**OPTN/UNOS Liver and Intestinal Organ Transplantation Committee**
**Meeting Summary**
**January 21, 2016**
**Conference Call**

**Ryutaro Hirose, MD, Chair**
**Julie Heimbach, MD, Vice Chair**

*Discussions of the full committee on January 21, 2016 are summarized below and will be reflected in the committee's next report to the OPTN/UNOS Board of Directors. Meeting summaries and reports to the Board are available at http://optn.transplant.hrsa.gov/ .*

## Committee Projects

### 1. Liver Distribution Redesign Modeling (Redistricting of Regions)

During the second public forum last June, the Committee received overwhelming feedback from the community that regional disparities in the MELD/PELD exception system are related to geographic disparities in access to transplant. In response to this feedback, the Chair presented the Committee with a 2016-2017 work plan to deliver on three interrelated projects that aim to improve equity in access to liver transplantation. By advancing proposals to establish a National Liver Review Board (or NLRB, currently out for first of projected two rounds of public comment) and revise HCC exception eligibility criteria (estimate August 2016 public comment), the Committee intends to build community consensus for the final redistricting proposal as well as optimize its benefits. The Committee anticipates releasing a redistricting proposal for public comment in August 2016.

## Committee Projects Pending Implementation

### 2. Reinstate Option to Override Unresolved Regional Review Board (RRB) Exception Requests

If the Regional Review Board does not approve an exception application within 21 days, current policy allows a transplant physician to register the candidate at the request MELD/PELD score following a conference call with the RRB. The case would then be automatically referred to the Liver and Intestinal Organ Transplantation Committee, and potentially the MPSC, for review. When this policy was first implemented in 2002, the physician could accomplish this by selecting the "no appeal/no withdrawal" button on the application after it was denied by the RRB. The button was inadvertently removed when a modification to the policy was subsequently implemented. In June 2009, the Board approved a proposal to reinstate the override button for unresolved exception requests. This is scheduled to be implemented on February 4, 2016. Within the next two weeks, Committee members will review and provide feedback on the final system notice.

## Implemented Committee Projects

### 3. Add Serum Sodium to the MELD Score

In June 2014, the Board approved a policy to modify the MELD score to include serum sodium concentration, which is an important predictor of survival among candidates for liver transplantation. On January 11, 2016, the MELD score was recalculated to incorporate serum sodium for candidates with a MELD score greater than 11. Programs

were given a 7-day grace period during implementation for candidates whose scores moved from one recertification category to give them time to obtain and report updated lab values.

Some patients and professionals have noticed that third party MELD calculators do not produce the correct MELD score now that serum sodium has been added. The MELD calculator available on the OPTN website will always produce results consistent with UNetSM. Please refer your patients to the MELD calculator on the OPTN website or double check your center's calculator to ensure its accuracy.

**4. Cap the Hepatocellular Carcinoma (HCC) Score at 35**

Despite modifications to increase equity among all candidates, candidates with Hepatocellular Carcinoma (HCC) exceptions still have significantly higher transplant rates and lower dropout rates (i.e., removal from the waiting list for death or being too sick) than non-HCC candidates. On October 8, 2015, the OPTN implemented the policy to cap the HCC exception score at 34. Candidates with HCC exceptions automatically receive exception points every three months. Capping the score at 34 prevents HCC candidates with multiple extensions from receiving offers under the "Share 35 Regional" policy.

After implementation, the Committee identified a conflict in policy regarding PELD candidates. Current policy states that after the 6 month delay, candidates less than 12 years old will receive a PELD 41 but then policy also states that all HCC scores will be capped at 34.

Although the public comment proposal and briefing paper clearly state that the scores will be capped at MELD/PELD 34, the Committee did not intend for the cap policy to apply to pediatric candidates, including adolescents with MELD scores. Since HCC is predominantly an adult disease, there is little evidence to suggest children exhibit similar dropout rates to adults. When modeling the proposed solution during the development of this proposal, PELD candidates were not capped. Furthermore, the intention of the cap policy was to prevent adult HCC candidates from receiving offers under the "Share 35 Regional" policy.

From January 1, 2014 through October 31, 2015, there were only 12 children less than 12 years old registered with an HCC exception. Of these only 3 had scores that were eventually greater than PELD 34. Only 4 of the 12 candidates met standardized exception criteria in policy and would have been subject to the automatic cap. As of January 21, 2016, no HCC candidates less than 12 years old have been capped since the implementation of this policy.

As an interim solution, the Committee is requesting a policy clarification that achieves the following:

- Candidates less than 12 years old receive a PELD 41 upon submission of the second extension.
- Candidates less than 12 years old do not have a cap on their subsequent extension scores. Only candidates with a MELD score are capped at 34.

The Committee will propose future modifications to exclude all HCC candidates less than 18 years old from both the 6 month delay in exception score assignment and the cap on the maximum score assignment upon extension. The Committee anticipates releasing these modifications for public comment in August 2016 as part of the proposal to revise HCC exception eligibility.

## Other Significant Items

### 5. Delegate Review of Cholangiocarcinoma (CCA) Patient Care Protocols

In order for a liver candidate to be approved for a standardized MELD/PELD exception for cholangiocarcinoma (CCA), Policy 9.3.E requires the candidate's transplant hospital to have a written protocol for patient care. The Committee unanimously voted to delegate responsibility for reviewing these protocols to a subcommittee appointed each July by the Chair.

## Upcoming Meetings

- February 25, 2016
- March 17, 2016