OPTN/UNOS Liver and Intestinal Organ Transplantation Committee Meeting Minutes November 2, 2017 Conference Call

Julie Heimbach, MD, Chair James Trotter, MD, Vice Chair

Introduction

The OPTN/UNOS Liver and Intestinal Organ Transplantation Committee met by conference call on 11/2/2017 to discuss the following agenda items:

- 1. HCC Implementation
- 2. Review of Current Policy Language Enhancing Liver Distribution Proposal
- 3. Variances

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

1. HCC Implementation

The Committee discussed an item related to the upcoming implementation of the *Changes to HCC Criteria* proposal.

Summary of discussion:

Prior to the meeting the Committee had been asked to respond to a request by UNOS Staff regarding the upcoming implementation of the *Changes to HCC Criteria* proposal. The HCC project included changes to the schedule of scores for pediatric HCC candidates. With the NLRB project to be implemented in 2018, the pediatric score schedules would change again, assigning a MELD or PELD score of 40 for all pediatric HCC cases. UNOS Staff raised the question whether implementing the new NLRB approved score assignment (MELD/PELD 40) for pediatric HCC cases should be implemented with the December 12th release of the HCC, instead of changing the policy on scores twice over the next several months.

Prior to the call, the Committee submitted feedback that uniformly agreed to provide pediatric HCC candidates with the score from the NLRB proposal, a MELD/PELD of 40. During the call, there was little discussion and the committee agreed on this implementation decision.

2. Overview of Data

The Committee discussed several items related to the current policy language for the *Enhancing Liver Distribution* proposal.

Summary of Discussion:

Following the in-person meeting in Chicago on October 10th 2017, UNOS staff identified areas of the final proposal that required clarification by the full committee and a second vote. The table in policy that describes the proximity points was re-organized to better explain the policy that the committee approved. This change was supported without further comment. The policy regarding waiting time sorting within each classification, was clarified to indicate that the "waiting time at the current or higher MELD or PELD score" excluded proximity points. The Committee agreed with this change without further comment. Within the allocation tables, UNOS staff reorganized the policy regarding the sharing threshold in Classification 3 of adult liver, and liver-intestine allocation. This change was done to provide clarity and maintain the intent of the Committee. The Committee agreed with this change with this change without further comment.

The Committee reviewed the policy language regarding allocation of livers by blood type. Current policy indicates that Status 1A or 1B candidates, or candidates with a MELD or PELD score greater than or equal to 30, transplant hospitals may specify if those candidates will accept a liver from a donor of any blood type. Due to the introduction of proximity points with the current liver proposal, the Committee needed to clarify whether the threshold of MELD/PELD 30 included proximity points (candidates with a MELD or PELD of 27) or needed to be specific to only refer to candidates with an allocation MELD or PELD of 30 (not include proximity points). Several committee members stated that the threshold should be based on a MELD of 30, without including proximity points. This would keep the policy the same as currently implemented policy. The Committee agreed to keep the intent of this policy the same, and add "Allocation" to the policy to emphasize that this threshold does not include proximity points.

UNOS staff presented a situation involving an import match under the new paradigm of "Region or Circle" allocation. This situation involves how to handle a liver that has traveled to an intended recipient, the intended recipient is not transplanted, the Host OPO then releases the liver to the OPO of the recipient's DSA, and a new match is run. The Committee was presented with several options on how to handle this situation with the introduction of the 150 nautical mile circle and proximity points in the current proposal. Several committee members stated that the added complexity to change the policy regarding import matches was not necessary. A committee member stated that changing the original proximity circle on the second match run could influence "gaming" and lead to unintended consequences. The Committee agreed that there would be no change to policy regarding import matches. Proximity points are provided candidates in the circle and DSA of the original donor hospital in the situation of an import match.

The Committee discussed voting on the final policy language of the proposal, however there was not a quorum of the Committee present to vote. The Committee agreed to revisit the vote on an upcoming conference call.

3. Variances

The Committee discussed the currently programmed liver variances and their relation the current proposal.

Summary of Discussion

There are 5 current variances to liver allocation. The split liver variance is not being addressed as part of the Committee's current review of liver variances. Regions 1 and 10 share for Status 1 patients on a common regional list. Pediatric donor livers are offered first to Status 1 patients within Region 1 and 10. Current policy has separate classifications for the DSA and Region with regards to allocation to Status 1A candidates for this subset of donor livers. The current proposal allocates regionally for Status 1A candidates for pediatric donors, therefore this variance is encompassed in the current proposal. Due to no longer serving its purpose as a variance to the national system, the Committee discussed that these variances would be terminated pending board approval and implementation of the current proposal.

The Hawaii DSA in Region 6 uses the standard distribution and allocation system with the following exception. Liver candidates with compatible blood types are included with identical blood types for blood type O donors. A committee member asked if this variance applies to candidates in Puerto Rico. UNOS staff replied that the variance was unique to Hawaii. The Committee members stated that the Puerto Rico program may be interested in a similar variance in the future. Due to its unique application and the variance's concurrence with the

current proposal, the Committee discussed extending the HIOP variance pending board approval and implementation of the current proposal.

Region 9 utilizes the standard distribution and allocation system for allocating livers with the following exception. As New York composes most of Region 9, the BOD approved an alternative local unit where "Statewide" classifications replace the DSA and Regional classifications. New York essentially shares all livers throughout Region 9. A committee member asked why this variance should continue. A Committee member stated that his variance has been in place for a long time and since it broadens sharing the Committee should discuss how to amend this variance in light of the new proposal. A committee member stated that the other statewide variances had previously been eliminated. However, another committee member replied that the New York situation is different because although it is a state, New York also serves as the majority of Region 9 (Vermont is included in Region 9 but does not have a liver program).

A committee member stated that they were surprised that variances still existed and that their region would likely be opposed to this variance, but they would need to discuss it with the region. A committee member stated that this variance has existed for over 20 years and without supporting the variance the current proposal would create a new disparity within Region 9, particularly in regards to the liver program in Rochester, NY. A committee member specified that it would be important to have consensus in Regions 1 and 2 since candidates in these regions would be within the circle of a donor in region 9, and thus this variance would affect them.

As stated previously on the call, there was not a quorum of the committee present necessary to take a vote on the variances. The Committee agreed to revisit the vote on an upcoming conference call.

Upcoming Meetings

- November 8th, 2017 Conference Call
 December 21st, 2017 Conference Call

Attendance

• Committee Members

- o Sandy Florman
- o Jennifer Watkins
- o William Chapman
- o Julie Heimbach
- o Shimul Shah
- o George Loss
- o Joe Roth
- Scott Biggins
- Sarah Schwarzenberg
- o James Trotter

• HRSA Representatives

- o Jim Bowman
- o Chris McLaughlin
- o Robert Walsh
- o Monica Lin
- SRTR Staff
 - o Bert Kasiske
 - o John Lake
- Other Attendees
 - o Yolanda Becker