

At-a-Glance

- **Proposal to modify the bylaws pertaining to *conditional approval status for liver transplant programs that perform living donor transplants***
- **Bylaw affected: Attachment I, Appendix B, Section D, (4) *Liver Transplant Programs that Perform Living Donor Liver Transplants* of the OPTN/UNOS Bylaws**
- **Membership and Professional Standards Committee**
- The proposed modification to the bylaws will clarify the expectation that the transplant center must inactivate or stop performing living donor liver transplants when transplant program personnel do not fully satisfy the criteria for full program approval by the end of the conditional approval period.
- **Affected groups:** Members transplant centers that perform or intend to perform living donor liver transplants.
- **Specific requests for comment**

Does this additional language clarify the existing options for liver programs that perform living donor transplants that are reaching the end of their conditional approval period?

Input is not being sought at this time on the option of conditional approval itself.

Proposal to modify the bylaws pertaining to conditional approval status for liver transplant programs that perform living donor transplants.

Bylaw affected: Attachment I, Appendix B, Section D, (4) *Liver Transplant Programs that Perform Living Donor Liver Transplants* of the OPTN/UNOS Bylaws

Membership and Professional Standards Committee

Summary and Goals of the Proposal:

The proposed modification to the bylaws will clarify the expectation that the transplant center must inactivate or stop performing living donor liver transplants when transplant program personnel do not fully satisfy the criteria for full program approval by the end of the conditional approval period.

Background and Significance of the Proposal:

The bylaws currently provide the option of conditional approval for programs that do not have a second living donor liver surgeon who fully meets the criteria as specified in the bylaws. However, the bylaws do not clearly delineate the path forward for programs that reach the end of the two-year conditional approval period (initial year plus a one-year extension) and still do not meet the requirements for full approval. The Committee agreed that it was important for the members to understand their options when facing this situation. Amending the bylaws should provide this clarity. The recommended changes are consistent with other sections of the bylaws and the current procedures followed by the Committee relative to programs that are not fully approved. When a term-limited approval status ends, a program is expected to fully meet the requirements, inactivate, or relinquish designated program status.

Background:

The approval process for programs performing living donor liver transplantation began in 2005, and since that time, 19 of the 72 liver programs that perform living donor liver transplants have been approved under this conditional option. Half of these programs have already achieved full approval and several have inactivated or withdrawn designated program status. Programs that have already passed their term end dates have been notified of their options – to fully meet the requirements, inactivate, or relinquish designated program status for the living donor liver component of their transplant program.

Inclusion of the proposed language in the bylaws provides a clear interpretation for the members by stating the options available to a program when it reaches the end of its conditional approval term. The Committee has been making an effort to develop bylaw language that is more helpful to the members as it continues to conduct an incremental rewrite of the bylaws. The proposal does not reflect a change in the committee's methods for reviewing these programs but does codify the way it presently operates. In other conditional approval pathways in the bylaws (Appendix B, Attachment I, Section XIII, D) similar language is included in each organ specific section so this modification also provides greater consistency between sections.

Collaboration: The MPSC sought input from the Liver and Intestinal Organ Transplantation Committee on this issue and considered its response during the January/February 2008 Committee meeting. The Liver and Intestinal Organ Transplantation Committee recommended, "that programs that do not meet

the criteria for approval by the end of the second year of conditional approval should voluntarily inactivate the living donor aspect of their program.” It further supported the MPSC’s proposal to add this language to the bylaws and further suggested that any changes to a program’s key personnel during the approval process should require the submission of a new application.

Supporting Evidence and/or Modeling:

This proposal clarifies existing bylaw language. Therefore, supporting evidence is not available or required.

Expected Impact on Program Goals, Strategic Plan, and Adherence to OPTN Final Rule:

Strategic Plan Goal: Improve compliance with policies to protect patient safety and preserve public trust. This proposal clarifies existing bylaw language regarding conditionally approved programs and the MPSC’s review process. This proposal clearly defines member responsibilities and expectations and should improve compliance with bylaws.

OPTN Final Rule: This proposal comports with Section §121.9 Designated Transplant Programs Requirements.

Plan for Evaluating the Proposal:

The bylaw language will be reviewed on a continual basis to ensure that it provides clear direction to the members.

Additional Data Collection:

This proposal does not require additional data collection.

Expected Implementation Plan:

The proposed change to the bylaws does not necessitate a change in the Committee’s methods for reviewing the conditionally approved programs. The Committee will continue to review all applications from liver programs that:

- wish to perform living donor liver transplants; and
- that experience a change in primary surgeon or physician.

Applicants that meet the conditional approval pathway will continue to be informed of the need for meeting the full approval requirements by the end of the conditional period, and the options that are available to the center if it does not meet the requirements. A transplant center that has conditional approval to perform living donor liver transplants should be aware of its conditional approval term end date. Additionally, the center should continuously monitor its progress towards complying with the requirements for full approval by the end of the conditional term.

This proposal will not require programming in UNetSM.

Communication and Education Plan:

Communication Activities			
Type of Communication	Audience(s)	Delivery Method(s)	Timeframe
Policy Notice	Relevant parties from Transplant Centers that perform living donor liver transplantation	Email members and constituent group leaders with link to document as posted on the UNOS and OPTN websites. General public will have access to document on web site and be alerted to newsroom article on the splashpage	30 day after Board meeting.
Short brief/blurb in the UNOS Update Magazine (“A matter of policy” section)	All primary and secondary readers of Update	Standard mailing (postal)	Once the proposal modification is approved, the notice will go in the next Update scheduled to go to press.

We will consider additional communication methods as needed.

Monitoring and Evaluation:

Member progress towards meeting the requirements for full approval will continue to be monitored by the Committee through the submission of routine reports. The Committee will be able to determine through these reports and additional inquiries if the center will be able to qualify for full approval or if it will become necessary for the center to inactivate or relinquish designated approval of the living donor liver component of the liver transplant program. The procedures will not change because of the proposal.

Policy or Bylaw Proposal:

The MPSC approved the following resolution to submit the proposed Bylaw modifications for public comment:

RESOLVED, that the bylaws, Appendix B, Attachment 1, Section XIII, D, (4), c be amended as shown below.

The Committee voted 26 For, 0 Against, 0 Abstentions.

The Committee approved a second motion asking the Board of Directors to approve this modification to the bylaws concurrent with public comment.

RESOLVED, that the proposed modifications to the bylaws, Appendix B, Attachment I, Section XIII, D (4) c as set forth above, shall be approved June 20, 2008, and concurrent with public comment. FURTHER RESOLVED, that live donor liver transplant program criteria shall be applied retroactively to Living Donor Liver Transplant Program applications received since March 1, 2005.

The Committee voted 26 For, 0 Against, 0 Abstentions.

Proposal

Proposed Modification to OPTN/UNOS Bylaws, Appendix B, Attachment 1, Section XIII, D (4)

(4) Liver Transplant Programs that Perform Living Donor Liver Transplants.

a. No Changes

b. No Changes

c. Conditional Approval Status: If the transplant center does not have on site a second surgeon who can meet the requirement for having performed 7 live donor liver procedures within the prior 5-year period, but who has completed the requirement for obtaining experience in 20 major hepatic resection surgeries (as described above), as well as all of the other requirements to be designated as a primary liver transplant surgeon, the program may be eligible for Conditional Approval Status. The transplant program can be granted one year to fully comply with applicable membership criteria with a possible one year extension. This option shall be available to new programs as well as previously approved programs that experience a change in key personnel. During this period of conditional approval, both of the designated surgeons must be present at the donor's operative procedure.

The program shall comply with such interim operating policies and procedures as shall be required by the Membership and Professional Standards Committee (MPSC).

This may include the submission of reports describing the surgeon's progress towards meeting the requirements and such other operating conditions as may be required by the MPSC to demonstrate ongoing quality and efficient patient care. The center must provide a report prior to the conclusion of the first year of conditional approval, which must document that that the surgeon has met or is making sufficient progress to meet the objective of performing 7 live donor liver procedures or that the program is making sufficient progress in recruiting and bringing to the program a transplant surgeon who meets this criterion as well as all other criteria for a qualified live donor liver surgeon. Should the surgeon meet the

requirements prior to the end of the period of conditional approval, the program may submit a progress report and request review by the MPSC.

The transplant program must comply with all applicable policies and procedures and must demonstrate continuing progress toward full compliance with Criteria for Institutional Membership.

The program's approval status shall be made available to the public.

If the program is unable to demonstrate that it has two designated surgeons on site who can fully meet the primary living donor liver surgeon requirements [as described above] at the end of the 2-year conditional approval period, it must stop performing living donor liver transplants by either

- (i) inactivating the living donor part of the program for a period up to 12 months, or
- (ii) relinquishing the designated transplant program status for the living donor part of the liver transplant program until it can meet the requirements for full approval.

The requirements for making changes in program status are described in Section II, C.