OPTN/UNOS Executive Committee
Meeting Minutes
November 14, 2018
Conference Call

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Introduction

The Executive Committee met via Citrix GoToTraining teleconference on 11/14/2018 to discuss the following agenda items:

1. New Project Approvals Recommended by the Policy Oversight Committee
2. Approve Correction to HCC Criteria for Auto Approval (OPTN Policy 9.5)
3. Review of Public Comment Submission to CMS Proposed Rule Change to Transplant Program CoPs
4. Project Update: Removing DSA and Region from Liver Allocation (Liver and Intestinal Transplantation Committee)
5. Project Update: Organ Distribution Frameworks (Geography Committee)

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

1. New Project Approvals Recommended by the Policy Oversight Committee

The Committee heard a recommendation by the Policy Oversight Committee to approve one new project:

- Modify the HOPE Act Variance to Include Other Organs (Ad Hoc Disease Transmission Advisory Committee)

Currently the HOPE Act has been limited to kidney and liver, but the law does not limit this and the community has asked for extension to heart and pancreas. There have been almost 90 HOPE Act transplants performed. The extension to other organs will require some IT effort.

Summary of discussion:

The Committee voiced its support for this project. After a motion was made and seconded, the Executive Committee approved the list of five projects to move into the evidence-gathering phase by a vote of 12 for; 0 against; 0 abstentions.

2. Approve Correction to HCC Criteria for Auto Approval (OPTN Policy 9.5)

The Liver and Intestinal Organ Committee recommended a correction of a drafting error in **OPTN Policy 9.5** (HCC Criteria for Auto Approval) to replace the phrase "< 6 months apart," to the intended "180 days or less apart" in policy language regarding the amount of time needed between MRI and CT scans when measuring the growth of lesions. The error was made in drafting to change the mathematical symbol to text. It would require no change in behavior nor cost to implement.

Summary of discussion:

After a motion was made and seconded, the Executive Committee approved the correction by a vote of 12 for; 0 against; 0 abstentions.

3. **Review of Public Comment Submission to CMS Proposed Rule Change to Transplant Program CoPs**

The Committee reviewed a draft comment on behalf of the OPTN in response to a CMS proposed rule change to transplant program conditions of participation (CoPs). The draft included feedback solicited from the Patient Affairs, Minority Affairs, Transplant Administrators, and Membership and Professional Standards Committees. The response was circulated for feedback and the presented version included previously recommended edits.

Summary of discussion:

After a motion was made and seconded, the Executive Committee approved the public comment submission by a vote of 12 for; 0 against; 0 abstentions.

4. **Project Update: Removing DSA and Region from Liver Allocation (Liver and Intestinal Transplantation Committee)**

The Chair of the Liver and Intestinal Transplantation Committee presented an update on their project, "Removing DSA and Region from Liver Allocation." The proposal went out for special public comment in October and the sponsoring committee voted 11-9 to recommend the broader 2-circle (B2C) model with a 29 MELD threshold to the Board for approval. This proposal includes two concentric circles, one 500nm for Status 1A and 1B patients and another 250nm circle for those with MELD/PELD at least 29. For those with MELD/PELD 15-28, livers would be allocated within 150nm, then 250nm, and finally 500nm before expanding an offer nationally to patients with Status 1A, 1B and MELD/PELD of at least 15. The B2C proposal prioritizes pediatric candidates for pediatric donor livers and has alternate allocation for DCD and donors >70 yrs of age that prioritizes distance. Intestine allocation would be using a 500nm circle from the donor hospital. The proposal also makes adjustments to NLRB and SLK policies. The proposal ends Region 9 variance but maintains the split liver variance and extends the Hawaii variance to Puerto Rico. It also adds an exception for Alaska that treats donors recovered in Alaska as if they originated in Seattle.

Summary of discussion:

The method for voting for the proposal and managing amendments was clarified. The greatest risk for the organization and network is if DSAs are maintained in allocation. The differences in defensibility between any possible amendments to the proposal are small in comparison to that risk. It is critical that any proposal voted on has rationale for any limiting factors in broadest possible sharing, demonstrating its compliance to the Final Rule.

The Board is the final arbiter, and it relies on the committees to do due diligence before bringing proposals to the Board. The Board should not simply rubber stamp, but it should generally trust the work of the committees. This particular proposal is a special case in that multiple options were presented to the community for public comment, with split support for said options. Amendments in this case are not out of the question, and there is a timeline in place that prevents additional work and research, though in general the Board should rely on the work of the committees. A printed outline of amendments and the decision tree will be provided to the Board members, and an appropriate display in the room will also be developed.

5. **Project Update: Organ Distribution Frameworks (Geography Committee)**

The Chair of the Ad Hoc Geography Committee presented an update on their project, "Organ Distribution Frameworks." The committee was charged with developing guiding principles for the use of geographic constraints in organ allocation, and to identify uniform concepts for organ-specific allocation policies aligned with the requirements of the Final Rule. With the principles having been approved in June 2018, the committee distributed Final Rule-compliant frameworks

for public comment in fall 2018. Continuous distribution was supported most broadly in public comment as the most equitable, flexible and compliant option, recognizing that efficiency and organ wastage should be considered. In addition, OPO performance, socioeconomic factors, and the prioritization of pediatric patients should also be considered as elements in any framework. The recommendation going before the Board for approval is the continuous distribution framework, as it was deemed the most flexible model for each organ's specific needs that provides for the most nuanced approach to distribution. Committees would be expected to work toward this framework in future allocation projects.

Summary of discussion:

At the Board meeting, it will be clarified how approval of a framework relates to the work of the Liver committee and other committees' allocation projects. The Ad Hoc Geography Committee received a presentation regarding state borders as an allocation system, but the committee determined that it was not likely to be deemed compliant with the Final Rule. As regions are combinations of states and deemed not compliant, a similar structure was regarded similarly.

Upcoming Meetings

- December 3, 2018 10:15-11:45am CST