

LIVER REGIONAL REVIEW BOARD OPERATIONAL GUIDELINES

Revised: 10/2009

1. Purpose

The purpose of regional review is to provide prompt peer review of exceptional cases not addressed by the MELD/PELD score.

2. Representation

- A. There shall be a minimum of three physicians on the board representing adult and pediatric, active liver transplant programs. Each active liver transplant program shall have the opportunity to be represented on the regional review board. On a national basis, the representatives on the Regional Review Boards (RRBs) vary in number. Since larger boards may pose operational/administrative problems, some of the RRBs rotate the membership to ensure that each program is represented on the Board for one term. Each region shall determine the length of "one term". The frequency of rotation will be determined by each region. There should be representation from both hepatology and surgery on the board. An individual involved in pediatric transplantation should also be included on pediatric cases; although the logistics of such representation may be challenging. The region may choose to include the regional representative to the Liver and Intestinal Organ Transplantation Committee on the review board as an organizational/continuity measure. In most cases, the regional representative to the Liver and Intestinal Organ Transplantation Committee will serve as the Regional Review Board Chair

Other health care providers, including non-transplant physicians may be included, such as one non-medical (public) representative as non-voting members to serve the purpose of public oversight. The non-transplant representatives should be familiar with transplant issues. Suggested sources for these representatives include medical ethics, public servants involved in health care policy, clergy, patients and donor family members. A possible source of these individuals would be those with previous OPTN/UNOS committee experience. Review board members who are appointed as General Public Members should not be employed by a member center having an active liver program.

- B. Each review board member is required to have **one or more alternate representatives** identified to UNOS and to the Review Board chair, to be contacted if the representative is not available for more than 72 hours. It is the responsibility of each member center to provide UNOS with the contact information for the review board member by providing the information for both the primary representative and the alternate representative to the UNOS Membership Department in writing through their Site Administrator. Should a representative leave their transplant center, then the center's alternate representative will become the permanent representative. If a regional chair should leave their center, the alternate still becomes the permanent representative and a new alternate is chosen. A member center may also appoint a new permanent representative and continue with the same alternate. An alternate member replacing a chair does not serve out the term as chair unless designated by the Regional Councilor or the RRB as described in 2A. Each Review Board should have an alternate chair to break a tie in the event that the case was submitted by the chair's center and no majority resolution is possible; it is recommended that immediate past Review Board chair serve as the alternate chair.
- C. If a member center withdraws or inactivates its liver program, it is no longer entitled to representation on the regional review board. The term of the member center's representative on the review board ends upon withdrawal or inactivation. Should a program reactivate, the member center shall again have representation on the regional review board.
- D. Each review board Chair shall be an active liver transplant practitioner but may not be required to represent his/her center as a review board member.

3. Responsibilities of the Review Board Members

- A. Vote, within 72 hours, on all MELD/PELD exception applications. If a majority vote has not been reached by the RRB within 21 days, the patient's transplant physician may choose to withdraw the application; otherwise, the patient will be assigned the most recently requested MELD/PELD score and the case will be referred to the Liver and Intestinal Organ Transplantation Committee. During this 21-day period, the center may opt to appeal a case that has been denied or found to be indeterminate (tied) by the RRB.
- B. Vote within 72 hours on all appeal cases. Appeals of RRB decisions will be submitted to the RRB for review both electronically (MELD/PELD) within 21 day timeframe.
- C. Prompt appointment of alternates. If an RRB member is unavailable at any time to review the exceptional case application, an alternate reviewer at their program should be designated and the appropriate arrangements within their office and with the UNOS office should be made to provide this individual with appropriate UNetSM site privileges.

UNOS staff will contact any members who have not voted on a case within 7 days of submission to the Review Board and notify the chair so that he/she may also contact the member. If the member is unavailable then UNOS staff will contact the alternate and notify the chair. If no alternate is available then the chair may be asked by UNOS staff to vote in order to close the case.

If a review board member:

- does not vote on a case in which the outcome is "failed to reach majority vote within 21 days;"
- on three separate instances within a 3 month period; and,
- has failed to give prior notification of his/her unavailability,
- the Chair has the authority to replace the non-responding member with an alternate.

If a center has a pattern of non-response as evidenced by the removal of two or more members from the review board, the chair may suspend the center'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 center's representation on the Review Board until such a time as the non-responding member center can satisfactorily assure the Chair of its willingness to participate in the system. The center may also be referred to the Liver and Intestinal Organ Transplantation Committee.

- D. All Review Board members and alternates will be required to sign a UNOS Confidentiality/Conflict of Interest Statement prior to service on the RRB.

4. Voting Procedures

A. Initial Review of MELD/PELD Exceptions

As part of the MELD/PELD Exception program in UNetSM, RRB members will be notified of new cases via electronic mail. Thus, RRB members must notify UNOS staff if they will not be available by e-mail for any reason (e.g., vacation) or if their e-mail address changes. Furthermore, all RRB members must have UNetSM access in order to fulfill their role on the RRB.

In order to access cases to be reviewed, click on the link in the e-mail that is sent to the member or go to <https://www.unet.unos.org/>, log in using the member's UNetSM username and password, and click on "Waitlist" and "RRB" in order to access the regional review board area.

Voting on an exception request is closed when no additional votes will change the outcome of the vote. Potential voting outcomes are appropriate, not appropriate, or indeterminate (tie) votes.

The chair will have the option to break a tie vote either positively - in which case the requested score is granted - or negatively - in which case the listing program may appeal. Once voting has closed on a case, the member will no longer have the ability to vote on that case (the vote "button" is no longer operational).

In cases in which neither the regular board member nor the alternate can be reached for 72 hours, the chair will also be allowed to make the final decision on the outcome of a case as long as the chair is from a different institution than the requesting center and is non-voting.

Requested MELD/PELD exception scores are not granted until the review board approves the request (except for HCC exceptional cases as specified under Policy 3.6.4.4 (Liver Transplant Candidates with Hepatocellular Carcinoma (HCC)), so a timely response is critical. If a representative does not expect to be able to access cases and conduct reviews for any period exceeding 72 hours, RRB members must arrange for an alternate for their program.

B. Exceptional case requests for diagnoses included in 3.6.4.5.1 – 3.6.4.5.6

Exception applications for liver candidates with hepatopulmonary syndrome, cholangiocarcinoma, cystic fibrosis, familial amyloid polyneuropathy (FAP), primary hyperoxaluria, or portopulmonary syndrome, meeting the criteria specified in 3.6.4.5.1-3.6.4.5.6, will be submitted to the RRB chair. The chair will determine, based on the information contained in the clinical narrative, whether the case meets the criteria in policy and is eligible for the applicable higher MELD/PELD score (initial applications and extensions). If the chair determines that the case meets the criteria, UNOS RRB staff will mark the case as 'approved.' If the chair determines that the case does not meet criteria, then the case will be submitted to the RRB for a vote. If the case originates from the chair's center, the alternate chair will decide on the case. If the alternate chair is unavailable, the case will be submitted to the RRB.

B- C. Appeal process

Member centers supporting the application of candidates whose listing or status upgrade is deemed inappropriate by the process described above may then appeal the decision of the review board. Additional information supporting the member request on behalf of the candidate and responding to the comments of dissenting reviewers will be submitted to the Review Board members for further consideration. All reviewer comments will be made available in UNetSM. If the appeal is not approved, at the request of the member center a telephone conference may be arranged between the board and a practitioner at the listing center serving as the candidate's advocate as soon as possible. The chair should work with UNOS staff to ensure that any decision of the RRB rendered during a conference call is captured in UNetSM and accurately reflect the comments of the reviewers who participated on the call; the conference call will be tape-recorded and archived at UNOS.

MELD/PELD exception application appeals may be submitted an indefinite number of times as long as the appeal is submitted within 21-days of the original submission date of the initial request.

If a pediatric case is appealed, pediatric representation is required on the conference call. If no pediatric surgeon or physician is eligible to vote on the case in the Region, one may be selected from another region to assist in the RRB's deliberation in a non-voting capacity at the request of the Review Board chair.

Status 1 listings not meeting the criteria in Policy 3.6 will be referred to the Liver and Intestinal Organ Transplantation Committee.

For MELD/PELD cases, the listing center may initiate a final appeal to the Liver and Intestinal Organ Transplantation Committee or the RRB may refer a case to the Liver and Intestinal Organ Transplantation Committee if the final outcome of the regional appeal is negative or split without a way to achieve a decisive vote (indeterminate outcome). The RRB may also refer a case to the Liver and Intestinal Organ Transplantation Committee if the listing center does not respond to requests for a

statement of intent to appeal, or to subsequent requests to submit additional information in support of the appeal. Referral of cases to the Liver and Intestinal Organ Transplantation Committee will include information about the number of previous case referrals from that center and the outcome of those referrals. Based on the finding of this review, the Liver and Intestinal Organ Transplantation Committee may refer the center to the Membership and Professional Standards Committee for disciplinary action. The Membership and Professional Standards Committee will have the option of determining that no action is required

Individual patients are not eligible to appeal board rulings. Listing centers will submit applications and appeals on behalf of their candidates.