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IMPORTANT POLICY NOTICE

To: Transplant Professionals

From: Karl J. McCleary, Ph.D., M.P.H.
UNOS Director of Policy, Membership and Regional Administration

RE: Summary of actions taken at the OPTN/UNOS Board of Directors
Meeting—November 17-18, 2008

Date: December 18, 2008

The attached report summarizes bylaw changes, policy changes and other actions the OPTN/UNOS Board of Directors approved at its November 2008 meeting.

This format allows you to scan the outcome of committee actions and quickly determine what, if anything, is required by you. You can also access the modified policy language by clicking on the link below the summary table. If you are interested in reviewing policy changes from previous board meetings, go to www.unos.org and click on Newsroom and then select “view all Policy Notices.” We have archived all policy notices from the March 2007 board meeting and forward.

Thank you for your careful review. If you have any questions about a particular notice within this document, please contact your regional administrator at (804) 782-4800.

Overview of Policy Modifications/Board Actions and Affected Professionals

Who should be aware of these actions? Please review the 4 notices included on the grid below and share with other colleagues as appropriate.

Policy/Bylaw Change or Board Action (Sponsoring Committee)	Directors of Organ Procurement	Lab Directors	Lab Supervisors	OPO Data Coordinators	OPO Executive Directors	OPO Medical Directors	OPO PR/Public Education Staff	OPO Procurement Coordinators	Transplant Administrators	Transplant Coordinators	Transplant Data Coordinators	Transplant Physicians	Transplant PR/Public Education Staff	Transplant Program Directors	Transplant Social Workers	Transplant Surgeons	Page #
	1 Modifications to Appendix 3D (Guidelines for the Development of Joint Written Agreements between Histocompatibility Laboratories and Transplant Programs) (Histocompatibility Committee)		X	X						X	X	X			X		
2 Conditional approval status for liver transplant programs that perform living donor transplants (Membership and Professional Standards Committee (MPSC))									X		X	X	X	X	X	X	4
3 Improving the safety of living donation by restricting the acceptance and transplant of living donor organs to OPTN member institutions. (Living Donor Committee)									X	X	X	X	X	X	X	X	5
4 Modifications to 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))									X	X	X	X	X	X	X	X	6

Notice of Policy Change: Modifications to Appendix 3D (Guidelines for the Development of Joint Written Agreements between Histocompatibility Laboratories and Transplant Programs) (Histocompatibility Committee)

Policy Affected: Appendix 3D

Action Required: Review Only

Effective Date: January 19, 2009

Professional Groups Affected by the Change:

Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Data Coordinators, Lab Directors, Lab Supervisors

Current Issue/Policy	Change or Addition	What You Need to Do
<p>OPTN Policy 3.5.17 <u>Prospective Crossmatching</u> requires that a transplant center and its designated histocompatibility laboratory share a joint written policy. Policy Appendix 3D contains guidelines to help histocompatibility laboratories and transplant programs develop a joint written agreement.</p>	<p>The Committee is adding language to Appendix 3D to remind laboratories to comply with OPTN Policy 3.1.4 <u>Waiting List</u> and to use two source documents for ABO verification if the lab is responsible for listing candidates on behalf of the transplant center.</p> <p>The list of elements in Appendix 3D will now include a process for ABO verification. This will help remind a transplant program and its histocompatibility laboratory that the ABO verification process must be present in the written agreement.</p>	<p>If your histocompatibility laboratory is responsible for listing candidates on behalf of the transplant center, you should develop a process to verify ABO that complies with OPTN Policy 3.1.4.</p>

To view the affected policy change, please turn to Exhibit 1.

Notice of Bylaw Change: Conditional approval status for liver transplant programs that perform living donor transplants (*Membership and Professional Standards Committee (MPSC)*)

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

Action Required: Review Only

Effective Date: June 20, 2008, concurrent with public comment*

Professional Groups Affected by the Change:

Transplant Administrators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Transplant Social Workers, Transplant Data Coordinators, and Transplant PR/Public Education Staff

Current Issue/Policy	Change or Addition	What You Need to Do
<p>Current bylaws allow the OPTN to grant conditional status to living liver programs. When living liver transplant programs reach the end of their two-year conditional approval period (initial year plus a one-year extension), the bylaws do not indicate what happens to those programs that still do not meet requirements for full approval. The MPSC agreed that it is important for the members to understand their options when facing this situation.</p>	<p>The bylaws amendment now clarifies the options that are available to programs that reach the end of the conditional approval period and have not yet met the requirements for full approval.</p>	<p>If your center has conditional approval to perform living donor liver transplants, you need to be aware of the day your conditional approval ends. Be sure to continuously monitor your progress to ensure that you have met all requirements by the end of your conditional term.</p> <p>When your program's conditional status ends you must meet all expected requirements. If you have not yet met them, you need to inactivate your program or relinquish your conditional program status.</p>

* This notice was previously distributed with the last policy notice. There were no changes made to the proposal following public comment.

To view the affected bylaw change, please turn to Exhibit 2.

Notice of Policy Change: Improving the safety of living donation by restricting the acceptance and transplant of living donor organs to OPTN member institutions.
(Living Donor Committee)

Policy Affected: Add OPTN Policy 3.3.7 (Center Acceptance of Organs from Living Donors)

Action Required: Review Urgently

Effective Date: January 19, 2009

Professional Groups Affected by the Change: Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Transplant Social Workers, Transplant Data Coordinators, Transplant PR/Public Education Staff

Current Issue/Policy	Change or Addition	What You Need to Do
Living donor transplant centers can currently accept an organ that was recovered at a non-OPTN/UNOS member hospital. Living donors whose organs are recovered at these institutions are not afforded the same protections provided at OPTN member transplant hospitals.	Living donor transplant centers can only transplant living organs that are recovered at OPTN/UNOS member transplant hospitals.	Your living donor transplant program must only transplant living donor organs that have been recovered at OPTN member transplant hospitals.

To view the affected policy change, please turn to Exhibit 3.

Notice of Bylaws Change: Modifications to 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))

Bylaw Affected: Appendix B, Section II, C *Inactive Membership Status*

Action Required: Review Only

Effective Date: Pending Implementation

Professional Groups Affected by the Change:

Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Transplant Social Workers, Transplant Data Coordinators, Transplant PR/Public Education Staff

Current Issue/Policy	Change or Addition	What You Need to Do
<p>The definition of functional inactivity for a transplant program does not currently include waiting list inactivation. The bylaws also do not define how the program should notify its patients if the program’s waiting list is inactivated.</p> <p>If a particular program is going to be inactive for an extended period of time, the member hospital can voluntarily inactivate or relinquish designated program status. The bylaws do not outline the process for program inactivation or relinquishment and timelines for patient transfer.</p>	<p>The definition of functional inactivity now includes waiting list inactivation. The definition also indicates that the MPSC will review waiting list inactivation as part of its performance review process. The modifications also explain exactly how the center must notify its patients if its waiting list becomes inactive.</p> <p>Sections 2 and 3 now outline requirements for members that choose to inactivate or close a transplant program. Changes also address how centers can notify and transfer candidates on its waiting list.</p> <p>The change also allows candidates on the waiting list of an inactivated or withdrawn transplant program to continue accruing waiting time while the inactivating program works to transfer the candidate.</p> <p>Finally, the modifications remove duplicate language from</p>	<p>If you plan to inactivate or withdraw from OPTN Membership, you should read the bylaws (click link below). These bylaws will explain how to remove candidates from your list and transition them to a new program, once your program has closed.</p> <p>If you still have candidates on your hospital’s waiting list after the transplant program has closed, you must remove these candidates from your waitlist within one year of the date your program closes.</p> <p>Once UNOS implements this change, we expect your transplant programs to comply with these requirements and respond to MPSC inquiries regarding periods of functional inactivity.</p> <p>Reports will be available within UNetSM for transplant programs to monitor periods of waiting</p>

Current Issue/Policy	Change or Addition	What You Need to Do
	Appendix B (Attachment I).	list inactivation. These reports will allow transplant programs to provide advance notice to candidates about periods of waiting list inactivation and allow prospective analysis for transplant programs to monitor cumulative periods of waiting list inactivation.

To view the affected bylaw change, please turn to Exhibit 4.

Affected Policy Language:

For your convenience in reviewing, new language is underlined and language that is to be removed is ~~stricken through~~.

APPENDIX 3D

**GUIDELINES FOR THE DEVELOPMENT OF JOINT WRITTEN AGREEMENTS BETWEEN
HISTOCOMPATIBILITY LABORATORIES AND TRANSPLANT PROGRAMS**

Histocompatibility testing provides clinicians with data to evaluate the immunological risk of proceeding to transplant. The timing and number of tests may vary depending upon specific needs of the program, waiting times, sensitizing events in individual patients or other considerations. These should be established to best suit the needs and concerns of each transplant program drawing upon the expertise of the histocompatibility laboratory. These guidelines summarize the recommended elements to be included in the joint agreements and provide background and discussion to support the recommendations. Data cited in reviews of histocompatibility testing for renal (1) and thoracic (2) transplantation formed the basis for these recommendations.

The following elements should be included in agreements developed between histocompatibility laboratories and transplant programs:

- A process to obtain accurate and timely history of allosensitization for each patient
- Selection of assay format for antibody screening and for crossmatching
- Selection of timing for periodic sample collection
- Selection of timing for performing antibody screening
- Criteria and a process for establishing a risk category for each patient and crossmatching strategy for each category
- Criteria and a process for use of Unacceptable Antigens or Acceptable Antigens for organ allocation
- Process for monitoring post-transplant or for monitoring desensitization protocols
- Process for ABO verification compliant with Policy 3.1.4 if laboratory is asked to list candidates for its transplant center

[No further changes]

To read the complete policy language visit www.unos.org or www.optn.org. From the UNOS Web site, select Resources from the main menu, and then select policies. From the OPTN Web site, select Policies from the main menu.

Affected Bylaw Language:

For your convenience in reviewing, new language is underlined and language that is to be removed is ~~stricken through~~.

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.

To read the complete bylaws language visit www.unos.org or www.optn.org. From the UNOS Web site, select Resources from the main menu, then select bylaws. From the OPTN Web site, select Policies from the main menu, then select bylaws.

Affected Policy Language:

For your convenience in reviewing, new language is underlined and language that is to be removed is ~~stricken through~~.

Policy 3.3.7 Center Acceptance of Organs from Living Center Acceptance and Transplant of Organs from Living Donors. Transplant centers that perform living donor transplants must only accept and transplant living donor organs recovered at OPTN member transplant hospitals.

To read the complete policy language visit www.unos.org or www.optn.org. From the UNOS Web site, select Resources from the main menu, then select policies. From the OPTN Web site, select Policies from the main menu, then select bylaws.

Affected Bylaws Language:

For your convenience in reviewing, new language is underlined and language that is to be removed is stricken through.

OPTN Version:

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 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) ~~(a)~~ (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:~~
- (b) failure to perform a transplant during the following stated periods of time:
- i. ~~No transplant performed in three months~~ In the case of kidney, liver, and heart transplant programs, within three consecutive months;
 - ii. ~~No transplant performed in six months~~ In the case of pancreas and lung programs, and within six consecutive months;
 - iii. ~~No transplant performed in one year~~ In the case of transplant programs located in stand-alone pediatric transplant hospitals, within twelve consecutive months.
- (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 their 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 programs identified to be functionally inactive shall be provided the opportunity to explain its inactivity through reports requested by the MPSC.

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

- Inactivates its waiting list or is unable to perform transplants for 15 consecutive days or more;
- Inactivates its waiting list or is unable to perform transplants for 28 cumulative days or more over any 365 consecutive day period;

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 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

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 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.

~~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.~~

~~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 UNetSM (short-term inactivation), or
- an inactive transplant program waiting list status in UNetSM and an inactive membership status (long-term inactivation).

A Member may voluntarily inactivate a transplant program, on a short-term or long-term basis, for reasons including but not limited 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.
- a. Short-Term Inactivation.** Short-term inactivation means that a transplant program may be inactive for up to 14 consecutive days. A Member may voluntarily inactivate a transplant program for a period not to exceed 14 days by changing the program's waiting list status in UNetSM.
- 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 each transplant program must provide potential candidates, candidates, and recipients with a written summary of 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 or more days consecutively. Members should voluntarily inactivate programs that are not able to serve potential candidates, candidates, or recipients, for a period of 15 or more days consecutively. Voluntary inactivation may extend for a period of up to 12 months.
- i. Notice to the OPTN Contractor.** When a Member intends to voluntarily inactivate 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 upon deciding to inactivate the transplant program
 - ii. Notice to the Patients.** When a Member intends to inactivate 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 patient notice to the OPTN contractor along with a list of potential candidates, candidates, recipients, and living donors who received the notice.

In the event of a natural disaster that adversely affects a transplant program, the patient notification requirements shall be applied reasonably and flexibly.

- iii. 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 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 multi-visceral organ transplant candidates, transfer must be completed within 30 days of inactivation; and
- vi) notwithstanding these guidelines, all active candidates who choose to transfer 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 candidates, recipients and living donors. Should the transplant program continue to provide follow-up care to transplant recipients and living donors, the program must continue to submit OPTN follow-up forms via UNetSM. 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 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 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 a designated transplant program status or it is terminated by the Secretary of HHS, 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. A Member transplant hospital must provide written notice to the OPTN contractor within 30 days of the intent to relinquish its designated transplant program status and the reasons therefor upon deciding to relinquish designated transplant program status.

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, recipients, and living donors currently being followed by the transplant program. Written notice should be mailed at least 30 days prior to the anticipated 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 reason(s) for 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, 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 patient notice to the OPTN contractor along with a list of potential candidate, candidate, and recipient names who received the notice.

- c. Transition Plan.** When a Member transplant hospital relinquishes a transplant program's designated program status or its designated program status is terminated, it must:
- i. promptly suspend organ implantation for the transplant program;
 - ii. assist potential candidates and 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 relinquishment or termination and update it throughout this process;
 - iv. indicate on the list provided 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 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.
 - v. expedite removal of all candidates from the transplant program's waiting list, or, if the patient requests, transfer the candidate to another OPTN Member transplant hospital;
 - vi. initiate transfer of all active candidates hospitalized at the transplant program to an accepting transplant hospital within seven days of relinquishment of the 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 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 must be transferred within seven days of relinquishment, 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;
 2. for lung candidates, active candidates should be transferred according to descending Lung Allocation Scores with highest scores first, followed by inactive candidates;
 3. 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;
4. for heart candidates, all Status 1A and 1B must be transferred within seven days of relinquishment;
 5. for multi-visceral organ transplant candidates, transfer must be completed within 30 days of 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. remove every transplant candidate from the transplant program's waiting list within 12 months of the program's relinquishment date.

A Member that relinquishes or terminates a designated transplant program may still have the ability to temporarily provide care to transplant candidates and provide follow-up care to transplant recipients and living donors. Should the transplant program continue to provide follow-up care to transplant recipients and living donors, the program must continue to submit OPTN follow up forms via UNetsm. Alternatively, transplant recipients may transfer care to another institution.

- 4. Waiting Time on Waiting List.** 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.

~~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.~~

- 5. Laboratory Tests.** The inactivated program remains responsible for evaluating its candidates. This includes, but is not limited to performing laboratory tests and evaluations required 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:

 - ~~(a) — No transplant performed in three months in the case of kidney, liver, and heart transplant programs,~~
 - ~~(b) — No transplant performed in six months in the case of pancreas and lung programs, and~~
 - ~~(c) — 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]

IIIV. Investigation of Personnel. [No change]

IV. OPO Affiliation. [No change]

VI. Histocompatibility Laboratory Affiliation. [No change]

VII. Transplant Surgeon and Physician. [No change]

UNOS Version:

APPENDIX B TO BYLAWS

UNITED NETWORK FOR ORGAN SHARING

II. Transplant Hospitals.

A. General. [No Change]

B. Survival Rates. [No Change]

C. ~~Inactive Membership Status. Functional Inactivity, 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 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 UNOS 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 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" is defined as any or all of the items below:

- (1) ~~(a) The inability to serve patients potential candidates, candidates, 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:~~
 - (b) failure to perform a transplant during the following stated periods of time:

- (i) ~~No transplant performed in three months~~ In the case of kidney, liver, and heart transplant programs, within three consecutive months;
- (ii) ~~No transplant performed in six months~~ In the case of pancreas and lung programs, and within six consecutive months;
- (iii) ~~No transplant performed in one year~~ In the case of transplant programs located in stand-alone pediatric transplant hospitals, within twelve consecutive months.

(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 their 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 programs identified to be functionally inactive, shall be provided the opportunity to explain its inactivity through reports requested by the MPSC.

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

- Inactivates its waiting list or is unable to perform transplants for 15 consecutive days or more;
- Inactivates its waiting list or is unable to perform transplants for 28 cumulative days or more over any 365 consecutive day period.

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 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-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 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.

~~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.~~

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

- an inactive transplant program waiting list status in UNetSM (short-term inactivation), or
- an inactive transplant program waiting list status in UNetSM and an inactive membership status (long-term inactivation).

A Member may voluntarily inactivate a transplant program, on a short-term or long-term basis, for reasons including but not limited 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.

a. Short-Term Inactivation. Short-term inactivation means that a transplant program may be inactive for up to 14 consecutive days. A Member may

voluntarily inactivate a transplant program for a period not to exceed 14 days by changing the program's waiting list status in UNetSM.

- i. Notice to UNOS. When a Member intends to voluntarily inactivate a transplant program on a short-term basis, the Member is not required to notify UNOS.
- ii. Notice to Patients. In accordance with Attachment I to Appendix B, Section VII transplant program must provide potential candidates, candidates, and recipients with a written summary of 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 or more days consecutively. Members should voluntarily inactivate programs that are not able to serve potential candidates, candidates, or recipients for a period of 15 or more days. Voluntary inactivation may extend for a period of up to 12 months.

i. Notice to UNOS. When a Member intends to voluntarily inactivate a transplant program for 15 or more days consecutively, it must provide written notice, including the reason(s) for inactivation, to the UNOS Executive Director upon deciding to inactivate the transplant program.

- ii. Notice to the Patients. When a Member intends to inactivate 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 patient notice to UNOS along with a list of potential candidates, candidates, recipients, and living donors who received the notice.

In the event of a natural disaster that adversely affects a transplant program, the patient notification requirements shall be applied reasonably and flexibly.

- iii. 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 UNOS 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 UNOS 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 UNOS 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 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 multi-visceral organ transplant candidates, transfer must be completed within 30 days of inactivation; and
 - vi) notwithstanding these guidelines, all active candidates who choose to transfer should be transferred within 60 days of inactivation.

- vii) The program must document and submit to UNOS 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 candidates, recipients and living donors. Should the transplant program continue to provide follow-up care to transplant recipients and living donors, the program must continue to submit follow-up forms via UNetSM. 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 UNOS. 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 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 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 a designated transplant program status or it is terminated by the Secretary of HHS, 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 UNOS. A Member transplant hospital must provide written notice to UNOS within 30 days of the intent to relinquish its designated transplant program status and the reasons therefor upon deciding to relinquish designated transplant program status.

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, recipients, and living donors currently being followed by the transplant program. Written notice should be mailed at least 30 days prior to the anticipated 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 reason(s) for 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, 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 patient notice to UNOS along with a list of potential candidate, candidate, and recipient names who received the notice.

c. Transition Plan. When a Member transplant hospital relinquishes a transplant program's designated program status or its designated program status is terminated, it must:

- i. promptly suspend organ implantation for the transplant program;
- ii. assist potential candidates and candidates in identifying designated transplant programs to which they can transfer;
- iii. provide a list to UNOS of all of the transplant program's candidates on the waiting list at the time of relinquishment or termination and update it throughout this process;
- iv. Indicate on the list provided 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 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.

- v. expedite removal of all candidates from the transplant program's waiting list, or, if the patient requests, transfer the candidate to another UNOS Member transplant hospital;
- vi. initiate transfer of all active candidates hospitalized at the transplant program to an accepting transplant hospital within seven days of relinquishment of the 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 UNOS 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 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 must be transferred within seven days of relinquishment, 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;
 - 2. for lung candidates, active candidates should be transferred according to descending Lung Allocation Scores with highest scores first, followed by inactive candidates;
 - 3. 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;
 - 4. for heart candidates, all Status 1A and 1B must be transferred within seven days of relinquishment;
 - 5. for multi-visceral organ transplant candidates, transfer must be completed within 30 days of 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 UNOS 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. remove every transplant candidate from the transplant program's waiting list within 12 months of the program's relinquishment date.

A Member that relinquishes or terminates a designated transplant program may still have the ability to temporarily provide care to transplant candidates and provide follow-up care to transplant recipients and living donors. Should the transplant program continue to provide follow-up care to transplant recipients and living donors, the program must continue to submit follow up forms via UNetsm. Alternatively, transplant recipients may transfer care to another institution.

- 4. Waiting time on waiting list.** 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.

~~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.~~

- 5. Laboratory Tests.** The inactivated program remains responsible for evaluating its candidates. This includes, but is not limited to performing laboratory tests and evaluations required 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 UNOS BYLAWS

Designated Transplant Program Criteria

~~**H. 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. The MPSC may also require, at 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 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 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:

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

- ~~(ii) No transplant performed in six months in the case of pancreas and lung programs, and~~
- ~~(iii) 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 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 take appropriate action.~~

~~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 UNOS and their patients as described above.~~

To read the complete bylaws language visit www.unos.org or www.optn.org. From the UNOS Web site, select Resources from the main menu, then select bylaws. From the OPTN Web site, select Policies from the main menu.