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Walter Graham, Executive Director

PUBLIC COMMENT NOTICE

To: OPTN/UNOS members and other interested persons

From: Karl J. McCleary, Ph.D., MPH, Director of Policy, Membership and Regional Administration

Re: OPTN/UNOS policy proposals for public comment

Date: September 28, 2007

This document contains a proposed Bylaws change from the Membership and Professional Standards Committee (MPSC). The change documents the Committee's current practice of holding informal discussions with Members during its review of survival rates and activity at transplant programs.

We are requesting your input on this proposal.

After the public comment period ends on December 21, 2007, the MPSC committee will review all feedback provided and make modifications as necessary. This proposal may be considered for approval by the OPTN/UNOS Board of Directors during its meeting on February 21, 2008.

Please visit www.optn.org or www.unos.org to provide feedback on this proposal. Alternatively, you may mail, fax, or e-mail your feedback. Please submit all comments no later than **December 21, 2007**.

UNOS appreciates your consideration and feedback on these important issues.

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The OPTN/UNOS Public Comment Process

What are UNOS and the OPTN?

The United Network for Organ Sharing (UNOS) is a tax-exempt medical, scientific, and educational membership organization. UNOS operates the national Organ Procurement and Transplantation Network (OPTN) under federal contract with the Department of Health and Human Services (DHHS). UNOS, operating as the OPTN, is charged with the following:

- developing organ allocation policies that are equitable and based on medical and scientific criteria.
- developing by-laws and policies that make the best use of organs donated for transplantation and assure quality of care
- addressing other issues related to organ transplantation in the United States.

What is Public Comment?

The National Organ Transplant Act (NOTA) and the OPTN contract with DHHS require that members of the public have an opportunity to provide input into the development of by-laws and policies. The OPTN uses public comment to gather this input from the transplant community and general public. Currently, policies and by-laws receive broad input from organizations and people with an interest in transplantation. These may include:

- transplant candidates, recipients and their families;
- donors and donor families;
- members of the OPTN; and
- interested individuals and organizations throughout the United States.

After the sponsoring committees circulate and discuss the proposals, the OPTN/UNOS Board of Directors may choose to adopt the proposals. All OPTN bylaws and policies are considered to be voluntary guidance for OPTN members, unless they are recommended by the Board of Directors and approved by the Secretary of DHHS as OPTN rules and requirements enforceable under Section 1138 of the Social Security Act. An example of a requirement that is enforceable under the Final Rule is the submission of accurate and complete data on OPTN forms and applications approved by the Office of Management of Budget (OMB), as specified by the Secretary. UNOS is responsible for updating these by-laws and policies and for monitoring compliance by OPTN members. Noncompliance with by-laws and policies is reported to the OPTN Membership and Professional Standards Committee and may lead to disciplinary action, including, designation as a member-not-in-good-standing by the Board of Directors.

Current Proposal

This document contains a Bylaws change being proposed by the Membership and Professional Standards Committee (MPSC). This proposed change documents the Committee's current practice of holding informal discussions with Members during its review of survival rates and activity at transplant programs. After the public comment feedback is received and additional discussions are held by the MPSC, this proposal may be considered for approval by the OPTN/UNOS Board of Directors during its meeting on **February 21, 2007**.

How Can You Participate?

You can request to receive a copy of every document that goes out for public comment by visiting www.unos.org or www.optn.org. If you are unable to access the internet, please submit a written request to UNOS at the address below. UNOS generally accepts comments from the public for 30 to 60 days after the proposals are published. We may occasionally hold public hearings to discuss certain proposals. Announcements of public hearings are also listed on the above Web sites.

Current Deadlines

The proposal in this document is being issued for public comment on **September 28, 2007**. In order for your comments to be considered, you must submit them electronically at www.optn.org or www.unos.org or by writing, faxing, or e-mailing them to the address below by **December 21, 2007**.

Public Comment Coordinator
United Network for Organ Sharing
700 North 4th Street
Richmond, VA 23218
FAX (804) 782-4896
E-mail: publiccomment@unos.org

UNOS Contact Persons

Please contact your UNOS Regional Administrator at (804) 782-4073 with any questions about this policy proposal. The UNOS Regional Administrators are as follows:

Shannon Edwards (edwardsf@unos.org)

Region 1 - Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Eastern Vermont

Region 4 - Oklahoma, Texas

Region 9 - New York, Western Vermont

Betsy Gans (gansel@unos.org)

Region 2 - Delaware, District of Columbia, Maryland, New Jersey, Pennsylvania, Northern Virginia, West Virginia

Region 6 - Alaska, Hawaii, Idaho, Montana, Oregon, Washington

Region 8 - Colorado, Iowa, Kansas, Missouri, Nebraska, Wyoming

Clifton McClenney (mcclence@unos.org)

Region 3 - Alabama, Arkansas, Florida, Georgia, Louisiana, Mississippi, Puerto Rico

Region 11 - Kentucky, North Carolina, South Carolina, Tennessee, Virginia

Chrystal Oley-Graybill (graybioe@unos.org)

Region 5 - Arizona, California, Nevada, New Mexico, Utah

Region 7 - Illinois, Minnesota, North Dakota, South Dakota, Wisconsin

Region 10 - Indiana, Michigan, Ohio

- 1. Proposed Modification to the OPTN Bylaws, Appendix B, *Transplant Hospitals*; Section B. *Survival Rates*; and Section C “*Inactive Membership Status*”; and Attachment I, Section II, “*Inactive Program Status*”; and to the UNOS Bylaws, Attachment I, Section II “*Inactive Program Status*” and Attachment II, Section XIII, C, (10) “*Survival Rates.*” (Membership and Professional Standards Committee)**

Summary/Performance Objective – Aim

This proposed change to the Bylaws documents the Membership and Professional Standards Committee’s (MPSC) current practice of holding informal discussions with Members during its review of survival rates and activity at transplant programs.

Background and Significance

These proposed modifications were considered by the MPSC during its August 1-2, 2007, meeting. The purpose of the proposal is to delineate when “informal discussions” may be held with an Institutional Member.

The Bylaws establish that a Member is entitled to an interview as part of its due process rights when the MPSC is considering taking specified actions against the members. However, the Committee found that it is useful to engage in discussions with the Member in other circumstances and it has been conducting informal discussions with members for several years; however, the process itself has not been codified in the Bylaws. This modification will document that the Committee can require the member to participate in a discussion when it is conducting performance reviews, including review of survival rates and activity, in a transplant program. The informal discussion can be conducted by the MPSC, or a subcommittee or work group, as the MPSC may direct. The purpose of the discussion is for the Committee to continue fact-finding, and at the same time encourage an open dialogue between the MPSC and the Member about its program. These discussions are conducted by conference call and are arranged in advance by UNOS staff.

The informal discussion established by the proposal is not an element of due process, nor is it a right of the Member.

Policy Proposal

The Committee approved the following resolution:

- ** RESOLVED, that the Committee supports the language in the proposal and agrees that the recommended modifications should be distributed for public comment.

The Committee voted 25 For, 0 Against, 0 Abstentions.

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, in its discretion, that the Member participate in a discussion regarding a performance review in the MPSC's quality improvement effort. 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 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. 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 in the MPSC's quality improvement effort. 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 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, in its discretion, that the Member participate in a discussion regarding a performance review in the MPSC’s quality improvement effort. 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 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 in the MPSC's quality improvement effort. 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 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, in its discretion, that the Member participate in a discussion regarding a performance review in the MPSC's quality improvement effort. 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 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:
 - (iv) No transplant performed in three months in the case of kidney, liver, and heart transplant programs,
 - (v) No transplant performed in six months in the case of pancreas and lung programs, and
 - (vi) 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. Transplant Programs.

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. The MPSC may also require, in its discretion, that the Member participate in a discussion regarding a performance review in the MPSC’s quality improvement effort. 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 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.