

OPTN/UNOS MEMBERSHIP AND PROFESSIONAL STANDARDS COMMITTEE REPORT

June 24-25, 2004

SUMMARY

I. Organ Availability Issues

- Action Items for Board Consideration

None

- Other Significant Issues

None

II. Patient Access Issues

- Action Items for Board Consideration

None

- Other Significant Issues

None

III. Action Items for Board Consideration:

- The Board of Directors is asked to approve two new transplant centers for membership. Additionally, the Committee will recommend approval of four new programs in existing member centers; three new hospital based histocompatibility laboratories, and one that is independent. (Item 1, Page 1).
- The Board of Directors is asked to renew public members that desired to continue their membership for another two-year term. (Item 1, Page 1).
- The Board of Directors is asked to grant full approval to three programs that now fully meet the membership requirements. (Item 5, Pages 1-2).

IV. Other Significant Items:

- The Committee reviewed 15 key personnel change applications at its January meeting and 8 at the May meeting. (Item 2, page 1).
- Heart/lung transplant programs. Following the October meeting, fifteen transplant centers were notified that they held approval for heart/lung programs without the benefit of approved lung and/or heart programs. The programs were given the option of withdrawing their heart/lung program approval or providing UNOS with information demonstrating that they meet the current requirements to provide heart/lung transplantation. The responses from the programs were reviewed during the January and May meetings, and the Committee determined that an ad hoc subcommittee should be formed to further consider the requests for exceptions. (Item 7, pages 2-3).

- The Committee was updated on the status of the OPTN Charter and Bylaws that describe the structure and operation of the OPTN. (Item 8, page 3)
- Development of Specific Criteria regarding Transplant Program Infrastructure: The Committee discussed its concerns relative to new applicants having the appropriate infrastructure to support a transplant program. They amended the application questions to require the applicant to further expand on the description of collaborative support provided to the program, especially in cases where off site facilities are involved. (Item 9, Page 3).
- Social Services Support and Transplant Pharmacists: The Committee reviewed two By-Law modification proposals from the OPTN/UNOS Transplant Administrators Committee. One proposed By-law change delineates a transplant program's specific responsibilities in providing psychiatric and social support services (psychosocial services) for transplant candidates, recipients, living donors, and family members. The second change proposes additional language that delineates the specific responsibilities of a clinical transplant pharmacist in an active transplant program. The Committee discussed both proposals and voted to support them. (Item 10, pages 3-4).
- Evaluation Plan Schedule: Staff updated the Committee on the proposed schedule for the Evaluation Plan, which is required by the Final Rule and by UNOS as the OPTN contractor with HRSA. (Item 11, page 4).
- Laboratory Directorship Guidelines: The Committee was asked to provide input on the draft guidelines for laboratory director responsibilities. The Committee discussed the guidelines and suggested that the Histocompatibility Committee would need to reformat and circulate these guidelines for public comment if they are to be incorporated into the current requirements. (Item 12, Pages 4-5).
- Standards for Certification of Live Liver Donor Transplant Programs and Live Kidney Donor Transplant Programs. Staff provided an update to the Committee relative to the status of the requirements. (Item 13, Pages 5-6).
- Islet Cell Transplant programs: The Committee reviewed its first application for a free standing islet cell transplant program and discussed the review process for these programs in general terms. (Item 14, Page 6).
- The Committee requested that additional policy language be added to the data submission policy to include automatic onsite audits for non-compliant programs at the program's expense. The purpose of the audit would be for UNOS to retrieve the missing data. The proposed policy amendment will be circulated for public comment prior to consideration for adoption by the Board of Directors. (Item 17, Page 7).

REPORT OF THE

OPTN/UNOS MEMBERSHIP AND PROFESSIONAL STANDARDS COMMITTEE

TO THE

**BOARD OF DIRECTORS
Minneapolis, Minnesota**

June 24-25, 2004

**Robert A. Metzger, M.D., Chairman
Kim M. Olthoff, M.D. Vice Chair**

I. Regular Committee Meetings The following report presents the Membership and Professional Standards Committee's deliberations and recommendations on matters considered by the Committee during its January 28-29, 2004, and May 4-5, 2004, meetings.

1. Membership Application Issues: The Committee recommends to the Board of Directors that two new transplant centers be approved for membership. Additionally, the Committee recommends approval of four new programs in existing member centers; three new hospital based histocompatibility laboratories, and one that is independent.

In addition to considering applications for new programs and laboratories, the Committee reviewed requests from public members that desired to continue their membership for another two-year term and recommends to the Board of Directors that these memberships be renewed.

2. Programs and Personnel Changes: At both its January and May meetings, the Committee reviewed and accepted programs changing status by voluntarily inactivating, withdrawing from membership, reactivating, or who had initiated new pancreas islet cell or intestinal transplant programs.

The Committee reviewed and approved member Key Personnel Changes. The Committee reviewed only those transplant programs that are not certified by CMS for Medicare reimbursement. Additionally, the Committee reviewed routine reports from programs that were previously conditionally approved.

3. Inactive Transplant Programs: During its January meeting, the Committee reviewed a request from a lung program that had an inactive membership status. Its one-year period in this status was expiring, and the center had requested reactivation. The Committee recommended that the hospital withdraw this program from membership and reapply when it is able to comply with conditions set forth during a review for a potential policy violation. The program was offered the option to continue in due process (hearing) if it did not agree with the Committee's determination. The hospital subsequently withdrew this program from membership.
4. Recommendation that Program's Approval Status be withdrawn: During its January meeting the Committee recommended that one pancreas and one kidney transplant program have their approval status withdrawn based on their lack of transplant procedure activity. Centers that do not accept the Committee's recommendation may accept an interview, the first step of due process. During its May meeting the Committee reconsidered the pancreas transplant program and rescinded its recommendation in light of new information supplied by the center. It also noted that the kidney program had inactivated.
5. Reports from Conditionally Approved Programs: During its January meeting, the Committee reviewed ongoing reports from four transplant programs that have conditional approval. Two programs will be recommended for full approval since they now fully meet the requirements. The two remaining programs were asked to continue reporting. During its May meeting, the Committee reviewed these two programs and determined that one of them

could be recommended for full approval. The remaining liver program appears to be on track to meet the requirements by the end of its conditional year. The Committee recommends to the Board of Directors that these programs be granted full approval.

In addition, in January the Committee reviewed a progress report from a pediatric heart program that was approved under the pediatric pathway. During its May meeting, the Committee noted that additional progress had not been made towards meeting the full requirements and expressed its expectation that the surgeon should complete the experience requirements for performing procurement procedures within the next two years.

6. **Due Process Proceedings:** During its January meeting, the Committee conducted four interviews. Three of the programs were under review by the Data Subcommittee's in its study of programs that appeared to be functionally inactive. During its October meeting, the Committee recommended that each of these centers withdraw its functionally inactive programs from membership. Each was given the opportunity to submit new information and/or interview before the Committee. Each program accepted and participated in an interview. Following the interviews the Committee determined that all three of the programs would be asked to provide additional information such as business plans for the programs. The Committee's previous recommendations for program withdrawal were held in abeyance until the programs have provided this information for review. The fourth interview was conducted with a center that wished to continue offering heart/lung transplantation as an option even though it does not conform to the present By-Laws, which state that a heart/lung transplant center "must have UNOS approved programs in both heart and lung transplantation." The Committee determined that this issue should be forwarded to a combined MPSC/Thoracic Organ Transplantation Committee for further consideration.

During its May meeting the Committee conducted one interview with a new hospital applying for an islet cell transplant program and another with a lung transplant program that had been recommended for inactive status. The islet cell program was recommended for approval pending receipt of several documents. The Committee continued its recommendation for inactivation of the lung transplant program that had low activity levels as well as less than expected one-year graft and patient survival rates. That program will be offered the opportunity to appeal this determination through a hearing if it does not accept the Committee's recommendation.

In January, the full MPSC also conducted hearings with representatives from an OPO and representatives from the heart and liver programs at a transplant center. These members were brought forward to the full Committee by the Policy Compliance Subcommittee (PCSC), which was investigating potential policy violations. Adverse actions against these members have been held in abeyance pending a review of the results of a re-audit and their progress implementing their correction action plans.

7. **Heart/lung transplant programs.** During its August 2002 meeting, the Committee considered a letter from a member transplant center that was prepared to withdraw its presently inactive lung transplant program, but wanted to be able to continue its heart/lung transplant program. The By-Laws state that a heart/lung transplant center "must have UNOS approved programs in both heart and lung transplantation." One of the questions raised was should the same requirement be applied equally to new programs and programs that were already approved. They opined that this matter raised valid concerns and referred the issue to the Thoracic Organ Transplantation Committee for its opinion. At its January 2003 meeting, the Committee was informed that the Thoracic Organ Transplantation Committee determined that the current requirements should not be amended other than to add an "out clause" which would allow for a "variance" in circumstances such as described above. They requested that the Thoracic Committee submit a proposal describing the circumstances under which a variance could be considered.

In July 2003, the Committee was informed that the Thoracic Organ Transplantation Committee had reconsidered the issue and had opined that it did not support a variance to the By-law that heart/lung programs must exist in centers that also have heart and lung transplant programs. The Committee agreed with this recommendation.

In light of this discussion, thirteen centers were notified that they held approval for heart/lung programs without the benefit of approved lung and/or heart programs. The centers were given the option of withdrawing their heart/lung program approval or providing UNOS with information that showed that they met the current requirements to provide heart/lung transplantation. As of the January meeting four of the programs had withdrawn their membership, three requested that they be allowed to continue their programs, and six have not responded.

The Committee reviewed the responses from the centers that wished to keep their programs, including the original center, which participated in interview, and determined that an ad hoc subcommittee should be formed to further consider their requests. The subcommittee participants should include members of the Membership and Professional Standards Committee, as well as the Thoracic Organ Transplantation Committee.

RESOLVED, that an ad hoc subcommittee should be formed to further consider the requests of several centers that wished to continue their heart/lung transplant programs without the benefit of also having an approved lung transplant program.

The Committee voted 17 For, 0 Against, 0 Abstentions.

When it met in May, the Committee was informed that five additional heart/lung programs had withdrawn and that one had not responded. The Subcommittee appointments are pending.

8. **OPTN Charter and By-Laws:** Staff provided an update on the OPTN Charter and By-Laws to the Committee at both its January and May meetings. The OPTN Charter and By-Laws were approved by the Board of Directors during their November 2003 meeting, with an implementation date of May 1, 2004. Staff presented the Committee with a draft implementation timeline and noted the steps that had been completed. Some of the larger projects include adjusting current applications as necessary to fit the new membership requirements; making programming changes to reflect terminology changes; and setting up the member electors system.
9. **Transplant Center Infrastructure:** During its May 2003, meeting the Committee discussed its concerns relative to new applicants having the appropriate infrastructure to support a transplant program. It was particularly concerned with the on site availability of support services and cases where the services might be contracted out to an off site entity. The Committee also discussed the current requirements as delineated in the By-Laws, Appendix B, Section III, C, (9) and (12)-(15). The Committee agreed that the by-laws are not specific regarding the on site availability of these services. In July 2003, a Subcommittee was formed to review these sections and draft a proposal that defines which services must be located on site (in the transplant facility) versus those to which the program must have immediate access. The Subcommittee included Art Thomson as chair, along with Dr. Vega, Dr. Metzger, and Ms. Allee. The Subcommittee met by phone on December 10, 2003, and agreed that it was not necessary to amend the current By-Laws. They did suggest changes to the application questions that would require the applicant to further expand on the description of collaborative support provided to the program, especially in cases where off site facilities are involved.

The changes included modifying the header for Section D of the General Section of a new center application to include the following statement: *“D. Collaborative Support: When answering the questions in this section, please articulate plans for any transplant-related services provided outside the hospital. This includes, but is not limited to plans to assure immediate access to services and to assure patient safety during transports to off-site facilities. Please also provide a letter of support or agreement from each off-site provider.”*

For new programs or programs that are seeking approval to reactivate, the Committee added the following question. *“Please articulate plans for any transplant-related services provided outside the hospital. This includes, but is not limited to plans to assure immediate access to services and to assure patient safety during transports to off-site facilities. Please also provide a letter of support or agreement from each off-site provider.”*

The Committee discussed and accepted these modifications to the forms.

RESOLVED, that the application questions be modified to ask the center to further expand on the description of collaborative support provided to the program, especially in cases where off site facilities are involved.

The Committee voted 17 For, 0 against, 0 abstentions.

10. **Social Services Support and Transplant Pharmacists:** In January, the Committee reviewed two By-Law modification proposals from the Transplant Administrators Committee. One proposed By-law change delineates a transplant program’s specific responsibilities in providing psychiatric and social support services (psychosocial services) for

transplant candidates, recipients, living donors, and family members. The second change proposes additional language that delineates the specific responsibilities of a clinical transplant pharmacist in an active transplant program. The goal of the proposal is to provide additional detailed information about the essential care provided by pharmacists and teams led by pharmacists, in an effort to assure that this care remains available to transplant recipients and the transplant team. The Transplant Administrator's Committee made it clear that it was not their goal to create membership requirements on par with the primary physician or surgeon with either of these proposals. The Committee discussed both proposals and voted to support them.

RESOLVED, that the Committee supports the recommendation of the Transplant Administrator's Committee, to submit for public comment, a proposal to modify Appendix B of the By-Laws, to include a delineation of a transplant program's specific responsibilities in providing psychiatric and social support services, as well as a description of responsibilities for a transplant pharmacist.

The Committee voted 16 For, 0 Against, 0 Abstentions.

During its May meeting the Committee reviewed the status of these proposals, including the public and regional comments, and again voted in support of the proposals.

RESOLVED, that the Committee supports the recommendations of the Transplant Administrator's Committee to modify Appendix B of the By-Laws, to include a delineation of a transplant program's specific responsibilities in providing psychiatric and social support services

The Committee voted 19 For, 0 Against, 0 Abstentions.

RESOLVED: The Committee supports the recommendations of the Transplant Administrator's Committee to modify Appendix B of the By-Laws, to include a description of responsibilities for a transplant pharmacist.

The Committee voted 20 For, 0 Against, 0 Abstentions.

11. **Evaluation Plan Schedule:** During the January meeting the staff updated the Committee on the proposed schedule for the Evaluation Plan, which is required by the OPTN Final Rule and by UNOS as the OPTN contractor with HRSA. Staff reported that we had previously submitted an Evaluation Plan but the suggestion was made at that time that we wait and redraft the Plan once the Charter and By-Laws for the OPTN were drafted and approved by the Board. The Board granted approval during its November 2003 meeting. A new Plan will be developed based on the newly approved Charter and By-Laws. The proposed schedule has already been submitted to DoT. UNOS staff will be working closely with the Committee and Subcommittees to ensure that the appropriate information is included in the Evaluation Plan.

During the May meeting, the Committee received an outline and update of the Evaluation Plan, which outlines how the OPTN is monitoring compliance and what is expected of OPTN/UNOS Members to stay in compliance. After revisions, a final copy is scheduled to be sent to all OPTN/UNOS Members by Fall 2004. The Committee also received a Metrics Presentation from Policy Compliance staff. The Metrics and Database system will be used in monitoring members for compliance and will assist the Policy Compliance Subcommittee, as well as the MPSC, in reviewing members and making recommendations.

12. **Laboratory Directorship Guidelines:** The Committee was briefed by Committee member, Dr. Malek Kamoun, on the continued work of the UNOS/ASHI Task Force on Multiple Laboratory Directorships. The goal of the Task Force was initially to develop criteria specifying how many labs a single director could serve. The Task Force developed guidelines for assessing director involvement and a draft was circulated to the Histocompatibility Committee and the ASHI Accreditation Review Board (ARB).

During their July 2003 meeting, the Committee was provided with these draft guidelines for laboratory director responsibilities for their input. The Committee discussed the guidelines and suggested that the Histocompatibility Committee would need to reformat and circulate these guidelines for public comment if they are to be incorporated

into the current requirements. The Committee also asked for clarification regarding the impact of the guidelines on labs that are served by a part-time director.

During the October 2003 meeting, the Committee was informed that the Histocompatibility Committee had discussed the proposal and the potential for developing it into guidelines that would go out for public comment. Furthermore, they had discussed the potential impact of these guidelines on laboratories that employ part-time directors. ASHI and the Histocompatibility Committee are working together to develop objective criteria for evaluating lab director requirements in these instances.

During its January 2004 meeting, the Committee was updated on the status of this proposal, which was sent out by ASHI for consideration by their membership. Their comment deadline was January 30, 2004. The Histocompatibility Committee considered the proposal during its January meeting and discussed the appropriate use of the document (use for director training review, accreditation, enhance the evaluation of directors during the inspection process.) They had not yet determined if policy changes should be made, but continued to work closely with ASHI to review the comments that are coming in.

The Histocompatibility Committee asked for additional guidance from the MPSC relative to the future use of the guidelines. Should they be used during inspection process? The Histocompatibility Committee believes that they would be of value in determining if a lab director is fully engaged in fulfilling his/her responsibilities but they would prefer to keep them as guidelines rather than recommending changes to the by-laws. It was pointed out by Committee members that they could be included as an appendix to the Charter and By-Laws and that it is possible that some elements should be included in the by-laws while others could remain as guidelines.

During the May meeting, Dr. Kamoun briefed the Committee on the current status of the proposal. The Histocompatibility Membership Subcommittee was formed and developed a draft for bylaw changes, which would go under personnel qualifications. The proposal would provide more details than the current requirements. The Histocompatibility Committee is in the final stages of preparing the documents to go out for public comment in August. That Committee anticipates bringing the proposal back the MPSC and the Board of Directors in the Fall.

In addition to by-laws changes, which further explain staff qualifications, the Histocompatibility Committee has developed other supplemental guidelines addressing such issues as director responsibilities when directing more than one laboratory, and laboratory performance.

Following Dr. Kamoun's briefing, the Committee raised several questions: How will the Histocompatibility Committee ensure that their decisions are consistent regarding personnel? Are there quantifiable measures that can be used? Dr. Kamoun pointed out that the Histocompatibility Committee determined that performance and overall outcome should be the ultimate measure of whether or not an individual is providing adequate and appropriate direction or clinical consultation. Proficiency testing was cited as an example. The Committee thought that the proposal needed to go a step further in describing or quantifying what is considered a good outcome.

There was further discussion about where the guidelines would fit into the By-laws, and it was determined that they could be treated as appendices. Staff agreed to work with the Histocompatibility Committee to determine appropriate placement.

13. Standards for Certification of Live Liver Donor Transplant Programs and Live Kidney Donor Transplant Programs.

In January, UNOS staff provided an update to the Committee relative to the status of the requirements. At its November 2003 meeting, the Board of Directors voted to defer implementation of standards for live kidney donor programs while the criteria for living donor liver programs were approved. The liver application was drafted based on the changes recommended to the Board. It is anticipated that the live kidney donor program requirements would be reintroduced at the June 2004 Board meeting.

Dr. Kim Olthoff mentioned that the ASTS is also working on guidelines for kidney training programs and that Dr. Henry is the chair of their Education Committee. They were not sure if there had been direct communication from the Living Donor Committee to the ASTS leadership about the development of these criteria, even though there are ASTS members on the Committee. It was suggested that staff should have Dr. Henry review the draft of the application when it is ready. The Criteria, as approved, should also be forwarded to Drs. Henry and Olthoff.

At the May meeting, the Committee was given a draft application for the living liver programs to review and provide their feed back to staff within two weeks.

In May, the Committee was also briefed on the status of the criteria development for living donor kidney transplant programs. They reviewed the minutes from April 29, 2004, meeting of the OPTN/UNOS Joint Ad Hoc Living Donor and Kidney/Pancreas Transplantation Subcommittee and discussed their concerns about whether or not the criteria go far enough to protect the living kidney donor.

The Committee concluded that this proposal should be sent back to the joint subcommittee for further review. They specifically asked for further clarification regarding what the qualifications are in terms of certifying both pathways (open and laparoscopic) to be approved. It is not clear in the proposal if once the program is approved to do open donor nephrectomy procedures, if the center has to come back to prove its meets the criteria for laparoscopic donor nephrectomies, or vice versa. The Committee also opined that the proposal should be go back out for public comment since so many changes have been made to the original document.

RESOLVED, that the Committee opined that this proposal should be sent back to the joint subcommittee for further review. They specifically asked for further clarification regarding what the qualifications are in terms of certifying both pathways to be approved.

The Committee voted: 20 For, 0 Against, 0 Abstentions.

During the discussion, the Committee also made the following recommendations:

- That a review of donor deaths since 1995 be conducted;
- That there be a clear mechanism defined in the polices for immediately reporting a live donor death to UNOS; and
- That two additional members of the Committee be appointed to the joint subcommittee. Dr. Henry is already a member. Drs. Hayes and Vernon were also appointed.

14. Islet Cell Transplant programs: During the January meeting, the Committee reviewed its first application for a free standing islet cell transplant program and discussed the review process for these programs in general terms. The Committee agreed that the new application form worked well in its present form, and could be distributed to the other programs. Additionally, it was noted that the FDA does not provide written documentation to programs that indicates that their IND has been approved. The Committee was concerned that it could not be assured that the programs are approved, as required in the By-Laws, without supporting documentation. Dr. Wong indicated that DoT staff could help clarify the status of the programs. It was agreed that UNOS staff would provide a list of registered islet cell programs to the DoT staff and they would validate their IND approval status. Subsequent to the meeting, it was learned that DoT would not be able to provide a list but suggestions were made for rewording the application. The application was amended to add a request for the center to provide documentation that verifies that the required IND application as reviewed by the FDA is in effect for their program. During the May meeting staff reported to the Committee that the applications had been mailed to all of the registered Islet Cell Transplant programs. Applications are to be returned by September 1, 2004.

15. Liver placement procedures. During its May meeting, the Committee reviewed a letter from a member who expressed concerns about the liver placement procedures in their local area. At issue were instances when a center accepted an offer only to turn it down much later, risking organ wastage. The Liver and Intestinal Organ Transplantation Committee previously reviewed this issue and opined that it did not support the practice as described in the OPO's letter. It voted to send the issue to the Membership and Professional Standards Committee for investigation and possible action.

The Committee was informed that there had been a subsequent meeting of the involved parties and that they were working towards an acceptable way to resolve future issues, including quarterly meetings. Following a brief discussion the Committee concluded that that transplant center and OPO should continue their efforts to work together and that a letter of encouragement should be sent in response.

RESOLVED, that the Committee encourages the transplant center and OPO to continue to work out issues of this nature at their quarterly meetings.

Voted 18 For, 1 Against, 0 Abstentions.

16. **Review of Appendix B of the By-Laws, Section III, C, 2(b)(ii):** The Committee had reviewed a specific change in key personnel at the January meeting that raised questions relative to the interpretation of the By-Laws. At their May meeting they revisited the interpretation of Section III, C, 2(b)(ii) which states “*In the case of a change in the primary transplant physician at a UNOS approved transplant program, if items (aa) iii or (cc) i-ii are not met, the replacement physician, whether a gastroenterologist/hepatologist or not, can function as a liver transplant physician for a maximum period of twelve months if the following conditions are met...*” The Committee wanted to make sure that they understood the criteria to intend that a physician who has not specialized in a particular organ could be qualified as the primary physician as long as they meet either the training requirements or the volume under experience requirements that are set forth in the by-laws. There was some question about whether or not the preamble to this section applied.

The Committee reviewed the intent of the criteria, the original policy proposal for the language, which was adopted by the Board in June 1999, and whether or not an individual has to be board certified in his/her subspecialty (e.g. gastroenterology) in addition to meeting the other requirements.

These pathways for meeting the criteria were developed by the Committee in order to facilitate the continued function of an established transplant program when there is an unexpected change in the primary transplant physician. It did not want programs in transition with extensive patient wait lists to have to shut down for some time if they could demonstrate ability to provide ongoing quality patient care. The pathways allow approval of a primary transplant physician who may not meet case volume or time on the job requirements. At the time the criteria were developed the Committee agreed that an individual would need to have achieved at least 50% of their volume/time in order to meet these pathways and meet certain other criteria designed to assure continued quality patient care at the institution. These pathways also permitted a physician who has not specialized in a particular organ to be qualified as the primary physician as long as they meet either the training requirements or the volume under experience requirements that are set forth in the by-laws.

17. **Review of Data Submission** – The Policy Compliance Subcommittee (PCSC) received an update as to the progress and completion of the Data Amnesty Project and members’ compliance to data submission. The Subcommittee also approved the internal proposals to monitor data submission. The Subcommittee requested that members who fail to achieve seventy-five percent submission of forms be referred to the PCSC and that internal submission standards mirror the current data submission language. The PCSC also requested that additional policy language be added to the data submission policy to include automatic onsite audits for non-compliant programs at the program’s expense. The purpose of the audit would be for UNOS to retrieve the missing data. The proposed policy amendment will be submitted for public comment prior to consideration by the Board of Directors.

RESOLVED, that the following addition to OPTN/UNOS Policy 7.0 (Data Submission Requirements), shall be distributed for public comment.

7.9 Data Submission Non-Compliance

At the discretion of the OPTN/UNOS Membership and Professional Standards Committee, UNOS Policy Compliance staff will audit Transplant Centers, Histocompatibility Labs, and OPOs that fail to remain compliant with OPTN/UNOS data submission policies. UNOS will conduct the audits at the Member’s expense. The purpose of the audit will be to retrieve the missing data the Member has failed to provide to the UNOS Transplant Registries.

The Committee voted: 20 For, 0 Against, 0 Abstentions.

**Attendance at the Membership and Professional Standards Committee Meeting
January 28-29, 2004**

Committee Members Attending

Robert A. Metzger, M.D.	Chairman & Region 3
Kim M. Olthoff, M.D.	Vice Chair & Region 2
Richard S. Luskin, MPA	Region 1
Larry R. Pennington, M.D.	Region 4
Margaret Allee, RN, MS, JD	Region 6
Edward R. Garrity, Jr., M.D.	Region 7
W. Ben Vernon, M.D.	Region 8
Dale A. Distant, M.D.	Region 9
Mitchell L. Henry, M.D.	Region 10
Carl L. Berg, M.D.	At Large
G. David DeStefano, MBA, CPTC	At Large
Niloo M. Edwards, M.D.	At Large
Susan Gunderson, MHA	At Large
Malek Kamoun, M.D., PhD	At Large
Janis M. Orłowski, M.D.	At Large
Janet M. Shaftel, RN, BSN	At Large
Edward D. Staples, M.D.	At Large
Arthur Thomson	At Large
J. David Vega, M.D.	At Large
Donna H. Wright, JD	At Large

Committee Members Unable to Attend

Laurie S. Garretson, RN, BSN	Region 5
Daniel H. Hayes, M.D.	Region 11
Paul M. Colombani, M.D.	At Large
Jacqueline A. O'Donnell, M.D.	At Large
Steve G. Peters, M.D.	At Large
Helen G. Spicer, RN	At Large

DOT Staff In Attendance

Hui-Shing Wong, M.D., JD	Ex Officio – Government Liaison
Renee Dupee, Esq.	Ex Officio – Government Liaison

SRTR Staff in Attendance

Randall Webb	SRTR Liaison
Douglas E. Schaubel, Ph.D.	SRTR Liaison

UNOS Staff in Attendance

Mary D. Ellison, PhD, MSHA	Assistant Executive Director for Federal Affairs
Douglas A. Heiney	Director, Membership and Policy Development
Sally H. Aungier	Manager, Membership Services
Margaret Eldredge	Membership Coordinator
Rose Harmon	Membership Coordinator
Denise Nurmi	Membership Coordinator
Cindy Sommers	Director, Policy Development
Deanna Sampson	Director, Policy Compliance
Josh Czarda	Assistant Director, Policy Compliance
Sandy Han	Policy Compliance Analyst
John Rosendale	Biostatistician
Darcy Davies	Biostatistician (By phone for Data Subcommittee meeting)

**Attendance at the Membership and Professional Standards Committee Meeting
May 4-5, 2004**

Committee Members Attending

Robert A. Metzger, M.D.	Chairman & Region 3
Kim M. Olthoff, M.D.	Vice Chair & Region 2
Richard S. Luskin, MPA	Region 1
Laurie S. Garretson, RN, BSN	Region 5
Margaret Allee, RN, MS, JD	Region 6
Edward R. Garrity, Jr., M.D.	Region 7
W. Ben Vernon, M.D.	Region 8
Dale A. Distant, M.D.	Region 9
Daniel H. Hayes, M.D.	Region 11
Carl L. Berg, M.D.	At Large
Paul M. Colombani, M.D.	At Large
G. David DeStefano, MBA, CPTC	At Large
Susan Gunderson, MHA	At Large
Malek Kamoun, M.D., PhD	At Large
Janis M. Orłowski, M.D.	At Large
Janet M. Shaftel, RN, BSN	At Large
Helen G. Spicer, RN	At Large
Edward D. Staples, M.D.	At Large
Arthur Thomson	At Large
J. David Vega, M.D.	At Large
Donna H. Wright, JD	At Large

Committee Members Unable to Attend

Larry R. Pennington, M.D.	Region 4
Mitchell L. Henry, M.D.	Region 10
Niloo M. Edwards, M.D.	At Large
Jacqueline A. O'Donnell, M.D.	At Large
Steve G. Peters, M.D.	At Large

DOT Staff In Attendance

Ginny McBride, RN, BS, CPTC	Ex Officio – Government Liaison
Hui-Shing Wong, M.D., JD	Ex Officio – Government Liaison

SRTR Staff in Attendance

Randall Webb	SRTR Liaison
--------------	--------------

UNOS Staff

Douglas A. Heiney	Director, Membership and Policy Development
Sally H. Aungier	Manager, Membership Services
Rose Harmon	Membership Coordinator
Denise Nurmi	Membership Coordinator
Jacqui O'Keefe	Membership Coordinator
Cindy Sommers	Director, Policy Development
Cliff McClenney	Assistant Director, Regional Administration and Membership Services
Deanna Sampson	Director, Policy Compliance
Josh Czarda	Assistant Director, Policy Compliance
Sandy Han	Policy Compliance Analyst
John Rosendale	Biostatistician

Guests in Attendance

Frank Delmonico, M.D.	In-coming Chairman
-----------------------	--------------------