

OPTN/UNOS Patient Affairs Committee

SUMMARY

Action Items for Board Consideration

- The Committee submitted proposed modifications to OPTN and UNOS Bylaws, Appendix A, Section 2.06A for public comment in March 2007. In response to feedback obtained from Regional Meetings, Committee Meetings, and the public, the Committee proposed the following amendments: limit notification of transplant center adverse actions to candidates and those candidates added to the wait list during the duration of the adverse action; limit notification of probation to the specific transplant program that was cited for the adverse action versus the entire transplant center; specify that additional extensive notification shall be at the discretion of the Executive Committee, Board, and/or the Secretary of HHS. (Item 1, pages 3-8)

Other Significant Items

- The Chair of the Kidney Transplantation Committee provided a progress report on kidney allocation policy development. The Committee reviewed the feedback obtained from the February 2007 Public Forum participants. The Committee discussed incorporating the concepts of Donor Profile Index (DPI) and Life Years Following Transplant (LYFT) and recent simulation results. (Item 2, pages 8-10)
- The Committee reviewed the Transplant Coordinators Subcommittee's brochure/release form to provide basic recipient information to donor families. The Committee unanimously supported the concept and provided specific suggestions for revisions. (Item 4, pages 10-11)
- The Committee discussed the referral from the Membership and Professional Standards Committee (MPSC) regarding the content of transplant centers' patient acceptance letters. Members supported the MPSC's recommendation of providing a separate OPTN/UNOS letter and identified specific information to include in this patient correspondence. (Item 5, page 11)

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**Report of the
OPTN/UNOS Patient Affairs Committee
to the Board of Directors**

**June 26, 2007
Richmond, Virginia**

**David Burgio, MPA, LFACHE, Chair
Ray Gabel, BA, Vice-Chair**

The following report contains the deliberations of the Patient Affairs Committee at its October 16, 2006 and April 16, 2007 meetings:

1. **Patient Access to Center Performance Information** -A series of conference calls was held from November 2006 through February 2007 to discuss the need for increased transparency in the current center performance review system. The Committee agreed that patients need more extensive information about Member violations in order to make informed decisions about their treatment. Members expressed concern that some patients may first learn of center performance problems through the media and that such information may be inaccurate and/or incomplete.

Upon consultation with the UNOS Membership and the Evaluation and Quality Departments and review of the Bylaws pertaining to patient notification of adverse actions, the Committee expressed concern that only the Member Not in Good Standing sanction required patient notification. The Committee supported a change in the Bylaws in order to require written notification for additional adverse actions, to further define who should receive notification, and to establish a time frame for such notification.

During a final conference call in February, by a vote of 10-0-0, the Committee unanimously supported notifying patients in the evaluation process, candidates, and recipients being followed by the center within 30 days of the following adverse actions being imposed: Probation, Member Not in Good Standing, Suspension of Member Privileges, Termination of Membership or Designated Transplant Program Status, and Action Specified in OPTN Final Rule. The Committee also agreed that any additional patients who are evaluated or candidates who are listed during the duration of the adverse action should also be notified. The bylaws modification proposal was distributed for public comment in March.

In the subsequent Committee Meeting on April 16, 2007, Members reviewed the feedback received from ten regional meetings, as well as the 25 responses submitted by the general public. The Committee noted the overall support of the intent of the proposal; however there was extensive discussion regarding the following concerns expressed by the public and regional meeting participants:

- Inability to monitor if patients in the evaluation process are notified
- Necessity of providing notification to patients/candidates/recipients of all programs when only one program was responsible for the adverse action
- Potential staff burden associated with extensive written notification
- Necessity of providing notification to patients being evaluated and recipients versus just candidates, especially considering that violations can differ considerably regarding the impact on patient safety
- Responsibility for the content of the written notification and whether additional notification should occur if and when the probationary period ends
- Potential for the notification of patients/candidates/recipients to cause considerable confusion and fear
- Likelihood of the media releasing information before patient notification occurs

Consensus was reached to limit notification to candidates and candidates added to the wait list during the duration of the adverse action (if applicable). Although the Committee expressed concern that the structure of transplant centers can differ greatly, they also agreed to limit notification of probation to the cited transplant program versus the entire transplant center. The Committee discussed how the violations that lead to adverse actions can differ greatly and that, in some cases, broader notification may be necessary. The Committee agreed that additional notification requirements (if necessary), as well as the content of the written notification, should be left to the discretion of the Executive Committee, Board of Directors and/or the Secretary of HHS.

The Communication and Education Plan and the Monitoring Plan are included as Exhibit A and Exhibit B, respectively.

Subsequent to the meeting, the Committee conducted a complete review of the responses from the general public, Regional Meetings, and Committee Meetings. The Committee appreciated the valuable, similar responses received from both the MPSC and OPO Committees. Members of these Committees sought clarification surrounding the broad use of the term Member within the proposal and inquired about potential notification requirements for OPO and histocompatibility lab Members. The Committee reviewed the original intent of the bylaws modification proposal as promoting increased transparency in the current transplant center performance review system in order to protect patients' safety and assist them in making informed decisions about their treatment. The Committee supports both the MPSC and OPO Committees in further examining the need for notification requirements that are relevant and specific to these Members.

The Committee recommends the following for consideration by the Board of Directors:

Resolved, that the following modifications shall be approved as set forth below, effective August 1, 2007.

Further resolved, that the modifications to Bylaws Section 2.06A(b)(3) "Probation" shall apply to members newly receiving the adverse action of probation on or after August 1, 2007.

2.06A Membership and Professional Standards Committee Action

(a) [no changes to subsection a]

(b) For Category II and III potential violations, the MPSC-PCSC shall report its action in writing to the full MPSC. The MPSC shall report its action in writing to the Board of Directors.

Category I, II, and III potential violations are generally defined as follows. Individual cases may vary depending upon the unique circumstances, and cases may move among the categories as circumstances may change.

- Category I = potential violation of OPTN requirements posing substantial, time sensitive threat to patient health or public safety,
- Category II = material breach of OPTN requirements, and
- Category III = dialogue with MPSC expected to correct any noncompliant behavior and lead to ongoing future compliance.

Actions available for all categories of potential violations may include, without limitation (see Figures A-2a and A2b for a general overview of these actions), the following. Sanctions listed under numbers (1) and (2) below may be imposed directly by action of either the MPSC-PCSC or MPSC. Sanctions

listed under numbers (3) – (7) below must be recommended by the MPSC to the Board of Directors and imposed by the Board, or may be imposed by the Executive Committee or the Board without recommendation of the MSPC. Unless specifically noted, the sanctions listed below may be taken in cases of : (i) noncompliance with policies or behavior posing risk to patient health or public safety covered by Section 1138 of the Social Security Act, 42 U.S.C. § 1320-b8, by virtue of (a) recommendation by the OPTN to be mandatory and designation by the Secretary of HHS for coverage, (b) determination by the Secretary of HHS to be mandatory under the OPTN Final Rule, or (c) determination of risk to the health of patients or to the public safety, which is confirmed by the Secretary of HHS, and (ii) noncompliance with all other OPTN requirements. Policies and behavior posing risk to patient health or public safety described under category (i) above are hereinafter referred to collectively as “policies covered by Section 1138 of the Social Security Act,” or individually as “policy covered by Section 1138 of the Social Security Act.”

The MPSC-PCSC or the MPSC may impose the following sanctions without referral to the Board of Directors for approval:

- (1) Reject Request for Corrective Action. The MPSC-PCSC or the MPSC may reject the request for corrective action, notice of which shall be provided to the Board of Directors;
- (2) Notice of Uncontested Violation, Letter of Warning or Letter of Reprimand. The MPSC-PCSC or the MPSC may issue a Notice of Uncontested Violation, Letter of Warning or a Letter of Reprimand, any of which is not an adverse action under the Bylaws but is meant to inform the Member of the need for the Member to ensure continuing compliance with OPTN requirements. The Board of Directors and the Secretary of HHS shall be notified of final decisions to issue a Notice of Uncontested Violation, Letter of Warning or a Letter of Reprimand. These categories of non-adverse actions are appropriate under the following circumstances:
 - (a) Notice of Uncontested Violation – There has been a violation of OPTN requirements with no substantial evidence of mitigating factors based on medical judgment, and there is believed to be no likelihood of recurrence. The Member is not entitled to an interview.
 - (b) Letter of Warning – There has been an apparent violation of OPTN requirements under circumstances in which medical judgment is credibly put forth as a partial mitigating factor and there is believed to be no likelihood of recurrence. The Member is not entitled to an interview.
 - (c) Letter of Reprimand – There has been an apparent violation of OPTN requirements under circumstances where medical judgment is not a credible mitigating factor and there is believed to be no likelihood of recurrence. The Member shall be entitled to an interview under the procedures described in Section 3.01A prior to any issuance of a Letter of Reprimand by the MPSC/PCSC or the MPSC.

The MPSC may make recommendations to the Board of Directors for the imposition of the following adverse sanctions or the Board of Directors or the Executive Committee may take such action without recommendation by the MSPC:

- (3) **Probation.** The MPSC may recommend that the Board of Directors or the Executive Committee, or either the Executive Committee or the Board of Directors on its own accord may place the Member on probation, which would be an adverse action under the Bylaws and would first entitle the Member to procedural rights as provided in Section 3.01A – 3.03A followed, in the case of initial recommendation by the MPSC, by a final recommendation by the MPSC to and, in any event, final action by the Board of Directors or the Executive Committee and notice to the Secretary of HHS of the final decision to place the Member on probation.

If the Member receiving the adverse action set forth in this section is a transplant center, then ~~W~~within 30 days of the Member's notification of Probation, as described herein, the Member shall provide written notice to all patients in the evaluation process, candidates associated with the transplant program cited for the adverse action, and recipients being followed by the Member, as prescribed by the Executive Committee and/or Board of Directors. The Member shall provide written notice to all additional patients evaluated and, as well as all candidates added to the national waitlist by the transplant program for the duration of the Probation, as prescribed by the Executive Committee and/or Board of Directors. Additional notification requirements shall be at the discretion of the Executive Committee and/or Board of Directors.

Probation may include one or more of the following or other actions deemed appropriate by the MPSC-PCSC/MPSC, Executive Committee, or the Board of Directors and will include notice to all Members.

- (a) Required submission of a compliance action plan or plan of correction developed to specifications as may be defined by the MPSC-PCSC/MPSC, with demonstration to the MPSC-PCSC/MPSC of adherence to the plan and correction of any non-compliant activity within some period of time.
- b) Unscheduled on-site audit(s) throughout the period of probation, to be performed by OPTN Contractor audit staff at the sole reasonable cost and expense of the Member. Such costs and expenses shall include, but not be limited to, travel and lodging expenses of OPTN Contractor staff.
- (c) Required submission of reports, data, or other evidence to the OPTN Contractor documenting correction of the non-compliant activity throughout the period of probation

(4) **Member Not in Good Standing.** The MPSC may recommend that the Board of Directors or Executive Committee, or either the Executive Committee or the Board of Directors on its own accord, may declare the Member a Member Not in Good Standing, which would be an adverse action under the Bylaws and would first entitle the Member to procedural rights as provided in Section 3.01A – 3.03A followed in the case of an initial recommendation by the MSPC by a final recommendation to, and in any event, final action by the Board of Directors or Executive Committee and notice to the Secretary of HHS of the final decisions to declare the Member a Member Not in Good Standing. Member Not in Good Standing includes all of the following plus any other action deemed appropriate by the Board of Directors, unless specifically limited to one or more of such actions by the Board of Directors or Executive Committee:

- (a) Withdrawal of voting privileges in OPTN affairs.
- (b) Suspension of the ability for any personnel named in the OPTN Contractor Membership database as associated with the Member - who are not otherwise eligible to serve by virtue of their association with a member in Good Standing - to sit on any Committee, hold office, and sit on the Board of Directors.
- (c) Formal notification, along with subsequent changes in such status, to the entire OPTN Membership as well as to the Chief Executive Officer of Institutional Members
- (d) Formal notification, along with subsequent changes in such status, to the Member's Chief Executive Officer or Administrator and to the state health commissioner or other appropriate state representative with oversight of health care institutions doing business in the Member's state.
- (e) Notice within reasonable limits and means, to ~~patients and~~ the general public in the area of the Member. Such notice may include, but is not limited to, communication using the OPTN website and/or as prescribed by the Board of Directors for distribution by the Member.

(f) If the Member receiving the adverse action set forth in this section is a transplant center, then ~~W~~within 30 days of the Member's notification of Member Not in Good Standing, as defined herein, the Member shall provide written notice to all ~~patients in the evaluation process, candidates associated with and recipients being followed by the Member, as prescribed by the Board of Directors. The Member shall provide written notice to all additional patients evaluated and,~~ as well as all candidates added to the national waitlist by the Member for such duration as prescribed by the Board of Directors. Additional notification requirements shall be at the discretion of the Executive Committee and/or Board of Directors.

(g) ~~(f)~~ The actions listed for a Member on probation.

(5) Suspension of Member Privileges. Only in the case of noncompliance with policies covered by Section 1138 of the Social Security Act, the MPSC may recommend that the Board of Directors or the Executive Committee, or either the Executive Committee or the Board of Directors on its own accord, may request approval from the Secretary to suspend the Member's ability to list patients on the waiting list, the Member's eligibility to receive organ offers for transplants and related services, and other membership privileges, any of which would be an adverse action under the Bylaws which would first entitle the Member to procedural rights as provided in Section 3.01A – 3.03A followed in the case of an initial recommendation by the MPSC by a final recommendation to and, in any event, final action by the Board of Directors or the Executive Committee and, if the decision is to move the request forward, submission of the recommendation to the Secretary of HHS for consideration.

If the Member receiving the adverse action set forth in this section is a transplant center, then ~~W~~within 30 days of the Member's notification of Suspension of Member Privileges, as defined herein, the Member shall provide written notice to all ~~patients in the evaluation process, candidates and recipients being followed by~~ associated with the Member, as prescribed by the Board of Directors and/or the Secretary of HHS. Additional notification requirements shall be at the discretion of the Executive Committee and/or Board of Directors.

Suspension of membership privileges may include one or more of the following or other actions deemed appropriate by the MPSC-PCSC/MPSC, the Executive Committee, or the Board of Directors:

- (a) Suspension of the privilege to hold office and/or sit on OPTN Board of Directors or Committees.
- (b) Suspension of voting privileges in OPTN affairs.
- (c) Suspension of the privilege to receive all organ offers or offers of particular organ types for transplantation and related services.
- (d) Suspension of the privilege to list all patients or patients in need of particular organ types on the Patient Waiting List.
- (e) The actions listed for a Member on probation and the actions listed for a Member Not in Good Standing

(6) Termination of Membership or Designated Transplant Program Status. Only in the case of noncompliance with policies covered by Section 1138 of the Social Security Act, the MPSC may recommend that the Board of Directors or the Executive Committee, or either the Executive Committee or the Board of Directors on its own accord, may request approval from the Secretary to terminate membership or designated transplant program status for one or more organs, which are adverse actions under the Bylaws and would first entitle the Member to procedural rights as provided in Section 3.01A – 3.03A followed in the case of an initial recommendation by the MPSC, by a final recommendation to and in any event, final action by the Board of Directors or the Executive Committee and, if the decision is to move the request forward, submission of the recommendation to the Secretary of HHS for consideration.

If the Member receiving the adverse action set forth in this section is a transplant center, then ~~W~~within 30 days of the Member's notification of Termination of Membership or Designated Transplant Program Status, as defined herein, the Member shall provide written notice to all ~~patients in the evaluation process, candidates and recipients being followed by~~ associated with the Member, as prescribed by the Executive Committee, Board of Directors and/or the Secretary of HHS. Additional notification requirements shall be at the discretion of the Executive Committee, Board of Directors and/or Secretary of HHS.

(7) Action Specified in OPTN Final Rule. Only in the case of noncompliance with policies covered by Section 1138 of the Social Security Act, the MPSC may recommend that the Board of Directors or the Executive Committee, or either the Executive Committee or the Board of Directors on its own accord, may recommend to the Secretary of HHS any action specifically identified in Section 121.10(c) of the OPTN Final Rule, 42 CFR § OPTN Bylaws, Appendix A2-6 December 14, 2006 121.10(c), which would be an adverse action under the Bylaws and would first entitle the Member to procedural rights as provided in Section 3.01A – 3.03A followed in the case of initial recommendation by the MPSC, by a final recommendation to and in any event, final action by the Board of Directors or the Executive Committee and, if the decision is to move the recommendation forward, submission of the recommendation to the Secretary of HHS for consideration.

Within 30 days of the Member's notification of the Action Specified in OPTN Final Rule, as defined herein, the Member shall provide written notice to all ~~patients in the evaluation process, candidates, and recipients being followed by~~ associated with the Member, as prescribed by the ~~Board of Directors and/or the Secretary of HHS.~~ The Member shall provide written notice to all additional patients evaluated and as well as all candidates added to the national waitlist by the Member for such duration as prescribed by the Executive Committee, Board of Directors, and/or the Secretary of HHS. Additional notification requirements shall be at the discretion of the Executive Committee, Board of Directors, and/or the Secretary of HHS.

2. Report from the Kidney Allocation Review Subcommittee (KARS) - Dr. Mark Stegall, Chair of the Kidney Transplantation Committee, discussed the limitations of the current kidney allocation system and described the formidable challenge of establishing an allocation system that balances the concepts of utility, equity, and efficiency. The Committee was informed about the Kidney Committee's focused public hearings and its efforts to obtain feedback from multiple constituencies.

The Committee was informed that the pediatric allocation and ECD schema will not be modified, but that the proposed changes would impact the allocation of SCD kidneys by using quality estimated net lifetime survival benefit (QENLSB) as criteria. The Committee was provided with preliminary simulation results in order to examine the impact of prioritizing QENLSB on the rank order for SCD kidneys. Dr. Stegall discussed dialysis related degeneration and newer data regarding the mortality rates of patients on dialysis. The Committee examined information comparing the benefit of transplantation versus dialysis and the significant variables in the survival benefit model in order to understand who benefits most from transplantation.

Upon being presented with information regarding discard rates, some members inquired about the potential for centers to turn down kidneys (especially ECD) due to concerns regarding their outcome data. Dr. Stegall mentioned that aggressive centers and those with longer waiting lists are more likely to accept ECD kidneys. Concerns were expressed that some patients are not given clear, current information regarding the benefits of transplantation and whether accepting ECD kidneys (versus waiting longer for SCD kidneys) is in their best interest, according to data. Members also expressed concern about education practices differing among centers. Dr. Stegall stated that additional new data can be helpful to patients and agreed that current ECD outcome data must be shared with patients to assist them in making informed decisions.

Upon members inquiring about their role in the KARS initiative, Dr. Stegall welcomed Committee representatives' participation in relevant Kidney Transplantation Committee conference calls and meetings in order to continue to serve as an advisory group. He also informed the Committee that there will be two forums next year, as well as the opportunity to provide additional feedback through the public comment period. The Chair, David Burgio, and a back-up member, Michael Mace, agreed to provide representation from the Committee. Members were encouraged to provide a written response to the Kidney Transplantation Committee to include perceived strengths and challenges of the ideas presented.

The Committee discussed the potential reaction from older patients and how the overall health of an older person can be better than a younger patient. Members also discussed how some patients deteriorate much faster on dialysis than others and that it depends on many factors, other than age. The Committee spoke about how the public and the media will respond to the proposed changes and the potential negative effect on donation decisions. The Committee inquired about the impact of changes in technology and improvements in immunosuppressants on the proposed allocation system. Members supported critical efforts to continue monitoring the outcome data on an ongoing basis.

Subsequent to the Fall Committee meeting, Michael Mace participated in the KARS Public Forum in February via live meeting. The Committee was provided with presentation slides and discussion summaries from the Forum in preparation for further dialogue at the April Committee meeting.

Dr. Stegall attended the April 16 Committee Meeting via Live Meeting to provide a progress report on kidney allocation policy development. He shared some of the feedback obtained from participants during the February 2007 Public Forum in Dallas, Texas and explained how this feedback contributed to modifications of the preliminary kidney allocation system recommendations.

Dr. Stegall demonstrated how implementing the new concepts of Donor Profile Index (DPI) and Life Years Following Transplant (LYFT) can increase the efficiency of the kidney transplantation system. The Committee reviewed the data elements that have been included and excluded as factors in predicting LYFT, as well as recent simulation results from incorporating LYFT into the current allocation system. Dr. Stegall discussed how time on dialysis would serve as an allocation factor, allowing candidates to accrue additional priority over time. He explained that the Kidney Transplantation Committee's overall efforts are focused on creating recommendations for a new kidney allocation system that is based on objective medical criteria, as required by the Final Rule.

Dr. Stegall discussed responses to common inquiries surrounding KARS, such as the following expressed concerns: 1) age as a factor in allocation; 2) fairness of the proposed allocation system; 3) predictability of waiting time; and 4) how the system will impact patient choice. Members discussed the potential reactions of patients, including confusion and fear of change, and the resulting need for extensive education. Dr. Stegall responded to questions surrounding access by discussing the potential need for a regional review board. The Committee also discussed the possible impact on living donation since LYFT scores may contribute to some candidates being considerably more or less likely to seek living donors.

Members were reminded that the KARS recommendations are not complete, and the final proposal will continue to be monitored after it is implemented. Dr. Stegall shared plans to obtain additional feedback and encouraged Members of the Committee to continue to provide their input.

3. Review of Committee Goals – The Committee discussed the conference call that was held with the OPTN/UNOS President and the Chair and Vice-Chair of the Committee to discuss the short and long term goals of the Patient Affairs Committee. They additionally reviewed the letter that was subsequently sent by President McDiarmid requesting that the Committee serve in an advisory role to the Kidney Transplantation Committee surrounding the KARS initiative. The Committee reviewed how the HHS

Program Goals serve to guide the focus of the Patient Affairs Committee and the other OPTN/UNOS Committees.

The Committee voted unanimously to support the following short-term Committee goals: 1) continue to provide PAC representation to work with the Kidney Transplantation Committee on the issue of KARS (Strategic Plan Goal: Increase recipient benefit of transplantation); 2) continue to work with the subcommittee of the Transplant Coordinators Committee to address the issue of providing recipient information to donor families (Program Goal: Increase the number of deceased donor organs transplanted, including DCD); 3) continue to provide PAC representation to work with the Kidney Transplantation Committee on the issue of paired kidney donation (Strategic Plan Goal: Support live donor transplantation).

4. Report on the Transplant Coordinators Joint Subcommittee - Committee Member Laura Ellsworth, who participated in the Transplant Coordinators Joint Subcommittee, discussed the concept of releasing basic recipient information to donor families. It was explained that the intent is to reinforce the donation decision, to provide donor families with a positive donation experience, and to potentially assist them in the grieving process. Members discussed how Subcommittee participants hoped that increases in deceased donation rates may occur as positive donation experiences may lead to donor families sharing their stories with others.

The Committee discussed how current practices differ among OPOs and centers. The Committee reviewed the draft brochure and provided feedback regarding its content. Members unanimously voted to support the concept of the brochure/release form, but mentioned the following concerns: 1) more input from donor families should be obtained; 2) geographic area may be providing too much information; 3) a more specific time frame for approaching patients should be defined; 4) the process needs to be streamlined across OPOs and centers; 5) the form provides patients with the option of refusing to release any information, though it is currently common practice to provide basic information. Members inquired about the process of communicating difficult information to donor families, such as during those instances when organs were not able to be used or when transplants were unsuccessful.

The Committee supported the form addressing the fact that patients' decisions to release or to not release information would not impact their ability to receive an organ for transplantation. They additionally responded favorably to the Subcommittee's decision to include information about more extensive correspondence with donor families. One member suggested that the Subcommittee's initiative should focus more exclusively on letter writing in order to accomplish the aforementioned goals. The Committee briefly discussed the possibility of further exploring the issue of educating patients regarding more extensive contact with donor families.

The five Committee members in the Joint Subcommittee, Laura Ellsworth, Michele Snyders, Ray Gabel, Bruce Brooks, and Lynn Martin, have continued to participate in the editing process since the Committee meeting.

During the April Committee Meeting, a Joint Subcommittee representative provided an update to the Committee, explaining that the brochure/release form had been finalized, as well as a survey to be sent to OPOs to assess their experience in obtaining recipient information for donor families. It was also explained that concerns had surfaced regarding monitoring requirements and financial resources for this project. More information will be available after the Transplant Coordinators Committee meets to discuss this issue in more detail.

5. **Referral from MPSC: Content of Patient Acceptance Letters** - The Committee discussed the referral from the Membership and Professional Standards Committee (MPSC) regarding potential content to include in transplant centers' patient acceptance letters. Sample letters from multiple centers were reviewed, as well as the policy notice informing centers that the patient services hotline number must be included in this correspondence. Members supported, by a vote of 14-1-0, the MPSC recommendation of providing a separate letter from the OPTN/UNOS to be included and referenced within the center patient acceptance letter. The Committee also supported the suggestions that the letter reference OPTN/UNOS websites for center specific data and inform patients of their ability to seek services at other centers. Members asked for additional clarification from the MPSC regarding the recommendation to include information on patient rights.

Upon examining the Patient Services report, the Committee discussed the following common inquiries through the hotline: the role of UNOS, transplant center contact information, transplant process, policies regarding wait list allocation, criteria for being placed on the wait list, living donation, center-specific data including survival rates, and requests for patient informational kits. Members also discussed the need to fully inform patients about multiple listing. The Committee agreed that the OPTN/UNOS letter should be written clearly and simply to accommodate the needs of a wide variety of literacy levels. Members also supported articulating the role of the OPTN/UNOS and the type of assistance provided by UNOS Patient Services staff.

There was discussion surrounding the possibility of including the patient services hotline number within this separate OPTN/UNOS letter versus the centers' patient acceptance letter to avoid confusion regarding this service. The Committee also discussed the benefits of potentially including information regarding how patients can vote on OPTN/UNOS policy proposals. Members Michelle Crossley and Lynn Martin agreed to serve as Committee representatives to follow up on this agenda item.

6. **Patient Access to Status on Waitlist** – The Committee discussed their perspectives on the need for a service that would enable patients to access information regarding their waitlist status. The Committee also briefly reviewed the portion of the OPTN contract that describes the need to develop a mechanism for patients to check their status at all times. Many Committee members remarked that it is the transplant centers' responsibility, not UNOS, to provide status information; however discussion ensued surrounding the challenges some patients face in efforts to access this information through their centers. There was also discussion about patients who have had errors in their amount of accrued wait time and how some of these inaccuracies have surfaced upon transferring to other centers. The Committee spoke about patients experiencing problems in remaining active on the national waiting list when their centers close, sometimes with little advanced notice.

The Committee reviewed the policy that requires centers to send patients a letter within ten days of being added to the waitlist announcing their active status on the wait list. The Committee agreed that patients are their own best advocates and that it is their responsibility to confirm their wait list status (and accrued wait time if relevant). It was noted that some centers inform their patients' dialysis centers when they are listed, which can assist with patient communication. The Committee discussed the possibility of requiring centers to develop an efficient, easily accessible system for providing wait list status information to their patients. Further clarification and information were requested regarding the contract in order to more clearly understand the nature of the problem and the need for the service. Two members, Bruce Brooks, and Pete Mazula, volunteered to serve as Committee representatives for further follow-up on this issue.

At the April Committee Meeting, the Committee was updated about an internal UNOS meeting that involved representatives from the Information Technology and Professional Services Departments to discuss this issue further. It was recommended that the Committee partner with the Transplant

Administrators Committee to define the term “status,” specify the fields to be incorporated in a potential system, and examine if such information would differ by organ. Communication between these two Committees will be pursued.

7. Patient and Professional Education – The Committee reviewed the Patient Services report from the UNOS Professional Services Department that provides a summary of the type and frequency of requests for information received through the patient services line. Discussion occurred regarding the considerable number of callers inquiring about the transplant wait list process. Members referred to the previous discussion about establishing a system to enable patients to check their status as they examined the significant frequency of calls from patients trying to confirm they are on the wait list.

There was a suggestion to track how callers are informed about the UNOS patient services line since the Committee expressed concern that many patients lack any knowledge about the organization’s mission and services. Members asked if most callers are referred by their transplant centers and if information pertaining to the patient services line is typically relayed through initial patient listing letters. The Committee was informed about UNOS staff members assisting callers in building specific data reports to enable them to make informed decisions.

During a November Committee conference call, the Committee discussed the need to ensure that patient educational material is readable and accessible. The Committee recommended that the OPTN and UNOS websites should be more user-friendly and relevant to the needs of patients. Concern was expressed regarding the complex nature of the data available on the SRTR website. The Committee discussed the need to simplify the process of obtaining frequently requested data. Requests were made to obtain sample initial patient listing letters to examine the potential need for centers to provide more detailed information to patients about data access, educational resources, and OPTN/UNOS responses to media stories.

During the April Committee meeting, as reported earlier, the Committee reviewed sample patient acceptance letters and the policy notice informing centers that the patient services hotline number must be included in this correspondence. The Committee continued to discuss the impact of this notification requirement on the frequency and types of calls received through the patient services line. Members were provided with information regarding the history and scope of the patient services database. They were also updated regarding the discussions of an internal UNOS working group composed of staff members from the Information Technology, Membership and Policy, and Professional Services Departments. The Committee was informed that these professionals are examining the need to add fields to more effectively categorize inquiries and to expand the system’s capabilities to build reports and track trends.

The Committee was provided with a demonstration of how to build data reports through the OPTN and SRTR websites, though technical errors were experienced.

8. Legislative Report - William G. Lawrence, J.D., UNOS Director of Patient Affairs, reviewed the current challenges related to paired kidney donation (PKD). Mr. Lawrence also reported that if the National Organ Transplant Act (NOTA) could be amended to clarify that kidney list and kidney paired donation does not involve the transfer of organs for valuable consideration, that there could be at least 2000 additional transplants per year. The Committee was informed about the role and strategies of the Transplant Roundtable group in Washington D.C., who are working together to introduce this bill in the House of Representatives in early Spring of 2007. Members were encouraged to express their written support of paired kidney donation, as it is hoped that the bill will pass in the 110th Congress.

Subsequent to the Committee meeting, Mr. Lawrence provided members with an update and developed a form letter to use in their legislative advocacy efforts. He has assisted Members in successfully identifying and corresponding with their local health legislative affairs representatives.

During the April Committee meeting, Mr. Lawrence informed the Committee that the bill successfully passed the House and Senate unanimously. Members learned that increased support was gained when the Congressional Budget Office determined it would save Medicare half a billion dollars within ten years (related to dialysis expense savings). He will continue to keep the Committee updated regarding progress towards the lengthy process of establishing a registry. He noted the importance of the living donation reimbursement grant (as described in more detail below), as it may potentially enable individuals to serve as living donors who otherwise could not due to financial barriers of travel costs, hotel expenses, and lost wages.

9. **Division of Transplantation (DoT)** - Richard Laeng, MPH, Program Analyst, Division of Transplantation, provided a brief description of the history and goals of the Breakthrough Collaborative. The Committee learned that Donate Life AmericaSM will be involved in the Collaborative to focus on increasing the number of donor registrations in each state. The Committee reviewed numerous data illustrating the positive impact of participation in the Collaborative. Discussion occurred surrounding the concern that the donor pool is experiencing such significant chronic disease and increasing BMI and that living donation rates have decreased recently.

During the April Committee meeting, Mr. Laeng discussed the HRSA and DoT funded National Living Donor Assistance Program, which will provide travel and subsistence financial assistance to living organ donors. He reviewed the program's background and goals and provided a general overview of the cooperative agreement and the role of the advisory and reimbursement review committees. Members learned about qualifying living donor expenses and pending eligibility criteria for reimbursement.

General concern was expressed regarding the current lack of long-term follow-up data on living donors, which is needed in order for potential living donors to make informed decisions. The Committee also remarked upon the critical need to improve efforts at providing education about the physical, psychological, and insurance-related risks associated with living donation. Members were informed that the living donation section of the popular UNOS patient booklet, "What Every Patient Needs to Know," and the UNOS patient website, Transplant LivingSM, have been updated to reflect current information about such risks. The Committee briefly discussed the contributions of the Society for Transplant Social Workers in their work with the Living Donor Committee surrounding the living donor evaluation form and process. Members supported the development of a booklet/brochure devoted exclusively to living donation.

Mr. Laeng also spoke with the Committee about the need to increase the input received from the general public surrounding the policy development process. He reported that only approximately 7,000 individuals routinely receive the public comment booklets. Members stressed the vital need to write proposals in simpler terminology to accommodate the wide variety of readers (many with non-clinical backgrounds). The Committee suggested the following groups may provide some assistance: Society for Transplant Social Workers, Council for Nephrology Social Workers, and Nurses Endorsing Transplantation. Members were encouraged to contact Mr. Laeng with additional recommendations. The Committee was informed that the revised version of, "What Every Patient Needs to Know" includes information regarding how the public can provide input on proposals.

10. **Data Report from UNOS Research Department** – Jennifer L. Wainright, Ph.D., Research Policy Analyst of UNOS, presented the Committee with data that were requested during the Spring meeting. The Committee reviewed the most frequent causes of donor death by month for 2005 and learned that cerebrovascular/stroke was the leading cause of death for all months but July and August, during which time head trauma was the number one cause.

The Committee additionally compared the performance of those OPOs that chose not to participate in the Collaborative, or who joined very recently, to those who have participated from the early stages of this initiative. The benefit of analysis of such data was very limited due to the small number of OPOs that are either not participating or who joined late in this project and due to the numerous factors that impact conversion rates. The Committee examined the overall increasing trend of the number of donors per month since the introduction of the Collaborative and remarked upon its positive impact.

The Committee examined the effect of participation in the TCIM workshop in June of 2006. Conclusions about the effectiveness of the workshop could not be made from analysis of the presented data due to the small number of participating OPOs, the limited period of time since the training, and the numerous factors that affect consent rates.

During the April Committee Meeting, Dr. Wainright provided a presentation regarding progress towards the HHS donor-related program goals. Members were informed about the specific number of Donation Service Areas (DSA) that have met or exceeded each goal. They also examined differences in progress across regions. There was a request of the Research Department to provide the Committee with 2006 conversion rate data. The Committee briefly discussed the scope and efforts of the Breakthrough Collaborative, including the implemented strategy of identifying and spreading best practices.

Upon reviewing data pertaining to Donation after Cardiac Death (DCD), members remarked upon the impact of transplant centers' recent development of individual DCD policies on the pursuit of DCD-related goals. The Committee also discussed the need for long-term outcome data on recipients of DCD organs.

The Committee inquired about the possibility of more aggressive transplant centers being at risk of adverse actions from lower survival rates associated with accepting sicker patients as transplant candidates and expanding the donor pool to include more DCD, ECD, and marginal organs. Representatives from the Membership and Policy Departments will provide a presentation at the next meeting to provide additional information and clarification regarding center performance evaluation. A representative of the SRTR will also speak to the Committee about how survival rates are calculated.

Dr. Wainright additionally provided a presentation to the Committee regarding pending modifications to one of the OPTN/UNOS websites. The specific location of the site will be determined by HRSA. Members responded favorably to the enhancements, which include providing users with easy access to center-specific wait list and transplant data. The Committee was pleased to learn that the websites promote transparency surrounding transplant center performance for the modifications will include the date of their last survey and their current OPTN membership status. Dr. Wainright explained the links available to enable users to obtain additional relevant data and learn more about specific patient issues and transplant terms. The Committee recommended including information regarding living donation and re-transplantation.

11. Metric to Monitor Time Between Wait List Approval for Listing and Actual Listing - The Committee discussed a referral from the MPSC to numerous OPTN/UNOS Committees that questioned the need for a metric to review transplant programs that have an excessive delay between approval for patient listing and actual activation on the OPTN/UNOS waitlist. Upon generally discussing the incident that led to the referral, Members concluded that this was an isolated incident and that there are numerous factors that can reasonably contribute to delays. The Committee did not support the need for the metric or any related bylaw/policy.

12. **DonorNet Presentation** – Leslie C. Lieblein, Business Systems Analyst of UNOS, provided the Committee with an update on recent changes to DonorNet®. Members were informed that the new system will be in place by April of 2007, at which time its use by members will be mandatory. The Committee learned about the OPTN contract requirement and the collaborative efforts of the Electronic Organ Placement Working Group that led to the development of the electronic organ placement system. The Committee was presented with a demonstration regarding how OPOs and transplant centers utilize the system. Ms. Lieblein reviewed the timeframe of the notification and evaluation process and informed the Committee that in December, a pilot group will use this live system in preparation for the full launch in April. The Committee discussed how the changes focus on enhancing patient safety and the allocation process.

13. **Communications Department Presentation** – Joel D. Newman, Assistant Director of the UNOS Communications Department, spoke with the Committee via live meeting about the role of the department with respect to media relations. The Committee learned about the type and frequency of requests for information and interviews from the media and the accessibility of the Communications staff. Mr. Newman described how the media and the general public are kept informed through news releases posted on the OPTN and UNOS websites and email notification services.

The Committee learned how staff members manage crises, address general inquiries, and handle issues of ongoing media interest, such as donor solicitation, financial incentive for donation, and specific Committee issues. The Committee was informed about the Department's more established relationships with certain reporters and how communication is fostered through these media representatives attending board meetings and obtaining interviews. The Committee was informed that OPTN/UNOS members are sent talking points and position statements when certain issues arise in order to keep them informed and equipped with a consistent, accurate response. They are additionally provided news releases, relevant articles, and updates on actions of the Board.

Shannon Gingras, Communications Specialist of the UNOS Communications Department, provided the Committee with a demonstration of the Transplant LivingSM website through a live meeting. The presentation included taking members through the newly available feature of customizing the website to make navigation easier and tailor the system to users' needs and interests. The Committee learned about the frequency and duration of site visits on a monthly basis and how updates are made. In response to members' inquiries, Ms. Gingras demonstrated how events and their accompanying links can be posted on the calendar in the website. The Committee was informed of the opportunity to participate in a second live meeting that would occur on November 1st in order to provide feedback on the living donation section of the website. Committee members Lynn Martin, Laura Ellsworth, Leslie High, and Emma Griswold expressed an interest in providing ongoing assistance with the review process. Subsequent to the meeting, three members participated in a live net meeting to provide feedback to Ms. Gingras regarding the Transplant Living website. Their input led to beneficial changes.

14. Consideration of Policy Changes Proposed by Other Committees

August 28-October 27, 2006 Public Comment Period:

1. Proposal for National Kidney Paired Donation (KPD) Program (Kidney Transplantation Committee)

The Committee discussed how this proposal relates to preliminary planning for a national kidney paired donation program since relevant legislation must pass before it can be implemented. Members briefly discussed general concerns surrounding expenses to living donors and the pending travel reimbursement grant program.

The Committee supported the proposal by a vote of 12-0-0.

2. Proposed Allocation System for Broader Sharing for Livers in Region 8 (Liver and Intestinal Organ Transplantation Committee)

The Committee agreed the proposed allocation system would be effective in promoting a broader sharing of livers in Region 8 and supported the ongoing evaluation efforts.

The Committee supported the proposed change by a vote of 12-0-0.

3. Proposed Modifications to OPTN/UNOS Policy 3.6.4.2 (Pediatric Candidate Status) (Liver and Intestinal Organ Transplantation Committee)

The Committee supported the proposed change by a vote of 12-0-0.

4. Proposed New OPTN/UNOS Policy 3.11.4.2 (Combined Liver-Intestine Organ from Donors 0-10 Years of Age) (Liver and Intestinal Organ Transplantation Committee)

The Committee supported the ability of this proposal to enable pediatric patients to have improved access to liver-intestine transplants.

The Committee supported this proposal by a vote of 11-0-0.

5. Proposed Modifications to OPTN/UNOS Policies 3.6.4.4 (Liver Transplant Candidates with Hepatocellular Carcinoma) (Liver and Intestinal Organ Transplantation Committee)

The Committee supported the proposal but agreed that additional research is needed since there are insufficient long-term data available.

The Committee supported the proposed change by a vote of 12-0-0.

6. Proposed Modifications to OPTN/UNOS Policy 3.6.11 (Allocation of Livers for Segmental Transplantation) (Liver and Intestinal Organ Transplantation Committee)

The Committee briefly discussed existing efforts to assist patients in making informed decisions about consenting to split liver transplantations.

The Committee supported the proposal by a vote of 11-0-0.

7. Proposed Modifications to OPTN/UNOS Policy 3.6.4.1 (Adult Candidate Status) (Liver and Intestinal Organ Transplantation Committee)

Upon reviewing the data, members agreed that this proposal would benefit those patients with failed liver transplants (within one week post transplant) by speeding up the process of restoring their level 1A status.

The Committee supported the proposed change by a vote of 12-0-0.

8. Proposed Modifications to OPTN/UNOS Bylaws Appendix B Attachment 1, Section VI (Transplant Surgeon and Physician) and Section XII (Transplant Programs) (Liver and Intestinal Organ Transplantation Committee)

The Committee supported the proposal, but briefly discussed the potential challenge for some centers to meet the required number of intestinal transplants and the possibility of stunting the growth of this field.

The Committee supported the proposal by a vote of 12-0-0

9. Proposed Modifications to OPTN/UNOS Policy 3.6.4.7 (Combined Liver-Intestine Candidates) (Liver and Intestinal Organ Transplantation Committee)

The Committee discussed the high mortality rates of candidates under eighteen who are awaiting liver-intestine transplants. The Committee supported the proposal's ability to assist these patients to receive transplants on a more timely basis. Members discussed the importance of ongoing efforts at performance measurement to monitor the impact of the proposal and the potential need for adjustment to the number of additional points.

The Committee supported the proposed change by a vote of 12-0-0.

10. Proposed Modifications to OPTN/UNOS Policy 3.6.2.2 (Liver Allocation to Candidates Willing to Accept an Incompatible Blood Type) (Liver and Intestinal Organ Transplantation Committee)

The Committee briefly discussed the types of patients who would be more willing to consider transplantation of livers of incompatible blood type.

The Committee supported the proposal by a vote of 12-0-0.

11. Proposed Modifications to OPTN/UNOS Policy 3.8.2 (Waiting Time Adjustment) (Pancreas Transplantation Committee)

The Committee mentioned their concern regarding potential manipulation of the system, but supported the rationale of accommodating these specific types of patients.

The Committee supported the proposed change by a vote of 12-0-0.

12. Proposed Modifications to OPTN/UNOS Policy 3.8.1 (Pancreas Organ Allocation) (Pancreas Transplantation Committee)

The Committee supported this proposal's ability to assist in addressing the challenges experienced by highly sensitized candidates to receive a well-matched pancreas transplantation.

The Committee supported the proposal by a vote of 12-0-0.

13. Proposed Modification to OPTN/UNOS Policy 3.7.2 (Geographic Sequence of Thoracic Organ Allocation) Modification of Zone D and Addition of Zone E (Thoracic Organ Transplantation Committee)

The Committee supported the proposal by a vote of 12-0-0.

14. Proposed Modification to OPTN/UNOS Policy 3.7.6 (Lung Allocation) Addition of PaCO₂ in the Lung Allocation System (Thoracic Organ Transplantation Committee)

The Committee supported the proposed change by a vote of 11-0-0.

15. Recommended Histocompatibility Guidelines” (Histocompatibility Committee)

The Committee agreed that this proposal supports the spread and implementation of best practices, as the majority of histocompatibility labs are already successfully using this technology to expedite the organ placement process. The Committee voiced their concern regarding having little information about the cost of implementing this practice, but hoped that this proposal would assist lab personnel in seeking to secure funding from administrators.

The Committee supported the proposal by a vote of 12-0-0.

16. Proposed Modifications to OPTN/UNOS Policy 3.5.11.3 (Panel Reactive Antibody) (Histocompatibility Committee)

The Committee supported the proposed change by a vote of 12-0-0.

17. Proposed Modification of Policy 2.2 (Evaluation of Potential Donors) (Membership and Professional Standards Committee)

The Committee supported the proposed change by a vote of 12-0-0.

18. Proposed Modifications to OPTN/UNOS Policy 3.5.9 (Minimum Information/Tissue for Kidney Offer) (Organ Availability Committee)

The Committee briefly discussed the potential for damage to kidneys as a result of the wedge biopsy, but concluded the available data on the benefits of this type of procedure supported its implementation.

The Committee supported the proposal by a vote of 12-0-0.

19. Proposed Modifications to Appendix B of the OPTN Bylaws (OPO Committee).

The Committee supported the proposal by a vote of 12-0-0.

August 28-September 27, 2006 Public Comment Period:

20. Proposed Modifications to OPTN/UNOS Policy 3.5.9 (Minimum Information/Tissue for Kidney Offer) (Organ Availability Committee)

The Committee agreed that patients benefit from standardizing biopsy criteria and reporting and reducing discards of procured donor kidneys.

The Committee supported the proposal with a vote of 9-0-0.

21. Proposed Modifications to OPTN/UNOS Policy 5.0 (Standardized Packaging and Transporting of Organs and Tissue Typing Materials) (Operations Committee)

The Committee supported efforts to ensure consistent transporting in order to maximize organ viability.

The Committee supported the proposal with a vote of 9-0-0.

22. Proposed Modifications to OPTN/UNOS Policy 3.1 (Organ Distribution: Definitions) (Operations Committee)

The Committee acknowledged the potential impact on staff, but supported this proposal's critical focus on patient safety.

The Committee supported the proposal with a vote of 9-0-0.

23. Proposed Modifications to Data Elements on UNetSM Transplant Recipient Follow-up (TRF) Form (Policy Oversight Committee)

The Committee acknowledged the importance of data reduction but supported the need to have relevant data available to assist in improving patient education efforts.

The Committee supported the proposal with a vote of 9-0-0.

March 2-April 30, 2007 Public Comment Period:

24. Proposed Modifications to Data Elements for Pediatric Candidates and Recipients on UNetSM Transplant Candidate Registration (TCR), Transplant Recipient Registration (TRR) and Transplant Recipient Follow-up (TRF) Forms (Pediatric Transplantation Committee)

The Committee supported the data reduction decisions of the Pediatric Transplantation Committee by a vote of 14-0-0.

25. Proposed Modifications to OPTN/UNOS Policy 7.1.5 "Reporting Definitions" and OPTN/UNOS Policy 7.3.2 "Submission of Organ Specific Transplant Recipient Registration Forms and Submission of Living Donor Registration Forms." (Living Donor Committee)

Discussion was held surrounding financial and staff resources associated with the recommended follow-up services for living donors. The Committee agreed that even more extensive data collection is preferred in order to assist potential living donors in making informed decisions, but supported the current proposal as being a necessary, critical first step.

The Committee supported the proposal with a vote of 14-0-0.

26. Proposed Modification to OPTN/UNOS Policy 7.3.3 "Submission of Living Donor Death and Organ Failure Data" (Living Donor Committee)

The Committee supported the proposal with a vote of 14-0-0.

27. Proposed Modifications to the UNetSM Living Donor Registration (LDR) and Living Donor Follow-up (LDF) Forms (Living Donor Committee)

The Committee supported the proposal with a vote of 14-0-0.

28. Proposed Modifications to Data Elements on UNetSM Deceased Donor Registration (DDR) Form. (Organ Availability Committee)

The Committee supported the proposal with a vote of 14-0-0.

29. Proposed Imminent Neurological and Eligible Death Definition Data Elements (OPO Committee)

The Committee supported the proposal with a vote of 14-0-0.

15. **Future policy proposal discussion and voting**: Members who had successfully utilized the Committee Management system reviewed their experience with the Committee. Remaining members were encouraged to contact the UNetSM help desk to obtain assistance in accessing the system. The Committee discussed the value and ongoing feasibility of conducting conference calls with representatives from those Committees with policy proposals and utilizing the committee management system for subsequent voting. The majority agreed that employing both methods of communication is preferred.

16. **Fall Meeting date**: October 15, 2007 in Chicago.

PATIENT AFFAIRS COMMITTEE

	October	April
	16	16
	In Person	In Person
NAME		
David Burgio MPA, LFACHE	x	X
Ray Gabel	X	By phone
Bonnie Boulanger ESQ	X	
Kenyon Murphy	x	X
Lynn Martin, MPH	x	X
Brian Hinsley	x	X
Michael Mace MSW	x	X
Michele Snyders MSW		X
Leslie High	x	X
Paul Meigs	x	X
Michelle Crossley RN, BSN		X
David Burgio MPA, LFACHE	x	X
Bruce Brooks	X	
Laura Ellsworth	X	X
Emma Griswold BS	X	X
Robert S Higgins MD		
Anne Lally MD		X
Michelle Christenson		X
Pete Mazula	x	X
Mary Carpenter		X
Joy Demas		
Richard Laeng MPH	x	X
Jim Galloway Ph.D.	By phone	By phone
Friedrich Port MD		
Karen Mock	x	X
Courtney Bland	X	X
Jennifer Wainright	x	X
Stacey Burson		By phone
William Lawrence	x	X