OPTN/UNOS Liver & Intestinal Organ Transplantation Committee Meeting Summary December 15, 2016 Conference Call

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Discussions of the full committee on December 15, 2016 are summarized below. All committee meeting summaries are available at https://optn.transplant.hrsa.gov.

Committee Projects

1. National Liver Review Board (NLRB) Guidance Documents: Hepatocellular Carcinoma (HCC) Exception Guidance, Pediatric Exception Guidance and Adult Exception Guidance

The Vice Chair of the Liver and Intestinal Organ Transplantation Committee (Committee) presented an update on the NLRB Guidance Documents public comment proposal that includes Hepatocellular Carcinoma (HCC) Exception Guidance, Pediatric Exception Guidance and Adult Exception Guidance. These guidance documents build upon the proposed NLRB structure that was previously distributed for public comment in January 2016. The Committee will consider/incorporate public feedback in 2017 and the full Committee will meet in March and review the NLRB Guidance and vote whether or not to send the NLRB Guidance to the OPTN/UNOS Board of Directors in June of 2017 for approval.

Adult MELD Exception Guidance

The Committee previously met in November and approved the Adult MELD Exception Guidance to be sent back out for a second round of public comment in January of 2017. The guidance document will help Review Board members make consistent decisions regarding the award of exceptions for adult candidates (18 years old or greater) with various conditions that do not meet the criteria for standardized exceptions in policy.

Pediatric MELD/PELD Exception Guidance

Liver candidates less than 18 years old receive a MELD or PELD score that is used for liver allocation. The score is intended to reflect the candidate's disease severity, or the risk of 3-month mortality without access to liver transplant. Currently there is no guidance to help review board members make decisions on pediatric exception requests. A group of pediatric liver transplant experts have been meeting to create such a document, and it was presented to the Liver Committee for review. The Committee members discussed, reviewed and approved the language for the Pediatric MELD/PELD Exception Guidance.

The Committee approved the Pediatric MELD/PELD Exception Guidance (16 support, 0 opposed, 0 abstentions) to send for Public Comment in January 2017.

Hepatocellular Carcinoma (HCC) Exception Guidance

Exception requests for candidates with HCC are the most common MELD exception. Though the Board approved changes to criteria for standardized HCC exceptions at its December 2016 meeting, there are candidates that will not meet the new criteria that will submit non-standardized exception requests to the review board. This guidance document will help the review board make consistent decisions in response to these requests. The Committee discussed the HCC Exception Guidance language and recommendations submitted by Subcommittee for the guidance document. The Committee provided additional recommendations for the HCC exception review board considering cases which are outside standard exceptions. After discussion a vote was taken to approve the language and changes as written in the document.

The Committee approved the HCC Exception Guidance (15 support, 0 opposed, 0 abstentions) to send for public comment in January 2017.

Upcoming Meeting

• December 29, 2016