OPTN/UNOS Executive Committee Meeting Minutes

March 26, 2019 Teleconference

Sue Dunn, Chair

Introduction

The Executive Committee met via teleconference on 03/26/2019 to discuss the following agenda items:

- 1. Welcome
- 2. MELD Exception Scores During National Liver Review Board (NLRB) Transition Proposal Special Public Comment
- 3. Critical Comments to HHS Regarding Liver Policy

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

1. Welcome

2. MELD Exception Scores During NLRB Transition Proposal Special Public Comment

Public comment was received regarding the proposal about transitioning the NLRB in light of the acuity circle model from 1/31/2019 to 3/22/2019. There were 293 comments and, 263 being votes at regional meetings and 30 being comments submitted to the OPTN website. Votes were broken down by member type, the vast majority being from transplant hospitals. Comments did not relate as much to the transition, which was the purpose of the public comment, but about going forward after the transition. Some suggestions were made about to size of the circle for NLRB and calculation of Median MELD at Transplant (MMaT) that will be useful during the transition and the monitoring period afterwards. Supportive versus non-supportive comments were broken down by region, state and member type and displayed in chart graph and map form for the committee members.

- Only use exception scores reviewed by the NLRB and scored according to the NLRB system, rather than existing RRB scores once broader sharing goes into effect on 4/30/2019.
 - The original plan was to have a 3-month transition to implementation of NLRB to ensure everyone would cycle to standardized NLRB scores according to MMaT, so one idea was to delay the acuity circle model.
 - NLRB could re-review all scores before the acuity circle takes effect, but this would not be possible due to time constraints.
 - Existing scores could be converted prior to the implementation of NLRB
- 2. Ensuring the candidates with exceptions for the same diagnosis who have the same MMaT are ordered according to who has been waiting the longest.

The Liver Committee formed a subcommittee to work out the details of a recommendation and formulate a recommendation, which was supported by the full committee. The recommendation is to have the NLRB and acuity circle allocation changes go into effect simultaneously. Most existing exception scores would be converted immediately. New forms will not be submitted during a window period and pending forms will be routed to NLRB for approval with the same conversion rules listed below. This was done just before close of public comment. The main

disadvantage of the recommendation of NRLB and acuity circle going into effect simultaneously is it does not allow for time between implementations. However, the time between 4/2/2019 and 4/30/2019 would probably still be insufficient time to allow all candidates to be converted prior to implementation, which is why the Liver Committee originally wanted a 3-month transition period.

Score Conversion Plan

- 1. Adult candidates (age 18 and above)
 - Exception scores of 40 will remain at 40
 - Standard diagnoses with exceptions scores of 22 to 39 are similar to standard scores will convert to MMaT -3 and then will be re-reviewed at time of score renewal.
 - Primary hyperoxaluria diagnoses with exception scores of 22 to 39 will convert to MMaT.
 - Exception scores less than 22 will remain unchanged.
- 2. Adolescent candidates (age 12 to 17)
 - Conversion would be similar to adults, except primary hyperoxaluria diagnosis scores of 22 to 39 will convert to MMaT+3.
- 3. Pediatric candidates (age less than 12)
 - Exception scores above 40 will remain unchanged
 - Standard diagnoses with exceptions scores below 40 will convert to MPaT.
 - Primary hyperoxaluria diagnoses would convert to MPaT +3.

Simultaneous implementation of NLRB and acuity circles will resolve two issues:

- 1. It will prevent candidates with exceptions for a shorter time to be ranked ahead of candidates with exceptions for a longer time.
- 2. It will prevent RRB-assigned scores from existing under the new allocation system.

Prior to implementation of the new system, there will be liver allocation and NLRB training, a Liver Town Hall and a webinar open forum.

A motion for the Executive Committee to adopt the Transition Policy of implementing the NLRB and allocation changes simultaneously following public comment as recommended by the Liver Committee was made and seconded.

A voice vote was taken and the results were as follows: 100% yes; 0% no; 0% abstained.

3. Critical Comments to HHS Regarding Liver Policy

The draft response letter to HRSA was adjusted based on discussions at the last Executive Committee meeting.

- It was recognized that the costs for transplantation especially around transportation were likely to increase with the new liver allocation policy.
- Allocation and distribution were adjusted.
- The makeup of the Board was repeated to remind everyone of all the stakeholders that were on the Board.
- Letters from Congressional representatives were acknowledged.

- Language used around debate questions amongst Committee members was cleaned up.
- More detail was given on the monitoring plan to make clear that the intention is to monitor the policy and share the data publicly as the policy moves forward.
- One last comment not added yet was around logistical challenges that might fit into the cost paragraph as, "There will be other logistical adjustments necessary as OPOs and transplant centers adopt the new policy and the impact of those changes will be closely monitored by the OPTN."

The letter itself is a public document and will be made available on the website or through email.

A motion for the Executive Committee to approve the response letter to the HRSA Administrator as drafted, as well as additions from this meeting (as outlined above), was made and seconded.

A voice vote was taken and the results were as follows: 100% yes; 0% no; 0% abstained.

Next steps

- All Executive Committee members will receive a copy of the letter to HRSA signed by the Chair.
- Timing of response to the critical comment letter and various congressional letters will be up to HRSA.
- The Executive Committee will reconvene on 4/12/2019 in Chicago noon to 4 p.m. CST. Travel arrangements should be made as soon as possible.