

**OPTN Liver and Intestinal Organ Transplantation Committee
National Liver Review Board (NLRB) Subcommittee**

June 4, 2025

Conference Call

James Pomposelli, MD, PhD, Chair

Introduction

The OPTN National Liver Review Board Subcommittee (the Subcommittee) met via WebEx teleconference on 06/04/2025 to discuss the following agenda items:

1. Continuous Distribution & Review Boards

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

1. Continuous Distribution & Review Boards

The Subcommittee discussed operational decisions related to review boards.

Summary of discussion:

The Chair wondered if there were opportunities to streamline or automate approval processes for certain diagnoses that have high approval rates by the NLRB. A member suggested that HCC exceptions where a candidate received treatment and the transplant program reports no tumor should be automatically approved.

Another member expressed interest in the implementation of the Adult Transplant Oncology Review Board. They asked to see data on the distribution of cases as well as the number of cases individual reviewers are reviewing. The member added that data on approval, denial, and appeal rates would also be helpful to review. Another member asked how many members are on the Adult Transplant Oncology Review Board.

The following discussions were in context of the NLRB operations for non-standard exceptions.

The Subcommittee considered the number of reviewers assigned to each case. Currently, five review board members are assigned to review a non-standard exception request. A member stated that five is sufficient. The member explained that adding more reviewers to a case would increase burden on the review board members. The member also supported maintaining an odd number of reviewers to ensure there are no ties.

The Subcommittee considered adjusting the timeline for non-standard exception review. Currently, the review board has 21 days to vote on a non-standard exception case. The Chair noted this seems like a long timeframe. Staff added that recent data shows the majority are voted on within the first week and very few cases remain open at the 21 day mark. A member stated they had some concern about shortening the timeframe because the purpose of the NLRB is to vote and not have non-standard exceptions automatically be assigned. The Chair stated that it is not right to penalize a candidate because the NLRB did not function correctly. Some members voiced support for shortening the review timeline to 14 days.

The Subcommittee considered the definition of majority. Currently, the definition of a majority vote for a non-standard exception is four affirmative votes out of five. Members considered updating the definition of majority to be “simply more than half”. A member noted that this would mean three out of five votes could approve a non-standard exception request which would be one less than the current state. Another member noted that the historic reason for the current four affirmative votes out of five was to ensure a super majority. The member noted that modifying it to be “simply more than half” would be more efficient. Members expressed interest in reviewing data to understand how many more cases may have been approved if the definition of majority was “simply more than half”. Another member expressed interest in reviewing data on approved vs denied exceptions within each review board.

The Subcommittee discussed whether extensions and expirations are needed for non-standard exceptions. A member noted that since liver allocation does not incorporate post-transplant survival and the first version of continuous distribution will also not incorporate it, extensions and expirations remain relevant. The member explained that through the extension processes, it can be reconfirmed that the candidate remains viable for transplant.

The Subcommittee discussed the prospective review of non-standard exceptions. A member stated it would be beneficial to understand whether this type of review is causing problems. To understand that, the member suggested reviewing data, if available, on the number of candidates who died or removed for too sick while a non-standard exception request was pending. The member suspected this was not a common occurrence and has never heard feedback on changing the prospective review to be a retrospective review. Members supported keeping the prospective review for non-standard exception requests.

The Subcommittee discussed the roles and responsibilities of NLRB reviewers. A member stated it is important to be clear on the responsibilities of being an NLRB reviewer to ensure that there is active and engaged participation. The members agreed that having a primary and alternate are appropriate. A member noted that it may be difficult for transplant programs to find two individuals able to both commit as primary representatives. Another member also stated that one-year terms are sufficient as it is easier to commit to than a longer term. Members supported keeping processes defined for removing unresponsive reviewers. Members noted that it is not a common occurrence, and it is important to ensure that reviewers of the NLRB remain engaged, and transplant programs are responsible for their participation.

The Subcommittee discussed the role of the NLRB Chair. Currently, the NLRB Chair is the past Chair of the OPTN Liver & Intestinal Organ Transplantation Committee and serves for two years. A member noted that the original intent was likely based on continuing to have historical knowledge and expertise but now that the NLRB has been established for a while this likely may not be as necessary. Members supported allowing the NLRB Chair to be an active Committee member that is in their third term. This would be a one-year term as NLRB Chair.

The following discussions were in context of appeals for non-standard exceptions.

Members supported the current appeals timeframes and have not heard feedback on any specific improvements that may be warranted.

A member suggested that it may be helpful to allow the alternative to observe the Appeals Review Team (ART) calls. The member stated that the transplant program would only be able to vote once but having both the primary and alternative representative may help the alternate representative be prepared when it is their turn to be the primary representative. Other members agreed.

The Subcommittee discussed the term lengths for the ART representatives. Currently, a representative serves a one-month term. Members noted that the time commitment is difficult, and it may be hard to find individuals that are able to commitment for longer than a month.

The Subcommittee discussed who should be allowed to be an ART leader. Currently, ART leaders must be current Committee members. A member stated that it is important to have Committee members act as ART leaders because they are most familiar with the policies and processes. Another member suggested that it could be expanded to include current and past Committee members to expand the pool of individuals capable of being ART leaders.

The Subcommittee discussed the definition of majority for appeals. The current definition is for an appeal reviewed by the NLRB, it must review four out of five affirmative votes. For an ART review and Committee review of appeals, it must receive majority plus one affirmative votes. A member stated that having four out of five affirmative votes for the first appeal reviewed by the NLRB makes sense because a having a high bar is important. Another member stated that the Subcommittee was considering modifying the definition of majority for NLRB review to be majority plus one (i.e. three affirmative votes out of five). A member stated it would not make sense for the initial NLRB review to have a different threshold than the initial appeal review by the NLRB.

Next steps:

The Subcommittee will continue to discuss this topic.

Upcoming Meetings

- TBD

Attendance

- **Subcommittee Members**
 - Aaron Ahearn
 - Allison Kwong
 - Cal Matsumoto
 - Chris Sonnenday
 - James Pomposelli
 - Neil Shah
 - Scott Biggins
 - Shimul Shah
- **SRTR Staff**
 - David Schladt
 - Jack Lake
 - Katie Siegert
- **UNOS Staff**
 - Alina Martinez
 - Ben Schumacher
 - Betsy Gans
 - Joel Newman
 - Matt Cafarella
 - Meghan McDermott
 - Niyati Upadhyay