

National Liver Review Board Operational Guidelines

1. Overview

The purpose of the National Liver Review Board (NLRB) is to provide fair, equitable, and prompt peer review of exceptional candidates whose medical urgency is not accurately reflected by the calculated MELD/PELD score. The NLRB will base decisions on policy, the guidance documents, and in cases which lack specific guidance, the medical urgency of the candidate as compared to other candidates with the same MELD or PELD score adjustment or specific MELD or PELD score.

The NLRB is comprised of specialty boards, including:

- Adult Transplant Oncology
- Adult Other Diagnosis
- Pediatrics, which reviews requests made on behalf of any candidate registered prior to turning 18 years old

The immediate past-Chair of the Liver and Intestinal Organ Transplantation Committee serves as the Chair of the NLRB for a two year term.

2. Representation

Every active liver transplant program may appoint a representative and alternate to each of the adult specialty boards. A liver transplant program with an active pediatric component may appoint a representative and alternate to the pediatric specialty board. Individuals may serve on more than one specialty board at the same time. Transplant programs are encouraged to appoint representatives from both hepatology and surgery who have active transplant experience. Liver transplant programs are not required to provide a representative to the NLRB.

Representatives and alternates serve a one year term. A liver transplant program may appoint the same representative or alternate to serve consecutive terms.

If a transplant hospital withdraws or inactivates its liver program, it may not participate in the NLRB. However, the transplant hospital's participation may resume once it has reactivated its liver program.

3. Representative and Alternate Responsibilities

Prior to each term of service, representatives and alternates are required to sign the *OPTN Confidentiality and Conflict of Interest Statement* and complete orientation training.

Representatives must vote within 7 days on all exception requests, exception extension requests, and appeals. A representative will receive an e-mail reminder after day 3 and day 5 if the representative has an outstanding vote that must be completed. On the eighth day, if the vote has not been completed, then the request will be randomly reassigned to another representative. The original reviewer will receive a notification that the request has been reassigned.

The representative must notify the OPTN in the OPTN Computer System of an absence, during which the alternate will fulfill the responsibilities of the representative.

If a representative or alternate does not vote on an open request within 7 days on more than 5% of the cases assigned to that reviewer within a 6 month period, the Chair may remove the individual from the NLRB. If a representative or alternate does not vote because a case is approved and closed before the 7 day timeframe expires, it is not considered a failure to vote. A representative or alternate who has been removed for failure to perform the duties required is not eligible to serve again for 3 years.

If a transplant program exhibits a pattern of non-responsiveness, as evidenced by the removal of two members from the NLRB, the Chair may suspend the program's participation for a period of three months after notifying the program director. Further non-compliance with the review board process may result in cessation of the program's representation on the NLRB until such a time as the transplant hospital can satisfactorily assure the Chair that it has addressed the causes of non-compliance.

4. Voting Procedure

An exception request is randomly assigned to five representatives of the appropriate specialty board. A representative may vote to approve or deny the request, or ask that the request be reassigned. The request must achieve four out of five affirmative votes in order to be approved. If the request does not achieve the necessary four affirmative votes, it is denied.

As part of the MELD/PELD Exception program in the OPTN Computer System, NLRB members are notified of new cases by email.

Voting on an exception request is closed either at the end of the appeal period or when no additional votes will change the outcome of the vote, whichever occurs earlier. Members no longer have the ability to vote once a request is closed.

5. Appeal Process

A liver program may appeal the NLRB's decision to deny an exception request. Candidates are not eligible to appeal exception requests. All reviewer comments are available in the OPTN Computer System. The NLRB advises programs to respond to the comments of dissenting reviewers in the appeal.

The same five members that reviewed the original request will review the appeal. The appeal must achieve four out of five affirmative votes in order to be approved. If the appeal does not achieve the necessary four affirmative votes, it is denied. If the appeal is denied, the liver program may request a conference call with the Appeals Review Team (ART).

If the ART denies the request, the liver program may initiate a final appeal to the Liver and Intestinal Organ Transplantation Committee (Liver Committee). Referral of cases to the Liver Committee will include information about the number of previous referrals from that program and the outcome of those referrals.

6. Appeals Review Team (ART)

At the beginning of each new service term, nine NLRB members from the Adult Other Diagnosis and Adult Transplant Oncology specialty boards are assigned to serve each month of the year on the Adult ART and nine NLRB

members from the Pediatric specialty board are assigned to serve each month of the year on the Pediatric ART. There may be multiple ARTs, depending on the volume of cases. Each ART will be scheduled to meet via conference call according to a predetermined schedule.

ART appeals from the Adult Other Diagnosis and Adult Transplant Oncology specialty boards will be reviewed by the Adult ART. ART appeals from the Pediatric specialty board will be reviewed by the Pediatric ART.

In the event of a planned absence, the ART member may designate their alternate to serve. The representative must notify the OPTN of this in the OPTN Computer System.

Five members of the ART must participate in the call. If at least five members do not attend the call, the appeal will be rescheduled for the following regularly scheduled conference call. If at least five members do not attend the second attempt to review the appeal, the candidate's exception request is automatically approved.

The appeal must achieve a majority plus one affirmative votes in order to be approved.

A representative at the petitioning program may serve as the candidate's advocate. If a representative is unable to attend the conference call, the program may ask for the appeal to be scheduled for the following regularly scheduled conference call. If after two attempts a representative is unable to attend the call, the ART will review the appeal without the program's participation. In the absence of a representative on the conference call, the program may submit written information for the ART's consideration.

A current member of the Liver Committee serving on either the Adult Other Diagnosis specialty board or Adult Transplant Oncology specialty board will be appointed to serve as the ART leader for the Adult ART prior to each service term. A current member of the Liver Committee or current member of the OPTN Pediatric Transplantation Committee (Pediatric Committee) serving on the Pediatric specialty board will be appointed to serve as the ART leader for the Pediatric ART prior to each service term. If no current member of either the Liver Committee or the Pediatric Committee is available to serve as the ART leader, prior members of each Committee or other members of the NLRB may be appointed to serve as ART leader. The ART leader will be prepared to lead ART discussion and provide feedback to the Liver Committee.

The ART will work with the OPTN to document the content of the discussion and final decision in the OPTN Computer System.

7. Liver Committee Review

The Liver Committee may delegate review to a subcommittee. If the review is delegated, majority is based on the size of the subcommittee.

Appeals to the Liver Committee will be considered electronically unless at least one member of the Liver Committee requests a conference call. If the case is discussed on a conference call, quorum is a majority of the Liver Committee (or the subcommittee, if delegated).

The appeal must achieve a majority affirmative votes in order to be approved.