UNOS DONATE LIFE
UNITED NETWORK FOR ORGAN SHARING

*Since 1984 — sharing organs, sharing data, sharing life.*

700 North 4th Street, Richmond, VA 23219
P.O. Box 2484, Richmond, VA 23218
tel: 804-782-4800
fax: 804-782-4817
www.unos.org

# 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—Feb. 20-21, 2008

**Date:** March 20, 2008

---

The attached report summarizes bylaw changes, policy changes and other actions the OPTN/UNOS Board of Directors approved at its February 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 **7** notices included on the grid 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 Sta | Transplant Program Directors | Transplant Social Workers | Transplant Surgeons | Page # |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Link | 1 | Modifications to Policy 3.1.4 (Waiting List) to clarify the phrase "two separate occasions" in reference to ABO typing requirements *(Operations Committee)* | | X | X | | | | | | X | X | | X | X | X | | X | 3 |
| Link | 2 | Modifications to Policy 5.4 (Packaging) to clarify organ packaging requirements *(Operations Committee)* | X | X | X | | X | X | | X | X | X | | X | | X | | X | 4 |
| Link | 3 | Modifications to Policy 2.2.8.1 to clarify that a urinalysis is a required test for all potential donors, regardless of the organ(s) to be recovered *(OPO Committee)* | X | | | X | X | X | | X | | | | | | | | | 5 |
| Link | 4 | Modifications to Policy 2.7.1 (Multiple Abdominal Organ Procurement) to assign the responsibility for documenting the non-procurement of the liver or pancreas during a multiple abdominal organ procurement to the OPO instead of the surgeon *(OPO Committee)* | X | | | X | X | X | | X | X | | | X | | X | | X | 6 |
| Link | 5 | Modifications to Policy 7.1.7 (Imminent Neurological Death) to remove the obligation to track all potential donor deaths to cardiac death, and to clarify that the definition of imminent death is applied at the time of disposition of the donor by the OPO *(OPO Committee)* | X | | | X | X | X | | X | | | | | | | | | 7 |
| Link | 6 | Modifications to Policy 7.1.3 (Reporting Definitions) that will require that each organ transplant must be followed until graft failure *(Policy Oversight Committee)* | | | | | | | | | X | X | X | X | X | X | X | X | 8 |
| Link | 7 | Modifications to the Bylaws, Appendix B, Section II, Paragraphs B and C that delineate when "informal discussions" may be held with an Institutional Member. *(Membership and Professional Standards Committee)* | | | | | | | | | X | | | X | | X | | X | 9 |

**Notice of Policy Change**—Clarification of "Two Separate Occasions" for ABO Typing (Operations Committee)

**Action Required:** Review Only

**Effective Date:** April 21, 2008

**Professional Groups Affected by the change:**
Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Lab Directors, Lab Supervisors, Transplant PR/Public Education Staff

| Current Issue/Policy | Proposed Change or Addition | What You Need to Do |
|---|---|---|
| Current policy states that a transplant program must confirm a potential candidate's blood type on two separate occasions prior to listing for organ transplant. | In order to monitor policy compliance more clearly, the UNOS Department of Evaluation and Quality wanted to clarify what "two separate occasions" meant in reference to ABO typing requirements.<br><br>"Two separate occasions" is defined as two samples drawn at **different** times and sent to the same or different labs. This must occur before a candidate may be listed for organ transplant. | Transplant programs must draw blood samples on **two separate occasions** to determine ABO type before listing a candidate for organ transplant. |

**Affected Policy Language:**

**3.1.4.2** Each transplant candidate must be ABO typed on two separate occasions prior to listing. Two separate occasions is defined as two samples, taken at different times, sent to the same or different labs.

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.

**Notice of Policy Change**—Packaging and Handling of Organs (Operations Committee)

**Action Required:** Review Only

**Effective Date:** April 21, 2008

**Professional Groups Affected by the change:**
OPO Executive Directors, Directors of Organ Procurement, OPO Procurement Coordinators, OPO Medical Directors, Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Lab Directors, Lab Supervisors,

| Current Issue/Policy | Proposed Change or Addition | What You Need to Do |
|---|---|---|
| Current policy uses generic language to address packaging materials and handling of organs. | In response to OPTN membership feedback, we added language that specifically addresses the use of biohazard plastic bags for packaging and universal precautions in the handling of organs. | When packaging organs in disposable transport boxes, OPOs must use a red plastic bio-hazard bag that is secured to be water tight. This allows both medical and non medical personnel to handle it safely. Place the red bag between the waxed cardboard box and the insulated material holding the wet ice and the organ.<br><br>Use universal precautions when packaging all organs from the donor's back table. You must place packaged organs from the surgical back table directly into the wet iced shipping container. |

**Affected Policy Language:**

**5.4 PACKAGING.** In all circumstances during which donor organ is transported outside the recovery facility, the Host OPO or the Transplant Center, as applicable is responsible for packaging, labeling, and handling the organ in a manner which ensures arrival without compromise to the organ(s). Proper insulation and temperature controlled packaging including adequate ice or refrigeration shall be used to protect the organs during transport. All packaged organs, using disposable transport boxes, must have a red plastic bio-hazard bag that is water tight secured to allow for safe handling by medical and non-medical personnel during transport. This red bag may be placed between the waxed cardboard box and the insulated material holding the wet ice and the organ.

All organs that have been packaged on the donor's back table must be handled using universal precautions. The packaged organs from the donor's surgical back table are to be placed directly into the wet iced shipping container.

**Notice of Policy Change**—Policy 2.2.8 Requirement for Urinalysis (OPO Committee)

**Action Required:** Review Only

**Effective Date:** April 21, 2008

**Professional Groups Affected by the change:** OPO Executive Directors, Directors of Organ Procurement, OPO Procurement Coordinators, OPO Data Coordinators, OPO Medical Directors

| Current Issue/Policy | Proposed Change or Addition | What You Need to Do |
|---|---|---|
| Organ Procurement Quality policy requires OPOs to document a "final urinalysis," however this test was not listed as one of the required tests for all potential donors. | We now list urinalysis as a required test for all potential donors (see revised policy language below). | OPOs must perform and document a urinalysis for <u>every</u> potential donor within 24 hours of cross clamp. |

**Affected Policy Language:**

Policy 2.2.8. Performing pertinent tests including:

2.2.8.1 For all Potential Donors:

- CBC;
- Electrolytes;
- Hepatitis screen; including HBsAg, HBcAb, and Anti-HCV:
- VDRL or RPR;
- Anti-HTLV I/II;
- Anti-CMV;
- EBV antibody screening;
- <u>Urinalysis within 24 hours of cross clamp;</u>
- Blood and urine cultures if the donor is hospitalized 72 hours or longer; and
- Chest x-ray

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.

**Notice of Policy Change**—Policy 2.7.1 Documentation of Non-procured Organs (OPO Committee)

**Action Required:** Review

**Effective Date:** April 21, 2008

**Professional Groups Affected by the change:** OPO Executive Directors, Directors of Organ Procurement, OPO Procurement Coordinators, OPO Data Coordinators, OPO Medical Directors, Transplant Administrators, Transplant Program Directors, Transplant Surgeons, and Transplant Physicians

| Current Issue/Policy | Proposed Change or Addition | What You Need to Do |
|---|---|---|
| Policy for multiple abdominal organ procurement states that the liver and pancreas are expected to be procured from donors if each organ is transplantable. If both the liver and pancreas are not procured, the surgeon(s) should write on the donor form the reasons why they failed to procure both organs.<br><br>In practice, the organ procurement coordinators, not the surgeons, are the ones who document these instances on the donor form. | The policy language will now clearly state that the organ procurement coordinator will document the reasons for non-procurement of the liver and pancreas. This change brings policy in line with current practice. | Organ procurement coordinators are responsible for documenting on the donor form the specific reason(s) for not procuring the liver and pancreas. |

**Affected Policy/Bylaw Language:**

**Policy 2.7.1.** Multiple Abdominal Organ Procurement. It is expected that both liver and pancreas should be procured from a donor if each organ is transplantable and/or recipients are identified for each organ. If both the liver and pancreas are not procured, the ~~surgeon(s)~~ OPO should document in writing on the donor form the specific reason(s) for failure to procure both organs.

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.

**Notice of Policy Change —** Policy 7.1.7 Imminent Neurological Death (OPO Committee)

**Action Required:** Review Urgently

**Effective Date:** April 21, 2008

**Professional Groups Affected by the change:** OPO Executive Directors, Directors of Organ Procurement, OPO Procurement Coordinators, OPO Data Coordinators, OPO Medical Directors

| Current Issue/Policy | Proposed Change or Addition | What You Need to Do |
|---|---|---|
| Imminent neurological death is a definition applied to patients who are referred to an OPO but do not yet meet the OPTN brain death criteria.<br><br>Current policy requires OPOs to track such patients to the point of cardiac death, regardless of whether the patient is determined to be a suitable candidate for donation.<br><br>Following patients whom the OPO has already deemed inappropriate for donation was seen as unnecessary and a misuse of OPO staff time by the OPO Committee. | Policy language requiring an OPO to track all potential donors classified as imminent until the point of cardiac death has been removed.<br><br>This definition does not necessarily apply to all patients that are referred. It will only apply if these specific criteria are present when the OPO certifies the final disposition of the organ donation referral. | For the purpose OPTN data submission, the OPO should apply this definition to referrals who meet the following requirements at the time when final disposition of the organ donor referral is certified:<br>• Less than 70 years old, and<br>• Severe neurological injury, and<br>• Requiring ventilator support; and<br>• Absence of at least three brain stem reflexes as documented upon clinical evaluation in the OPO record or donor hospital chart, BUT has not been declared legally brain dead according to hospital policy. |

Click Here to View the Modified Policy Language

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.

**Notice of Policy Change**—Modifications to Policy 7.1.3–Reporting Definitions (Policy Oversight Committee)

**Action Required:** Review Only

**Effective Date:** Summer 2008 (Implementation Date TBD)

**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 | Proposed Change or Addition | What You Need to Do |
|---|---|---|
| Currently, all transplant recipients must be followed until death or retransplantation. If the graft fails, we expect transplant centers to make every reasonable effort to follow surviving recipients for at least two years. | Transplant personnel must now follow each organ transplant until graft failure **only**. | Centers no longer need to submit post-graft failure follow-up forms. However, if one of the transplanted organs is still functioning we will still generate follow-up forms (e.g., the case of a kidney-pancreas transplant where the kidney fails but the pancreas is still functioning.)<br><br>We will send transplant centers a system notice to alert them of the final implementation date. |

**Affected Policy/Bylaw Language:**

**7.1.3.** Each organ transplant must be followed until graft failure. ~~The follow-up period for all transplant recipients will be until death or retransplantation. Following graft failure, every reasonable effort should be made to follow surviving recipients for a minimum of two years.~~

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.

**Notice of Bylaw Change—**Modifications to Appendix B, Section II, Paragraphs B and C in the UNOS and OPTN Bylaws (Membership and Professional Standards Committee (MPSC)).

**Action Required:** Review Only

**Effective Date:** March 20, 2008

**Professional Groups Affected by the change:**
Transplant Administrators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians,

| Current Issue/Policy | Proposed Change or Addition | What You Need to Do |
|---|---|---|
| CurrentBylaws do not define "informal discussions" with the MPSC, or the circumstances under which they could be held with a member.<br><br>Additionally, the Survival Rates Bylaw currently states that "incomplete follow-up data will be treated as a graft loss or patient death in the context of this analysis." | New bylaw language specifies when the MPSC might hold an "informal discussion" with an institutional member. The MPSC may require a member to participate in an informal discussion when it is conducting a review of:<br><br>• transplant program survival rates; and/or<br>• transplant program activity.<br><br>The MPSC will conduct informal discussions according to the principles of confidential medical peer review (see Section 2.07A of Appendix A of the OPTN and UNOS Bylaws).<br><br>Incomplete follow up data is <u>not</u> treated as a graft loss or patient deaths. This bylaw language has been removed. | If the MPSC determines that a transplant center should participate in an informal discussion, it will send a written notice to the member. The member should communicate its accepantance and provide any other requested information by the deadline stated in the letter. |

Click Here to View the Modified Bylaw Language

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.

**Notice of Policy Change —** Policy 7.1.7 Imminent Neurological Death (OPO Committee)

**Affected Policy Language:**

7.1.7. Imminent Neurological Death. Imminent Neurological Death is defined as a patient who is 70 years old or younger with severe neurological injury and requiring ventilator support who upon clinical evaluation documented in the OPO record or donor hospital chart, has an absence of at least three brain stem reflexes but does not yet meet the OPTN definition of an eligible death. Specifically that the patient has not yet been legally declared brain dead according to hospital policy. ~~and who eventually deteriorates to cardiac death (during the referred hospitalization.~~ Persons with any condition which would exclude them from being reported as an eligible death would also be excluded from consideration for reporting as an imminent death. For the purposes of submitting data to the OPTN, the OPO should apply the definition of imminent neurological death to a patient that meets the definition of imminent death at the time when the OPO certifies the final disposition of the organ donation referral.

Brain Stem Reflexes:

- Pupillary reaction
- Response to iced caloric
- Gag Reflex
- Cough Reflex
- Corneal Reflex
- Doll's eyes reflex
- Response to painful stimuli
- Spontaneous breathing

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.

**Notice of Bylaw Change**—Modifications to Appendix B, Section II, Paragraphs B and C in the UNOS and OPTN Bylaws (Membership and Professional Standards Committee (MPSC)).

**Affected Bylaw Language:**

**Appendix B, Section II, Paragraphs B and C in the UNOS and OPTN Bylaws**

**Note: Double underline/Double Strikeouts are changes recommended by the MPSC post public comment.**

**OPTN Bylaws, Appendix B**

**B. Survival Rates.** In the distribution of survival rates of all OPTN Members a transplant program with a low (as defined below) survival rate would be subject to evaluation by the Membership and Professional Standards Committee ("MPSC") to determine if the low survival rate may be accounted for by patient mix or some other unique clinical aspect of the transplant program in question. The MPSC may conduct a site visit to the program at Member expense and may require the Member to adopt a plan for quality. 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 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.

Those programs whose actual observed patient and/or graft survival rates fall below their expected rates by more than a threshold will be reviewed. The absolute values of relevant parameters in the formula may be different for different organs, and may be reviewed and modified by the MPSC, subject to Board approval.

While the precise numerical criteria may be selected by the MPSC, the initial criteria employed to identify programs with low patient and/or graft survival rates will include the finding that observed events minus expected events is >3 and the observed events divided by expected events is greater than 1.5; and there exists an one sided p value of <0.05.

Observed events represent deaths or graft losses as reported in UNOS database. Expected events represent deaths or graft losses as calculated utilizing organ specific transplant models. ~~Incomplete follow-up data will be treated as a graft loss or patient deaths in the context of this analysis.~~

If a program's performance cannot be explained by patient mix or some other unique clinical aspect of the transplant program in question, the Member, in cooperation with the MPSC, shall adopt and promptly implement an appropriate plan for quality

improvement. The Member's failure to do so shall constitute a violation of UNOS requirements.

**C.** **Inactive Membership Status.** An OPTN 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 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:

(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 Member fails to take either action voluntarily, the Membership and Professional Standards Committee may recommend that the Board of Directors notify the Secretary of HHS of the situation in the case of transplant programs approved by the Secretary of HHS for reimbursement under Medicare or transplant programs in Federal hospitals, or 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 (with a copy to the entity that operates the OPTN under contract with HHS (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 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 the OPTN Contractor and their patients as described above.

**UNOS Bylaws, Appendix B "Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership"**

**II. Transplant Hospitals.**

A. No changes

**B.** **Survival Rates.** In the distribution of survival rates of all UNOS members a transplant program with a low (as defined below) survival rate would be subject to evaluation by the Membership and Professional Standards Committee ("MPSC") to determine if the low survival rate may be accounted for by patient mix or some other unique clinical aspect of the transplant program in question. The MPSC may conduct a site visit to the program at Member expense and may require the Member to adopt a plan for quality improvement. 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.

Those programs whose actual observed patient and/or graft survival rates fall below their expected rates by more than a threshold will be reviewed. The absolute values of relevant parameters in the formula may be different for different organs, and may be reviewed and modified by the MPSC, subject to Board approval.

While the precise numerical criteria may be selected by the MPSC, the initial criteria employed to identify programs with low patient and/or graft survival rates will include the finding that observed events minus expected events is >3 and the observed events divided by expected events is greater than 1.5; and there exists an one sided p value of <0.05.

Observed events represent deaths or graft losses as reported in UNOS database. Expected events represent deaths or graft losses as calculated utilizing organ specific transplant models. ~~Incomplete follow-up data will be treated as a graft loss or patient deaths in the context of this analysis.~~

If a program's performance cannot be explained by patient mix or some other unique clinical aspect of the transplant program in question, the Member, in cooperation with the MPSC, shall adopt and promptly implement an appropriate plan for quality improvement. The Member's failure to do so shall constitute a violation of UNOS requirements.

**C.** **Inactive Membership 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 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:

(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:

(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 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.

**ATTACHMENT I**
**TO APPENDIX B OF UNOS BYLAWS**

**Designated Transplant Program Criteria**

**I. Facilities and Resources. No changes**

**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. 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:

(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:

(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.

**XIII. <u>Transplant Programs</u>.**

**A. No changes**
**B. No changes**

C. Sections (1) – (9) No changes

**(10) Survival Rates.** In the distribution of survival rates of all UNOS members a transplant program with a low (as defined below) survival rate would be subject to evaluation by the Membership and Professional Standards Committee ("MPSC") to determine if the low survival rate may be accounted for by patient mix or some other unique clinical aspect of the transplant program in question. The MPSC may conduct a site visit to the program at Member expense and may require the Member to adopt a plan for quality improvement. <u>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.</u>

<u>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.</u>

Those programs whose actual observed patient and/or graft survival rates fall below their expected rates by more than a threshold will be reviewed. The absolute values of relevant parameters in the formula may be different for different organs, and may be reviewed and modified by the MPSC, subject to Board approval.

While the precise numerical criteria may be selected by the MPSC, the initial criteria employed to identify programs with low patient and/or graft survival rates will include the finding that observed events minus expected events is >3 and the observed events divided by expected events is greater than 1.5; and there exists an one sided p value of <0.05.

Observed events represent deaths or graft losses as reported in UNOS database. Expected events represent deaths or graft losses as calculated utilizing organ specific transplant models. ~~Incomplete follow-up data will be treated as a graft loss or patient deaths in the context of this analysis.~~

If a program's performance cannot be explained by patient mix or some other unique clinical aspect of the transplant program in question, the Member, in cooperation with the MPSC, shall adopt and promptly implement an appropriate plan for quality improvement. The Member's failure to do so shall constitute a violation of UNOS requirements.

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.