regulatory compliance of policies be checked throughout the policy development process.
- A member suggested bringing people who may oppose the policy to the table during the development process. He reported that by identifying and engaging these groups early on, there may be less controversy towards the end of the process.

- A member recommended involving people who work in the field every day in the development of policies as a way to incorporate and work through logistical challenges.

Next Steps:

The liver policy is scheduled to be implemented on April 30, 2019. The OPTN will have a post-implementation evaluation process, will report the impacts of the policy publicly, and will propose modifications to the public if data suggests changes are warranted.

3. Public Comment Updates

OPTN public comment period closed on March 22, 2019. This is a review of the community's overall sentiment towards potential policy changes.

Summary of discussion:

- Staff presented a chart showing the level and amount of support or opposition each proposal received over the public comment period. Staff explained how the Likert scale, sentiment chart is now available for all committees with the new public comment system.

Upcoming Meetings

- April 23 (teleconference)
- May 9 –May 10 (In-person)