This is an Addendum to the MPSC report, and contains additional action items recommended by the MPSC during its October 15-16, 2008, meeting.

OPTN/UNOS Membership and Professional Standards Committee Report
November 17-18, 2008
Summary - Addendum

Action Items for Board Consideration:

- The Board of Directors is asked to approve one new transplant center for kidney transplantation. (Item 1, Page 3).
- The Board of Directors is asked to approve designated program status for one new program in an existing member transplant center. (Item 1, Page 3).
- The Board of Directors is asked to approve continued membership for one medical/scientific organization. (Item 1, Page 3).
- The Board of Directors is asked to grant changes in status to four programs. (Item 1, Page 3).
- The Board of Directors is asked to approve modifications to Appendix B, Section II, C of the OPTN/UNOS Bylaws. These modifications will better define functional inactivity, voluntary inactive membership transplant program status, relinquishment of designated transplant program status, and termination of designated transplant program status. (Item 2, Pages 4-17).

Other Significant Items:

- The Committee reviewed the comments received in response to the proposed modifications to the Bylaws, Appendix B, Attachment I, Section XIII, D, (4) (Liver Transplant Programs that Perform Living Donor Liver Transplants), Part C (Conditional Approval Status). (Item 3, Pages 17-20).

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Report of the
OPTN/UNOS Membership and Professional Standards Committee
To the Board of Directors
Richmond, VA
November 17-18, 2008
James J. Wynn M.D., Chair
Carl L. Berg, M.D., Vice Chair

I. Regular Committee Meetings. The Membership and Professional Standards Committee (MPSC) met on October 15-16, 2008, in Chicago, Illinois. Its deliberations and recommendations are provided below. This report contains additional information and recommendations of the Committee and supplements the July meeting report also distributed to the Board.

1. Membership Application Issues: The Committee recommends that the Board of Directors approve one new transplant center and one new program in an existing member center. In addition to considering applications for institutional membership, the Committee reviewed an application for continued medical/scientific (two-year terms), and recommends approval by the Board of Directors.

   The Committee reviewed two transplant programs that had previously voluntarily inactivated and approved reinstatement of each program's active status. The Committee also reviewed change in key personnel applications for two programs and agreed that approval of the applications could be granted under conditional pathways.

   The Committee considered requests from four hospitals that asked to extend the inactive status of their programs beyond the initial one-year period. The current bylaws provide the option of an extension to the inactive status period if the center demonstrates to the Committee *"the benefit of such extension, together with a plan and timeline for re-starting transplantation at the program which shall include assurance that all OPTN membership criteria will be met at the time of re-starting transplantation."* The Committee approved one request and denied three that had not provided a well defined plan and timeline for reactivation.

2. Proposed Modifications to the OPTN and UNOS Bylaws, Appendix B, Section II, C, and Appendix B, Attachment 1 of the OPTN Bylaws: These proposed changes to the Bylaws will clarify the current definition of Functional Inactivity by including information about waiting list inactivation in UNet$^{sm.}$ The proposal defines short-term voluntary inactivation as inactivation of a program waiting list in UNet^{sm} for 14 days or fewer; and long-term voluntary inactivation as inactivation of membership status based on the expectation the program will remain inactive for greater than 14 days. These modifications also specify exactly what a member must do in terms of notifying candidates when a program voluntarily inactivates or relinquishes its designated program status (long-term inactivation).

   Background: The MPSC developed this bylaw proposal after an MPSC work group reviewed active OPTN members that inactivated their waiting list for more than 14 days. This work group reviewed existing bylaw language and observed that the bylaws did not reference waiting list inactivation and did not provide the center with details about notifying transplant candidates that they might not receive organ offers during the period that the waiting list is inactive. In reviewing existing bylaw language, work group members also noted concern with the process for candidate wait time transfer upon program inactivation.

If adopted, the modified bylaw language will clarify responsibilities for transplant programs and provide the MPSC with a way to monitor waiting list inactivation. The bylaw also ensures that candidates will not lose accrued wait time, consistent with organ specific policy, while the inactivated program works to transfer the candidate to an alternative transplant program. Candidates will be better informed of periods when organ offers will not be made to the transplant program on their behalf. These modifications provide Members with clear expectations when considering program inactivation.

The MPSC will monitor the frequency of waiting list inactivation and trends since bylaw adoption. The MPSC will evaluate the responses to its inquiries to active programs with inactive waiting lists, both those greater than 14 consecutive and/or 28 or more cumulative days in a 365-day period. These data can be captured through existing fields in UNet^{sm} and through the UNOS Research Department.

The Committee will also monitor how frequently members that inactivate a transplant program for the long-term meet waiting list transfer requirements.

The proposal was distributed for public comment from June 30 to September 24, 2008. Responses received and regional and committee discussions during the public comment period noted confusion with regard to the definitions of short-term and long-term inactivation as a "status" and the definition of "functional inactivity" serving as a trigger for MPSC review. During the October 15-16, 2008, MPSC meeting, the Committee recommended additional language to address this confusion. The Committee also clarified definitions within the bylaws and modified the arrangement to more clearly articulate intent.

Additionally, the Pancreas Transplantation Committee recommended the exclusion of pancreas islet transplant programs from the MPSC review of functional inactivity based upon the nature of pancreas islet transplantation. The MPSC agreed with this exclusion and also recommended that intestinal transplant programs be excluded, as reflected under proposed Section C,1(iv.).

UNOS also received feedback and questions regarding implementation and monitoring of this bylaw proposal. Of particular interest was how the MPSC would monitor waiting list inactivation for cumulative periods of 28 days or more. Figures 1 and 2 in the attached briefing paper **(Exhibit M-3)** provide a graphic view of the rolling periods as well as some examples. For each meeting, the UNOS Research Department will prepare a report for the MPSC inclusive of any programs that showed an inactive wait list cumulative total of 28 days or more in any 365-day period and any programs that showed an inactive wait list consecutive total of 15 days or more in any 365 day period. Additionally, the UNOS Information Technology staff are developing a report that will permit Members to monitor their cumulative waiting list inactivity. It is anticipated that this report will be available during the summer of 2009.

The MPSC voted on October 15, 2008, to further amend the modifications to the Bylaws, based upon feedback received during the public comment period. A briefing paper with the proposed bylaw language, public comment feedback, and the Committee's responses to public comment feedback is attached as **Exhibit M-3**.

The Committee offers the following recommendation for consideration by the Board of Directors:

**** RESOLVED, that the proposed modifications to the OPTN and UNOS Bylaws, Appendix B, Section II, C, and Appendix B, Attachment 1 of the OPTN Bylaws, as set forth below, having been distributed for public comment and subsequent**

reconsideration by the Committee, shall be approved and implemented pending distribution of appropriate notice and programming in UNet[SM].

The Committee voted 27 For, 0 Against, 0 Abstentions

A resource assessment for this proposal is also attached **(Exhibit M-1)**.

The modifications to the OPTN and UNOS Bylaws, Appendix B, Section II, C, and Appendix B, Attachment 1 of the OPTN Bylaws appear below. The language included below shows the existing language, the language distributed for public comment (shown with underlines and strikethroughs) and the language modified after public comment is noted with new language added after public comment double underlined and deleted language marked with ~~double strikethroughs~~.

Proposed Modification to OPTN and UNOS Bylaws.

APPENDIX B TO BYLAWS

Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership

I. Organ Procurement Organizations. [No Change]

II. Transplant Hospitals.

A. General. [No Change]

B. Survival Rates. [No Change]

C. ~~Inactive Membership Status.~~ Functional Inactivity, ~~Voluntary Inactive Membership~~ Inactive Transplant Program Status, Relinquishment of Designated Transplant Program Status and Termination of Designated Transplant Program Status. ~~A Member Transplant Hospital that fails to remain functionally active with respect to any designated transplant program (as defined below) may voluntarily stop transplantation at that transplant program for a period of up to twelve months by notice to the Executive Director, or may relinquish designated transplant program status for the program. This voluntary action to stop transplantation may be extended beyond twelve months upon request to the MPSC and demonstration to the MPSC's satisfaction of the benefit of such extension, together with a plan and timeline for re-starting transplantation at the program which shall include assurance that all OPTN membership criteria will be met at the time of re-starting transplantation.~~ [The following section moved with changes below] ~~The MPSC may also require, in its discretion, that the Member participate in a discussion regarding a performance review. The discussion may be with the MPSC, a subcommittee or work group, as the MPSC may direct. The discussion referenced above will be conducted according to the principles of confidential medical peer review, as described in Section 2.07A of Appendix A to the OPTN Bylaws. The discussion is not an adverse action or an element of due process. A Member who participates in a discussion with the MPSC is entitled to receive a summary of the discussion.~~

For the purposes of these bylaws, a candidate is defined as an individual who has been added to the waiting list. A potential candidate is defined as an individual who is under evaluation for transplant by the transplant program. Each reference to a candidate includes potential candidates if and as applicable.

1. **Functional Inactivity**. Transplant programs must remain functionally active. Transplant program functional activity will be reviewed periodically by the Membership and Professional Standards Committee (MPSC).

For purposes of these Bylaws, "~~functionally inactive~~ Functional Inactivity" ~~means~~ is defined as any or all of the items below:

~~(1)~~ (~~i~~a) The inability to serve ~~patients,~~ potential candidates, candidates, ~~and~~ or recipients, ~~as a group,~~ for ~~a sustained and significant time period, where~~ a period of 15 days or more consecutively ~~is presumed to be sustained and significant, or~~ ;

~~(2) No transplant performed for a period of time defined as:~~

(~~ii~~b~~) that a transplant has not been performed~~ failure to perform a transplant during the following stated periods of time:

i. ~~No transplant performed in three months~~ ~~I~~in the case of kidney, liver, and heart transplant programs, within three consecutive months;

ii. ~~No transplant performed in six months~~ ~~I~~in the case of pancreas and lung programs, ~~and~~ within six consecutive months;

iii. ~~No transplant performed in one year~~ ~~I~~in the case of ~~transplant programs located in~~ stand-alone pediatric transplant hospitals, within twelve consecutive months.

(~~iii~~c) waiting list inactivation of 15 or more consecutive days and/or 28 cumulative days or more over any 365 consecutive day period.

(d) given the experimental and evolving nature, functional inactivity thresholds and waiting list notification requirements regarding functional inactivity have not been established for pancreatic islet and intestinal transplant programs.

~~with no explanation deemed satisfactory by the MPSC that the program remains qualified pursuant to the criteria defined in this Appendix B to provide transplant services.~~

Any program~~s~~ identified to be functionally inactive shall be provided the opportunity to explain ~~the period of~~ its inactivity through reports requested by the MPSC.

A transplant program must provide written notice to candidates when the transplant program:

(a) Inactivates its waiting list or is unable to perform transplants for 15 consecutive days or more over any 365 consecutive day period;

(b) Inactivates its waiting list or is unable to perform transplants for 28 cumulative days or more over any 365 consecutive day period;

[Section moved from above, with changes]The MPSC may also require, at its discretion, that the Member participate in an informal discussion regarding a performance review. The informal discussion may be with the MPSC, a subcommittee or work group, as the MPSC may direct.

The discussion referenced above will be conducted according to the principles of confidential medical peer review, as described in Section 2.07A of Appendix A to the ~~OPTN~~ Bylaws. The discussion is not an adverse action or an element of due process. A Member who participates in an informal discussion with the MPSC is entitled to receive a summary of the discussion.

A functionally inactive transplant program ~~may~~ should voluntarily inactivate for a period of up to twelve months by providing written notice to the Executive Director. If the transplant program expects to be inactive for more than twelve months, the Member should ~~or must~~ relinquish designated transplant program status for the program in accordance with these bylaws.

The MPSC may recommend that a program inactivate or relinquish its designated transplant program status due to the program's functional inactivity. If the program fails to inactivate or relinquish its designated transplant status upon the MPSC's recommendation to do so, the ~~Committee~~ MPSC may recommend the Board of Directors take appropriate action in accordance with Appendix A of these Bylaws. Potential adverse actions are defined under Section 3.01A of the bylaws. Additionally, the Board of Directors may notify the Secretary of HHS of the situation. This action will also apply in the case of transplant programs approved by the Secretary of HHS for reimbursement under Medicare ~~or~~ and in the case of transplant programs in Federal hospitals.

~~If the Member fails to take either action voluntarily, the Membership and Professional Standards Committee may recommend that the Board of Directors take appropriate action in accordance with Appendix A of these Bylaws in all other cases, which action may include those defined as adverse under Section 3.01A. Program inactivation or relinquishment of designated transplant program status involves (i) prompt suspension of transplantation, (ii) notice to patients of the need to inactivate, removal of these patients from the program's waiting list, or – if the patient desires – transfer of the patient to the list of another Member Transplant Hospital, and (iii) assistance for patients in identifying the designated transplant programs to which they can transfer. Upon submission and review of information establishing that the Member has again become active in human organ transplantation and that all other criteria for membership are met, the Membership and Professional Standards Committee shall recommend to the Board of Directors that the Member be designated as an active member.~~

[Section Moved, with modifications to **4. Waiting Time on Waiting List**]
~~To assure equity in waiting times, and facilitate smooth transfer of patients from the waiting list of a program that is inactivated or relinquishes designated transplant status, patients on the waiting list of a designated transplant program at the time of inactivation or relinquishment of designated status may retain existing waiting time and continue to accrue waiting time appropriate to their status on the waiting list at the time of inactivation or relinquishment of designated status~~

~~of their program for a maximum of 90 days following that program's inactivation or relinquishment of designated status. This total acquired waiting time may be, with agreement of the accepting center, transferred to the patient's credit when s(he) is listed with a new program.~~

~~It is expected that all Transplant Hospitals will duly inform their patients on the waiting list if there will be an extended period of time when a designated transplant program will be unable to perform transplants. Programs that are not able to serve patients, as a group, for a period of 15 consecutive days or more are further expected to notify UNOS and their patients as described above.~~

2. **Inactive Transplant Program Status~~ Voluntary~~**

For the purposes of these bylaws, inactive transplant program status is defined as:

- an inactive transplant program waiting list status in UNet^{SM} (short-term inactivation), or
- an inactive transplant program waiting list status in UNet^{SM} and an inactive membership status (long-term inactivation).

~~**Inactive Status – Voluntary.**~~A Member may voluntarily inactivate~~its~~ a transplant program, on a short-term or long-term basis, for reasons including but not limited to:

- ~~not being able to~~inability to meet functional activity requirements;
- temporarily lacking required physician and/or surgeon coverage;
- substantial change in operations that require temporary cessation of transplantation.

~~Voluntary inactivation may be short term or long term.~~

a. Short-Term Inactivation

Short-term inactivation means that a transplant program may be inactive for up to 14 consecutive days. A Member ~~transplant hospital~~ may voluntarily inactivate ~~its~~a transplant program for a period not to exceed 14 days by changing the program's waiting list ~~program~~status in UNet^{SM}.

i. **Notice to the OPTN Contractor.** When a Member intends to voluntarily inactivate a transplant program on a short-term basis, the Member is not required to notify the OPTN contractor.

ii. **Notice to Patients.** In accordance with Attachment I to Appendix B, Section VII~~(A)(1)~~, ~~all~~each transplant program~~s~~ must provide potential candidates, ~~potential recipients~~ candidates, and recipients with a written summary of ~~the~~its Program Coverage Plan at the time of listing or when there are any substantial changes in program or personnel.

b. Long-Term Inactivation

Long-term inactivation means inactivation of a transplant program for 15 ~~days~~ or more~~.~~ days consecutively. Members should voluntarily inactivate~~P~~programs~~-~~that are not able to serve potential candidates, candidates, ~~and~~ or recipients~~, as a group~~,for a period of

15 ~~consecutive days~~ or more days consecutively~~ may voluntarily inactivate for a period of up to twelve months~~. Voluntary inactivation may extend for a period of up to 12 months.

i. Notice to the OPTN Contractor. When a ~~A~~Member ~~that~~intends to voluntarily inactivate ~~its~~ a transplant program for 15 or more days consecutively, it must provide written notice, including the reason(s) for inactivation, to the OPTN Executive Director~~and~~ upon deciding to inactivate the transplant program.~~ A transplant program must also provide written notice to candidates on the waiting list in instances when it is unable:~~

~~1) to perform transplants for 15 consecutive days or more over any 365 day period; or~~

~~2) to perform transplants for 28 cumulative days or more over any 365 day period.~~

ii. Notice to the Patients. When ~~the~~a Member intends to inactivate~~s~~ a transplant program for 15 or more days consecutively, it must provide:

a) written notice to the transplant program's potential candidates, candidates, recipients, and living donors currently being followed by the transplant program. Written notice should be mailed at least 30 days prior to the anticipated inactivation date by certified mail/return receipt requested. Written notice must be mailed no later than seven days following inactivation and include:

1) the reason(s) for inactivating the transplant program;

2) notice that while still on the waiting list of the inactive program the candidate cannot receive an organ offer through this member program;

3) options for potential candidates, candidates, recipients, and living donors to transfer to an alternative designated transplant program with the phone number of the administrative office of the inactivating program to help with potential candidate, candidate, recipient, and living donor transfers.

The Member must provide a representative copy of the written notice to the OPTN contractor along with a list of potential candidates, candidates, recipients, and living donors who received the notice.

3. Transition Plan

When the Member inactivates a transplant program for 15 or more days consecutively, it must:

a) promptly suspend organ implantation for that transplant program;

b) assist potential candidates and candidates in identifying designated transplant programs to which they can transfer;

c) provide a list to the OPTN contractor of all of the transplant program's candidates at the time of inactivation and update it throughout this process;

d) indicate on the list provided the decision of each potential candidate and each candidate to transfer, with the following additional information:

   i) if a candidate or potential candidate chooses not to transfer to an alternative transplant program, provide the reason and indicate whether the candidate has been completely informed of the implications of this decision; or

   ii) if a candidate or potential candidate chooses to transfer, indicate the transplant program to which the candidate is transferring. Periodic updates will be required as to the status of each candidate's transfer progress until the candidate is evaluated by the accepting program and an official decision is made regarding the candidate's listing status.

e) expedite removal of all candidates from the inactive transplant program's waiting list, or, if the candidate requests, transfer the candidate to another OPTN Member transplant hospital;

f) initiate transfer of all active candidates or potential candidates hospitalized at the inactive transplant program to an accepting transplant hospital within seven days of inactivation of the transplant program. The inactive transplant program must complete the transfer process within 14 days unless transfer would be unsafe or discharge is anticipated within that time; or circumstances outside of the program's control exist that prevent transfer within 14 days. The program must document and submit to the OPTN contractor all efforts for transfer of its hospitalized candidates or potential candidates if it is unable to meet the time periods within this section.

g) provide a priority list of the most urgent candidates or potential candidates at the inactive transplant program with an individualized plan of transfer, potential alternative transplant programs, and a timeline for transferring these candidates according to the following priorities:

   i) for liver candidates, all Status 1A and 1B candidates ~~should~~must be transferred within seven days of program inactivation, followed by all active candidates in descending MELD/PELD score order, with all candidates whose MELD/PELD score exceeds 25 to be

transferred within 30 days, followed by all inactive candidates;

ii) for lung candidates, active candidates should be transferred according to descending Lung Allocation Scores followed by inactive candidates;

iii) for kidney candidates, those whose PRA(measured or calculated) is over 80% should be transferred first, followed by all other active candidates in order of waiting time, then transfer of all inactive candidates;

iv) for heart candidates, all Status 1A and 1B must be transferred within seven days of inactivation;

v) for multivisceral organ transplant candidates, transfer must be completed within 30 days of inactivation; and

vi) notwithstanding these guidelines, all active candidates should be transferred within 60 days of inactivation.

vii) The program must document and submit to the OPTN contractor all efforts for transfer of its candidates if it is unable to meet the time periods within this section.

h document all efforts to transfer candidates to an alternative designated transplant program including all contacts made to facilitate the transfer of candidates; and

i) remove every transplant candidate from the inactive transplant program's waiting list within 12 months of the program's inactivation date in the cases when a program does not intend to reactivate.

Transplant programs that inactivate for 15 or more days consecutively may still have the ability to provide care to transplant recipients. Should the transplant program continue to provide follow-up care to transplant recipients, the program must continue to submit OPTN follow-up forms via UNet℠. Alternatively, transplant recipients may transfer care to another institution.

Extension of Voluntary Inactive Program Status Beyond Twelve Months. A Member transplant hospital may request an extension of voluntary inactive program status beyond twelve months by making a request to the MPSC. The request must demonstrate to the MPSC's satisfaction the benefit of such an extension, and be accompanied by a comprehensive plan with a timeline for re-starting transplantation at the program. This demonstration must include assurance that all membership criteria will be met at the time of re-starting transplantation.

Reactivation After Voluntary Long Term Inactivation. A Member transplant hospital may reactivate its program after long term voluntary inactivation by submitting application materials deemed appropriate by the MPSC that establishes that the program has again become active in organ transplantation and that all criteria for membership are met. The Membership and Professional Standards Committee shall recommend to the Board of Directors that the Board so notify the Secretary of HHS.

3. Relinquishment or Termination of Designated Transplant Program Status

Relinquishment of Designated Transplant Program Status means that a Member may voluntarily give up its designated transplant program status upon written notice to the OPTN. Members that relinquish designated transplant program status are voluntarily closing the transplant program.

Termination of Designated Transplant Program Status means that a Member's designated program status is ~~may be~~ terminated by the Secretary of the Department of Health and Human Services ("Secretary"). In the case of noncompliance with policies covered by Section 1138 of the Social Security Act, the MPSC may recommend that the Board of Directors and/or the Executive Committee ~~on its own accord, may~~ request approval from the Secretary to terminate a Member's designated transplant program status in accordance with Appendix A Section 2.06A of these Bylaws. The Board of Directors and/or the Executive Committee may, on its own accord, request such approval from the Secretary.

Once a Member relinquishes ~~its~~ a designated transplant program status or it is terminated by the Secretary of HHS, ~~the subject~~ that transplant program may no longer perform organ transplants. The Member must facilitate the transfer of the subject transplant program's candidates to another transplant program.

a. Notice to the OPTN Contractor. ~~The~~ A Member transplant hospital must provide written notice to the OPTN contractor within 30 days of the intent to relinquish ~~the following when~~ its designated transplant program status and the reasons therefore upon deciding to relinquish designated transplant program status. ~~is relinquished or terminated~~:

~~1) written notice to the OPTN contractor within 30 days of the intent to relinquish designated transplant program status and the reasons therefore; and~~

~~2)~~

b. Notice to the Patients. When a Member transplant hospital intends to relinquish its designated transplant program status, or its designated transplant program status is terminated, it must provide:

i) written notice to the transplant program's potential candidates, candidates, ~~and~~ recipients, and living donors currently being followed by the transplant program. Written notice should be mailed ~~within~~ at least 30 days prior to the anticipated ~~inactivation~~ date of relinquishment or termination by certified mail/return receipt requested. Written notice must be

mailed no later than seven days following relinquishment/termination and include:

1. the ~~program's~~ reason(s) for ~~relinquishing~~ loss of designated transplant program status;
2. notice that while still on the waiting list of the inactive program the candidate cannot receive an organ offer through this member program;
3. options for potential candidates, candidates, ~~and~~ recipients, and living donors to transfer to an alternative designated transplant program with the phone number of the administrative office of the inactivating program to help with potential candidate, candidate, and recipient transfers; and

The Member transplant hospital must provide a representative copy of the written notice to the OPTN contractor along with a list of potential candidate, candidate, and recipient names who received the notice.

~~B~~c. Transition Plan

When a ~~The~~ Member transplant hospital relinquishes a transplant program's designated program status or it's designated program status is terminated, it must ~~perform the following activities when one of its transplant program's designated status is relinquished or terminated~~:

i. ~~the subject transplant program must~~ promptly suspend organ implantation for the transplant program;

ii. assist potential candidates and ~~waitlisted~~ candidates in identifying designated transplant programs to which they can transfer;

iii. provide a list to the OPTN contractor of all of the transplant program's candidates on the waiting list at the time of ~~inactivation~~ relinquishment or termination and update it throughout this process;

iv. indicate on the list provided ~~each candidate's decision~~ the decision of each potential candidate and each candidate to transfer, with the following additional information:

1. if a candidate or potential candidate chooses not to transfer to an alternative transplant program, provide the reason and indicate whether the candidate has been completely informed of the implications of this decision; or
2. if a candidate or potential candidate chooses to transfer, indicate ~~to which the~~ transplant program to which the candidate is transferring. Periodic updates will be required as to the status of ~~that~~ each candidate's transfer progress until the candidate is evaluated by the accepting program and an official ~~acceptance~~ decision is made regarding the candidate's listing status.

v. expedite removal of all candidates from the ~~subject~~ transplant program's waiting list, or, if the patient requests,

transfer the candidate to another OPTN Member transplant hospital;

vi. initiate transfer ~~any~~ of all active candidates hospitalized at the ~~inactive~~ transplant program to an accepting transplant hospital within seven days of ~~inactivation~~ relinquishment of the ~~subject~~ transplant program. The transplant program must complete the transfer process within 14 days unless transfer would be unsafe or discharge is anticipated within that time; or circumstances outside of the program's control exist that prevent transfer within 14 days. The program must document and submit to the OPTN contractor all efforts to transfer its hospitalized candidates if it is unable to meet the time periods within this section.

vii. provide a priority list of the most urgent candidates listed at the ~~subject~~ transplant program with an individualized plan of transfer, potential alternative transplant programs, and a timeline for transferring these candidates according to the following priorities:

1. for liver candidates, all Status 1A and 1B candidates ~~should~~ must be transferred within seven days of ~~inactivation~~ relinquishment, followed by all active ~~MELD/PELD candidates in order of score with all candidates with a MELD/PELD > 25~~ candidates in descending MELD/PELD score order, with all candidates whose MELD/PELD score exceeds 25 to be transferred within 30 days, followed by all inactive candidates;
2. for lung candidates, ~~those~~ active candidates should be transferred according to ~~with~~ descending Lung Allocation Scores ~~in descending order~~ with highest scores first, followed by ~~the~~ inactive candidates;
3. for kidney candidates, those whose PRA (measured or calculated) is over ~~all active highly sensitized (PRA~~>80%~~)~~ ~~candidates~~ should be transferred first, followed by all other active candidates in order of waiting time, then transfer of all inactive candidates;
4. for heart candidates, ~~those with~~ all Status 1A and 1B must be transferred within ~~30 days~~ seven days of ~~inactivation;~~ relinquishment;
5. for multivisceral organ transplant candidates, transfer must be completed within 30 days of ~~inactivation~~ relinquishment; and
6. notwithstanding these guidelines, all active candidates should be transferred within 60 days of relinquishment; and;
7. The program must document and submit to the OPTN contractor all efforts for transfer of its

candidates if it is unable to meet the time periods within this section.

viii. document all efforts to transfer candidates to an alternative designated transplant program including all contacts made to facilitate the transfer of candidates~~.~~; and

ix. ~~have~~remove every transplant candidate ~~removed~~ from the ~~subject~~ transplant program's waiting list within 12 months of the program's ~~inactivation~~ relinquishment date.

A Member ~~transplant programs~~ that ~~inactivate~~ relinquishes or terminates a designated transplant program may still have the ability to provide follow-up care ~~for~~ to transplant recipients. Should the transplant program continue to provide follow-up care ~~for~~ to transplant recipients, the program must continue to submit OPTN follow up forms ~~in~~ via UNet[sm]. ~~Additionally~~ Alternatively, transplant recipients may transfer care to another institution.

~~5~~4. Waiting time on waiting list.
[Moved from previous section, with changes]
To assure equity in waiting times, and facilitate smooth transfer of candidates from the waiting list of ~~a program that is inactivated or relinquishes designated transplant status,~~ affected programs (i.e. programs that voluntarily inactivate, relinquish or lose designated transplant program status), candidates on the waiting list in such instances may retain existing waiting time and continue to accrue waiting time appropriate to their status on the waiting list at the time of the programs' inactivation, relinquishment, or loss of designated status. ~~for a maximum of 90 days following that program's inactivation, relinquishment or loss of designated status.~~ This total acquired waiting time will ~~may~~ be~~, with agreement of the accepting center,~~ transferred to the candidate's credit when s(he) is listed with a new program.

~~If the candidate remains on the waitlist of an inactivated program past the maximum 90 days stated above then a Waiting Time Modification per OPTN/UNOS Policy 3.2.1.8 Waiting Time Modification will be required.~~

~~6~~5. Laboratory T~~t~~ests. The inactivated program remains responsible for evaluating its candidates. This includes, but is not limited to, ~~must obtain~~ performing ~~the required~~ laboratory tests and evaluations required ~~of candidate follow-up~~ to maintain the candidate's appropriate status on the waiting list until the time of transfer.

III. Histocompatibility Laboratories. [No Change]

ATTACHMENT I
TO APPENDIX B OF THE OPTN BYLAWS

[No change] A transplant program that meets the following criteria shall be qualified as a designated transplant program to receive organs for transplantation:

I. Facilities and Resources. [No change]

II. ~~**Inactive Program Status**. Designated transplant programs qualified in accordance with these Attachment I criteria that fail to remain functionally active shall voluntarily stop transplantation at that transplant program for a period of up to twelve months by notice to the Executive Director, or may relinquish designated transplant program status for the program. This voluntary action to stop transplantation may be extended beyond twelve months upon request to the MPSC and demonstration to the MPSC's satisfaction of the benefit of such extension, together with a plan and timeline for re-starting transplantation at the program which shall include assurance that all OPTN membership criteria will be met at the time of re-starting transplantation. For purposes of these Bylaws, "functionally inactive" is defined as:~~

~~(1) The inability to serve patients, as a group, for a sustained and significant time period, where a period of 15 days or more is presumed to be sustained and significant, or~~

~~(2) No transplant performed for a period of time defined as:~~

~~(c) No transplant performed in three months in the case of kidney, liver, and heart transplant programs,~~
~~(d) No transplant performed in six months in the case of pancreas and lung programs, and~~
~~(e) No transplant performed in one year in the case of transplant programs located in stand-alone pediatric transplant hospitals, with no explanation deemed satisfactory by the MPSC that the program remains qualified pursuant to the criteria defined in this Appendix B to provide transplant services.~~

~~If the program fails to take either action voluntarily, the Membership and Professional Standards Committee may recommend that the Board of Directors take appropriate action in accordance with Appendix A of these Bylaws, which action may include those defined as adverse under Section 3.01A. Program inactivation or relinquishment of designated transplant program status involves (i) prompt suspension of transplantation, (ii) notice to patients (with a copy to the organization under contract with HHS to operate the OPTN (OPTN Contractor)) of the need to inactivate, removal of these patients from the program's waiting list, or - if the patient desires - transfer of the patient to the list of another OPTN Member Transplant Hospital, and (iii) assistance for patients in identifying the designated transplant programs to which they can transfer. Upon submission and review of information establishing that the Member has again become active in human organ transplantation and that all other criteria for OPTN membership are met, the Membership and Professional Standards Committee shall recommend to the Board of Directors that the Board so notify the Secretary of HHS.~~

~~To assure equity in waiting times, and facilitate smooth transfer of patients from the waiting list of a program that is inactivated or relinquishes designated transplant status, patients on the waiting list of a designated transplant program at the time of inactivation or relinquishment of designated status may retain existing waiting time and continue to accrue waiting time appropriate to their status on the waiting list at the time of inactivation or relinquishment of designated status of their program for a maximum of 90 days following that program's inactivation or relinquishment of designated status. This total acquired waiting time may be, with agreement of the accepting center, transferred to~~

~~the patient's credit when s(he) is listed with a new program.~~

~~It is expected that all designated transplant programs will duly inform their patients on the waiting list if there will be an extended period of time when the program will be unable to perform transplants. Programs that are not able to serve patients, as a group, for a period of 15 consecutive days or more are further expected to notify the OPTN Contractor and their patients as described above.~~

III. **Reporting Changes in Key Personnel.** [No change]

III~~V~~. **Investigation of Personnel.** [No change]

IV. **OPO Affiliation.** [No change]

V~~I~~. **Histocompatibility Laboratory Affiliation.** [No change]

VI~~I~~. **Transplant Surgeon and Physician.** [No change]

3. Living Donor Liver Requirements: This modification to the Bylaws clarifies the expectation that the transplant center must inactivate and 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.

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 did not clearly explain the options for programs that reached 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 and amending the Bylaws should provide this clarity. The recommended changes were 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 (LDL) transplantation began in 2005. It became apparent after the bylaws were implemented that about 30 of the centers would likely fall short of meeting the requirement to have two fully qualified surgeons. Ultimately, a joint work group consisting of members from the MPSC, the Liver and Intestinal Organ Transplantation Committee, the Living Donor Committee, and the Pediatric Transplantation Committee was formed for the purpose of considering the development of criteria for conditional program approval when the second living donor liver surgeon had not met all of the minimum requirements. This work group recommended that up to a two-year conditional period be allowed for these programs. The Board of Directors considered the proposed bylaw changes during its March 2006, meeting and amended the Committee's resolution by eliminating the option of a second year of conditional approval. During its May 2006 meeting the MPSC reviewed the public comments that had been received and was concerned about the elimination of the second year option. The Committee agreed to reinstate the originally proposed language that allowed for a possible extension to the one year conditional period. This option was finally

approved in the bylaws in September 2006. Centers that did not meet the requirements at the end of the second year would not be qualified to continue as an approved program.

Since that time, 19 of the 72 liver programs that perform living donor liver transplants have been conditionally approved under this option. All but three 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 clear guidance 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.

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 conditional period should require the submission of a new application.

During the May 2008 meeting, the Committee reviewed specific changes to the Bylaws and agreed on language that should be forwarded to the Board of Directors for approval concurrent with public comment. This request was made because a number of the conditionally approved programs would be reaching the end of their terms in June. On June 20, 2008, the Board of Directors approved this modification to the Bylaws concurrent with public comment as requested by the MPSC. The Board further agreed to apply the program criteria retroactively to the programs that perform Living Donor Liver Transplant. The conditionally approved programs that applied for approval after March 1, 2005, would benefit from this clarification.

The proposal was distributed for public comment from June 30 to September 24, 2008. While the Committee received a number of comments regarding the living donor liver requirements as a whole, they unanimously agreed that there was no need to ask the board to consider any changes to the bylaw language that the Board of Directors approved in June. A briefing paper with the proposed bylaw language, public comment feedback, and the Committee's responses to public comment feedback is attached as **Exhibit M-4**. The resource assessment is also attached **(Exhibit M-2)**.

** RESOLVED, that the proposed modifications to the Bylaws, Appendix B, Attachment I, Section XIII, D (4) c as set forth below, shall be approved without further modifications.

The Committee voted 28 For, 0 Against, 0 Abstentions.

Modifications 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.

<u>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 in above] at the end of the 2-year conditional approval period, it must stop performing living donor liver transplants by either</u>

<u>(i) inactivating the living donor part of the program for a period up to 12 months, or</u>

<u>(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.</u>

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

Attendance at the Membership and Professional Standards Committee Meeting
October 15-16, 2008

NAME	POSITION	Attended July 22-24, 2008	Attended Oct 15-16 2008
James Wynn MD	Chair	X	X
Carl Berg MD	Vice Chair/Reg Rep	X	X
Paul Morrissey MD	Regional Rep.	X	X
Lynt Johnson MD, MBA	Regional Rep.	X	X
George Loss Jr, MD, PhD	Regional Rep.	X	X
David Nelson MD	Regional Rep.	X	X
Christopher Marsh MD	Regional Rep.	X	X
Karen Nelson Ph.D., D(ABHI)	Regional Rep.	X	X
Yolanda Becker MD, FACS	Regional Rep.	X	X
Michael Voigt MD	Regional Rep.	X	X
David Conti MD	Regional Rep.	*	X
Lynn Driver CPTC	Regional Rep.	X	X
Charles Alexander RN, MSN, MBA, CPTC	At Large	X	X
Sharon Bartosh MD	At Large		X
Tim Brown	At Large	X	X
Jonathan Chen MD	At Large	X	X
Todd Dewey MD	At Large	X	X
Barry Friedman RN, BSN, MBA, CPTC	At Large	X	X
James Gleason	At Large	X	X
John Herre MD	At Large	X	X
Benjamin Hippen M.D.	At Large	X	X
Donald Hricik MD	At Large	X	X
Ian Jamieson MBA, MHA	At Large	X	X
Richard Luskin MPA	At Large	X	X
Jerry McCauley MD, MPH	At Large	X	X
Patricia McDonough RN, CPTC, CCTC	At Large	X	
Brendan McGuire MD	At Large	X	X
Michael Mulligan MD	At Large	X	X
Claus Niemann M.D.	At Large	X	
Fuad Shihab MD	At Large	X	X
Mark Zucker MD, JD, FACC, FACP	At Large	X	X
James Burdick MD	Ex Officio		
Christopher McLaughlin	Ex Officio	X	X
Robert Walsh	Ex Officio	X	X
Charlotte Arrington MPH	SRTR Liaison	X	X
Douglas Schaubel Ph.D.	SRTR Liaison	X	

NAME	POSITION	Attended July 22-24, 2008	Attended Oct 15-16 2008
Robert Wolfe, Ph.D.	SRTR Liaison		X
Sally Harris Aungier	Committee Liaison	X	X
David Kappus MAS	Committee Liaison	X	X
Terri Bessom MBA, CPhT	Support Staff	X	X
Heather Bowman	Support Staff		X
Elizabeth Coleburn	Support Staff	X	X
Erick Edwards Ph.D.	Support Staff	X	X
Alex Garza	Support Staff	X	X
Suzanne Gellner JD, CHC	Support Staff	*	X
Linda Gobis	Support Staff	X	X
Walter Graham	Support Staff	X	X
Karl McCleary Ph.D., M.P.H.	Support Staff	X	X
Aaron McKoy	Support Staff		X
Joel Newman	Support Staff		X
Jacqueline O'Keefe MBA	Support Staff	X	X
Ann Paschke	Support Staff	X	
John D. Persons III, Esq.	Support Staff		X
Leah Slife	Support Staff	X	*

* Participated by conference call

Exhibit M-1

Resource Assessment and Impact Summary

November 2008

Resource Assessment Snapshot	Staff Hours Estimate	Staff Cost Estimate
Total Implementation Estimate (hours and cost)	1,110	$59,230
Annual Maintenance Estimate (hours and cost savings)	380	- $41,123
Programming Requirement	Requires programming in UNet℠	
Project Size	Medium	

Membership and Professional Standards Committee

Proposal to change the OPTN/UNOS Bylaws to better define functional inactivity, voluntary inactive membership transplant programs status, relinquishment of designated transplant program status, and termination of designated transplant program status.

OPTN/UNOS Bylaw Appendix B, Section II, C

This bylaw proposal clarifies the current definition of Functional Inactivity by including information about waiting list inactivation in UNet℠. The proposal defines short-term voluntary inactivation as inactivation of a programs waiting list in UNet℠ for 14 days or fewer; and long-term voluntary inactivation as inactivation of membership status based on the expectation the program will remain inactive for greater than 14 days. These modifications also specify exactly what a member must do in terms of notifying candidates when a program voluntarily inactivates or relinquishes its designated program status (long-term inactivation).

Resource Assessment Summary

If approved, this proposed bylaw change will require programming in UNet℠. Programming changes will not be evident, nor modify the end users UNet℠ experience. 97% (1,080 hours) of the implementation efforts will be managed primarily by UNOS IT, Policy/Membership/Regional Administration (PMR), and Research staff. Estimated staff implementation cost is approximately $59K.

Implementation: During implementation, IT will need to dedicate staff to perform analysis, design and build. Of the 840 estimated IT hours required to implement, a considerable amount of time will be spent in testing to mitigate the risk of inaccurate calculation of candidate waiting time and improper reporting of program inactivity.

PMR staff will play an intricate role during the implementation phase. PMR staff will prepare and execute a policy notice, develop protocol, perform analysis to determine if there are membership database changes required to asses reporting needs, collaborate with MPSC, monitor compliance, and communicate processes and expectations with members and other various tasks deemed necessary.

Research staff will need to support implementation by modifying Research analysis datasets and STAR files, work with PMR staff to create compliance monitoring reports and assist IT by participating in testing efforts.

UNOS Staff Resources: Implementation Effort Estimate

Department	Implementation Staff Hours Estimate	Implementation Staff Cost Estimate
Communications	0	
Corporate Counsel	0	
Evaluation and Quality (DEQ)	30	
Information Technology (IT)	840	
Policy/Membership/Regional Administration (PMR)	190	
Professional Services	0	
Research	50	
Implementation Estimate (hours and cost)*	**1,110**	**$59,230**

*Reflects anticipated 2008-2009 fiscal year expense for salary, benefits, and indirect costs related to the estimated staff hours and does not include potential staff hours in departments not depicted.

Exhibit M-1 (Continued)

Annual Maintenance: 380 hours of DEQ, PMR, and Research staff will be required to support this bylaw change annually. Support activities performed by compliance, review board, regional administrator and member services staff include:

review of inactive programs
monitor, track and document urgent candidates
monitor transferred candidates
progress monitoring
compliance reporting
refinement of protocol
communication and meetings with the MPSC
policy required duties
continuous support and communication with members and the general public
develop and perform analyses to assess impact of policy

This is a decommissioning effort for IT. There is a maintenance cost savings of - $41,123 (-750 hours) because the change will reduce the complexity of calculating candidate waiting time.

UNOS Staff Resources: Annual Maintenance Estimate

Department	Annual Maintenance Staff Hours Estimate
Communications	0
Corporate Counsel	0
Evaluation and Quality (DEQ)	70
Information Technology (IT)	0
Policy/Membership/Regional Administration (PMR)	290
Professional Services	0
Research	20
Annual Maintenance Estimate (hours)	**380**

*Staff hours in departments not depicted above are excluded from this total.

Affected Groups
Transplant Administrators
Transplant Coordinators
Transplant Physicians and Surgeons
Transplant Program Directors
Transplant Candidates

Exhibit M-2

Resource Assessment and Impact Summary

November 2008

Resource Assessment Snapshot	Staff Hours Estimate	Staff Cost Estimate
Total Implementation Estimate (hours and cost)	60	$2,834
Annual Maintenance Estimate (hours)	30	
Programming Requirement	Does not require additional data collection or programming in UNet℠	
Project Size	Small	

Membership and Professional Standards Committee

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

OPTN/UNOS Bylaw Attachment I, Appendix B, Section D, (4)

This bylaw modification proposal 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 criteria for full program approval by the end of the conditional approval period.

Resource Assessment Summary

If approved, this proposal will not require programming changes in UNet℠, but requires 60 hours of staff time of Policy/Membership/Regional Administration department and the Department of Evaluation and Quality to execute.

Implementation: Implementation efforts in preparation and execution of the policy notice, development and/or modification to the process to monitor and support transition due process activities for programs that inactivate or relinquish term-limited approval of living donor liver program status, and communication/education of members are shared among UNOS staff.

UNOS Staff Resources: Implementation Effort Estimate		
Department	Implementation Staff Hours Estimate	Implementation Staff Cost Estimate
Communications	0	
Corporate Counsel	0	
Evaluation and Quality (DEQ)	30	
Information Technology (IT)	0	
Policy/Membership/Regional Administration (PMR)	30	
Professional Services	0	
Research	0	
Implementation Estimate (hours and cost)*	60	$2,834

*Reflects anticipated 2008-2009 fiscal year expense for salary, benefits, and indirect costs related to the estimated staff hours and does not include potential staff hours in departments not depicted.

Annual Maintenance: Yearly compliance monitoring and reporting requires 30 additional staff hours.

UNOS Staff Resources: Annual Maintenance Estimate	
Department	Annual Maintenance Staff Hours Estimate
Communications	0
Corporate Counsel	0
Evaluation and Quality (DEQ)	10
Information Technology (IT)	0
Policy/Membership/Regional Administration (PMR)	20
Professional Services	0
Research	0
Annual Maintenance Estimate (hours)*	30

*Staff hours in departments not depicted above are excluded from this total.

Exhibit M-2 (Continued)

- **Affected Groups**
  - Member transplant centers that perform or intend to perform living donor liver transplants.

Exhibit M-3

BRIEFING PAPER **OPTN/UNOS**

Proposal to change the OPTN/UNOS Bylaws to better define functional inactivity, voluntary inactive membership transplant program status, relinquishment of designated transplant program status, and termination of designated transplant program status

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Exhibit M-3

BRIEFING PAPER **OPTN/UNOS**

Proposal to change the OPTN/UNOS Bylaws to better define functional inactivity, voluntary inactive membership transplant program status, relinquishment of designated transplant program status, and termination of designated transplant program status

Membership and Professional Standards Committee (MPSC)

Summary and Goals of the Proposal:

This bylaw proposal clarifies the current definition of Functional Inactivity by including information about waiting list inactivation in UNet[sm]. The proposal defines short-term voluntary inactivation as inactivation of a program waiting list in UNet[sm] for 14 days or fewer; and long-term voluntary inactivation as inactivation of membership status based on the expectation the program will remain inactive for greater than 14 days. These modifications also specify exactly what a member must do in terms of notifying candidates when a program voluntarily inactivates or relinquishes its designated program status (long-term inactivation).

Background and Significance of the Proposal:

The MPSC developed this bylaw proposal after an MPSC work group reviewed active OPTN members that inactivated their waiting list for more than 14 days. This work group reviewed existing bylaw language and observed that the bylaws did not reference waiting list inactivation and did not provide the center with details about notifying transplant candidates that they might not receive organ offers during the period that the waiting list is inactive. In reviewing existing bylaw language, work group members also noted concern with the process for candidate wait time transfer upon program inactivation.

If adopted, the modified bylaw language will clarify responsibilities for transplant programs and provide the MPSC with a way to monitor waiting list inactivation. The bylaw also ensures that candidates will not lose accrued wait time, consistent with organ specific policy, while the inactivated program works to transfer the candidate to an alternative transplant program. Candidates will be better informed of periods when organ offers will not be made to the transplant program on their behalf. These modifications provide Members with clear expectations when considering program inactivation.

While these modifications are an improvement, transplant programs may feel additional burden since they must notify candidates in writing when a program inactivates its waiting list for 15 or more consecutive days and/or 28 or more cumulative days in a 365 day period. This added burden may be in the form of increased patient questions and calls regarding correspondence from the transplant program, or may be an increased financial burden related to the costs of providing written notification to all candidates on the waiting list. Additionally, transplant programs may be required to respond to MPSC inquiries regarding waiting list inactivation once the bylaw is adopted.

Supporting Evidence and/or Modeling:

The purpose of this proposal is to clarify existing bylaw language. Therefore, the Committee did not conduct an evidence review or require any modeling.

Exhibit M-3

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 functional inactivity and the MPSC's review of transplant program performance. Member responsibilities and expectations are clearly defined in the proposal and will result in improved interpretation of and compliance with bylaw requirements.

Plan for Evaluating the Proposal:

The MPSC will monitor the frequency of waiting list inactivation and trends since bylaw adoption. The MPSC will evaluate the responses to its inquiries to active programs with inactive waiting lists, both those greater than 14 consecutive and/or 28 or more cumulative days in a 365-day period. These data can be captured through existing fields in UNet^{sm} and through the UNOS Research Department.

The Committee will also monitor how frequently members that inactivate a transplant program for the long-term meet waiting list transfer requirements. This information is also available through existing UNet^{sm} data fields.

The MSPC will evaluate the effects of the bylaw proposal at each meeting in 2009, and thereafter upon implementation.

Additional Data Collection:

This bylaw proposal should not result in additional data collection.

Expected Implementation Plan:

Transplant centers will be required to notify candidates of periods when their waiting list default is set to inactive for 15 or more consecutive days or 28 or more cumulative days in a year. Centers must notify candidates in writing. In the case of a long-term program inactivation, centers must notify the OPTN in writing and send a representative copy of the patient notification and a list of all patients that received the notification.

Existing bylaw language stipulates that a candidate can continue to accrue waiting time up to 90 days after a program inactivates. However, it may take more than 90 days for some programs to transition candidates to other centers and in these cases, the candidates lose waiting time. If this bylaw modification is implemented, candidates that lost waiting time (time beyond the 90-day limit) during the transition from an inactivated program to the new center and are still on a waiting list will receive wait time reinstatement in the amount of the lost time.

The MPSC will monitor transplant program compliance with requirements contained in the proposal.

This proposal will require programming in UNet^{sm}; however, this programming will not be evident to the end user and will not change the transplant center's staff member's current use of UNet^{sm} in any way.

Communication and Education Plan:

Communication Activities			
Type of Communication	Audience(s)	Delivery Method(s)	Timeframe
Policy Notice (blast email of PDF containing summaries of all policy changes approved at the board meeting).	Administrators Program Directors Surgeons Physicians Transplant Coordinators	E-mail from the UNOS Communications mailbox	30 days after Board approval
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 story will go in the next Update scheduled to go to press.
Brief article for websites or electronic newsletters of transplant-related associations.	NATCO ATC AST ASTS	UNOS Communications will send Web masters the material and the Web masters will post it on the site.	Articles written in advance and sent to Web masters immediately following board approval.

We will consider additional communication methods as needed.

Monitoring and Evaluation:

Concerning waiting list inactivation, the MPSC Data Subcommittee will monitor compliance with bylaw requirements as part of its existing review of functional inactivity. UNOS Staff will print a list of all Members that ever inactivated their waiting list for more than 14 consecutive days and/or 28 cumulative days over a rolling 365-day period. UNOS will send a letter and questionnaire to programs and request that they specify reasons for their waiting list inactivation and confirm that they notified candidates of this inactivation.

UNOS Staff in Policy, Membership, and Regional Administration already work with Members that voluntarily inactivate a transplant program (long term inactivation, relinquish designated program status) and help these transplant programs with the transition. If a Member is found to be noncompliant with the bylaw, Staff will refer the Member to the MPSC. The Committee will follow its normal process for investigation and may take action as defined in Appendix A of the Bylaws.

Policy or Bylaw Proposal:

The MPSC voted on May 6, 2008, to distribute the following proposed modifications to the Bylaws for public comment, by a vote of 26 For, 0 Against, 0 Abstentions.

Exhibit M-3

The modifications to Appendix B, Section II, C appear below. For your convenience, we present the new language as it would look if this proposal is approved. Following the proposed new language is the existing language with new language underlined and deleted language marked with ~~strikethroughs~~.

Proposed Language to OPTN and UNOS Bylaws

APPENDIX B TO BYLAWS

Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership

I. Organ Procurement Organizations. [No Change]

II. Transplant Hospitals.

A. General. [No Change]

B. Survival Rates. [No Change]

C. Functional Inactivity, Voluntary Inactive Membership Transplant Program Status, Relinquishment of Designated Transplant Program Status and Termination of Designated Transplant Program Status.

1. **Functional Inactivity**. Transplant programs must remain functionally active. Transplant program functional activity will be reviewed periodically by the Membership and Professional Standards Committee (MPSC).

For purposes of these Bylaws, "Functional Inactivity" means any or all of the items below:

(i) The inability to serve potential candidates, candidates, and recipients, as a group, for a period of 15 days or more;
(ii) that a transplant has not been performed during the following stated periods of time:
(a) In the case of kidney, liver, and heart transplant programs, within three consecutive months;
(b) In the case of pancreas and lung programs, within six consecutive months;
(c) In the case of stand-alone pediatric transplant hospitals, within twelve consecutive months.
(iii) waiting list inactivation of 28 cumulative days or more over any 365 consecutive day period.

Programs identified to be functionally inactive shall be provided the opportunity to explain the period of inactivity through reports requested by the MPSC.

The MPSC may also require, at its discretion, that the Member participate in an informal discussion regarding a performance review. The informal discussion may be with the MPSC, a subcommittee or work group, as the MPSC may direct.

The discussion referenced above will be conducted according to the principles of confidential medical peer review, as described in Section 2.07A of Appendix A to the Bylaws. The discussion is not an adverse action or an element of due process. A Member who participates in an informal discussion with the MPSC is entitled to receive a summary of the discussion.

A functionally inactive transplant program may voluntarily inactivate for a period of up to twelve months by providing written notice to the Executive Director, or must relinquish designated transplant program status for the program in accordance with these bylaws.

The MPSC may recommend that a program inactivate or relinquish its designated transplant program status due to the program's functional inactivity. If the program fails to inactivate or relinquish its designated transplant status upon the MPSC's recommendation to do so, the Committee may recommend the Board of Directors take appropriate action in accordance with Appendix A of these Bylaws. Potential adverse actions are defined under Section 3.01A of the bylaws. Additionally, the Board of Directors may notify the Secretary of HHS of the situation. This action will apply in the case of transplant programs approved by the Secretary of HHS for reimbursement under Medicare or in the case of transplant programs in Federal hospitals.

2. Inactive Status-Voluntary.

Inactive Status – Voluntary. A Member may voluntarily inactivate its transplant program for reasons including but not limited to:

i) not being able to meet functional activity requirements;
ii) temporarily lacking required physician and/or surgeon coverage;
iii) substantial change in operations that require temporary cessation of transplantation.

Voluntary inactivation may be short term or long term.

a. Short Term Inactivation

Short term inactivation means that a transplant program may be inactive for up to 14 consecutive days. A Member transplant hospital may voluntarily inactivate its transplant program for a period not to exceed 14 days by changing the waiting list program status in UNet^{sm}.

Notice. In accordance with Appendix B Section VII(A)(1), all transplant programs must provide candidates, potential recipients and recipients with a written summary of the Program Coverage Plan at the time of listing or when there are any substantial changes in program or personnel.

b. Long Term Inactivation

Long term inactivation means inactivation of a transplant program for 15 days or more. Programs that are not able to serve potential candidates, candidates, and recipients, as a group, for a period of 15 consecutive days or more may voluntarily inactivate for a period of up to twelve months.

Notice. A Member that intends to voluntarily inactivate its transplant program must provide written notice to the Executive Director. A transplant program must also provide written notice to candidates on the waiting list in instances when it is unable:

1) to perform transplants for 15 consecutive days or more over any 365 day period; or
2) to perform transplants for 28 cumulative days or more over any 365 day period.

Extension of Voluntary Inactive Program Status Beyond Twelve Months. A Member transplant hospital may request an extension of voluntary inactive program status beyond twelve months by making a request to the MPSC. The request must demonstrate to the MPSC's satisfaction the benefit of such an extension, and be accompanied by a comprehensive plan with a timeline for re-starting transplantation at the program. This demonstration must include assurance that all membership criteria will be met at the time of re-starting transplantation.

Reactivation After Voluntary Long Term Inactivation. A Member transplant hospital may reactivate its program after long term voluntary inactivation by submitting application materials deemed appropriate by the MPSC that establishes that the program has again become active in organ transplantation and that all criteria for membership are met. The Membership and Professional Standards Committee shall recommend to the Board of Directors that the Board so notify the Secretary of HHS.

3. Relinquishment or Termination of Designated Transplant Program Status

Relinquishment of Designated Transplant Program Status means that a Member may voluntarily give up its designated transplant program status upon written notice to the OPTN. Members that relinquish designated transplant program status are voluntarily closing.

Termination of Designated Transplant Program Status means that a Member's designated program status may be terminated by the Secretary of the Department of Health and Human Services ("Secretary"). In the case of noncompliance with policies

covered by Section 1138 of the Social Security Act, the MPSC may recommend that the Board of Directors and/or the Executive Committee on its own accord, may request approval from the Secretary to terminate a Member's designated transplant program status in accordance with Appendix A Section 2.06A of these Bylaws.

Once a Member relinquishes its designated transplant program status or it is terminated by the Secretary of HHS, the subject transplant program may no longer perform organ transplants. The Member must facilitate the transfer of the subject transplant program's candidates to another transplant program.

a. Notice

The Member transplant hospital must provide the following when its designated transplant program status is relinquished or terminated:

1) written notice to the OPTN contractor within 30 days of the intent to relinquish designated transplant program status and the reasons therefore; and
2) written notice to the transplant program's potential candidates, candidates and recipients currently being followed by the transplant program. Written notice should be mailed within 30 days prior to the anticipated inactivation date by certified mail/return receipt requested and include:
    i. the program's reasons for relinquishing designated transplant program status;
    ii. notice that while still on the waiting list of the inactive program the candidate cannot receive an organ offer through this member program;
    iii. options for potential candidates, candidates, and recipients to transfer to an alternative designated transplant program with the phone number of the administrative office of the inactivating program to help with potential candidate, candidate, and recipient transfers; and

The Member transplant hospital must provide a representative copy of the written notice to the OPTN contractor along with a list of potential candidate, candidate, and recipient names who received the notice.

b. Transition Plan

The Member transplant hospital must perform the following activities when one of its transplant program's designated status is relinquished or terminated:

1) the subject transplant program must promptly suspend organ implantation;
2) assist potential candidates and waitlisted candidates in identifying designated transplant programs to which they can transfer;
3) provide a list to the OPTN contractor of all of the transplant program's candidates on the waiting list at the time of inactivation and update it throughout this process;
4) indicate on the list provided each candidate's decision to transfer, with the following additional information:

i. if a candidate chooses not to transfer to an alternative transplant program, provide the reason and indicate whether the candidate has been completely informed of the implications of this decision; or
ii. if a candidate chooses to transfer, indicate to which transplant program the candidate is transferring. Periodic updates will be required as to the status of that candidate's transfer progress until the candidate is evaluated by the accepting program and an official acceptance is made regarding the candidate's listing status.

5) expedite removal of all candidates from the subject transplant program's waiting list, or, if the patient requests, transfer the candidate to another OPTN Member transplant hospital;
6) transfer any active candidate hospitalized at the inactive transplant program to an accepting transplant hospital within seven days of inactivation of the subject transplant program unless transfer would be unsafe or discharge is anticipated within that time;
7) provide a priority list of the most urgent candidates listed at the subject transplant program with an individualized plan of transfer, potential alternative transplant programs, and a timeline for transferring these candidates according to the following priorities:
    i. for liver candidates, all Status 1 candidates should be transferred within seven days of inactivation, followed by all active MELD/PELD candidates in order of score with all candidates with a MELD/PELD > 25 to be transferred within 30 days, followed by all inactive candidates;
    ii. for lung candidates, those active candidates with Lung Allocation Scores in descending order with highest scores first, followed by the inactive candidates;
    iii. for kidney candidates, all active highly sensitized (PRA>80%) candidates first, followed by all other active candidates in order of waiting time, then transfer of all inactive candidates;
    iv. for heart candidates, those with Status 1A and 1B must be transferred within 30 days of inactivation;
    v. for multivisceral organ transplant candidates, transfer must be completed within 30 days of inactivation; and
    vi. notwithstanding these guidelines, all active candidates should be transferred within 60 days; and
8) document all efforts to transfer candidates to an alternative designated transplant program including all contacts made to facilitate the transfer of candidates.
9) have every transplant candidate removed from the subject transplant program's waiting list within 12 months of the program's inactivation date.

Transplant programs that inactivate still have the ability to provide care for transplant recipients. Should the transplant program continue to provide follow-up care for transplant recipients, the program must continue to submit OPTN follow up forms in UNet[sm]. Additionally, transplant recipients may transfer care to another institution.

4. Waiting time on waitlist.
To assure equity in waiting times, and facilitate smooth transfer of candidates from the waiting list of affected programs (i.e. programs that voluntarily inactivate, relinquish or lose designated transplant program status), candidates on the waiting list in such instances may retain existing waiting time and continue to accrue waiting time appropriate to their status on the waiting list at the time of the programs' inactivation, relinquishment, or loss of designated status. This total acquired waiting time will be transferred to the candidate's credit when s(he) is listed with a new program.

5. Lab tests.
The inactivated program must obtain the required laboratory tests of candidate follow-up to maintain the candidate's appropriate status on the list until the time of transfer.

III. Histocompatibility Laboratories. [No Change]

ATTACHMENT I
TO APPENDIX B OF THE OPTN BYLAWS

[No change] A transplant program that meets the following criteria shall be qualified as a designated transplant program to receive organs for transplantation:

I. Facilities and Resources. [No change]

II. Reporting Changes in Key Personnel. [No change]

III. Investigation of Personnel. [No change]

IV. OPO Affiliation. [No change]

V. Histocompatibility Laboratory Affiliation. [No change]

VI. Transplant Surgeon and Physician. [No change]

Current language with Proposed Language in Strikeouts and Underlines for OPTN and UNOS Bylaws

Exhibit M-3

APPENDIX B TO BYLAWS

Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership

I. Organ Procurement Organizations. [No Change]

II. Transplant Hospitals.

A. General. [No Change]

B. Survival Rates. [No Change]

C. ~~**Inactive Membership Status.**~~ **Functional Inactivity, Voluntary Inactive Membership Transplant Program Status, Relinquishment of Designated Transplant Program Status and Termination of Designated Transplant Program Status**. ~~A Member Transplant Hospital that fails to remain functionally active with respect to any designated transplant program (as defined below) may voluntarily stop transplantation at that transplant program for a period of up to twelve months by notice to the Executive Director, or may relinquish designated transplant program status for the program. This voluntary action to stop transplantation may be extended beyond twelve months upon request to the MPSC and demonstration to the MPSC's satisfaction of the benefit of such extension, together with a plan and timeline for re-starting transplantation at the program which shall include assurance that all OPTN membership criteria will be met at the time of re-starting transplantation.~~ [The following section moved with changes below] ~~The MPSC may also require, in its discretion, that the Member participate in a discussion regarding a performance review. The discussion may be with the MPSC, a subcommittee or work group, as the MPSC may direct. The discussion referenced above will be conducted according to the principles of confidential medical peer review, as described in Section 2.07A of Appendix A to the OPTN Bylaws. The discussion is not an adverse action or an element of due process. A Member who participates in a discussion with the MPSC is entitled to receive a summary of the discussion.~~

1. **Functional Inactivity**. Transplant programs must remain functionally active. Transplant program functional activity will be reviewed periodically by the Membership and Professional Standards Committee (MPSC).

For purposes of these Bylaws, "~~functionally inactive~~ Functional Inactivity" means any or all of the items below:

~~(1)~~ (i) The inability to serve ~~patients,~~ potential candidates, candidates, and recipients, as a group, for ~~a sustained and significant time period, where~~ a period of 15 days or more ~~is presumed to be sustained and significant, or~~ ;

~~(2) No transplant performed for a period of time defined as:~~

(ii) that a transplant has not been performed during the following stated periods of time:

(d) ~~No transplant performed in three months~~ In the case of kidney, liver, and heart transplant programs, within three consecutive months;

(e) ~~No transplant performed in six months~~ ~~I~~in the case of pancreas and lung programs, ~~and~~ within six consecutive months;

(f) ~~No transplant performed in one year~~ ~~I~~in the case of ~~transplant programs located in~~ stand-alone pediatric transplant hospitals, within twelve consecutive months.

(iii) waiting list inactivation of 28 cumulative days or more over any 365 consecutive day period.

~~with no explanation deemed satisfactory by the MPSC that the program remains qualified pursuant to the criteria defined in this Appendix B to provide transplant services.~~

Programs identified to be functionally inactive shall be provided the opportunity to explain the period of inactivity through reports requested by the MPSC.

[Section moved from above, with changes]The MPSC may also require, at its discretion, that the Member participate in an informal discussion regarding a performance review. The informal discussion may be with the MPSC, a subcommittee or work group, as the MPSC may direct.

The discussion referenced above will be conducted according to the principles of confidential medical peer review, as described in Section 2.07A of Appendix A to the ~~OPTN~~ Bylaws. The discussion is not an adverse action or an element of due process. A Member who participates in an informal discussion with the MPSC is entitled to receive a summary of the discussion.

A functionally inactive transplant program may voluntarily inactivate for a period of up to twelve months by providing written notice to the Executive Director, or must relinquish designated transplant program status for the program in accordance with these bylaws.

The MPSC may recommend that a program inactivate or relinquish its designated transplant program status due to the program's functional inactivity. If the program fails to inactivate or relinquish its designated transplant status upon the MPSC's recommendation to do so, the Committee may recommend the Board of Directors take appropriate action in accordance with Appendix A of these Bylaws. Potential adverse actions are defined under Section 3.01A of the bylaws. Additionally, the Board of Directors may notify the Secretary of HHS of the situation. This action will apply in the case of transplant programs approved by the Secretary of HHS for reimbursement under Medicare or in the case of transplant programs in Federal hospitals.

~~If the Member fails to take either action voluntarily, the Membership and Professional Standards Committee may recommend that the Board of Directors take appropriate action in accordance with Appendix A of these Bylaws in all other cases, which action may include those defined as adverse under Section 3.01A. Program inactivation or relinquishment of designated transplant program status involves (i) prompt suspension of transplantation, (ii) notice to patients of the need to inactivate, removal of these patients from the program's waiting list, or - if the patient desires - transfer of the~~

~~patient to the list of another Member Transplant Hospital, and (iii) assistance for patients in identifying the designated transplant programs to which they can transfer. Upon submission and review of information establishing that the Member has again become active in human organ transplantation and that all other criteria for membership are met, the Membership and Professional Standards Committee shall recommend to the Board of Directors that the Member be designated as an active member.~~

[Section Moved, with modifications to **4. Waiting Time on Waiting List**]
~~To assure equity in waiting times, and facilitate smooth transfer of patients from the waiting list of a program that is inactivated or relinquishes designated transplant status, patients on the waiting list of a designated transplant program at the time of inactivation or relinquishment of designated status may retain existing waiting time and continue to accrue waiting time appropriate to their status on the waiting list at the time of inactivation or relinquishment of designated status of their program for a maximum of 90 days following that program's inactivation or relinquishment of designated status. This total acquired waiting time may be, with agreement of the accepting center, transferred to the patient's credit when s(he) is listed with a new program.~~

~~It is expected that all Transplant Hospitals will duly inform their patients on the waiting list if there will be an extended period of time when a designated transplant program will be unable to perform transplants. Programs that are not able to serve patients, as a group, for a period of 15 consecutive days or more are further expected to notify UNOS and their patients as described above.~~

2. Inactive Status-Voluntary.

Inactive Status – Voluntary. A Member may voluntarily inactivate its transplant program for reasons including but not limited to:

i) not being able to meet functional activity requirements;
ii) temporarily lacking required physician and/or surgeon coverage;
iii) substantial change in operations that require temporary cessation of transplantation.

Voluntary inactivation may be short term or long term.

a. Short Term Inactivation
Short term inactivation means that a transplant program may be inactive for up to 14 consecutive days. A Member transplant hospital may voluntarily inactivate its transplant program for a period not to exceed 14 days by changing the waiting list program status in UNet^{sm}.

Notice. In accordance with Appendix B Section VII(A)(1), all transplant programs must provide candidates, potential recipients and recipients with a written summary of the Program Coverage Plan at the time of listing or when there are any substantial changes in program or personnel.

b. Long Term Inactivation

Long term inactivation means inactivation of a transplant program for 15 days or more. Programs that are not able to serve potential candidates, candidates, and recipients, as a group, for a period of 15 consecutive days or more may voluntarily inactivate for a period of up to twelve months.

Notice. A Member that intends to voluntarily inactivate its transplant program must provide written notice to the Executive Director. A transplant program must also provide written notice to candidates on the waiting list in instances when it is unable:

1) to perform transplants for 15 consecutive days or more over any 365 day period; or
2) to perform transplants for 28 cumulative days or more over any 365 day period.

Extension of Voluntary Inactive Program Status Beyond Twelve Months. A Member transplant hospital may request an extension of voluntary inactive program status beyond twelve months by making a request to the MPSC. The request must demonstrate to the MPSC's satisfaction the benefit of such an extension, and be accompanied by a comprehensive plan with a timeline for re-starting transplantation at the program. This demonstration must include assurance that all membership criteria will be met at the time of re-starting transplantation.

Reactivation After Voluntary Long Term Inactivation. A Member transplant hospital may reactivate its program after long term voluntary inactivation by submitting application materials deemed appropriate by the MPSC that establishes that the program has again become active in organ transplantation and that all criteria for membership are met. The Membership and Professional Standards Committee shall recommend to the Board of Directors that the Board so notify the Secretary of HHS.

3. Relinquishment or Termination of Designated Transplant Program Status

Relinquishment of Designated Transplant Program Status means that a Member may voluntarily give up its designated transplant program status upon written notice to the OPTN. Members that relinquish designated transplant program status are voluntarily closing.

Termination of Designated Transplant Program Status means that a Member's designated program status may be terminated by the Secretary of the Department of Health and Human Services ("Secretary"). In the case of noncompliance with policies covered by Section 1138 of the Social Security Act, the MPSC may recommend that the Board of Directors and/or the Executive Committee on its own accord, may request approval from the Secretary to terminate a Member's designated transplant program status in accordance with Appendix A Section 2.06A of these Bylaws.

Once a Member relinquishes its designated transplant program status or it is terminated by the Secretary of HHS, the subject transplant program may no longer perform organ transplants. The Member must facilitate the transfer of the subject transplant program's candidates to another transplant program.

a. Notice

The Member transplant hospital must provide the following when its designated transplant program status is relinquished or terminated:

1) written notice to the OPTN contractor within 30 days of the intent to relinquish designated transplant program status and the reasons therefore; and
2) written notice to the transplant program's potential candidates, candidates and recipients currently being followed by the transplant program. Written notice should be mailed within 30 days prior to the anticipated inactivation date by certified mail/return receipt requested and include:
    1. the program's reasons for relinquishing designated transplant program status;
    2. notice that while still on the waiting list of the inactive program the candidate cannot receive an organ offer through this member program;
    3. options for potential candidates, candidates, and recipients to transfer to an alternative designated transplant program with the phone number of the administrative office of the inactivating program to help with potential candidate, candidate, and recipient transfers; and

The Member transplant hospital must provide a representative copy of the written notice to the OPTN contractor along with a list of potential candidate, candidate, and recipient names who received the notice.

b. Transition Plan

The Member transplant hospital must perform the following activities when one of its transplant program's designated status is relinquished or terminated:

1) the subject transplant program must promptly suspend organ implantation;
2) assist potential candidates and waitlisted candidates in identifying designated transplant programs to which they can transfer;
3) provide a list to the OPTN contractor of all of the transplant program's candidates on the waiting list at the time of inactivation and update it throughout this process;
4) indicate on the list provided each candidate's decision to transfer, with the following additional information
    1. if a candidate chooses not to transfer to an alternative transplant program, provide the reason and indicate

whether the candidate has been completely informed of the implications of this decision; or

2. if a candidate chooses to transfer, indicate to which transplant program the candidate is transferring. Periodic updates will be required as to the status of that candidate's transfer progress until the candidate is evaluated by the accepting program and an official acceptance is made regarding the candidate's listing status.

5) expedite removal of all candidates from the subject transplant program's waiting list, or, if the patient requests, transfer the candidate to another OPTN Member transplant hospital;
6) transfer any active candidate hospitalized at the inactive transplant program to an accepting transplant hospital within seven days of inactivation of the subject transplant program unless transfer would be unsafe or discharge is anticipated within that time;
7) provide a priority list of the most urgent candidates listed at the subject transplant program with an individualized plan of transfer, potential alternative transplant programs, and a timeline for transferring these candidates according to the following priorities:
    1. for liver candidates, all Status 1 candidates should be transferred within seven days of inactivation, followed by all active MELD/PELD candidates in order of score with all candidates with a MELD/PELD > 25 to be transferred within 30 days, followed by all inactive candidates;
    2. for lung candidates, those active candidates with Lung Allocation Scores in descending order with highest scores first, followed by the inactive candidates;
    3. for kidney candidates, all active highly sensitized (PRA≥80%) candidates first, followed by all other active candidates in order of waiting time, then transfer of all inactive candidates;
    4. for heart candidates, those with Status 1A and 1B must be transferred within 30 days of inactivation;
    5. for multivisceral organ transplant candidates, transfer must be completed within 30 days of inactivation; and
    6. notwithstanding these guidelines, all active candidates should be transferred within 60 days; and
8) document all efforts to transfer candidates to an alternative designated transplant program including all contacts made to facilitate the transfer of candidates.
9) have every transplant candidate removed from the subject transplant program's waiting list within 12 months of the program's inactivation date.

Transplant programs that inactivate still have the ability to provide care for transplant recipients. Should the transplant program continue to provide follow-up care for transplant recipients, the program must continue to submit

OPTN follow up forms in UNet[sm]. Additionally, transplant recipients may transfer care to another institution.

~~5~~4. Waiting time on waiting list.
[Moved from previous section, with changes]
To assure equity in waiting times, and facilitate smooth transfer of candidates from the waiting list of ~~a program that is inactivated or relinquishes designated transplant status,~~ affected programs (i.e. programs that voluntarily inactivate, relinquish or lose designated transplant program status), candidates on the waiting list in such instances may retain existing waiting time and continue to accrue waiting time appropriate to their status on the waiting list at the time of the programs' inactivation, relinquishment, or loss of designated status. ~~for a maximum of 90 days following that program's inactivation, relinquishment or loss of designated status.~~ This total acquired waiting time will ~~may~~ be~~,~~ ~~with agreement of the accepting center,~~ transferred to the candidate's credit when s(he) is listed with a new program.

~~If the candidate remains on the waitlist of an inactivated program past the maximum 90 days stated above then a Waiting Time Modification per OPTN/UNOS Policy 3.2.1.8 Waiting Time Modification will be required.~~

~~6~~5. Lab tests. The inactivated program must obtain the required laboratory tests of candidate follow-up to maintain the candidate's appropriate status on the list until the time of transfer.

III. Histocompatibility Laboratories. [No Change]

ATTACHMENT I
TO APPENDIX B OF THE OPTN BYLAWS

[No change] A transplant program that meets the following criteria shall be qualified as a designated transplant program to receive organs for transplantation:

II. Facilities and Resources. [No change]

II. ~~Inactive Program Status~~. ~~Designated transplant programs qualified in accordance with these Attachment I criteria that fail to remain functionally active shall voluntarily stop transplantation at that transplant program for a period of up to twelve months by notice to the Executive Director, or may relinquish designated transplant program status for the program. This voluntary action to stop transplantation may be extended beyond twelve months upon request to the MPSC and demonstration to the MPSC's satisfaction of the benefit of such extension, together with a plan and timeline for re-starting transplantation at the program which shall include assurance that all OPTN membership criteria will be met at the time of re-starting transplantation. For purposes of these Bylaws, "functionally inactive" is defined as:~~

~~(1) The inability to serve patients, as a group, for a sustained and significant time period, where a period of 15 days or more is presumed to be sustained and significant, or~~

~~(2) No transplant performed for a period of time defined as:~~

~~(g) No transplant performed in three months in the case of kidney, liver, and heart transplant programs,~~
~~(h) No transplant performed in six months in the case of pancreas and lung programs, and~~
~~(i) No transplant performed in one year in the case of transplant programs located in stand-alone pediatric transplant hospitals, with no explanation deemed satisfactory by the MPSC that the program remains qualified pursuant to the criteria defined in this Appendix B to provide transplant services.~~

~~If the program fails to take either action voluntarily, the Membership and Professional Standards Committee may recommend that the Board of Directors take appropriate action in accordance with Appendix A of these Bylaws, which action may include those defined as adverse under Section 3.01A. Program inactivation or relinquishment of designated transplant program status involves (i) prompt suspension of transplantation, (ii) notice to patients (with a copy to the organization under contract with HHS to operate the OPTN (OPTN Contractor)) of the need to inactivate, removal of these patients from the program's waiting list, or - if the patient desires - transfer of the patient to the list of another OPTN Member Transplant Hospital, and (iii) assistance for patients in identifying the designated transplant programs to which they can transfer. Upon submission and review of information establishing that the Member has again become active in human organ transplantation and that all other criteria for OPTN membership are met, the Membership and Professional Standards Committee shall recommend to the Board of Directors that the Board so notify the Secretary of HHS.~~

~~To assure equity in waiting times, and facilitate smooth transfer of patients from the waiting list of a program that is inactivated or relinquishes designated transplant status, patients on the waiting list of a designated transplant program at the time of inactivation or relinquishment of designated status may retain existing waiting time and continue to accrue waiting time appropriate to their status on the waiting list at the time of inactivation or relinquishment of designated status of their program for a maximum of 90 days following that program's inactivation or relinquishment of designated status. This total acquired waiting time may be, with agreement of the accepting center, transferred to the patient's credit when s(he) is listed with a new program.~~

~~It is expected that all designated transplant programs will duly inform their patients on the waiting list if there will be an extended period of time when the program will be unable to perform transplants. Programs that are not able to serve patients, as a group, for a period of 15 consecutive days or more are further expected to notify the OPTN Contractor and their patients as described above.~~

III. **Reporting Changes in Key Personnel.** [No change]

III~~V~~. **Investigation of Personnel.** [No change]

IV. **OPO Affiliation.** [No change]

V~~I~~. **Histocompatibility Laboratory Affiliation.** [No change]

VII. Transplant Surgeon and Physician. [No change]

Public Comment Responses:

1. Public Comment Distribution

Has the proposal been distributed for public comment? Yes
Date of distribution: 06/30/2008
Public comment end date: 09/24/2008

As of 9/24/2008, 31 responses have been submitted to UNOS regarding this policy proposal.

Public Comment Response Tally					
Type	**Response Total**	**In Favor**	**In Favor as Amended**	**Opposed**	**No Opinion/ No Comment**
Individual Comments	31	24 (77.42%)	0 (0%)	1 (3.23%)	6 (19.35%)
Regional Comments	11	11 (100%)	0 (%)	0 (%)	0 (%)
Committee Comments	10	10 (100%)	0 (%)	0 (%)	0 (%)

2. Primary Public Comment Concerns/Questions

During the public comment period, much of the discussion related to implementation of the 365-day rolling period for MPSC review. Figures 1 and 2 provide a reference of how the MPSC will implement this requirement for monitoring.

3. Regional Public Comment Responses

Region	Meeting Date	Motion to Approve as Written	Approved as Amended (see below)	Did Not Consider
1	9/8/08	14 yes, 0 no, 0 abstentions		
2	9/3/08	26 yes, 0 no, 0 abstentions		
3	9/22/08	19 yes, 0 no, 0 abstentions		
4	8/22/08	18 yes, 1 no, 0 abstentions		
5	9/9/08	16 yes, 0 no, 0 abstentions		
6	9/4/08	22 yes, 0 no, 0 abstentions		
7	8/21/08	13 yes, 0 no, 0 abstentions		
8	9/11/08	13 yes, 0 no, 0 abstentions		
9	9/10/08	14 yes, 0 no, 0 abstentions		
10	8/26/08	17 yes, 0 no, 0 abstentions		
11	9/23/08	14 yes, 0 no, 0 abstentions		

Region 1: The region approved the proposal but raised the question regarding the timetable for sending letters to candidates when there has been an unforeseen period of inactivity.

4. Committee Public Comment Responses

Ad Hoc International Relations committee
The Ad Hoc International Relations Committee reviewed this proposal and voted on it electronically. The Committee supported this proposal: 2-Support; 0-Oppose; 0-Abstention.

Kidney Transplantation Committee
The MPSC specifically asks if the time periods (60 days) for waiting list transfers are considered achievable. The Committee discussed this question at length and had some additional questions. First, it was unclear whether the time period of sixty days meant that all candidates at the closing center had to be active on another center's waiting list. Centers have different acceptance criteria for transplant candidates and some candidates may require additional testing. If the closing center has a lot of candidates on its waiting list, other centers in the donor service area may be unable to absorb the volume. The Committee was also concerned about the notification requirements for centers that choose to go into inactive status voluntarily. Some on the Committee suggested that a center could inactivate, notify its candidates early in the process and then remain inactive without further communication to its candidates for up to a year. The Committee requests that there be specific guidelines describing how notification should take place in these circumstances to ensure that candidates are not left uninformed for long periods of time.

Committee Response:
The 60-day time period for waiting list transfers is meant to serve as a guideline to ensure that the inactivating transplant program work expeditiously to transfer all active candidates from the wait list. The MPSC recognizes that centers may utilize acceptance criteria unique from the inactivating transplant program and this can impact meeting the 60-day transfer period. However, the MPSC is also aware of numerous transplant programs that inactivate and still have candidates on the wait list for more than six-months. The ultimate goal is to ensure that the candidates at the inactivated transplant program have access to organs as quickly as possible to minimize disruption to the patient. Additionally, transplant programs that inactivate with a large list may not be able to meet the 60-day threshold. This requirement is a "should" and not an absolute. The requirement, as proposed, is that every transplant candidate (active and inactive candidates) be removed from the inactivated transplant program wait list within 12 months of the program's inactivation date.

With regard to the Kidney Transplantation Committee's suggestion regarding the inactivated transplant program notifying candidates early in the process but do not follow up with candidates for up to a year: the OPTN requires that upon notification of program inactivation, the program submit reports every two weeks on the status of the wait list transfers and will forward noncompliant Members to the MPSC for consideration.

Liver and Intestinal Organ Transplantation committee
The Committee supported this proposal by a vote of 12 in favor, 0 opposed, and 0 abstentions.

Minority Affairs Committee
The committee determined that there was no minority impact from the proposed policy.

Pancreas Transplantation Committee
The Pancreas Transplantation Committee reviewed this proposal at its July 18, 2008 meeting. The Committee was concerned that centers may not be able to transfer candidates within 60 days of relinquishment of designated program status because the transfer is dependent on another center's ability to accept and work up these candidates. Additionally, the Committee thought that these requirements would be difficult for islet programs to meet, particularly if the program is in between clinical protocols. The Committee supported this proposal with an amendment that it does not apply to islet transplantation programs because of the experimental nature of the islet transplantation field. (14-Support, 0-Oppose, 1-Abstain)

Committee Response:

The question of transfer within 60-days has been addressed under the Kidney Transplantation Committee response above.

Recognizing the experimental and evolving nature of pancreas islet transplantation, the MPSC has modified the language under the definitions of functional inactivity to exclude pancreas islet transplant programs from functional inactivity and waiting list notification requirements (see Section 1: Functional Inactivity).

Patient Affairs Committee
The Patient Affairs Committee supported the proposal with a vote of 13-0-0.

Pediatric Transplantation committee
After discussion, a member questioned whether small programs with a surgeon on vacation requiring temporary inactivation should even be transplant programs. Members felt strongly that small programs that could be in this situation must be very clear with candidates at the time of listing regarding coverage plans and the option of multiple listing to avoid inactivation on the wait list due to provider who is unavailable for up to 14 days.

Equally, members agreed that there must be protection for candidates hospitalized in a center that is inactivated. What should be done with a Status 1 candidate when a program must inactivate suddenly (i.e. the surgeon dies, etc.) and arrangements cannot be made for transfer, as noted in Appendix B, Section II, C, 3b (6) and (7)? A suggestion was made to revise the policy language to include initiate transfer to reflect that a program may be working in good faith to accomplish the transfer, but still be unsuccessful in its efforts due to patient volume or other issues. It was acknowledged that a candidate's lack of insurance, for example, may make transfer difficult if not impossible in some instances.

After discussion, the Committee supported the proposal in principle, including notification of all transplant candidates and recipients of temporary and/or permanent inactivation as well as good faith efforts to these patients in reasonable time and according to medical status. The Committee requested that the MPSC consider modifications to the proposed bylaw language to ensure that expectations regarding the transfer of candidates can be met. (Committee vote: 16 in favor, 0 opposed, 0 abstentions)

Committee Response:

Current Bylaws do not limit transplant program membership to those programs with more than one surgeon or physician. The Bylaws do require that single surgeon/physician programs notify candidates at the time of listing of this situation and the potential to have organ offers declined due to surgeon

availability. As with all notification requirements, this notification requirement is subject to verification by the Department of Evaluation and Quality.

The MPSC agrees with the recommendation to add initiate to Section II, C, 3b (6) and added additional language regarding the transfer process and candidate removal from the inactivating transplant program relating to limitations of alternative transplant program acceptance.

Policy Oversight Committee
This proposal clarifies the definition of "functional inactivity" to include waiting list inactivation in UNetSM. The proposed language also defines short and long-term voluntary inactivation and specifies responsibilities for Member institutions that choose to inactivate a transplant program, including patient notification requirements. Currently, the bylaws define functional inactivity based on a lack of transplant activity, but do not specifically address waiting list inactivation. The MPSC reviewed data for several programs with inactive wait lists for greater than 14 days, with some inactive for more than 100 days. The MPSC was concerned that candidates were not notified of periods greater than 14 days during which the waiting list was set to "inactive" and therefore no organ offers would be made on their behalf. Under this proposal, candidates must be notified of these periods of wait list inactivation. The proposal also clarifies responsibilities for transplant programs that voluntarily inactivate and removes duplicative language from Attachment I of Appendix B. If the proposal is adopted, the MPSC will include waiting list inactivation as part of its functional inactivity review process. Programs that inactivate a wait list for greater than 14 consecutive days or 28 cumulative days in a year will be identified for MPSC Data Subcommittee review. Committee members asked why the threshold of 14 days was selected, and were informed that this time period is already used by the bylaws. The Committee had no further comments.

In September, the Committee reviewed the key points of this proposal. The proposal scored highest in the Patient Safety and Transplantation Oversight category, with an overall score of 7.0. The Committee voted to support this proposal by a vote of 7 in favor, 0 opposed, and 0 abstentions.

Thoracic Organ Transplantation committee
The Thoracic Committee reviewed and voted on this proposal electronically. The Committee supports this proposal: 10-Support; 0-Oppose; 1-Abstention.

Transplant Coordinators Committee
The Committee supported this proposal by a vote of 10 in favor, 0 opposed, and 0 abstentions.

5. Individual Public Comment Responses

Comment 1:
vote: No Opinion

"I want to know before 14 days if my transplant center stops performing transplants. People on the list are customers not just a number on a list."

Committee Response:

The purpose of this bylaw modification is to ensure patients are aware of these periods of inactivation. The MPSC discussed the 14-day threshold at length during the development of this proposal,

considering practicality based on transplant center workload and patient awareness. This was the agreed compromise. Your center may be more aggressive than the requirements outlined.

Comment 2:
Of most interest to the AFL, with regard to this proposed policy change, is the clarification that transplant candidates will not lose accrued wait time should their transplant center choose to go inactive for any period of time. We support the clarification that requires transplant centers to better inform candidates of these inactive periods and to reassign wait listed candidates to active transplant centers so eligible candidates would not lose an available liver during an inactive period of their assigned transplant centers. This change to the bylaws will maintain equity and fairness for all transplant candidates. We urge that UNOS do everything possible to ensure patients who are organ candidates at transplant centers that go inactive be transferred to other transplant centers with minimal disruption. We further urge the Committee to continue to monitor this policy to ensure that adequate communication with patients and equity for transplant center transfers remain a priority.

Committee Response:
The committee appreciates the AFL's support of this proposal.

Post Public Comment Consideration:

Responses received and regional and committee discussions during the public comment period noted confusion with regard to the definitions of short-term and long-term inactivation as a "status" and the definition of "functional inactivity" serving as a trigger for MPSC review. To address this confusion we clarified definitions within the bylaws and modified organization to more clearly articulate intent. Some of the changes reflected within *Section 2 – Inactive Status – Voluntary* denoted with double-strikethroughs and <u>double-underlines</u> attempt to further clarify these definitions.

Additionally, the Pancreas Transplantation Committee recommended the exclusion of pancreas islet transplant programs from the MPSC review of functional inactivity based upon the nature of pancreas islet transplantation. The MPSC agreed with this exclusion and also recommended that intestinal transplant programs be excluded, as reflected under Section C.1.(iv.).

Note: though the changes made after the public comment period look substantial, the Committee rearranged the same information to make sure the bylaws are as clear as possible.

UNOS also received feedback and questions regarding implementation and monitoring of this bylaw proposal. Of particular interest was how the MPSC would monitor waiting list inactivation for cumulative periods of 28 days or more. Figures 1 and 2 provide a graphic view of the rolling periods as well as some examples. For each meeting, the UNOS Research Department will prepare a report for the MPSC inclusive of any programs that showed an inactive wait list cumulative total of 28 days or more in any 365-day period and any programs that showed an inactive wait list consecutive total of 15 days or more in any 365 day period. Additionally, the UNOS Information Technology staff are developing a report to allow Members to monitor their cumulative waiting list inactivity. It is anticipated that this report will be available Summer 2009.

The MPSC voted on October 15, 2008, to further amend the modifications to the Bylaws based upon feedback received during the public comment period. The Committee vote was 27 For, 0 Against, 0 Abstentions.

Exhibit M-3

The modifications to Appendix B, Section II, C appear below. The language included below shows the existing language, the language distributed for public comment (shown with underlines and strikethroughs) and the language modified after public comment is noted with new language added after public comment double underlined and deleted language marked with ~~double strikethroughs~~.

Changes to *Proposed Language to OPTN and UNOS Bylaws* distributed for public comment 6/30/08.

APPENDIX B TO BYLAWS

Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership

I. Organ Procurement Organizations. [No Change]

II. Transplant Hospitals.

A. General. [No Change]

B. Survival Rates. [No Change]

C. ~~Inactive Membership Status.~~ Functional Inactivity, ~~Voluntary Inactive Membership~~ Inactive Transplant Program Status, Relinquishment of Designated Transplant Program Status and Termination of Designated Transplant Program Status. ~~A Member Transplant Hospital that fails to remain functionally active with respect to any designated transplant program (as defined below) may voluntarily stop transplantation at that transplant program for a period of up to twelve months by notice to the Executive Director, or may relinquish designated transplant program status for the program. This voluntary action to stop transplantation may be extended beyond twelve months upon request to the MPSC and demonstration to the MPSC's satisfaction of the benefit of such extension, together with a plan and timeline for re-starting transplantation at the program which shall include assurance that all OPTN membership criteria will be met at the time of re-starting transplantation.~~ [The following section moved with changes below] ~~The MPSC may also require, in its discretion, that the Member participate in a discussion regarding a performance review. The discussion may be with the MPSC, a subcommittee or work group, as the MPSC may direct. The discussion referenced above will be conducted according to the principles of confidential medical peer review, as described in Section 2.07A of Appendix A to the OPTN Bylaws. The discussion is not an adverse action or an element of due process. A Member who participates in a discussion with the MPSC is entitled to receive a summary of the discussion.~~

For the purposes of these bylaws, a candidate is defined as an individual who has been added to the waiting list. A potential candidate is defined as an individual who is under evaluation for transplant by the transplant program. Each reference to a candidate includes potential candidates if and as applicable.

1. **Functional Inactivity**. Transplant programs must remain functionally active. Transplant program functional activity will be reviewed periodically by the Membership and Professional Standards Committee (MPSC).

For purposes of these Bylaws, "~~functionally inactive~~ Functional Inactivity" ~~means~~ is defined as any or all of the items below:

~~(1)~~ (~~i~~a) The inability to serve ~~patients,~~ potential candidates, candidates, ~~and~~ or recipients, ~~as a group,~~ for ~~a sustained and significant time period, where~~ a period of 15 days or more consecutively ~~is presumed to be sustained and significant, or~~ ;

~~(2) No transplant performed for a period of time defined as:~~

(~~ii~~b~~) that a transplant has not been performed~~ failure to perform a transplant during the following stated periods of time:

i. ~~No transplant performed in three months~~ I~~i~~n the case of kidney, liver, and heart transplant programs, within three consecutive months;

ii. ~~No transplant performed in six months~~ I~~i~~n the case of pancreas and lung programs, ~~and~~ within six consecutive months;

iii. ~~No transplant performed in one year~~ I~~i~~n the case of ~~transplant programs located in~~ stand-alone pediatric transplant hospitals, within twelve consecutive months.

(~~iii~~c) waiting list inactivation of 15 or more consecutive days and/or 28 cumulative days or more over any 365 consecutive day period.

(d) given the experimental and evolving nature, functional inactivity thresholds and waiting list notification requirements regarding functional inactivity have not been established for pancreatic islet and intestinal transplant programs.

~~with no explanation deemed satisfactory by the MPSC that the program remains qualified pursuant to the criteria defined in this Appendix B to provide transplant services.~~

Any program~~s~~ identified to be functionally inactive shall be provided the opportunity to explain ~~the period of~~ its inactivity through reports requested by the MPSC.

A transplant program must provide written notice to candidates when the transplant program:

(a) Inactivates its waiting list or is unable to perform transplants for 15 consecutive days or more over any 365 consecutive day period;

(b) Inactivates its waiting list or is unable to perform transplants for 28 cumulative days or more over any 365 consecutive day period;

[Section moved from above, with changes]The MPSC may also require, at its discretion, that the Member participate in an informal discussion regarding a performance review. The informal discussion may be with the MPSC, a subcommittee or work group, as the MPSC may direct.

The discussion referenced above will be conducted according to the principles of confidential medical peer review, as described in Section 2.07A of Appendix A to the ~~OPTN~~ Bylaws. The discussion is not an adverse action or an element of due process. A Member who participates in an informal discussion with the MPSC is entitled to receive a summary of the discussion.

A functionally inactive transplant program ~~may~~ should voluntarily inactivate for a period of up to twelve months by providing written notice to the Executive Director. If the transplant program expects to be inactive for more than twelve months, the Member should ~~or must~~ relinquish designated transplant program status for the program in accordance with these bylaws.

The MPSC may recommend that a program inactivate or relinquish its designated transplant program status due to the program's functional inactivity. If the program fails to inactivate or relinquish its designated transplant status upon the MPSC's recommendation to do so, the ~~Committee~~ MPSC may recommend the Board of Directors take appropriate action in accordance with Appendix A of these Bylaws. Potential adverse actions are defined under Section 3.01A of the bylaws. Additionally, the Board of Directors may notify the Secretary of HHS of the situation. This action will also apply in the case of transplant programs approved by the Secretary of HHS for reimbursement under Medicare ~~or~~ and in the case of transplant programs in Federal hospitals.

~~If the Member fails to take either action voluntarily, the Membership and Professional Standards Committee may recommend that the Board of Directors take appropriate action in accordance with Appendix A of these Bylaws in all other cases, which action may include those defined as adverse under Section 3.01A. Program inactivation or relinquishment of designated transplant program status involves (i) prompt suspension of transplantation, (ii) notice to patients of the need to inactivate, removal of these patients from the program's waiting list, or - if the patient desires - transfer of the patient to the list of another Member Transplant Hospital, and (iii) assistance for patients in identifying the designated transplant programs to which they can transfer. Upon submission and review of information establishing that the Member has again become active in human organ transplantation and that all other criteria for membership are met, the Membership and Professional Standards Committee shall recommend to the Board of Directors that the Member be designated as an active member.~~

[Section Moved, with modifications to **4. Waiting Time on Waiting List**]
~~To assure equity in waiting times, and facilitate smooth transfer of patients from the waiting list of a program that is inactivated or relinquishes designated transplant status, patients on the waiting list of a designated transplant program at the time of inactivation or relinquishment of designated status may retain existing waiting time and continue to accrue waiting time appropriate to their status on the waiting list at the time of inactivation or relinquishment of designated status of their program for a maximum of 90 days following that program's inactivation or relinquishment of designated status. This total acquired waiting time may be, with agreement of the accepting center, transferred to the patient's credit when s(he) is listed with a new~~

~~program.~~

~~It is expected that all Transplant Hospitals will duly inform their patients on the waiting list if there will be an extended period of time when a designated transplant program will be unable to perform transplants. Programs that are not able to serve patients, as a group, for a period of 15 consecutive days or more are further expected to notify UNOS and their patients as described above.~~

2. **Inactive Transplant Program Status~~ Voluntary~~**

For the purposes of these bylaws, inactive transplant program status is defined as:

- an inactive transplant program waiting list status in UNet^{SM} (short-term inactivation), or
- an inactive transplant program waiting list status in UNet^{SM} and an inactive membership status (long-term inactivation).

~~**Inactive Status – Voluntary.**~~A Member may voluntarily inactivate~~its~~ a transplant program, on a short-term or long-term basis, for reasons including but not limited to:

- ~~not being able to~~inability to meet functional activity requirements;
- temporarily lacking required physician and/or surgeon coverage;
- substantial change in operations that require temporary cessation of transplantation.

~~Voluntary inactivation may be short term or long term.~~

a. Short-Term Inactivation

Short-term inactivation means that a transplant program may be inactive for up to 14 consecutive days. A Member ~~transplant hospital~~ may voluntarily inactivate ~~its~~a transplant program for a period not to exceed 14 days by changing the program's waiting list ~~program~~status in UNet^{SM}.

i. **Notice to the OPTN Contractor.** When a Member intends to voluntarily inactivate a transplant program on a short-term basis, the Member is not required to notify the OPTN contractor.

ii. **Notice to Patients.** In accordance with Attachment I to Appendix B, Section VII~~(A)(1)~~, ~~all~~each transplant program~~s~~ must provide potential candidates, ~~potential recipients~~ candidates, and recipients with a written summary of ~~the~~its Program Coverage Plan at the time of listing or when there are any substantial changes in program or personnel.

b. Long-Term Inactivation

Long-term inactivation means inactivation of a transplant program for 15 ~~days~~ or more ~~-~~days consecutively. Members should voluntarily inactivate~~P~~programs ~~-~~that are not able to serve potential candidates, candidates, ~~and~~ or recipients~~, as a group~~,for a period of 15 ~~consecutive days~~ or more days consecutively~~ may voluntarily inactivate for a period of up to twelve months~~. Voluntary inactivation may extend for a period of up to 12 months.

i. Notice to the OPTN Contractor. When a ~~A~~Member ~~that~~intends to voluntarily inactivate ~~its~~ a transplant program for 15 or more days consecutively, it must provide written notice, including the reason(s) for inactivation, to the OPTN Executive Director~~and~~ upon deciding to inactivate the transplant program. ~~A transplant program must also provide written notice to candidates on the waiting list in instances when it is unable:~~

~~1) to perform transplants for 15 consecutive days or more over any 365 day period; or~~

~~2) to perform transplants for 28 cumulative days or more over any 365 day period.~~

ii. Notice to the Patients. When ~~the~~a Member intends to inactivate~~s~~ a transplant program for 15 or more days consecutively, it must provide:

a) written notice to the transplant program's potential candidates, candidates, recipients, and living donors currently being followed by the transplant program. Written notice should be mailed at least 30 days prior to the anticipated inactivation date by certified mail/return receipt requested. Written notice must be mailed no later than seven days following inactivation and include:
   1) the reason(s) for inactivating the transplant program;
   2) notice that while still on the waiting list of the inactive program the candidate cannot receive an organ offer through this member program;
   3) options for potential candidates, candidates, recipients, and living donors to transfer to an alternative designated transplant program with the phone number of the administrative office of the inactivating program to help with potential candidate, candidate, recipient, and living donor transfers.

The Member must provide a representative copy of the written notice to the OPTN contractor along with a list of potential candidates, candidates, recipients, and living donors who received the notice.

3. Transition Plan

When the Member inactivates a transplant program for 15 or more days consecutively, it must:

a) promptly suspend organ implantation for that transplant program;
b) assist potential candidates and candidates in identifying designated transplant programs to which they can transfer;
c) provide a list to the OPTN contractor of all of the transplant program's candidates at the time of inactivation and update it throughout this process;

d) indicate on the list provided the decision of each potential candidate and each candidate to transfer, with the following additional information:
   i) if a candidate or potential candidate chooses not to transfer to an alternative transplant program, provide the reason and indicate whether the candidate has been completely informed of the implications of this decision; or
   ii) if a candidate or potential candidate chooses to transfer, indicate the transplant program to which the candidate is transferring. Periodic updates will be required as to the status of each candidate's transfer progress until the candidate is evaluated by the accepting program and an official decision is made regarding the candidate's listing status.

e) expedite removal of all candidates from the inactive transplant program's waiting list, or, if the candidate requests, transfer the candidate to another OPTN Member transplant hospital;

f) initiate transfer of all active candidates or potential candidates hospitalized at the inactive transplant program to an accepting transplant hospital within seven days of inactivation of the transplant program. The inactive transplant program must complete the transfer process within 14 days unless transfer would be unsafe or discharge is anticipated within that time; or circumstances outside of the program's control exist that prevent transfer within 14 days. The program must document and submit to the OPTN contractor all efforts for transfer of its hospitalized candidates or potential candidates if it is unable to meet the time periods within this section.

g) provide a priority list of the most urgent candidates or potential candidates at the inactive transplant program with an individualized plan of transfer, potential alternative transplant programs, and a timeline for transferring these candidates according to the following priorities:
   i) for liver candidates, all Status 1A and 1B candidates ~~should~~must be transferred within seven days of program inactivation, followed by all active candidates in descending MELD/PELD score order, with all candidates whose MELD/PELD score exceeds 25 to be transferred within 30 days, followed by all inactive candidates;
   ii) for lung candidates, active candidates should be transferred according to descending Lung Allocation Scores followed by inactive candidates;
   iii) for kidney candidates, those whose PRA(measured or calculated) is over 80% should be transferred first,

followed by all other active candidates in order of waiting time, then transfer of all inactive candidates;

iv) for heart candidates, all Status 1A and 1B must be transferred within seven days of inactivation;

v) for multivisceral organ transplant candidates, transfer must be completed within 30 days of inactivation; and

vi) notwithstanding these guidelines, all active candidates should be transferred within 60 days of inactivation.

vii) The program must document and submit to the OPTN contractor all efforts for transfer of its candidates if it is unable to meet the time periods within this section.

h document all efforts to transfer candidates to an alternative designated transplant program including all contacts made to facilitate the transfer of candidates; and

i) remove every transplant candidate from the inactive transplant program's waiting list within 12 months of the program's inactivation date in the cases when a program does not intend to reactivate.

Transplant programs that inactivate for 15 or more days consecutively may still have the ability to provide care to transplant recipients. Should the transplant program continue to provide follow-up care to transplant recipients, the program must continue to submit OPTN follow-up forms via UNet℠. Alternatively, transplant recipients may transfer care to another institution.

Extension of Voluntary Inactive Program Status Beyond Twelve Months. A Member transplant hospital may request an extension of voluntary inactive program status beyond twelve months by making a request to the MPSC. The request must demonstrate to the MPSC's satisfaction the benefit of such an extension, and be accompanied by a comprehensive plan with a timeline for re-starting transplantation at the program. This demonstration must include assurance that all membership criteria will be met at the time of re-starting transplantation.

Reactivation After Voluntary Long Term Inactivation. A Member transplant hospital may reactivate its program after long term voluntary inactivation by submitting application materials deemed appropriate by the MPSC that establishes that the program has again become active in organ transplantation and that all criteria for membership are met. The Membership and Professional Standards Committee shall recommend to the Board of Directors that the Board so notify the Secretary of HHS.

3. Relinquishment or Termination of Designated Transplant Program Status

Relinquishment of Designated Transplant Program Status means that a Member may voluntarily give up its designated transplant program status upon written notice to the

OPTN. Members that relinquish designated transplant program status are voluntarily closing the transplant program.

Termination of Designated Transplant Program Status means that a Member's designated program status is ~~may be~~ terminated by the Secretary of the Department of Health and Human Services ("Secretary"). In the case of noncompliance with policies covered by Section 1138 of the Social Security Act, the MPSC may recommend that the Board of Directors and/or the Executive Committee ~~on its own accord, may~~ request approval from the Secretary to terminate a Member's designated transplant program status in accordance with Appendix A Section 2.06A of these Bylaws. The Board of Directors and/or the Executive Committee may, on its own accord, request such approval from the Secretary.

Once a Member relinquishes ~~its~~ a designated transplant program status or it is terminated by the Secretary of HHS, ~~the subject~~ that transplant program may no longer perform organ transplants. The Member must facilitate the transfer of the subject transplant program's candidates to another transplant program.

a. Notice to the OPTN Contractor. ~~The~~ A Member transplant hospital must provide written notice to the OPTN contractor within 30 days of the intent to relinquish ~~the following when~~ its designated transplant program status and the reasons therefore upon deciding to relinquish designated transplant program status. ~~is relinquished or terminated~~:

~~1) written notice to the OPTN contractor within 30 days of the intent to relinquish designated transplant program status and the reasons therefore; and~~

~~2)~~

b. Notice to the Patients. When a Member transplant hospital intends to relinquish its designated transplant program status, or its designated transplant program status is terminated, it must provide:

i) written notice to the transplant program's potential candidates, candidates, ~~and~~ recipients, and living donors currently being followed by the transplant program. Written notice should be mailed ~~within~~ at least 30 days prior to the anticipated ~~inactivation~~ date of relinquishment or termination by certified mail/return receipt requested. Written notice must be mailed no later than seven days following relinquishment/termination and include:

1. the ~~program's~~ reason(s) for ~~relinquishing~~ loss of designated transplant program status;
2. notice that while still on the waiting list of the inactive program the candidate cannot receive an organ offer through this member program;
3. options for potential candidates, candidates, ~~and~~ recipients, and living donors to transfer to an alternative designated transplant program with the phone number of the administrative office of the inactivating program to help with potential candidate, candidate, and recipient transfers; and

The Member transplant hospital must provide a representative copy of the written notice to the OPTN contractor along with a list of potential candidate, candidate, and recipient names who received the notice.

~~B~~c. Transition Plan

When a ~~The~~ Member transplant hospital relinquishes a transplant program's designated program status or it's designated program status is terminated, it must ~~perform the following activities when one of its transplant program's designated status is relinquished or terminated~~:

i. ~~the subject transplant program must~~ promptly suspend organ implantation for the transplant program;

ii. assist potential candidates and ~~waitlisted~~ candidates in identifying designated transplant programs to which they can transfer;

iii. provide a list to the OPTN contractor of all of the transplant program's candidates on the waiting list at the time of ~~inactivation~~ relinquishment or termination and update it throughout this process;

iv. indicate on the list provided ~~each candidate's decision~~ the decision of each potential candidate and each candidate to transfer, with the following additional information:

1. if a candidate or potential candidate chooses not to transfer to an alternative transplant program, provide the reason and indicate whether the candidate has been completely informed of the implications of this decision; or
2. if a candidate or potential candidate chooses to transfer, indicate ~~to which~~the transplant program to which the candidate is transferring. Periodic updates will be required as to the status of ~~that~~ each candidate's transfer progress until the candidate is evaluated by the accepting program and an official ~~acceptance~~ decision is made regarding the candidate's listing status.

v. expedite removal of all candidates from the ~~subject~~ transplant program's waiting list, or, if the patient requests, transfer the candidate to another OPTN Member transplant hospital;

vi. initiate transfer ~~any~~ of all active candidates hospitalized at the ~~inactive~~ transplant program to an accepting transplant hospital within seven days of ~~inactivation~~relinquishment of the ~~subject~~ transplant program. The transplant program must complete the transfer process within 14 days unless transfer would be unsafe or discharge is anticipated within that time; or circumstances outside of the program's control exist that prevent transfer within 14 days. The program must document and submit to the OPTN contractor all efforts to transfer its hospitalized candidates if it is unable to meet the time periods within this section.

vii. provide a priority list of the most urgent candidates listed at the ~~subject~~ transplant program with an individualized plan of transfer,

potential alternative transplant programs, and a timeline for transferring these candidates according to the following priorities:

1. for liver candidates, all Status 1A and 1B candidates ~~should~~ must be transferred within seven days of ~~inactivation~~relinquishment, followed by all active ~~MELD/PELD candidates in order of score with all candidates with a MELD/PELD > 25~~ candidates in descending MELD/PELD score order, with all candidates whose MELD/PELD score exceeds 25 to be transferred within 30 days, followed by all inactive candidates;
2. for lung candidates, ~~those~~ active candidates should be transferred according to ~~with~~ descending Lung Allocation Scores ~~in descending order~~ with highest scores first, followed by ~~the~~ inactive candidates;
3. for kidney candidates, those whose PRA (measured or calculated) is over ~~all active highly sensitized (PRA≥~~80%~~) candidates~~ should be transferred first, followed by all other active candidates in order of waiting time, then transfer of all inactive candidates;
4. for heart candidates, ~~those with~~ all Status 1A and 1B must be transferred within ~~30 days~~ seven days of ~~inactivation;~~ relinquishment;
5. for multivisceral organ transplant candidates, transfer must be completed within 30 days of ~~inactivation~~ relinquishment; and
6. notwithstanding these guidelines, all active candidates should be transferred within 60 days of relinquishment; and;
7. The program must document and submit to the OPTN contractor all efforts for transfer of its candidates if it is unable to meet the time periods within this section.

viii. document all efforts to transfer candidates to an alternative designated transplant program including all contacts made to facilitate the transfer of candidates~~.~~; and

ix. ~~have~~remove every transplant candidate ~~removed~~ from the ~~subject~~ transplant program's waiting list within 12 months of the program's ~~inactivation~~ relinquishment date.

A Member ~~transplant programs~~ that ~~inactivate~~ relinquishes or terminates a designated transplant program may still have the ability to provide follow-up care ~~for~~ to transplant recipients. Should the transplant program continue to provide follow-up care ~~for~~ to transplant recipients, the program must continue to submit OPTN follow up forms ~~in~~ via UNet[sm]. ~~Additionally~~ Alternatively, transplant recipients may transfer care to another institution.

~~5~~4. Waiting time on waiting list.

[Moved from previous section, with changes]

To assure equity in waiting times, and facilitate smooth transfer of candidates from the

waiting list of ~~a program that is inactivated or relinquishes designated transplant status,~~ affected programs (i.e. programs that voluntarily inactivate, relinquish or lose designated transplant program status), candidates on the waiting list in such instances may retain existing waiting time and continue to accrue waiting time appropriate to their status on the waiting list at the time of the programs' inactivation, relinquishment, or loss of designated status. ~~for a maximum of 90 days following that program's inactivation, relinquishment or loss of designated status.~~ This total acquired waiting time will ~~may~~ be~~,~~ ~~with agreement of the accepting center,~~ transferred to the candidate's credit when s(he) is listed with a new program.

~~If the candidate remains on the waitlist of an inactivated program past the maximum 90 days stated above then a Waiting Time Modification per OPTN/UNOS Policy 3.2.1.8 Waiting Time Modification will be required.~~

~~6~~5. Laboratory T~~t~~ests. The inactivated program remains responsible for evaluating its candidates. This includes, but is not limited to, ~~must obtain~~ performing ~~the required~~ laboratory tests and evaluations required ~~of candidate follow-up~~ to maintain the candidate's appropriate status on the waiting list until the time of transfer.

III. Histocompatibility Laboratories. [No Change]

ATTACHMENT I
TO APPENDIX B OF THE OPTN BYLAWS

[No change] A transplant program that meets the following criteria shall be qualified as a designated transplant program to receive organs for transplantation:

III. Facilities and Resources. [No change]

II. ~~**Inactive Program Status**. Designated transplant programs qualified in accordance with these Attachment I criteria that fail to remain functionally active shall voluntarily stop transplantation at that transplant program for a period of up to twelve months by notice to the Executive Director, or may relinquish designated transplant program status for the program. This voluntary action to stop transplantation may be extended beyond twelve months upon request to the MPSC and demonstration to the MPSC's satisfaction of the benefit of such extension, together with a plan and timeline for re-starting transplantation at the program which shall include assurance that all OPTN membership criteria will be met at the time of re-starting transplantation. For purposes of these Bylaws, "functionally inactive" is defined as:~~

~~(2) The inability to serve patients, as a group, for a sustained and significant time period, where a period of 15 days or more is presumed to be sustained and significant, or~~

~~(2) No transplant performed for a period of time defined as:~~

~~(c) No transplant performed in three months in the case of kidney, liver, and heart transplant programs,~~

~~(d) No transplant performed in six months in the case of pancreas and lung programs, and~~

~~(e) No transplant performed in one year in the case of transplant programs located in stand-alone pediatric transplant hospitals, with no explanation deemed satisfactory by the MPSC that the program remains qualified pursuant to the criteria defined in this Appendix B to provide transplant services.~~

~~If the program fails to take either action voluntarily, the Membership and Professional Standards Committee may recommend that the Board of Directors take appropriate action in accordance with Appendix A of these Bylaws, which action may include those defined as adverse under Section 3.01A. Program inactivation or relinquishment of designated transplant program status involves (i) prompt suspension of transplantation, (ii) notice to patients (with a copy to the organization under contract with HHS to operate the OPTN (OPTN Contractor)) of the need to inactivate, removal of these patients from the program's waiting list, or - if the patient desires - transfer of the patient to the list of another OPTN Member Transplant Hospital, and (iii) assistance for patients in identifying the designated transplant programs to which they can transfer. Upon submission and review of information establishing that the Member has again become active in human organ transplantation and that all other criteria for OPTN membership are met, the Membership and Professional Standards Committee shall recommend to the Board of Directors that the Board so notify the Secretary of HHS.~~

~~To assure equity in waiting times, and facilitate smooth transfer of patients from the waiting list of a program that is inactivated or relinquishes designated transplant status, patients on the waiting list of a designated transplant program at the time of inactivation or relinquishment of designated status may retain existing waiting time and continue to accrue waiting time appropriate to their status on the waiting list at the time of inactivation or relinquishment of designated status of their program for a maximum of 90 days following that program's inactivation or relinquishment of designated status. This total acquired waiting time may be, with agreement of the accepting center, transferred to the patient's credit when s(he) is listed with a new program.~~

~~It is expected that all designated transplant programs will duly inform their patients on the waiting list if there will be an extended period of time when the program will be unable to perform transplants. Programs that are not able to serve patients, as a group, for a period of 15 consecutive days or more are further expected to notify the OPTN Contractor and their patients as described above.~~

II~~I~~. **Reporting Changes in Key Personnel.** [No change]

III~~V~~. **Investigation of Personnel.** [No change]

IV. **OPO Affiliation.** [No change]

V~~I~~. **Histocompatibility Laboratory Affiliation.** [No change]

VI~~I~~. **Transplant Surgeon and Physician.** [No change]

Exhibit M-3

Figure 1

The following figure was developed after the public comment period to further clarify how the MPSC will monitor transplant programs with inactive wait lists. This figure defines the rolling 365-day period.

Conceptual View of Rolling 365-Day Periods			
		Period 1	
Dates	1-Jan-09		31-Dec-09
Days	1		365
		Period 2	
Dates	2-Jan-09		1-Jan-10
Days	1		365
		Period 3	
Dates	3-Jan-09		2-Jan-10
Days	1		365
Etc…			

Based upon the MPSC meeting cycle, the Committee will be provided with a report for X number of periods showing all programs with a single instance of waiting list inactivation of 15 days or more. Also, the programs with an inactive wait list, with the greatest cumulative number of days (28 days or more) will be included on the report.

For example, if there are 85 days between MPSC meetings, the committee will receive a report with a total of 85 periods of 365-consecutive days in each period. If implemented effective January 1, 2009, and the MPSC meets in May 2009, the first set of periods will not include a total of 365-consective days.

Exhibit M-3

Figure 2

The following figure was developed after the public comment period to further clarify how the MPSC will monitor transplant programs with inactive wait lists. This figure provides three situational examples that could come before the MPSC.

Example: *Single instance of wait list inactivation >14 days & How rolling 365-Day period may change days contributed to inactive wait list period*

	Center A	*Start Date*	*# of Days Inactive*	*# of Days WL inactive for Review Period*	*Running total: cumulative # of days*
Period 1	Instance 1 of WL Inact	1/1/09	5	5	5
	Instance 2 of WL Inact	3/1/09	15	15	20
	Instance 3 of WL Inact	12/27/09	13	5	25
	Total # of Cumulative Days WL Inactivated in Period 1			25	
	Center A should have notified patients of waiting list inactivation for this period.				
	Because Period 1 ends 12/31/09, the last period of waiting list inactivation only contributed 5 total days, resulting in a total of 25 cumulative days in Period 1.				

Example: *How rolling 365-Day period may change days contributed to inactive wait list period*

	Center A	*Start Date*	*# of Days Inactive*	*# of Days WL inactive for Review Period*	*Running total: cumulative # of days*
Period 2	Instance 1 of WL Inact	1/1/09	5	4	4
	Instance 2 of WL Inact	3/1/09	15	15	19
	Instance 3 of WL Inact	12/27/09	13	6	25
	Total # of Cumulative Days WL Inactivated in Period 2			25	
	Center A should have notified patients of waiting list inactivation for this period.				
	Because Period 2 begins on 1/2/09 and ends on 1/1/10, the first instance of waiting list inactivation contributed 4 days, the last instance contributed 6 days to the total of 25 cumulative days in Period 2 .				

Example: *Program reaching cumulative wait list inactivation of 28 days or more in 1 Period*

	Center B	*Start Date*	*# of Days Inactive*	*# of Days WL inactive for Review Period*	*Running total: cumulative # of days*
Period 1	Instance 1 of WL Inact	1/10/09	3	3	3
	Instance 2 of WL Inact	3/15/09	7	7	10
	Instance 3 of WL Inact	6/27/09	7	7	17
	Instance 4 of WL Inact	8/20/09	4	4	21
	Instance 5 of WL Inact	11/22/09	13	13	34
	Instance 6 of WL Inact	12/22/09	7	7	41
	Total # of Cumulative Days WL Inactivated in Period 1			41	
	Within Instance 5, the program reaches the 28 day threshold and must notify patients.				

Exhibit M-4

BRIEFING PAPER **OPTN/UNOS**

Proposal to Modify the Bylaws pertaining to *Conditional Approval Status for Liver Transplant Programs that Perform Living Donor Transplants*.
Bylaws, Attachment I, Appendix B, Section D, (4) *Liver Transplant Programs that Perform Living Donor Liver Transplants*

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Exhibit M-4

BRIEFING PAPER **OPTN/UNOS**

Proposal to Modify the Bylaws pertaining to *Conditional Approval Status for Liver Transplant Programs that Perform Living Donor Transplants*.
Bylaws, Attachment I, Appendix B, Section D, (4) *Liver Transplant Programs that Perform Living Donor Liver Transplants*

Sponsoring Committee: 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 and 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 explain the options 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 and 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 (LDL) transplantation began in 2005. It became apparent after the bylaws were implemented that about 30 of the centers would likely fall short of meeting the requirement to have two fully qualified surgeons. Ultimately, a joint work group consisting of members from the MPSC, the Liver and Intestinal Organ Transplantation Committee, the Living Donor Committee, and the Pediatric Transplantation Committee was formed for the purpose of considering the development of criteria for conditional program approval when the second live donor liver surgeon had not met all of the minimum requirements. This work group recommended that up to a two-year conditional period be allowed for these programs. The Board of Directors considered the proposed bylaw changes during its March 2006, meeting and amended the Committee's resolution by eliminating the option of a second year of conditional approval. During its May 2006 meeting the MPSC reviewed the public comments that had been received and was concerned about the elimination of the second year option. The Committee agreed to reinstate the originally proposed language that allowed for a possible extension to the one year conditional period this option was finally approved in the bylaws in September 2006. Centers that did not meet the requirements at the end of the second year would not be qualified to continue as an approved program.

Since that time, 19 of the 72 liver programs that perform living donor liver transplants have been conditionally approved under this option. All but three 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 clear guidance 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.

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 conditional period should require the submission of a new application.

Supporting Evidence and/or Modeling:
This proposal clarifies the existing process by adding language to the bylaws. 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/or 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 will be made aware of 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 from the onset. 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 UNet℠.

Communication and Education Plan:

Communication Activities			
Type of Communication	**Audience(s)**	**Delivery Method(s)**	**Timeframe**
Policy Notice	Relevant parties from Transplant Centers that perform 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/notice 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.

Education/Training Activities			
Education/Training Description	**Audience(s)**	**Deliver Method(s)**	**Timeframe and Frequency**
Not required			

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 when its conditional term ends. The OPTN procedures will not change because of the proposal.

Exhibit M-4

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.

The Board of Directors approved the resolutions above on June 20, 2008.

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.

Public Comment Responses:

1. Public Comment Distribution

Has the proposal been distributed for public comment? yes
Date of distribution: 06/30/2008
Public comment end date: 09/24/2008

Public Comment Response Tally					
Type	**Response Total**	**In Favor**	**In Favor as Amended**	**Opposed**	**No Comment**
Individual Comments	41	18 (43.9%)	0	12(29.2%)	11 (26.8%)
Regional Comments	11	9 (81.8%)	0	2 (18.1%)	0
Committee Comments	9	9(100%)	0	0	0

** + 1 Committee tied (6%)

2. Primary Public Comment Concerns/Questions

- This proposal will prevent some centers that only do pediatric living donor transplants (may not be pediatric only transplant centers but only do LRD in pediatric recipients) from continuing to offer this with significant success.
- it forces liver transplant programs to perform a certain number of living donor liver transplants in order for the second surgeon to meet the requirements for the living donor program to remain open.

- A left lateral segmentectomy is not the same operation and does not have the same risk associated with it as a left or right lobectomy. Therefore the criteria for certification should be different and continuing certification should be similarily different.

3. Regional Public Comment Responses

Region	Meeting Date	Motion to Approve as Written	Approved as Amended (see below)	Did Not Consider
1	9/8/08	10 yes, 0 no, 3 abstentions		
2	9/3/08	25 yes, 0 no, 0 abstentions		
3	9/22/08	5 yes, 14no, 2 abstentions		
4	8/22/08	2 yes, 12 no, 6 abstentions		
5	9/9/08	14 yes, 0 no, 2 abstentions		
6	9/4/08	16 yes, 0 no, 6 abstentions		
7	8/21/08	9 yes, 0 no, 3 abstentions		
8	9/11/08	14 yes, 0 no, 0 abstentions		
9	9/10/08	12 yes, 0 no, 1 abstention		
10	8/26/08	17 yes, 0 no, 1 abstention		
11	9/23/08	9 Yes, 2 no, 3 abstentions		
	Total	133 Yes, 28 No, 27 Abstentions		

Region 2 Comments: The regions supported the proposal but agreed that the language should be clarified so that centers can not relinquish their program status for a period of time and then reapply for another 2 years of conditional approval.

Committee Response:
All applications are subject to MPSC review. The Committee agreed that an application of nature would have to stand on its own merits.
Appendix A 1.07 of the Bylaws provides the following guidance to the MPSC when considering reapplications after it has made an adverse recommendation:

1.07A ***Reapplication After Adverse Membership Decision***

An applicant who has been denied UNOS membership or designated transplant program status shall be reconsidered for membership or designation for transplantation for the particular organ upon reapplication. The reapplication will be evaluated based on membership criteria in effect at the time of reapplication. Any such reapplication shall be processed as an initial application and the applicant shall submit such additional information as the MPSC or the Board of Directors may require to demonstrate that the basis for the earlier adverse action no longer exists.

Region 3 Comments: Region 3 voted (18-0-0) that the following comments be sent to the MPSC, Living Donor Committee, and Liver/Intestine Committee.
The Liver Living Donor Program Criteria needs to be better defined and include:

- Criteria that address results.

- Pediatric vs. Adult.
- Criteria that addresses Left Lateral Segment vs. Lobectomy.
- Criteria that addresses Left Lobe vs. Right Lobe.

Committee Response:
The Committee appreciates the input from the region and agrees that the requirements for living donor liver transplant surgeons should be reviewed in light of the current state of living donor transplantation. The Committee will be asking the Liver/Intestinal Transplantation Committee, the Living Donor Committee, and the Pediatric Transplantation Committee to review, and if appropriate make suggestions of possible changes to the current requirements. However, there are several existing programs that have been granted conditional approval and it remains important to provide this explanation of the process for them.

Region 4 Comments: The region did not support this proposal on the basis that it forces liver transplant programs to perform a certain number of living donor liver transplants in order for the second surgeon to meet the requirements for the living donor program to remain open. The members think that the proposal will force centers to perform living donors when it is not necessary.

Committee Response: The MPSC considered this comment but thought that that this issue could be raised relative to any of the bylaw requirements.

4. Committee Public Comment Responses

AD HOC INTERNATIONAL RELATIONS COMMITTEE

The Ad Hoc International Relations Committee reviewed the proposal and voted electronically (1-Support; 1-Oppose; 0-Abstention). A member commented on this proposal as follows:

"This proposal will prevent some centers that only do pediatric living donor transplants (may not be pediatric only transplant centers but only do LRD in pediatric recipients) continue to offer this with significant success. The demand for these cases are generally much lower volume than adults - volume of pediatric versus adult transplant overall. The risk is also significantly different between a left lateral segmentectomy than a right or left lobectomy. By approving this policy change, there is zero recourse to such impacted centers to continue to provide this resource in underserved areas. The suggestion that surgeons just go to a high volume center and do a few cases to get the experience really is not addressing the issue at hand. UNOS should not continue the policy of not addressing real concerns that impact access to transplant."

Committee Response:
While the issue of adult-to-pediatric transplants is not the focus of this policy charge, we recognize that there may be unique issues in this situation, and plan to ask that this issue be addressed by a workgroup.

Exhibit M-4

ETHICS COMMITTEE

No comment submitted

EXECUTIVE COMMITTEE

No comment submitted

FINANCE COMMITTEE

No comment submitted

HISTOCOMPATIBILITY COMMITTEE

No comment submitted

KIDNEY TRANSPLANTATION COMMITTEE

The Kidney Transplantation Committee did not evaluate this proposal.

LIVER AND INTESTINAL ORGAN TRANSPLANTATION COMMITTEE

The Committee supported this proposal by a vote of 12 in favor, 1 opposed, and 0 abstentions.

Committee Response:
The Committee appreciates this committee's support for the proposal.

LIVING DONOR COMMITTEE

The Living Donor Committee supports this proposal as a necessary step to help protect living liver donors. Transplant programs that do not fully satisfy the criteria for full program approval by the end of the conditional approval period, should not be performing living donor transplants. However, members of the Committee did recommend that the MPSC seek feedback from the Transplant Community and consider modifying the current physician requirements for living liver program certification.

Committee Response:
The Committee appreciates this committee's support for the proposal.

MEMBERSHIP AND PROFESSIONAL STANDARDS COMMITTEE

Sponsoring Committee.

MINORITY AFFAIRS COMMITTEE

The committee determined that there was no minority impact from the proposed policy

Committee Response:
The Committee appreciates this committee's support for the proposal.

OPERATIONS COMMITTEE

The Operations Committee did not consider this proposal.

OPO COMMITTEE

No comment submitted

ORGAN AVAILABILITY COMMITTEE

The OAC did not consider this proposal.

PANCREAS TRANSPLANTATION COMMITTEE

No comment.

PATIENT AFFAIRS COMMITTEE

The Patient Affairs Committee supported the proposal with a vote of 13-0-0.

Committee Response:
The Committee appreciates this committee's support for the proposal.

PEDIATRIC TRANSPLANTATION COMMITTEE

Upon review, the Committee was concerned that the number of required procedures is somewhat arbitrary, as there is no specific data to support it. Members noted that pediatric programs will be affected and that cutting down the number of living donor programs will make it harder for candidates

to have access to technical variants. The Committee requested data on the number of pediatric centers that are currently performing living donor transplants but will not be able to meet the criteria (as evidenced by those who have requested conditional approval but are now withdrawing their applications). A member questioned whether the MPSC might entertain changes to its requirements based on the number of left lateral segment versus right lobe procedures completed by a center. Members agreed that relatively arbitrary standards may impair the pediatric community from offering living related donor transplant, a key component to both managing candidates and the waiting list.

The Committee agreed to request the desired data from the MPSC for review by the Committee's Liver Working Group. A conference call will be held to review this data and determine whether pediatric programs with existing living donor programs will be negatively impacted and whether a compromise can be sought that will not impact living donor or living donor recipient safety.

The Committee voted unanimously to authorize the Liver Working Group to submit a public comment response on its behalf before the September 24 deadline. (Committee vote: 16 in favor, 0 opposed, 0 abstentions)

As a result, the Committee's Liver-Intestine Working Group met by teleconference/LiveMeeting on August 21, 2008 to: (1) review this data, (2) determine whether pediatric programs with existing living donor programs will be negatively impacted and whether a compromise can be sought that will not impact living donor or living donor recipient safety, and (3) offer a final public comment response to the MPSC.

After discussion, the Working Group voted unanimously (4 in favor, 0 opposed, 0 abstentions) to support the MPSC's modifications to clarify how conditional approval for living donor liver programs should be handled if requirements are not met at the end of the conditional approval period. The Working Group will address its concerns regarding the number and type of required procedures as a separate initiative in conjunction with the MPSC, Liver-Intestine, and Living Donor Committees at a later date.

Committee Response:
The MPSC supports this initative.

POLICY OVERSIGHT COMMITTEE

The bylaws currently include 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 and still do not meet the requirements for full approval. The proposed language will provide clear direction by stating the options available to a program when it reaches the end of its conditional approval term. Under the proposed change to the bylaw, 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. This change was approved by the Board in June 2008, concurrent with public comment. This preliminary approval allowed UNOS to give more specific direction to 5 programs that fell into this category. The proposed changes

would also allow centers applying for a living liver donor transplant program to understand what will be expected of them, which should help improve compliance with the bylaw. The Committee had no comments about this proposal.

In September, the Committee reviewed the key points of this proposal. The staff liaison noted that some negative comments on the proposal have been "off-topic," in that they address the parts of the policy that are not included in the proposal. The proposal scored highest in the Patient Safety and Transplantation Oversight category, with an overall score of 7.9. The Committee voted to support this proposal by a vote of 9 in favor, 0 opposed, and 0 abstentions

Committee Response:
The Committee appreciates this committee's support for the proposal.

THORACIC ORGAN TRANSPLANTATION COMMITTEE

The Thoracic Committee reviewed and voted on this proposal electronically. The Committee supports this proposal: 10-Support; 0-Oppose; 1-Abstention. A Committee member had the following comment:

"Although I support the proposal, there is no significant impact on Thoracic transplantation."

Committee Response:
The Committee appreciates this committee's support for the proposal.

TRANSPLANT ADMINISTRATORS COMMITTEE

The Committee did not consider this proposal.

TRANSPLANT COORDINATORS COMMITTEE

The Committee supported this proposal by a vote of 10 in favor, 0 opposed, and 0 abstentions.

Committee Response:
The Committee appreciates this committee's support for the proposal.

5. Individual Public Comment Responses

Insert the individual comments from the public comment tool with the Committee's response.

Comment 1:

vote: Oppose

Date Posted: 08/26/2008

Clearly, living liver donation needs to be regulated as the ramifications of living donor complications are great for transplantation in general. Living donor hepatectomies must be performed by qualified, trained, hepatobiliary surgeons. As we know, there is a big difference in the risk to the donor (the real issue here) who undergoes a left lateral segmentectomy vs. a full right or left lobectomy for donation. Without hesitation, the bylaws must make a distinction between these two procedures. Currently, I work at an institution where we are the only program that offers this option to children in a 3-state radius. If this designation is taken away (due to the number criteria), these children and their families will be forced to travel great distances to seek treatment. This can be a significant obstacle for these families, many of whom are already disadvantaged. I respectfully request that the designation of a pediatric living donor liver transplant program be separated from the over-all living liver donation designation. We are fortunate in our area not to need adult living donor liver transplant to get our patients transplanted.

Committee Response:

The Committee appreciates your comments and agrees that the requirements for living donor liver transplant surgeons should be reviewed in light of the current state of living donor transplantation. The Committee will be asking the Liver/Intestinal Transplantation Committee, the Living Donor Committee, and the Pediatric Transplantation Committee to review, and if appropriate make suggestions of possible changes to the current requirements. However, there are several existing programs that have been granted conditional approval and it remains important to provide this explanation of the process for them.

Additionally, based on the comments received there would seem to be a desire for a form of conditional approval to continue to exist, so an explanation of the process for those programs that may granted conditional approval in the future would still be necessary.

Comment 2:

vote: Oppose

Date Posted: 08/26/2008

I believe the proposal is inherently flawed as the entire proposal related to the certification and approval of living liver donor programs is flawed. It assumes the donor risk of a left lateral sementectomy is the same as a left lobectomy and right lobectomy. All of the research would suggest otherwise. The entire proposal is intended to protect living liver donors and to develop criteria that will ensure the technical expertize of the surgeons performing the surgery. A left lateral segmentectomy is not the same operation and does not have the same risk associated with it as a left or right lobectomy. Therefore the criteria for certification should be different and continuing certification should be similarily different.

The current Living Liver Donor Criteria for surgeons needs to be re-evaluated first with regard to lumping all living donor liver procedures together. Additionally, the current certification conditions do

not account for programs that only offer the live donor option for pediatric recipients. There is agreement in the community that criteria need to be in place and only experienced hepatobiliary and transplant surgeons should be given certification.
This proposal will significanly impact access to transplant for pediatric candidates by limiting the number of programs that can offer living liver donor transplant. I believe this is not the intent of the existing proposal or the proposed modification. However, this proposal will severely impact pediatric transplant programs that do not have adult counterparts and will limit access to this life-saving procedures for pediatric patients.
The Collaborative is pushing eliminating death of pediatric candidates on the waiting list - this modification to an existing flawed policy is likley to negatively impact this initiative. Not every family can afford to travel long distances to centers that meet the criteria outlined. Insurance carriers will not support sending pediatric candidates to distant centers for this procedure. In a time when we are trying to increase the number of candidates transplanted, and living donation being a specific and focused initiative, this seems to be counter intuitive to everything we are working toward. I urge the transplant community to take a step back and not implement a modification to an existing policy that is inherently flawed and will negatively impact the entire transplant community.

Committee Response:
See Response to Comment 1

Comment 3:
vote: Oppose
Date Posted: 08/26/2008
Please make a provision for those programs that would like to continue with a pediatric program only. Thank you.

Committee Response:
See Response to Comment 1

Comment 4:
vote: Oppose
Date Posted: 08/27/2008
Separate consideration needs to be made for transplant programs that perform only left-lateral segmentectomy for the purpose of donation to a pediatric patient. The risks of left-lateral segmentectomy are significantly lower as this is a technically easier surgery. We are currently the only transplant program in a 3-state area (LA, MS, AK) to perform this life-saving surgery for pediatric candidates. Under the current proposal, we (as well as our patient population in this 3-state area) would lose approval to perform such a surgery. Our pediatric patients would then be unneccessarily forced to seek surgery even further away from home, which for many is not financially possible.

Committee Response:
See Response to Comment 1

Comment 5:
vote: Oppose
Date Posted: 08/26/2008
The current proposal unfairly impacts pediatric transplant programs offering living donor transplant. In most pediatric living donor transplants the left lateral segment is used for transplant. Left lateral segmentectomy is a much lower risk procedure associated with far fewer risks and complications, in both donors and recipients, than right lobe adult to adult living donor transplants. Surgical requirements are different for left lateral segment transplants in pediatric recipients, and the MPSC proposal for conditional approval status needs to reflect this difference. Thus, if implemented, this proposal would unfairly impact living donor pediatric transplantation. In order to not disadvantage pediatric transplant recipients, the current UNOS proposal must be amended to account for the fundamental difference between the living donor procedures used for adult and pediatric recipients.

Committee Response:
See Response to Comment 1

Comment 6:
vote: Oppose
Date Posted: 08/28/2008
The proposed bill would leave no option for children in LA, MS, or AK except going to the select few centers. Provision for programs that want to continue with a pediatric program should be made.

Committee Response:
See Response to Comment 1

Comment 7:
vote: Oppose
Date Posted: 08/26/2008
This policy lumps together adult and pediatric procedures which severely impacts facilities that choose to remain pediatric only. This would negatively impact pediatric patients on the transplant waiting list in a 3 state area in our region of the country.

Committee Response:
See Response to Comment 1

Comment 8:
vote: Oppose
Date Posted: 08/21/2008
This proposal seems premature as the current Living Donor Criteria for surgeons needs to be re-evaluated first with regard to lumping all living donor liver procedures together. Performing a left lateral segmentectomy is a technically easier operation and the criteria for continued certification should be different than those that exist for ensuring the safety of left and right lobe donors. Donor risk is significantly different for a left lateral segemtectomy. The current certification conditions are too restrictive for programs that only offer the live donor option for pediatric recipients. Certainly there should be criteria and only experienced hepatobiliary and transplant surgeons should be given certification but this proposal will hurt pediatric transplant programs that do not have adult

counterparts and will limit access to these life-saving procedures for our patients (and unnecessarily require families to travel great distances and possibly lead to increased morbidity and even mortality in our case, we are the only UNOS qualified program in a 3 state area). Once a program meets the requirements based on their surgeons experience there should be a defined mechanism to continue (even if conditionally) that is different for programs that only want to offer left lateral segmentectomy to pediatric recipients.

Committee Response:
See Response to Comment 1

Comment 9:
vote: Oppose
Date Posted: 08/28/2008
This proposal would hinder the opportunity for patients and families with pursuing a living related donor procedure that could in turn enhance and improve the quality of life for the majority of pediatric patients in the Tri-State area. From a psycho-social perspective, there is no greater negative impact on a family then having a progressively sick child who may be possibly becoming terminal. Sustaining the opportunity for a parent or loved one to provide a living related liver donor procedure will provide patients and families with a great deal of hope and have an increased impact that could never be accomplished through the limits of cadaveric organ donation. Patients and families who are living with the every day struggles of liver disease should not have to encounter yet another tremendous obstacle of limiting their treatment options. This will not simply increase the morbidity and mortality, but it will also raise the need for additional high maintenance mental health services with adjusting to living with a progressively chronic illness. Exploring alternative mechanisms for different transplant centers would be a more viable option as pediatric patients and families should not have their options limited when choosing to have a living related liver donor procedure.

Committee Response:
See Response to Comment 1

Comment 10:
vote: Oppose
Date Posted: 08/29/2008
To have such a program and one that is done well, is important to the state of Louisiana as well as its citizens. New Orleans and Louisiana have already experienced tremendous setbacks due to the hurricane and families having to relocate. The passing of this initiative would further debilitate a city and state in the rebuilding process. Children excel when they are allowed to remain in their familiar surroundings rather than be uprooted, especially during a time of crisis/illness. As a parent and future Social Worker, I would much rather my child have the opportunity to receive medical care close to home from a center that has qualified surgeons and staff. The thought of losing such a center as well as the fact that we would have to relocate to obtain adequate healthcare for my child under the name of bureaucracy is appalling to me. I am curious as to where the children of our area are currently going and/or would then be expected to go if there are no qualifying centers in the area. Hopefully the fact that the number of living donor surgeries is so low because there are not that many sick children, but I am sure the reality of the situation is that many have to go out of the local area. When considering this new change in policy, please make an exception for programs that are dedicated to primarily live donor liver surgeries in pediatric patients.

Committee Response:
See Response to Comment 1

Comment 11:
vote: Oppose
Date Posted: 09/24/2008
Transplant programs that perform only pediatric living donor transplants should be taken into account before passing any bylaws. It is technically easier for surgeons to perform the left lateral segmentectomies used in pediatric transplants and certified surgeons should be allowed to continue to do so at least on a conditional basis. Tulane Medical Center is the only transplant center in a tristate area currently able to perform pediatric liver living donor transplants. Being the daughter of a transplant recipient, I believe the implications of potentially being uprooted from your home, family and other support systems could be damaging to successful transplant outcomes.

Committee Response:
See Response to Comment 1

Comment 12:
vote: Support
Date Posted: 07/03/2008
Important addendum to policy

Committee Response:
The Committee appreciates this response.

Comment 13:
vote: Support
Date Posted: 07/02/2008
The proposal makes it clear that non-compliant programs must not continue to operate living donor programs. I applaud the effort to model program certification in liver transplantation and look forward to similar effort for the other organs, especially all those engaging in transplantation from living donors.

Committee Response:
The Committee appreciates this response.

Comment 14:
vote: Support
Date Posted: 09/15/2008

Excerpt from letter from the American Liver Foundation

> Secondly, the Living Donor Committee proposes to modify the UNOS bylaws to clarify the expectations that a transplant center must inactivate or stop performing living donor liver transplants when transplant personnel do not fully satisfy the criteria for full program approval by the end of the conditional approval period, or after two years with conditional approval status. It is our opinion that this language fully clarifies the options for living donor liver programs that have reached the end of their two year conditional approval period. ALF supports this clarification and finds that the changes are consistent with other sections of the bylaws that address programs lacking full approval status.

Committee Response:
The Committee appreciates this response.

Comment 15:
vote: Oppose
Date Posted: 09/08/2008
Please see attached letter from ASTS.

Committee Response:
See Response to Comment 1

Exhibit M-4

ASTS

American Society of Transplant Surgeons

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September 3, 2008

James J. Wynn, MD
Chairman
Membership and Professional Standards Committee
Organ Procurement and Transplantation Network
United Network for Organ Sharing
P.O. Box 2484
700 North 4th Street
Richmond, VA 2371

Dear Dr. Wynn:

The American Society of Transplant Surgeons (ASTS) appreciates this opportunity to comment on the proposal to modify the bylaws pertaining to conditional approval status for liver transplant programs that perform living donor transplants. While the ASTS supports the concept that there should always be two UNOS-qualified transplant surgeons involved in living donor liver transplantation, the basis of the requirement of having two surgeons who have performed seven living donor operations in order to increase donor safety seems to be arbitrary and not evidence-based. These requirements appear to be a reaction to the few reported living donor deaths in centers that actually already met these requirements.

If a program has one qualified surgeon, any liver transplant surgeon otherwise meeting the requirements of UNOS to be a liver transplant surgeon would be qualified to be an assistant. There is also no data to support the requirement of 20 hepatic resections over the time period of five years as a means of improving patient safety or decreasing morbidity or mortality. This policy would actually allow living donor operations to be performed by two new fellowship graduates with seven live donors each, while preventing one experienced surgeon who had performed 50 live donor operations from performing live donor liver transplants with an experienced UNOS qualified transplant surgeon as assistant (if he/she had not also performed 20 hepatic resections).

Exhibit M-4

In a time when patients are being added to the list at a greater rate than deceased donors are increasing, we should be trying to provide greater access to live-donor liver transplantation rather than restricting access as this policy does. Data from the A2ALL multi-center consortium have demonstrated a benefit to patients on the waiting list who receive live-donor liver transplants even at lower MELD scores. We have an opportunity to increase the benefit of liver transplantation by providing greater access to live-donor liver transplantation. If there are centers with one experienced surgeon who meets the qualifications to be a live-donor liver surgeon, the conditional approval or even full approval should be continued provided that there is another UNOS-qualified liver transplant surgeon on site.

We appreciate the opportunity to provide input on this process. If you have any questions, please contact the ASTS Executive Director, Katrina Crist, at 703-414-7870 or katrina.crist@asts.org.

Sincerely,

John P. Roberts, MD
President

CC: Robert S. Higgins, MD, MSHA
Walter K. Graham, JD
Clifton E. McClenney

American Society of Transplant Surgeons

Post Public Comment Consideration:
The MPSC reviewed the comments received on the proposal during its meeting on October 15-16. 2008. While the Committee received a number of comments regarding the living donor liver requirements as a whole, they unanimously agreed that there was no need to ask the Board of Directors to consider any changes to the bylaw language that the Board of Directors approved in June.

** RESOLVED, that the proposed modifications to the Bylaws, Appendix B, Attachment I, Section XIII, D (4) c as set forth above, shall be approved without further modifications.

The Committee voted 28, For, 0 Against, 0 Abstentions.

In response to the comments the Committee did agree that the requirements for living donor liver transplant surgeons should be reviewed in light of the current state of living donor transplantation. The Committee will be asking the Liver/Intestinal Transplantation Committee, the Living Donor Committee, and the Pediatric Transplantation Committee to review, and if appropriate make suggestions of possible changes to the current requirements. However, there are several existing programs that have been granted conditional approval and it remains important to provide this explanation of the process for them. Additionally, based on the comments received there would seem to be a desire for a form of conditional approval to continue to exist, so an explanation of the process for those programs that may granted conditional approval in the future would still be necessary.

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.

<u>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</u>

<u>(i) inactivating the living donor part of the program for a period up to 12 months, or</u>
<u>(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.</u>

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