

**OPTN/UNOS Executive Committee  
Meeting Summary  
06/11/2018  
Richmond, VA**

**Dr. Yolanda Becker, Chair**

**Introduction**

The Executive Committee met on 06/11/2018 to discuss the following agenda items (\*denotes voting item):

1. *POC Project Portfolio Review*  
Jennifer Milton, POC Chair and James Alcorn, UNOS Policy Director
2. *New Project approval: OPO-Based Voting Rights\**  
Jennifer Milton, POC Chair and James Alcorn, UNOS Policy Director
3. *Retrospective Approval of Clerical Changes\**  
James Alcorn, UNOS Policy Director
4. *2018 Board & Committee Needs Assessment*  
Yolanda Becker, Board President
5. *Committee Governance Subcommittee Update*  
Yolanda Becker, Board President
6. *Response to HRSA Administrator re: Liver Allocation*  
Brian Shepard, UNOS CEO

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

**1. POC Project Portfolio Review**

Jennifer Milton, POC Chair and James Alcorn, UNOS Policy Director

Ms. Milton reported that the POC has reviewed six new projects since last, provided recommendations to the Executive Committee at the monthly conference calls, and in May reviewed the entire portfolio of active projects underway by the Committee to ensure that they are on target and still aligned and meeting the strategic goals.

Highlights were shown of the five projects that have already been considered and voted on by the Executive Committee.

**2. New Project approval: OPO-Based Voting Rights\***

Jennifer Milton, POC Chair and James Alcorn, UNOS Policy Director

A project that was reviewed by the POC in April needs the vote of the Executive Committee, and it is sponsored by the MPSC. It is a project to put to public comment the consideration to allow hospital-based OPO voting rights instead of tying their voting rights to those of the transplant center. The Policy Oversight Committee voted 9 yes, 3 no, and 1 abstention to approve the project, and the concerns that were noted included that all of the stakeholders were not identified in the project form. Several members of the POC questioned how it could increase efficiency, and those concerns were addressed in the meeting. All of the comments and more detailed scores were provided in the meeting materials. The impact on the current strategic alignment was shown, and it would be a very small project that would account for barely 1% of the total resources with impact on strategy five.

Across the board, there are 14 projects that are in the "evidence gathering" status, and three of those were flagged for lack of sufficient progress. The POC approved them continuing, but there

is concern about the efficiency and progress. Those committees will be asked to come back (two from the Kidney Committee and one from Pancreas) at future POC meetings to provide updates and to continue considering if they are worth continuing. The two from Kidney both involved the KPD pilot program. One is to allow deceased donor change into the pilot program, and the second one is repairing the chains. The one from Pancreas was the broadening of allocation across compatible blood types.

The current strategic plan alignment was shown

VOTE:

Does the Executive Committee approve the new MPSC project for hospital-based OPO voting rights to proceed to the evidence gathering phase?

Passed unanimously.

**3. Retrospective Approval of Clerical Changes\***

James Alcorn, UNOS Policy Director

James Alcorn presented the retrospective approval of clerical changes to OPTN policies (mini-brief). The bylaws permit staff to make clerical or non-substantive changes to the policies. Those can go into effect immediately and then require a retrospective review by the Executive Committee. Three different changes were presented to the Committee including Policy 9.10.A (Regional Accuracy), Bylaw L.11.A (Right to Appear before the Board of Directors), and additional citations to "Manipulation of the Organ Allocation System Waitlist Priority through the Escalation of Medical Therapies" white paper.

VOTE:

Do you approve these clerical changes to OPTN Policies/Bylaws?

Passed unanimously.

**4. 2018 Board & Committee Needs Assessment**

Yolanda Becker, Board President

The Subcommittee meets to look at a needs assessment for the Nominating Committee, review and make recommendations on Board structure and the recruitment process, and conducts a committee needs assessment.

The process for the annual board needs assessment starts at the time of the Board Election. The Subcommittee looks at things as diverse as skill sets, race/ethnicity, gender, professional perspective, geography, balance in patient/donor populations, organ-specific expertise, and more events/projects requiring particular skill sets.

In looking at the 2019-2020 board, the Subcommittee considered the board members with terms continuing in 2019 and at the associate councilors who will become regional councilors on July 1, 2019. The regional distribution was shown in terms of the numbers of members and the percent of the Board that each region represents. When looking at the regional distribution, there is increased representation in Regions 7 and 10, and some representation was lost in Regions 1 and 11. Looking at race and ethnicity, the ethnicity of the Board has increased. The gender balance in 2019-2020 is 50/50. Classifications were also shown for 2019-2020 including MD vs. non-MD, surgery vs. medicine, and patient/donor family representation. The patient and donor representatives were shown, and the needs that have been identified for the 2019/2020 cycle were shown including skill sets in corporate governance, non-profit organizations, and healthcare finance. In addition, they would like to see practice specialization in infectious disease and additional thoracic expertise.

The considerations of the Subcommittee were shared: Region 7 has a higher percentage of representation, and Regions 4 and 6 have the lowest. There is need to increase diversity among the entire Board and specifically for the patient and donor affairs representatives. Efforts continue with regard to gender balance, and there is a continued aim for balance between surgical and non-surgical transplant MDs.

Dr. Becker then presented the OPTN Committees Needs Assessment including the regional distribution showing over representation in Region 7 but more committee representation in Regions 1 and 6, which is by design; race/ethnicity, which is increasing in color; gender balance, which is at almost the 50/50 mark; classification, showing good representation; practice specialization, which is reflective of the volume of transplants; patient representation; and patient and donor representatives.

#### Question

Has there been any dialog about how the Regions will use the information in their process of selecting leadership for the regions and recommended membership to the committees?

Dr. Becker replied that the regional administrators have done a good job of talking with the specific regions, and the Board governance is presented usually at the fall regional meetings. There was a suggestion that the organization would need to discuss how decisions regarding the Board are made at the regional level, and the input into that process from the Executive Committee is advisory as opposed to directive.

### **5. Committee Governance Subcommittee Update**

Yolanda Becker, Board President

The Committee Governance Report was presented. The "Committee on Committees" was put together to look at how the community is engaged and how the work on committees is done. The Committee started its work in the summer of 2016, and the first thing that was done was to look at the bio form. In the spring of 2018, there was a public comment cycle where the Committee presented a proof of concept committee structure to get feedback. The Committee stayed together to be able to respond and hear some of the public comment and then move forward. Many constituents in the community were concerned about keeping the current suite of responsibilities, particularly where policy making was concerned. In the proof of concept pilot, there won't be any changes in the current suite of responsibilities. The PAC structure and membership will be kept the same, but recipients and patients from other committees will be added for different perspectives. Expectations will be set for adding increased committee and board communications.

The workgroup on committee structure completed its work in May, and in its final few meetings proposed that they proceed with test structure from the proposal. The proof of concept will run from July to December and will test participation of additional volunteers that are already engaged with the OPTN. There will be new ways to communicate and collaborate. Basecamp seems to be working well with good interaction. The charge is to determine how to empower the constituent voice and improve intra-committee communication. The project will not make any changes to bylaws, change the Committee's ability to propose or sponsor projects, or change current member status.

The data that is gathered during the proof of concept will then be assessed. There will be participant and public feedback, engagement surveys, Basecamp analytics, and public comment. The goal will be to identify what lessons are learned, and a report will be before the Board by December 2018. Next steps will be determined in concert with the community.

## Questions

Who is going to have oversight of next steps, and who is responsible for answering questions that come up along the way?

The Committee on Committees is an ad hoc group that is a project of the Executive Committee. If specific things come up, the Executive Committee will have to figure out the best, most efficient way to answer those. A work group may need to be formed.

Would a pilot of making a regional meeting available on WebX be helpful to test whether virtual engagement in the organization would be beneficial?

There has been talk about expanding regional meetings in a way that people can participate virtually.

## **6. Response to HRSA Administrator re: Liver Allocation**

Brian Shepard, UNOS CEO

The Committee spent a great deal of time working through principles about geographic allocation, and the action item for the Board is approval of those principles, which are a re-statement of the regulation.

There is a liver-specific analysis that has to be done, and that is a result of the letter from HRSA to the OPTN asking that they analyze the liver policy that's going into effect in December and answer specific questions. The secretary of HHS received a letter that under the regulation is considered a critical comment allowing a process of review and analysis. It argues that not only the current liver policy but also the incoming liver policy are non-compliant with the Final Rule because of the use of Regions and DSAs.

The letter asks the Secretary to take immediate action, and the Secretary then sent the OPTN a letter through the HRSA administrator asking for the review. There is currently no lawsuit. There is direction by HRSA for OPTN to do an analysis in relation to four specific questions, and the deadline is June 25th, 2018. There is not a plan currently to make an amendment to the liver policy, but IT is figuring out what the contingency plan is if it ends up in Court.

HRSA is seeking the OPTN's views on whether the following aspects of the revised allocation policy are aligned with NOTA and the Final Rule: 1) Using DSAs as units of allocation; 2) Using OPTN regions as units of allocation; 3) Using proximity points in relation to DSAs; and, 4) Using median MELD in DSAs in granting exceptions.

Next steps were reviewed culminating in the EC final approval of a letter to HRSA on Friday the 22nd.

## Discussion

The need to pass the principles was underscored as being critical to the work of moving forward in a manner that is legally compliant.

The point was also made that while there are permissible restrictions on geographic distribution in the Final Rule, the DSAs are a problematic proxy for that. There has to be a better framework than what is currently used in order to do that. There has to be a rational, defensible, explainable way that OPTN's geographic restrictions support the valid reasons in the Final Rule.

The principles are not intended to exclude or ignore other responsibilities from NOTA. They are intended to reframe that particular piece of the Final Rule. Going forward, there are still legal responsibilities to address the other areas.

A question was raised about the allocation policies in terms of their cumulative effect on socioeconomic inequities, but that is a conversation that will be engaged in at a later time. The requirements in 121.4 mirror the high-level requirements in NOTA, and 121.4 tells the broad areas in which the OPTN shall develop policies, including how to elect officers and directors and other broad policy making areas. 128 sets forth the specific criteria that need to be included in allocation policies. They are not inconsistent; they are talking about different things.

There was a comment that though the questions do need to be addressed, they isolate specific parts of the total system for allocation, which can't really be done. It's not an equation that solves to a single solution. The response has to take everything into account, everything as a whole, and there was concern about isolating each question. The geographic principles may help to narrow the scope.