OPTN/UNOS Membership and Professional Standards Committee
Report to the Board of Directors
November 16-17, 2009
Orlando, Florida

Summary

I. Action Items for Board Consideration

- The Board of Directors is asked to approve the following center-specific actions. (Item 1, Page 4-5):
  - Approval of one new independent laboratory and four new non-institutional members;
  - Approval to 219 designated Kidney Transplant Programs that have applied to perform Living Donor Kidney Transplantation;
  - Full approval to four new programs in existing transplant centers; and
  - Approval of changes in program status:
    - Full approval to a program that has reactivated.
    - Approve an extension of inactive status.
    - Change fully approved program to conditional status.

- The Board of Directors is also asked to approve the following proposals to amend the bylaws and policies.
  - Proposed Bylaw Modifications to Clarify the Process for Reporting Changes in Key Personnel. (Appendix B, Section II, E (Key Personnel); Bylaws, Appendix B, Attachment 1, Section III (Changes in Key Personnel)). This proposal to change the bylaws will clarify when Transplant Hospitals must notify UNOS of changes in key personnel and further clarifies the expectation that member institutions that cannot notify UNOS within the expected time frame must inactivate or withdraw the membership of the affected program(s). (Item 2, Page 6-15).
  - Proposed Bylaw Modifications to Reconcile Volume Requirements for Primary Transplant Physicians: This proposal to change the Bylaws, Appendix B, Attachment I, XIII, D will reconcile the patient volume discrepancies, which currently exist between the requirements for full and conditional OPTN/UNOS program approval when evaluating the qualifications of primary physicians at kidney, liver, and pancreas transplant programs. (Item 3, Pages 15-18).
  - Preventing the Appearance of Potential Conflicts of Interest Regarding Declaration of Death and Organ Procurement: This proposal to add new Policy 3.4.1 (Avoidance of Conflicts of Interest) adds language stipulating that members are obligated avoid conflicts of interest associated with having the same person declare death and perform organ procurement and transplantation. (Item 4, Pages 19-20).
  - Notification of Potential Adverse Action by other Regulatory Agencies: This proposal would change the Bylaws, Appendix B, Sections I-III to require members to notify the OPTN Contractor when a final adverse action is taken by a regulatory agency (or its designee). The proposed change would extend the notification period to 10 business days and clarify the required documentation. (Item 5, Pages 20-25).

II. Other Significant Items

- Annual Committee Goals: During its July meeting, the Committee was presented with the goals that had been approved for the year and the progress made on those goals that were already in process. (Item 6, Page 25).

- Program-Related Actions and Personnel Changes: The Committee reviewed 51 and approved 49 personnel change applications during the July meeting. (Item 7, Page 25).

- Due Process Proceedings and Informal Discussions: During the July meeting, the Committee conducted three interviews with member transplant centers. Additionally, the Data Subcommittee, which met on July 21, convened two informal discussions with member transplant centers. (Item 8, Page 25).

- Living Donor Related Bylaws: The Committee was updated on the plans to review the bylaws related to living donor transplantation. A joint work group comprised of members from the MPSC, Living Donor Committee, Pediatric Transplantation Committee, Kidney Transplantation Committee, and the Liver and Intestinal Organ Transplantation Committee was formed to discuss this issue. The Committee also reviewed preliminary feedback from the Liver and Intestinal Organ Transplantation Committee on some questions regarding potential changes that had been discussed at a previous meeting and its status of developing requirements for intestinal transplant programs. (Item 9, Page 25-26).

- Live Donor Adverse Events Reporting: As required in Policy 12.8.4 (Submission of Living Donor Death and Organ Failure Data), transplant programs must report all instances of live donor deaths and failure of the live donor's native organ function within 72 hours after the program becomes aware of the live donor death or failure of the live donors' native organ function. The Committee reviewed three reported instances. Additionally, staff presented an analysis of living donor deaths not reported to the Patient Safety System (PSS). (Item 11, Page 26-27).

- Inactive Bylaw Modification: During the July meeting, the MSPC was informed that the Executive Committee approved its request that the Board-approved bylaw language have an effective date of August 1, 2009. Additionally, the Committee affirmed the Data Subcommittee recommendation to review the reports of programs with inactive waiting lists and programs with candidates still on the waiting list after program inactivation before codifying a process for Data Subcommittee review. (Item 12, Page 27).

- OPO Performance Metrics: The Committee was updated on the work of the OPO Performance Metrics Work Group, which is comprised of members of the OPO Committee and the MPSC. It is tasked with developing performance metrics to maximize the utilization of organs. (Item 13, Pages 27).

- Acceptance Rates: The SRTR presented a brief overview of the methodology for calculating organ and offer acceptance rates. Only organs that were accepted for transplant within the first 50 offers, or to the first 3 centers are included. Additional exclusions such as DCD, ECD and others ensure that only "good" organs are used in the analysis. Organ acceptance rates are based on offers to centers while offer acceptance rates are based on offers to individual candidates. The Committee had no issues to discuss based on the presentation. (Item 14, Page 27).

- Modified Flagging Methodology: UNOS staff presented a retrospective analysis of the modified flagging criteria proposed by the SRTR. In summary, the analysis showed that using the proposed method, the MPSC would flag fewer programs overall, while flagging more medium and high volume programs. The analysis also showed that the proposed method would flag > 80% of the programs considered to be "true positives" using the current flagging method and would flag fewer of the current false positives. The Data Subcommittee will consider the issue in more detail. (Item 15, Page 28).

- Composite Pre-Transplant Metric (CPM): UNOS staff presented a proposal for a new methodology for monitoring program specific pre-transplant outcomes, with an emphasis on detecting and preventing severe problems in a program's ability to serve its waitlisted patients. The Composite Pre-transplant Metric (CPM) takes into account risk-adjusted mortality rates, transplant rates and acceptance (organ and offer based) rates provided by the SRTR. Programs are ranked based on a single composite score that is a weighted sum of their pre-transplant observed-to-expected ratio of all four metrics, accounting for varying sample sizes across institutions. A working group will consider the merits of this approach for monitoring of pre-transplant performance. (Item 16, Page 28).

- Scanning Serologies in DonorNet®: The Committee requested that the OPO Committee consider requiring that OPOs scan serology source documents (as PDFs) into DonorNet® so that source documents may be viewed by the staff at potential recipients' transplant centers and OPOs during the organ offer process. The MPSC reviewed the OPO Committee's response at its July 2009 meeting. (Item 17, Page 28).

- Data Coordination Responsibilities and Guidelines: The Committee was informed that a memo had been sent to the OPO, Histocompatibility, Transplant Administrators, and Transplant Coordinators committees requesting feedback on the necessity to codify the responsibilities and expectations for primary data coordinators in the bylaws. No feedback was provided to the MPSC during the July meeting, but will likely be discussed in December. (Item 18, Page 28).

- Voting Status of Hospital Based OPOs and Laboratories: The Committee discussed a request that hospital based OPOs be granted OPTN voting rights as a part of their membership under the parent transplant center. The Committee agreed to form a work group to explore this issue as well as the voting status of hospital-based labs. (Item 19, Page 28-29).

- Patterns and Trends of Member Compliance and MPSC Actions: Staff presented a summary of trends of OPO and transplant center site survey results. Information included top policy violations found during site surveys, as well as the percentages of programs and centers that meet MPSC thresholds for performance on routine and follow up surveys. Staff presented a possible path for future trend analysis to the Committee. (Item 20, Page 29).

- Process for Letters of Reprimand, Probation, and Member Not in Good Standing: If the Committee considers recommending an adverse action such as Probation or Member Not in Good Standing or is considering issuing a Letter of Reprimand, the applicant or member is entitled to an interview. Historically, if a member waived its right to an interview for a proposed action, the Department of Evaluation and Quality would, on behalf of the Committee, issue the proposed sanction without further committee

deliberation. Staff requested that the Committee consider whether to formally standardize this practice in all cases where a member waives its right to an interview. The Committee decided that, in the case of Letters of Reprimand, it would proceed with the proposed sanction. For recommendations of Probation or Member Not in Good Standing, if the member waives its right to an interview the Committee will re-evaluate the resolution. (Item 22, Page 29).

- UNOS Actions: The Committee members agreed that actions regarding Bylaws and Policy, and program-specific decisions made during the OPTN session would be accepted as UNOS actions. (Item 27, Page 30-31).

OPTN/UNOS Membership and Professional Standards Committee
Report to the Board of Directors
November 16-17, 2009
Orlando, Florida

Charles Alexander, RN, BSN, MBA, CPTC, Chair
David Mulligan, M.D., Vice Chair

I. Regular Committee Meetings. The Membership and Professional Standards Committee (MPSC) met on July 22-23, 2009, in Chicago, Illinois and on September 25, 2009, by conference call and Microsoft Live Meeting. The Committee's deliberations and recommendations are provided below.

1. Membership Application Issues: The Committee is charged with determining that member clinical transplant programs, organ procurement agencies, histocompatibility laboratories, and non-institutional members meet and remain in compliance with the Criteria for Institutional Membership and transplant program approval. During each meeting, it considers actions regarding the status of current members and new applicants. The Committee took the actions reported below during its July meeting.

   The Committee recommends that the Board of Directors approve two new histocompatibility laboratories, and four new programs in an existing member centers. It also recommended approval for new and continued membership for existing non-institutional members.

   During the July meeting, the Committee reviewed one transplant program that had previously voluntarily inactivated and approved reinstatement of the program's active status. The Committee also reviewed a change in key personnel application for one program and agreed that approval of the application could be granted under conditional pathway. Another key personnel change application was discussed, and the Committee determined that the application was ruled incomplete because the foreign equivalency documentation provided did not demonstrate that the individual had the appropriate board certification required to qualify as a primary physician.

   The Committee also considered and recommends approval of a request from a hospital that asked to extend the inactive status of their pancreas transplant programs beyond the initial one-year period. The current bylaws provide the option of an extension to the inactive status period if the center demonstrates to the Committee *"the benefit of such extension, together with a plan and timeline for re-starting transplantation at the program which shall include assurance that all OPTN membership criteria will be met at the time of re-starting transplantation."*

   Living Donor Applications**:** During the July meeting, the Committee received an overview from staff on the ongoing application process for approving programs that perform living donor kidney (LDK) transplantation. The applications were distributed by region in October, November and December 2008 to all centers that have approved kidney transplant programs. All applications were to be completed and submitted to UNOS by March 31, 2009.

   During the September meeting, the Committee reviewed and agreed that 219 transplant hospitals met the requirements to conduct living donor kidney transplantation. At the time of the September meeting, there were 17 applications still under review, and one center had indicated it did not perform living donor transplants and would not be submitting an application. The Committee agreed on a way for reviewing these remaining applications upon their completion in

October, so that all programs desiring to continue doing living donor kidney transplants could receive final approval at the November 2009 Board of Directors meeting.

2. Proposal to change the Bylaws, to clarify the process for reporting changes in key personnel. Appendix B, Section II, E (Key Personnel); Bylaws, Appendix B, Attachment 1, Section III (Changes in Key Personnel): This proposal to change the bylaws will clarify when Transplant Hospitals must notify UNOS of changes in key personnel and further clarifies the expectation that member institutions that cannot submit a notice within the expected time frame must inactivate their membership status or withdraw the designated program of the affected program(s). This proposed language places greater emphasis on submitting complete applications and informs the member of the steps that will be taken if the member fails to provide notice of a change in key personnel or satisfactorily complete an application.

   The Committee identified the following goals while developing this proposal:
   - Minimize the time a center takes to submit a change in key personnel application when an individual is no longer available to the program.
   - Inform programs of the time line for submitting the complete Key Personnel Change Application.
   - Ensure that transplant programs have qualified personnel in key positions continuously.
   - Clarify that centers must inactivate the membership status or withdraw designated program status if key personnel requirements are not met.

   Proposal Background:
   During its November 13-14, 2007 meeting, the Committee formed a work group to address Committee goals. In particular, the Work Group was asked to review the efficiency and effectiveness of currently used member qualification assessment methods and recommend improvements to the process. The Work Group was also asked to consider whether or not the current level of program review was adequate to ensure ongoing compliance and competency, and if there were areas that could be improved.

   The Work Group identified several areas of concern in the existing bylaws related to changes in key personnel:
   - Members are often unaware of the notification requirements in the bylaws and did not routinely notify the MPSC staff immediately when they experienced a change in key personnel.
   - Members have not consistently submitted completed key personnel change applications within 30-days of a change in key personnel.
   - The majority of applications submitted are missing required information or documentation. It often takes months for members to supply follow up information as requested by staff or the MPSC so that the application can be resolved. Some applications remain open or unresolved for extended periods in the review process. This delay increases the potential risk to patient safety, since the center has not demonstrated that it is staffed with individuals who meet the minimum key personnel requirements.
   - Centers that do not have a surgeon or physician on site who meets the key personnel requirements will submit applications naming unqualified individuals, seemingly in order to "buy time" while they recruit qualified individuals.
   - Members sometimes presume that once an individual has been named in any application that they have been "UNOS certified" and that they do not need to submit any new information regarding the individual's ability to meet the current requirements.

   The Work Group suggested to that the Committee that is should recommend changing the bylaw language regarding time limits for notifying and submitting applications to UNOS about changes

in key personnel. The Committee agreed that these changes would allow more timely oversight of the notification process and allow it to readily address the concern that some applications are drawn out for long periods because the centers do not submit complete information initially.

Final Proposal:
The Committee agreed not to forward the proposal to the Board of Directors during the June 2009 meeting because of the large number of thoughtful public comments received. The Committee agreed that it needed to take the time necessary to consider amending the proposal to address the comments. The Committee was particularly concerned with the amount of misinformation there was in the field about the process for changing key personnel and it was sensitive to the need to make the bylaws more specific and yet easy to follow. It agreed to place less of an expectation on members to be familiar with all pertinent sections of the bylaws, such as Appendix A, and how these requirements were all tied together while residing in different sections of the Bylaws.
The Committee also noted a number of concerns that were related to process and resources but indicated these were not issues that would be written into the Bylaws. The Committee supports many of these suggestions but noted that resource limitations would preclude the development of tools such as web-based applications for the immediate future. It is anticipated that this could be carried out in conjunction with a re-write of the Membership Database, which is planned over the next 2-3 years. It did however agree that in the short term educational tools could be developed in conjunction with the bylaws. For example, a facts sheet for the application process could be developed, and changes can be made to the Evaluation Plan that further describes the application process in detail.

The Committee met on September 25 by conference call to consider the final revisions to this proposal. It agreed to amend the proposal to more clearly address these specific areas:

- Short term absences and reference to program coverage plans.
- Reinstatement process for returning key personnel.
- Reference to succession planning.
- Remove reference to 15-days.
- Sudden and unexpected changes in key personnel
- Minimum of 30 days to submit an application.
- Specified 7 business days to submit written notification.
- Implications if notice if not given within 7 days.
- Implications if application is incomplete

The Committee agreed to forward this amended proposal to the Board for their consideration.

**** RESOLVED, that the following modifications to Bylaw, Appendix B, Section II, E (Key Personnel); and Bylaw, Appendix B, Attachment 1, Section III (Changes in Key Personnel), having been distributed for public comment and subsequent reconsideration by the Committee, are approved effective December 17, 2009:**

The Committee Voted 23 For, 1 Against, 1 Abstention.

Final Proposal

Double underline or double strike out as shown below are those changes made following public comment.

APPENDIX B TO BYLAWS
OPTN

Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership

I. No Changes

II. Transplant Hospitals.

A. – D. No Changes

E. Key Personnel. For each designated organ transplant program, the Transplant Hospital must identify a primary transplant surgeon and primary transplant physician and demonstrate that they meet the requirements set forth in the Bylaws, Appendix B, Attachment I. Where applicable these individuals must be the same individuals reported to the Center for Medicaid and Medicare Services (CMS) as serving in this capacity.

~~The Transplant Hospital must identify for any designated transplant program (as defined below) qualified as a transplant program by other than the requirements set forth in Attachment I and sub-attachments to Appendix B the primary surgeon and primary physician reported to the Center for Medicaid and Medicare Services (CMS) and demonstrate whether these individuals meet the requirements specified in this Appendix B, Attachment I, Section VI, and applicable sub-attachments.~~

~~When the Transplant Hospital learns that one or more of these individuals plan to leave, the OPTN Contractor must be notified immediately. At least 30 days (if possible) prior to the departure of the individual, the Transplant Hospital shall submit to the OPTN Contractor the name of the replacement physician or surgeon, Curriculum Vitae, and information documenting whether the individual meets the requirements specified in this Appendix B, Attachment I, Section VI, and applicable sub-attachments.~~

~~Failure to inform the OPTN Contractor of changes in primary physician and surgeon shall result in recommendation to the Board of Directors that the Board so notify the Secretary, and/or take appropriate action in accordance with Appendix A of these Bylaws, which action may include those defined as adverse under Section 3.01A.~~

[Note: The single underlined text above is removed because it is not relevant to the new program approval process, which is the primary focus of this section of the bylaws.]

ATTACHMENT I
TO APPENDIX B OF THE OPTN BYLAWS

A transplant program that meets the following criteria shall be qualified as a designated transplant program to receive organs for transplantation:

I. Facilities and Resources [No changes]

II. Reporting ~~Changes in~~ Key Personnel Changes: Designated transplant programs must have key personnel -specifically a primary transplant surgeon and a primary transplant physician- who meet certain minimum levels of commitment to and knowledge of organ procurement and transplantation as specified below. All programs should develop a succession plan that addresses changes in key personnel staffing.

When a designated transplant program is informed of ~~learns that~~ a key personnel change it must notify ~~(such as the primary transplant surgeon or the primary transplant physician) upon whose participation the program's OPTN approval is based, plans to leave or is not substantively able to participate in the program for 15 or more consecutive days (such as military leave or temporary leave of absence)~~, the OPTN Contractor ~~must be notified immediately~~ within 7 business days in writing, as described below in "Reporting Key Personnel Changes". The member must ~~also~~ then follow the procedures for applications that are described in the Bylaws, Appendix A, Section 1.03A. Designated programs are also responsible for maintaining Program Coverage Plans as described below in Section VI. The Program Coverage Plan should address instances when key personnel are unavailable to perform their transplant duties for short periods of time.

Reporting Key Personnel Changes:

(A) ~~Key Personnel Changes where t~~The primary transplant surgeon and/or primary transplant physician departs from the program and/or is no longer involved with the program: When the Transplant Hospital is informed ~~learns~~ that one or more of these individuals plan to leave or otherwise cease their active participation in the transplant program, the OPTN Contractor must be notified ~~immediately~~ within 7 business days in writing. ("OPTN Contractor Notification Date")

No less than ~~At least~~ 30 days ~~(if possible)~~ prior to the end of the individual's active participation in the program ~~(including also military leave or temporary leave of absence), departure of the key person,~~. the Transplant ~~Center~~ Hospital is required to ~~shall~~ submit to the OPTN Contractor ~~the name of the replacement key person, Curriculum Vitae~~, a complete Personnel Change Application, which ~~and information demonstating and documentsing compliance with OPTN criteria for a designated transplant program. Whether~~ documents that the proposed new primary transplant surgeon or physician ~~individual~~ meets the requirements specified in this Appendix B, Attachment I, Section VI, and applicable sub-attachments.

If the Transplant Hospital receives less than 60 days advance notice of the key personnel change taking place, then the Transplant Hospital must submit a complete application (see paragraph above) to the OPTN Contractor within 30 days from the OPTN Contractor Notification Date.

If a ~~P~~program~~s~~ ~~that are~~ is unable to verify or propose through a complete Personnel Change Application that it has ~~they have~~ on site both a transplant surgeon and a transplant physician who meet the requirements for primary transplant surgeon and physician the Transplant Hospital must ~~should~~ ~~voluntarily~~ inactivate ~~their~~ the program's membership, or relinquish or terminate its Designated Transplant Program Status as described in Appendix B, Section II, C of the Bylaws.

(B) ~~Key Personnel Changes where t~~The primary transplant surgeon and/or primary transplant physician remains involved in the program as an additional transplant surgeon or ~~/~~physician:

When the Transplant Hospital plans to change the individual designated as the primary transplant surgeon or primary transplant physician, the OPTN Contractor must be notified ~~immediately~~ within 7 business days in writing.
~~At least~~ No less than 30 days prior to the change in the individual's status, the Transplant Hospital ~~shall~~ is required to submit a complete Personnel Change Application to the OPTN Contractor.~~,~~ This Personnel Change Application ~~which~~ documents that the individual meets the requirements specified in the~~is~~ Bylaws, Appendix B, Attachment I, Section VI, and applicable sub-attachments.

The transition to the new designated primary transplant surgeon or physician becomes effective after the application has been reviewed and approved by the Membership and Professional Standards Committee (MPSC) or an Ad hoc Subcommittee of the MPSC, as described below in the Processing Applications section of the bylaws.

C. The primary transplant surgeon and/or primary transplant physician will not be involved with the program on a temporary basis such as periods of military or medical leave: (Temporary here is defined as greater than 30 days but less than 1 year.)
When the Transplant Hospital learns that one or more of these individuals must take a temporary leave of absence or otherwise temporarily cease their active participation in the transplant program, the OPTN Contractor must be notified within 7 business days in writing.

At least 30 days prior to the end of the individual's active participation in the program, the Transplant Hospital is required to submit to the OPTN Contractor a complete Personnel Change Application. This application documents compliance with OPTN criteria for a designated transplant program and indicates that the proposed new primary transplant surgeon or physician meets the requirements specified in the Bylaws, Appendix B, Attachment I, Section VI, and applicable sub-attachments.

If the Transplant Hospital receives less than 60 days notice of that the key personnel change will take place, the Transplant Hospital must submit a complete application (see paragraph above) to the OPTN Contractor within 30 days from the OPTN Contractor Notification Date.

If a program is unable to verify or propose through a complete Personnel Change Application that it has on site both a transplant surgeon and a transplant physician who meet the requirements for primary transplant surgeon and physician, the Transplant Hospital must inactivate the program's membership, or relinquish or terminate its Designated Transplant Program Status as described in Appendix B, Section II, C of the Bylaws.

D. Option for Reinstatement: If the previously named primary transplant surgeon or primary transplant physician returns to the same organ transplant program within 1 year of his/her departure date the individual can be considered for reinstatement as the primary transplant surgeon or physician if the Transplant Hospital submits a written reinstatement request to the OPTN Contractor. This written reinstatement request must include the following documentation:
(1) A letter from the transplant program director, department chair, or chief of the division, attesting to the individual's current working knowledge; and
(2) A letter from the individual confirming his/her commitment to the program and on site availability.

(3) A current letter from the hospital credentialing committee verifying that the individual meets the requirements and is qualified and able to resume their previous role.

The Membership and Professional Standards Committee (MPSC) or an Ad hoc Subcommittee of the MPSC, as described below under Processing Applications, will review Requests for Reinstatement. In cases where reinstatement of an individual surgeon or physician may affect the program's status, the MPSC will recommend the appropriate new program status and any special conditions as indicated.

E. Failure to Provide Notification:

(1) Failure to inform the OPTN Contractor of a change in primary transplant surgeon and/or primary transplant physician within the time frames specified above may result in the MPSC imposing a sanction on the member. A sanction may include a Notice of Uncontested Violation, Letter of Warning, or Letter of Reprimand, as described in detail in Appendix A of these Bylaws.

(2) Failure to inform the OPTN Contractor of any changes in ~~key personnel may in~~ primary transplant surgeon and/or primary transplant physician or to submit the required Personnel Change Application shall result in ~~disciplinary action~~ a recommendation to the Board of Directors (Board) that the Board take appropriate action in accordance with Appendix A of these Bylaws. Potential adverse actions that the Board may choose to take are defined under Section 3.01A of the Bylaws. Additionally, the Board of Directors may notify the Secretary of HHS of the situation.

F. **Processing Applications:** For processing of applications to change key personnel, the Membership and Professional Standards Committee (MPSC) Chair is authorized to appoint an Ad hoc Subcommittee of at least two committee members, other than the MPSC chair, to review the credentials of the proposed new key personnel. The Subcommittee is empowered to provide, with the concurrence of the MPSC Chair, interim approval effective until review by the full MPSC as its next meeting. Such interim approval shall not extend beyond the next meeting of the full MPSC and shall automatically expire if the full MPSC does not approve the interim action. Designated transplant programs are responsible for maintaining qualified key personnel for the program, without regard to the status of applications for change in key personnel.

APPENDIX B TO BYLAWS, UNITED NETWORK FOR ORGAN SHARING
Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership

APPENDIX B TO BYLAWS - UNITED NETWORK FOR ORGAN SHARING

II. Transplant Hospitals.

A-D No changes

E. Key Personnel. For each designated organ transplant program, the Transplant Hospital must identify a primary transplant surgeon and primary transplant physician and demonstrate that they meet the requirements set forth in the Bylaws, Appendix B, Attachment I. Where applicable these individuals must be the same individuals reported

to the Center for Medicaid and Medicare Services (CMS) as serving in this capacity.

~~The Transplant Hospital must identify for any designated transplant program (as defined below) qualified as a transplant program by other than the requirements set forth in Attachment I and sub-attachments to Appendix B the primary surgeon and primary physician reported to the Center for Medicaid and Medicare Services (CMS) and demonstrate whether these individuals meet the requirements specified in this Appendix B, Attachment I, Section VI, and applicable sub-attachments.~~

~~When the Transplant Hospital learns that one or more of these individuals plan to leave, UNOS must be notified immediately. At least 30 days (if possible) prior to the departure of the individual, the Transplant Hospital shall submit to UNOS the name of the replacement physician or surgeon, Curriculum Vitae, and information documenting whether the individual meets the requirements specified in this Appendix B, Attachment I, Section VI, and applicable sub-attachments.~~

~~Failure to inform UNOS of changes in primary physician and surgeon shall result in recommendation to the Board of Directors that the Board take appropriate action in accordance with Appendix A of these Bylaws, which action may include those defined as adverse under Section 3.01A.~~

ATTACHMENT I
TO APPENDIX B OF UNOS BYLAWS
Designated Transplant Program Criteria

I.-II. No Changes

III. Reporting ~~Changes in~~ Key Personnel Changes. Designated transplant programs must have key personnel – specifically a primary transplant surgeon and a primary transplant physician- who meet certain minimum levels of commitment to and knowledge of organ procurement and transplantation as specified below. All programs should develop a succession plan that addresses changes in key personnel staffing.

When a designated transplant program is informed of ~~learns that~~ a key personnel change it must notify ~~(such as the primary transplant surgeon or the primary transplant physician) upon whose participation the program's approval is based, plans to leave or is not substantively able to participate in the program for 15 or more consecutive days (such as military leave or temporary leave of absence)~~. UNOS ~~must be notified~~ ~~immediately~~ within 7 business days in writing, as described below in "Reporting Key Personnel Changes. The member must also follow the procedures for applications that are described in the Bylaws, Appendix A, Section 1.03A. Designated programs are also responsible for maintaining Program Coverage Plans as described below in Section VI. The Program Coverage Plan should address instances when key personnel are unavailable to perform their transplant duties for short periods of time.

Reporting Key Personnel Changes:

(1) ~~Key Personnel Changes where t~~The primary transplant surgeon and/or primary transplant physician is no longer involved with the program:

When the Transplant Hospital ~~learns~~ is informed that one or more of these individuals plans to leave, or otherwise cease their active participation in the transplant program, UNOS must be notified ~~immediately~~ within 7 business days in writing. ("UNOS Notification Date")

No less than ~~At least~~ 30 days ~~(if possible)~~ prior to the end of the individual's active participation in the program ~~departure of the key person~~, the ~~program~~ Transplant ~~Center~~ Hospital is required to ~~shall~~ submit to UNOS ~~the name of the replacement key person, Curriculum Vitae,~~ a complete Key Personnel Change Application, which ~~and information demonstrating and~~ documents~~ing~~ ~~compliance with UNOS criteria for a designated transplant program~~ that the proposed new primary surgeon or physician meets the requirements specified in the Bylaws, ~~this~~ Appendix B, Attachment I and applicable subsections.

If the Transplant Hospital receives less than 60 days advance notice of the key personnel change taking place, then the Transplant Hospital must submit a complete application (see paragraph above) to UNOS within 30 days from the UNOS Notification Date.

If a p~~P~~rograms ~~that are~~ is unable to verify or propose through a complete Personnel Change Application that it has ~~demonstrate that they have~~ on site both a transplant surgeon and a transplant physician who meet the requirements for primary transplant surgeon and physician the Transplant Hospital must ~~should voluntarily~~ inactivate the~~ir~~ the program's membership, or relinquish or terminate its Designated Transplant Program Status as described in Appendix B, Section II, C of the Bylaws.

(2) ~~Key Personnel Changes, where t~~The primary transplant surgeon and/or primary transplant physician remains involved in the program as an additional transplant surgeon or ~~/~~physician:

When the Transplant Hospital plans to change the individual designated as the primary transplant surgeon or primary transplant physician, UNOS must be notified ~~immediately~~ within 7 business days in writing. At least 30 days prior to the change in the individual's status, the Transplant Hospital shall submit a complete Personnel Change Application to UNOS, which documents that the individual meets the requirements specified in this Appendix B, Attachment I, Section VI, and applicable sub-attachments.

~~At least~~ No less than 30 days prior to the change in the individual's status, the Transplant Hospital ~~shall~~ is required to submit a complete Personnel Change Application to UNOS.~~,~~ This Personnel Change Application ~~which~~ documents that the individual meets the requirements specified in the~~is~~ Bylaws, Appendix B, Attachment I, Sections VII and XIII and applicable sub-attachments.

The transition to the new designated primary transplant surgeon or physician becomes effective after the application has been reviewed and approved by the Membership and Professional Standards Committee (MPSC) or an Ad hoc Subcommittee of the MPSC, as described below in the Processing Applications section of the Bylaws.

3. The primary transplant surgeon and/or primary transplant physician will not be involved with the program on a temporary basis such as periods of military or medical leave:
(Temporary here is defined as greater than 30 days but less than 1 year.)
When the Transplant Hospital learns that one or more of these individuals must take a temporary leave of absence or otherwise temporarily cease their active participation in the transplant program, UNOS must be notified within 7 business days in writing.

   At least 30 days prior to the end of the individual's active participation in the program, the Transplant Hospital is required to submit to UNOS a complete Personnel Change Application. This application documents compliance with UNOS criteria for a designated transplant program and indicates that the proposed new primary transplant surgeon or physician meets the requirements specified in the Bylaws, Appendix B, Attachment I, Sections VII and XIII and applicable sub-attachments.

   If the Transplant Hospital receives less than 60 days notice of that the key personnel change will take place, the Transplant Hospital must submit a complete application (see paragraph above) to UNOS within 30 days from the UNOS Notification Date.

   If a program is unable to verify or propose through a complete Personnel Change Application that it has on site both a transplant surgeon and a transplant physician who meet the requirements for primary transplant surgeon and physician, the Transplant Hospital must inactivate the program's membership, or relinquish or terminate its Designated Transplant Program Status as described in the Bylaws, Appendix B, Section II, C.

4. Option for Reinstatement: If the previously named primary transplant surgeon or primary transplant physician returns to the same organ transplant program within 1 year of his/her departure date the individual can be considered for reinstatement as the primary transplant surgeon or physician if the Transplant Hospital submits a written reinstatement request to UNOS. This written reinstatement request must include the following documentation:
   (a) A letter from the transplant program director, department chair, or chief of the division, attesting to the individual's current working knowledge; and
   (b) A letter from the individual confirming his/her commitment to the program and on site availability.
   (c) A current letter from the hospital credentialing committee verifying that the individual meets the requirements and is qualified and able to resume their previous role.

   The Membership and Professional Standards Committee (MPSC) or an Ad hoc Subcommittee of the MPSC, as described below under Processing Applications, will review Requests for Reinstatement. In cases where reinstatement of an individual surgeon or physician may affect the program's status, the MPSC will recommend the appropriate new program status and any special conditions as indicated.

5. Failure to Provide Notification:
   (a) Failure to inform UNOS of a change in primary transplant surgeon and/or primary transplant physician within the time frames specified above may result in the MPSC imposing a sanction on the member A sanction may include a Notice

of Uncontested Violation, Letter of Warning, or Letter of Reprimand, as described in detail in the Bylaws, Appendix A.

(b) Failure to inform ~~the OPTN Contractor~~ UNOS of any changes in ~~key personnel may in~~ primary transplant surgeon and/or primary transplant physician or to submit the required Personnel Change Application shall result in ~~disciplinary action~~ a recommendation to the Board of Directors (Board) that the Board take appropriate action in accordance with Appendix A of the Bylaws. Potential adverse actions that the Board may choose to take are defined under Section 3.01A of the Bylaws. Additionally, the Board of Directors may notify the Secretary of HHS of the situation.

6. Processing Applications: For processing of applications to change key personnel, the Membership and Professional Standards Committee (MPSC) Chair is authorized to appoint an Ad hoc Subcommittee of at least two committee members, other than the MPSC chair, to review the credentials of the proposed new key personnel. The Subcommittee is empowered to provide, with the concurrence of the MPSC Chair, interim approval effective until review by the full MPSC as its next meeting. Such interim approval shall not extend beyond the next meeting of the full MPSC and shall automatically expire if the full MPSC does not approve the interim action. Designated transplant programs are responsible for maintaining qualified key personnel for the program, without regard to the status of applications for change in key personnel.

3. Proposed Bylaw Modifications to Reconcile Volume Requirements for Primary Transplant Physicians: During its October 2008 meeting, the Committee discussed potential changes to the bylaws related to the experience and training requirements for primary transplant physicians. In 2006, the Committee recommended and the Board approved approval for changes to the experience levels that primary physicians needed to meet for kidney (45), liver (50) and pancreas (8). Inadvertently, these changes were not carried over to the related bylaws for the conditional pathways, so technically a conditionally approved primary physician could be fully approved at the end of their one-year conditional period with significantly fewer cases being followed.

This was not the intent of the original bylaw change so the Committee was asked to consider modifying the conditional pathway volume requirements. The Committee agreed that modifications needed to be made and input was provided by committee members regarding what changes would be appropriate. The proposed changes were distributed for public comment in June 2009.

The Committee met on September 25 by conference call to consider the final revisions to this proposal. The Committee recommended only a simple clarifying amendment to the pancreas section, as shown below with double underlines below. They agreed to forward this amended proposal to the Board for its consideration.

**** RESOLVED, that the following modifications to the Bylaws, Appendix B, Attachment I, XIII, D, having been distributed for public comment and subsequent reconsideration by the Committee, are approved effective December 17, 2009.**

The Committee Voted 25 For, 0 Against, 0 Abstentions

APPENDIX B TO BYLAWS
UNOS
Attachment I, XIII, Transplant Programs, D, (1),Kidney Transplantation

(jj) In the case of a change in the primary kidney transplant physician at a UNOS approved kidney transplant program, if items (cc) iii or (ee) i-ii are not met, the replacement physician, a nephrologist can function as a kidney transplant physician for a maximum period of twelve months if the following conditions are met:

(i) That the remaining parts of (cc) or (ee), as applicable, are met.

(ii) That the individual has been involved in the primary care of ~~15~~ **23** or more kidney transplant recipients, and has followed these patients for a minimum of 3 months from the time of their transplant. The application must be supported by a recipient log. Such a log should include at least the medical record and/or UNOS identification number of the recipient and date of transplant. Beginning January 1, 2007, this log should be signed by the program director, division chief, or department chair from program where the experience was gained.

(iii) That if the individual is qualifying as primary transplant physician by virtue of acquired clinical experience, this experience is equal to 12 months on an active kidney transplant service as the kidney transplant physician or under the direct supervision of a qualified kidney transplant physician and in conjunction with a kidney transplant surgeon at a UNOS approved kidney transplant center. This 12 month period of experience on the transplant service must be acquired over a maximum of 2 years.

(iv) That a consulting relationship with counterparts at another ~~UNOS~~ member transplant center approved for kidney transplantation has been established and documented.

(v) That activity reports are submitted to UNOS at two month intervals describing the transplant activity and results, physician recruitment efforts, and such other operating conditions as may be required by the Membership and Professional Standards Committee to demonstrate to the satisfaction of the Committee ongoing quality and efficient patient care. The reports must show that the individual is making sufficient progress to meet the objective of involvement in the primary care of at least ~~30~~ **45** kidney transplant recipients or that the program is making sufficient progress in recruiting and bringing to the program a transplant physician who meets this criterion as well as all other UNOS criteria for a qualified renal transplant physician by the date that is 12 months from the date of approval of the program under this section.

(vi) If the program is unable to demonstrate that it has an individual on site who can meet the requirements as described in sections (cc), (dd), (ee), (ff), (gg), (hh), or (ii) above at the end of 12 months, it shall inactivate. The requirements for program inactivation are described in Section II. The Membership and Professional Standards Committee may consider on a case by case basis, and grant a six month extension to a program that provides substantive evidence of progress towards completing the requirements but is unable to complete the requirements within one year.

Attachment I, XIII, Transplant Programs, D, (3), Liver Transplantation

(hh) In the case of a change in the primary liver transplant physician at a UNOS approved transplant program, if items (aa) iii or (cc) i-ii are not met, the replacement physician, must be a gastroenterologist/hepatologist and can function as a liver transplant physician for a maximum period of twelve months if the following conditions are met:

(i) That the remaining parts of (aa) or (cc), as applicable, are met.

(ii) That the individual has been involved in the primary care of ~~15~~ **25** or more liver transplant recipients, and has followed these patients for a minimum of 3 months from the time of their transplant. The application must be supported by a recipient log. Such a log should include at least the medical record and/or UNOS identification number of the recipient and date of transplant. Beginning January 1, 2007, this log must be signed by the director and/or the primary transplant physician at the transplant program where the individual trained or gained this experience.

(iii) That if the individual is qualifying as primary transplant physician by virtue of acquired clinical experience, this experience must be a minimum of 12 months on an active liver transplant service as the qualified liver transplant physician or under the direct supervision of a qualified liver transplant physician and in conjunction with a liver transplant surgeon at a UNOS approved liver transplant center or an active foreign liver transplant program accepted as equivalent by the MPSC. This 12 month period of experience on the transplant service must be acquired over a maximum of 2 years.

(iv) That a consulting relationship with counterparts at another ~~UNOS~~ member transplant center approved for liver transplantation has been established and documented.

(v) That activity reports are submitted to UNOS at two month intervals describing the transplant activity and results, physician recruitment efforts, and such other operating conditions as may be required by the Membership and Professional Standards Committee to demonstrate to the satisfaction of the Committee ongoing quality and efficient patient care. The reports must show that the individual is making sufficient progress to meet the objective of involvement in the primary care of at least ~~30~~ **50** transplant recipients or that the program is making sufficient progress in recruiting and bringing to the program a transplant physician who meets this criterion as well as all other UNOS criteria for a qualified liver transplant physician by the date that is 12 months from the date of approval of the program under this section.

Attachment I, XIII, Transplant Programs, D, (5), Pancreas Transplantation

(ee) In the case of a change in the primary transplant physician at a UNOS approved pancreas transplant program, if items (aa) iii or (cc) i-ii are not met, the replacement physician, a nephrologist/endocrinologist/diabetologist can function as a pancreas transplant physician for a maximum period of twelve months if the following conditions are met:

(i) That the remaining parts of (aa) or (cc), as applicable, are met.

(ii) That if the individual is qualifying as primary transplant physician by virtue of training, the individual has been involved in the primary care of ~~5~~ **4** or more pancreas transplant recipients, and has followed these patients for a minimum of three months from the time of their transplant. The application must be supported by a recipient

log. Such a log should include at least the medical record and/or UNOS identification number of the recipient and date of transplant. Beginning January 1, 2007, this log must be signed by the program director, division chief, or department chair from program where the experience was gained.

(iii) That if the individual is qualifying as the primary pancreas transplant physician by virtue of acquired clinical experience, this experience is equal to 12 months on an active pancreas transplant service as the pancreas transplant physician or under the direct supervision of a qualified pancreas transplant physician and in conjunction with a pancreas transplant surgeon at a UNOS approved pancreas transplant center. Additionally, the individual will have been involved in the primary care of eight or more pancreas transplant recipients, and have followed these patients for a minimum of three months from the time of their transplant. This 12 month period of experience on the transplant service must be acquired over a maximum of 2 years. The application must be supported by a recipient log. Such a log should include at least the medical record and/or UNOS identification number of the recipient and date of transplant.

(iv) That a consulting relationship with counterparts at another ~~UNOS~~ member transplant center approved for pancreas transplantation has been established and documented.

(v) That activity reports are submitted to UNOS at two month intervals describing the transplant activity and results, physician recruitment efforts, and such other operating conditions as may be required by the Membership and Professional Standards Committee to demonstrate to the satisfaction of the Committee ongoing quality and efficient patient care. The reports must show that the individual is making sufficient progress to meet the objective of involvement in the primary care of at least ~~10~~ **8** (training) or 15 (experience),as applicable, transplant recipients or that the program is making sufficient progress in recruiting and bringing to the program a transplant physician who meets this criterion as well as all other UNOS criteria for a qualified pancreas transplant physician by the date that is 12 months from the date of approval of the program under this section.

(vi) If the program is unable to demonstrate that it has an individual on site who can meet the requirements as described in sections (aa), (bb), (cc), or (dd), above at the end of 12 months, it shall inactivate. The requirements for program inactivation are described in section II. The Membership and Professional Standards Committee may consider, on a case by case basis, and grant a six month extension to a program that provides substantive evidence of progress towards completing the requirements but is unable to complete the requirements within one year.

4. Preventing the Appearance of Potential Conflicts of Interest Regarding Declaration of Death and Organ Procurement: This proposal adds language to the Policies stipulating that members are obligated avoid conflicts of interest associated with having the same person declare death and perform organ procurement and transplantation. The ultimate goal of this proposed change is to prohibit the same physician from declaring a patient's death and participating in the removal or transplant of organs from that decedent.

Background:
During its meetings in May and July 2008, the Committee discussed an issue discovered during a committee directed peer visit. During their review, the peer team noted concerns relating to a

single surgeon who had been involved in the declaration of death in organ donors, and was subsequently involved in the procurement and transplantation of their organs. The team informed the center at the end of the visit of the potential conflict this practice presents and reported its concerns to the MPSC.

The MPSC discussed the issue at length on May 7, 2008, and referenced the Revised Uniform Anatomical Gift Act of 2006 (UAGA), Section 14, Part I:

> *Neither the physician who attends the decedent at death nor the physician who determines the time of the decedent's death may participate in the procedures for removing or transplanting a part from the decedent.*

The UAGA further defines Anatomical Gift as "*a donation of all or part of a human body to take effect after the donor's death for the purpose of transplantation, therapy, research, or education*."

While Policy 2.2.1 states that the host Organ Procurement Organization (OPO) is responsible for verifying that potential donor death has been pronounced according to applicable laws, there was no Bylaw that specifically prohibited a physician from declaring death and then later participating in procuring and transplanting those organs or tissues. The Committee agreed on the need to amend the policies and bylaws to address the points made in the UAGA and to require surgeons who were involved in declaration of donor death to not be involved in organ procurement and transplantation. The Committee agreed that a subcommittee should be formed to conduct this review. The Subcommittee, which met first by conference call in September 2008, agreed to develop a proposal for the full Committee to consider. Input was later sought from the Ethics and OPO Committees and they both agreed that the first draft of the policy proposal was too complex and suggested that the MPSC consider a simpler approach.

Under the revised proposal, the OPTN Contractor may conduct reviews and evaluations of the members, and those who are found to be non-compliant will be handled in a manner described in Appendix A of the Bylaws. This approach would allow the Committee to consider actions against a transplant center that appears to have violated the policy. The present requirements only give the option of making an adverse recommendation against an organ procurement organization when the OPO fails to verify that potential donor death was pronounced according to applicable laws. The Committee considered amending the bylaws only to reference the UAGA but that was not considered a practical option since the states/jurisdictions have enacted different versions of the UAGA.

Final Proposal:
The Committee met on September 25, 2009, by conference call to consider this proposal and the comments received during the public comment period. Based on concerns about the OPTN role in enforcing state/jurisdictional laws, the Committee agreed to remove the suggested bylaws language that pertained to following state laws. They also agreed to amend the Policy language to clarify the physician may not participate in the operative procedures. The modification to the policy language is shown below as a double underline.

The Committee agreed to forward this amended proposal to the Board for their consideration.

**** RESOLVED, that the following modifications to Policy 3.4 (Organ Procurement, Distribution and Alternative Systems for Organ Distribution or Allocation), having been distributed for public comment and subsequent reconsideration by the Committee, are approved effective December 17, 2009.**

The Committee voted 24 For, 0 Against, 0 Abstentions

Proposed Change to Policy

3.4 ORGAN PROCUREMENT, DISTRIBUTION AND ALTERNATIVE SYSTEMS FOR ORGAN DISTRIBUTION OR ALLOCATION. The following policies apply to organ procurement, distribution and alternative systems for organ distribution or allocation.

3.4.1 Avoidance of Conflicts of Interest. Neither the attending physician of the decedent at death nor the physician who determines the time of the decedent's death may participate in the operative procedure for removing or transplanting an organ from the decedent. For purposes of this section, "organ" is defined as set forth in the OPTN Final Rule (42 C.F.R Part 121.2), and "decedent" is defined as a deceased individual whose body is or may become the source of a donated organ.

[Following sections renumbered only]

5. Notification of Potential Adverse Action by Other Regulatory Agency: During its July 2009, meeting, the Committee reviewed the proposal that was distributed for public comment and recommended additional modifications to clarify the proposed bylaw language that requires transplant programs, OPOs, and histocompatibility laboratories to notify the OPTN Contractor of threatened or real adverse actions taken by regulatory agencies.

During the September 25, 2009, conference call, the Committee considered feedback received during the public comment period. Discussed by many regions and committees during the public comment period, concern was expressed regarding the terms "state and federal" regulatory agencies. The primary concern was that localities such as Washington, D.C. and Puerto Rico may not be captured using the terms "state and federal" agencies. The MPSC agreed with this concern and recommended the language be changed to, "the regulatory agency of its respective jurisdiction."

Additionally, the Committee expressed concern with language proposed in the transplant hospital section, requiring OPTN Contractor notification when an adverse action has been taken, "…against any of its transplant programs." The Committee recommended changing this section to include, "adverse actions taken against or that may impact any of its transplant programs."

During the September 25, 2009, conference call, the Committee unanimously approved the following language for approval by the Board of Directors:

**** RESOLVED, that the following modifications to Appendix B, Sections I, II, and III in the Bylaws, having been distributed for public comment and subsequent reconsideration by the Committee, are approved effective December 17, 2009.**

The Committee voted 23 For, 0 Against, and 0 Abstentions

The modifications to the bylaw language are shown below with double underlines and ~~double strike-throughs~~.

APPENDIX B TO BYLAWS
OPTN

Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership

I. Organ Procurement Organizations.

General. An organization designated as an organ procurement organization by the Secretary of the Department of Health and Human Services (HHS) under Section 1138(b) of the Social Security Act or an organization that meets all requirements for such designation other than OPTN membership (OPO) is eligible for membership in the OPTN.

OPOs shall abide by applicable provisions of the National Organ Transplant Act, as amended, 42 U.S.C. 273 *et seq*.; the requirements set forth in the OPTN Final Rule, 42 CFR Part 121; these Bylaws; and OPTN policies.

OPOs shall also submit to reviews (including on-site reviews) and requests for information as may be necessary to determine compliance with the OPTN Final Rule, 42 CFR Part 121; these Bylaws; and OPTN policies. Failure to conform with such requirements shall be cause for corrective action described in Appendix A of these Bylaws.

Each OPO shall fully inform the OPTN Contractor in writing within ~~five (5)~~ 10 business days, ~~to include copies of all related correspondence or reports,~~ when ~~any of the following events occur:~~

~~(1)~~ an adverse action has been taken against it ~~that leads to or threatens material change in the OPO's eligibility to procure organs or be reimbursed for organ procurement costs by Medicare or a state Medicaid program, including but not limited to any threatened or actual termination of Medicare designated status; and (2) any threatened or actual adverse action~~ by ~~a state or federal~~ the regulatory agency of its respective jurisdiction or ~~it's~~ the regulatory agency's designee ~~that would impose a significant limitation upon the OPO's ability to procure organs~~.

[No further changes to this section]

II. Transplant Hospitals.

A. General. A hospital (i) that aspires to perform organ transplants, as evidenced by submission of an active application for designated transplant program status for at least one organ type, or in which organ transplantation is performed, and (ii) that participates in the Medicare or Medicaid programs (Transplant Hospital) is eligible for membership in the OPTN.

Transplant Hospitals shall abide by applicable provisions of the National Organ Transplant Act, as amended, 42 U.S.C. 273 *et seq*.; the requirements set forth in the OPTN Final Rule, 42 CFR Part 121; these Bylaws; and OPTN policies.

Transplant Hospitals shall also submit to reviews (including on-site reviews) and requests for information as may be necessary to determine compliance with the OPTN Final Rule, 42 CFR Part 121; these Bylaws; and OPTN policies.

~~For each of its organ-specific transplant programs,~~ A Transplant Hospital shall fully inform the OPTN Contractor in writing within ~~five (5)~~ 10 business days~~, to include copies of all related correspondence or reports,~~ when an adverse action has been taken against or may impact ~~related to~~ any of its transplant programs ~~has been taken~~ ~~any of the following events occur: (1) an adverse action that leads to or threatens material change in the status of the program's eligibility to perform or be reimbursed for organ transplants for Medicare or state Medicaid beneficiaries, in the status of the program's eligibility to perform or be reimbursed for organ transplants for Medicare or state Medicaid beneficiaries, including but not limited to initial approval of eligibility and any threatened or actual termination of eligibility; and (2) any threatened or actual adverse action~~ by ~~a state or federal~~ the regulatory agency of its respective jurisdiction or ~~its~~the regulatory agency's designee ~~(e.g., the Joint Commission on Accreditation of Healthcare Organizations) which would impose a significant limitation upon the program's ability to serve transplant candidates or recipients~~.

[No further changes to this section]

III. Histocompatibility Laboratories.

General. An independent histocompatibility laboratory that serves at least one Transplant Hospital that is active in the field of human organ transplantation within its service area (Histocompatibility Laboratory) is eligible for membership in the OPTN. For purposes of the OPTN Charter and Bylaws, independence from Transplant Hospital(s) served shall be defined by demonstration of a distinct governing body for the Histocompatibility Laboratory that is separate and not under the direct or indirect control of the governing body of any of the Histocompatibility Laboratory's Transplant Hospitals or of the governing body of a commonly controlled group of the Histocompatibility Laboratory's Transplant Hospitals.

To attain membership in the OPTN, such a laboratory must conform to the Standards for Histocompatibility Testing set forth in Attachment II and applicable sub-attachments. The evaluation of each applicant laboratory will be performed in accordance with the OPTN Bylaws.

Additionally, Histocompatibility Laboratories shall abide by applicable provisions of the National Organ Transplant Act, as amended, 42 U.S.C. 273 *et seq.*; the requirements set forth in the OPTN Final Rule, 42 CFR Part 121; these Bylaws; and OPTN policies.

Histocompatibility Laboratories shall also submit to reviews (including on-site reviews) and requests for information as may be necessary to determine compliance with the OPTN Final Rule, 42 CFR Part 121; these Bylaws; and OPTN policies. Failure to conform with such requirements shall be cause for corrective action described in Appendix A of these Bylaws.

Each Histocompatibility Laboratory shall fully inform the OPTN Contractor in writing within ~~five (5)~~ 10 business days, ~~to include copies of all related correspondence or reports,~~ when ~~any of the following events occur:~~

~~1)~~ an adverse action has been taken against it ~~that leads to or threatens material change in the laboratory's ability to perform histocompatibility testing or be reimbursed for the costs of such~~

~~testing by Medicare or a state Medicaid program, including but not limited to any threatened or actual termination of Medicare participation; and~~

~~(2) any threatened or actual adverse action~~ by ~~a state or federal~~ the regulatory agency of its respective jurisdiction or ~~its~~the regulatory agency's designee ~~that would impose a significant limitation upon the laboratory's ability to perform histocompatibility testing for the benefit of transplant candidates and recipients~~.

[No further changes to this section]

APPENDIX B TO BYLAWS
UNITED NETWORK FOR ORGAN SHARING

Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership

I. Organ Procurement Organizations.

General. An organization designated as an organ procurement organization by the Secretary of the Department of Health and Human Services (HHS) under Section 1138(b) of the Social Security Act or an organization that meets all requirements for such designation other than OPTN membership (OPO) is eligible for membership in the OPTN.

OPOs shall abide by applicable provisions of the National Organ Transplant Act, as amended, 42 U.S.C. 273 *et seq*.; the requirements set forth in the OPTN Final Rule, 42 CFR Part 121; these Bylaws; and OPTN policies.

OPOs shall also submit to reviews (including on-site reviews) and requests for information as may be necessary to determine compliance with the OPTN Final Rule, 42 CFR Part 121; these Bylaws; and OPTN policies. Failure to conform with such requirements shall be cause for corrective action described in Appendix A of these Bylaws.

Each OPO shall fully inform the OPTN Contractor in writing within ~~five (5)~~ 10 business days, ~~to include copies of all related correspondence or reports,~~ when ~~any of the following events occur: (1)~~ an adverse action has been taken against it ~~that leads to or threatens material change in the OPO's eligibility to procure organs or be reimbursed for organ procurement costs by Medicare or a state Medicaid program, including but not limited to any threatened or actual termination of Medicare designated status; and (2) any threatened or actual adverse action~~ by ~~a state or federal~~ the regulatory agency of its respective jurisdiction or ~~its~~the regulatory agency's designee ~~that would impose a significant limitation upon the OPO's ability to procure organs~~.

[No further changes to this section]

II. Transplant Hospitals.

A. General. A hospital (i) that aspires to perform organ transplants, as evidenced by submission of an active application for designated transplant program status for at least one organ type, or in which organ transplantation is performed, and (ii) that participates in the Medicare or Medicaid programs (Transplant Hospital) is eligible for membership in the OPTN.

Transplant Hospitals shall abide by applicable provisions of the National Organ Transplant Act, as amended, 42 U.S.C. 273 *et seq*.; the requirements set forth in the OPTN Final Rule, 42 CFR Part 121; these Bylaws; and OPTN policies.

Transplant Hospitals shall also submit to reviews (including on-site reviews) and requests for information as may be necessary to determine compliance with the OPTN Final Rule, 42 CFR Part 121; these Bylaws; and OPTN policies. ~~For each of its organ-specific transplant programs, a~~

A Transplant Hospital shall fully inform the OPTN Contractor in writing within ~~five (5)~~ 10 business days, ~~to include copies of all related correspondence or reports,~~ when ~~any of the following events occur: (1)~~ an adverse action an adverse action has been taken against or may impact ~~related to~~ any of its transplant programs ~~has been taken~~ ~~that leads to or threatens material change in the status of the program's eligibility to perform or be reimbursed for organ transplants for Medicare or state Medicaid beneficiaries, in the status of the program's eligibility to perform or be reimbursed for organ transplants for Medicare or state Medicaid beneficiaries, including but not limited to initial approval of eligibility and any threatened or actual termination of eligibility; and (2) any threatened or actual adverse action~~ by ~~a state or federal~~ the regulatory agency of its respective jurisdiction or ~~its~~the regulatory agency's designee ~~(e.g., the Joint Commission on Accreditation of Healthcare Organizations) which would impose a significant limitation upon the program's ability to serve transplant candidates or recipients~~.

[No further changes to this section]

III. Histocompatibility Laboratories.

General. An independent histocompatibility laboratory that serves at least one Transplant Hospital that is active in the field of human organ transplantation within its service area (Histocompatibility Laboratory) is eligible for membership in the OPTN. For purposes of the OPTN Charter and Bylaws, independence from Transplant Hospital(s) served shall be defined by demonstration of a distinct governing body for the Histocompatibility Laboratory that is separate and not under the direct or indirect control of the governing body of any of the Histocompatibility Laboratory's Transplant Hospitals or of the governing body of a commonly controlled group of the Histocompatibility Laboratory's Transplant Hospitals.

To attain membership in the OPTN, such a laboratory must conform to the Standards for Histocompatibility Testing set forth in Attachment II and applicable sub-attachments. The evaluation of each applicant laboratory will be performed in accordance with the OPTN Bylaws. Additionally, Histocompatibility Laboratories shall abide by applicable provisions of the National Organ Transplant Act, as amended, 42 U.S.C. 273 *et seq*.; the requirements set forth in the OPTN Final Rule, 42 CFR Part 121; these Bylaws; and OPTN policies.

Histocompatibility Laboratories shall also submit to reviews (including on-site reviews) and requests for information as may be necessary to determine compliance with the OPTN Final Rule, 42 CFR Part 121; these Bylaws; and OPTN policies. Failure to conform with such requirements shall be cause for corrective action described in Appendix A of these Bylaws.

Each Histocompatibility Laboratory shall fully inform the OPTN Contractor in writing within ~~five (5)~~ 10 business days, ~~to include copies of all related correspondence or reports,~~ when ~~any of the following events occur: 1~~) an adverse action has been taken against it ~~that leads to or~~

~~threatens material change in the laboratory's ability to perform histocompatibility testing or be reimbursed for the costs of such testing by Medicare or a state Medicaid program, including but not limited to any threatened or actual termination of Medicare participation; and (2) any threatened or actual adverse action~~ by ~~a state or federal~~ the regulatory agency of its respective jurisdiction or ~~its~~the regulatory agency's designee ~~that would impose a significant limitation upon the laboratory's ability to perform histocompatibility testing for the benefit of transplant candidates and recipients~~.

[No further changes to this section]

6. Overview of Annual Committee Goals: During the July meeting, updates were provided to the Committee on the goals that were approved for the 2009-2010 as well the goals that were tasked to the Committee in previous years. A list of the goals is provided below and each is addressed in more detail later in this report.
    - Review bylaws pertaining to program certification for currency and relevance. (Item 2).
    - Review the living donor program requirements for currency and relevance and to determine if the original goal of the requirements (to improve the process of living donation and transplantation through standardized levels of experience and quality) is being met. (Items 9 and 11)
        - Examination of program requirements regarding adult and pediatric living donor recoveries
        - Separation of care for living donors
        - Consideration of living donor program performance metric(s)
        - Implement, monitor, and oversee compliance with bylaws and policies pertaining to programs that do living donor transplants
    - Develop and consider use of pre-transplant program performance metrics for flagging. (Items 16).
    - Consider processes for reviewing programs with evolving problems, including post-transplant or personnel problems. (Items 2 and 16).
    - Participate in the bylaws rewrite project. (Items 2,3,4,5,9,10 and 12).
    - Clarification of member responsibilities for complying with bylaws and policies [such as conflicts of interest regarding declaration of death and organ procurement]. (Items 2, 4, and 5).
    - OPO Metrics: Continue to work with the OPO Committee to evaluate the use of OPO Metrics to assess performance (Items 12).

7. Program-Related Actions and Personnel Changes: During its July meeting, the Committee reviewed and accepted programs changing status by voluntarily inactivating or withdrawing from designated program status. Additionally, during the July meeting, the Committee reviewed 51 and approved 49 Key Personnel Changes.

8. Due Process Proceedings: During its July meeting, the Committee conducted interviews with three member transplant centers.

9. Living Donor Related Bylaws: During the July meeting, the Committee was updated on the plans to review the bylaws related to living donor transplantation. A joint work group comprised of members from the MPSC, Living Donor Committee, Pediatric Transplantation Committee, Kidney Transplantation Committee, and the Liver and Intestinal Organ Transplantation Committee was formed to discuss this issue. The Committee also reviewed preliminary feedback

from the Liver and Intestinal Organ Transplantation Committee on some questions regarding potential changes that had been discussed at a previous meeting. These recommendations will be considered by the joint work group as it develops proposals for amending the bylaws.

10. Bylaws Pertaining to Liver and Intestinal Transplant Programs: In a June 2009 memo, the MPSC asked the Liver and Intestinal Organ Transplantation Committee for input on the bylaws pertaining to liver transplant physicians. The MPSC has reviewed several applications where the individual being proposed as the primary liver transplant physician has not completed a gastroenterology fellowship, but has completed one in transplant hepatology and received board certification in Transplant Hepatology from the American Board of Internal Medicine (ABIM). These individuals meet the ABIM criteria for obtaining certification through a special pathway available to individuals who trained outside the U.S.

    The MPSC asked the Liver and Intestinal Organ Transplantation Committee (LIOTC) to review the bylaws related to the primary liver transplant physician requirements and provide feedback on the following:

    - Should the bylaws be expanded to include a pathway for individuals who have completed a transplant hepatology fellowship but did not complete a gastroenterology fellowship?
    - Should the board certification requirements be amended to allow Transplant Hepatology as an alternative to Gastroenterology Boards?

    During the July MPSC meeting, Dr. Pomfret reported that the LIOTC had met on July 15 and discussed this issue. It agreed that it is a complex matter and will require further discussion and input from the professional associations. The MPSC will be kept abreast of these ongoing discussions.

    Intestinal Transplant Program Requirements: During its October 2008, meeting the MPSC agreed to ask the Liver and Intestinal Organ Transplantation Committee (LIOTC) for input regarding activity levels for intestinal transplant programs as discussed by the Performance Metrics and Certification Work Group and for an update regarding their efforts to develop membership criteria for intestinal transplant programs. At present, intestinal transplant programs are not evaluated on an ongoing basis for activity, performance, or staffing.

    During the July meeting, Dr. Pomfret summarized the ongoing discussion of the LIOTC with regard to the requirements that were being considered for the surgeons. She indicated the development of physician requirements was difficult because of the multi-disciplinary approach to managing liver recipients. The MPSC will be kept informed of further developments.

11. Update on Policy 12.8.4 (Submission of Living Donor Death and Organ Failure Data): As required in Policy 12.8.4 (Submission of Living Donor Death and Organ Failure Data), transplant programs must report all instances of live donor deaths and failure of the live donor's native organ function within 72 hours after the program becomes aware of the live donor death or failure of the live donors' native organ function. The Committee reviewed three reported living donor kidney adverse events and found no policy violations or ongoing patient safety issues.

    Deaths Not Reported to the Patient Safety System: UNOS staff presented an analysis of living donor deaths since January 1, 2006, that were not reported to the Patient Safety System (PSS). Between 2006 and 2008, 26 living donor deaths occurred within 2 years of donation. Of these deaths, 15 were not reported through the PSS. Several programs did not know of the deaths and knowledge of them came from the Social Security Death Master File (SSDMF). Other programs reported the deaths via the Living Donor Follow-up form and stated that they were unaware of the policy requirement to report these deaths in the PSS. Some of the deaths occurred prior to July 1,

2006 when Policy 12.8.4 went into effect, so the programs were not required to report them. The Committee agreed to send Notices of Uncontested Violation to six kidney transplant programs who did not report living donor adverse outcomes through the PSS. The programs knew about these deaths because they did report them in the living donor follow up form. The notices were sent emphasizing the educational purpose for issuing them. The Committee conversed about the reasons why centers report losing living donors to follow up and then not providing desired information. The Committee expressed support for the ongoing work of the Living Donor Committee to develop minimum standards for complete data reporting and thresholds for center review.

The Committee considered several process related questions:

- Should potential Category I events be considered by larger group rather than a subcommittee?

There may be cases where the full committee should consider the issue rather than a subcommittee. The Committee agreed that it should be left up to the discretion of the Chair and Vice Chair.

- How should centers that did not report through the PSS be handled?

After July 1, 2006, it is a policy violation if the living donor adverse event falls under Policy 12.8.4 and an action needs to be taken by the Committee. Policy 12.8.4 requires reporting once a program knows, so the program cannot be held accountable for adverse events for which they have no knowledge i.e. solely by SSMDF discovery.

12. Inactive Bylaw Modification: During the July meeting, the Committee was informed that the Executive Committee approved its request that the Board approved bylaw language have an effective date of August 1, 2009. Additionally, the Committee affirmed the Data Subcommittee recommendation to review the reports of programs with inactive waiting lists and programs with candidates still on the waiting list after program inactivation before codifying a process for Data Subcommittee review.

13. OPO Performance Metrics Work Group: The OPO Performance Metrics Work Group, chaired by Charles Alexander, comprises members of the OPO Committee and the MPSC and is tasked with developing performance metrics to maximize the utilization of organs. The group first met in April 2008 and requested a data analysis from the SRTR to develop a model for calculating expected yield per donor. An ordinal logistic regression model was based on OPTN/UNOS data from June 1, 2000 to May 30, 2007 and included data on donors from whom at least one organ was transplanted. Factors in the model were derived from the deceased donor registration form. Factors that were considered to reflect OPO practices were deliberately excluded from the model. The model concordance was 0.8. From the model, 15 of 58 DSAs were identified as having an actual number of organs transplanted per donor that was significantly below expected ($p < 0.05$). An enhanced analysis was requested that would include more recent data as well as donors from whom no organs were transplanted.

14. Acceptance Rates: The SRTR presented a brief overview of the methodology for calculating organ and offer acceptance rates. Only organs that were accepted for transplant within the first 50 offers, or to the first 3 centers are included. Additional exclusions such as DCD, ECD and others ensure that only "good" organs are used in the analysis. Organ acceptance rates are based on offers to centers while offer acceptance rates are based on offers to individual candidates. The acceptance rate models will be included in the Composite Pre-Transplant Performance Metric. The Committee had no issues to discuss based on the presentation.

15. Modified Flagging Methodology: Continuing the Data Subcommittee's goal to review existing performance metrics and the ongoing work with the SRTR staff in modifying post-transplant outcome flagging methods, UNOS staff presented a retrospective analysis of the modified flagging criteria proposed by the SRTR. In summary, the analysis showed that using the proposed method, the Committee would flag fewer programs overall, while flagging more medium and high volume programs. The analysis also showed that the proposed method would flag > 80% of the programs considered"true positives" using the current flagging method and would flag fewer of the current false positives. The Data Subcommittee will consider the issue in more detail.

16. Composite Pre-Transplant Metric (CPM): UNOS staff presented a proposal for a new methodology for monitoring program specific pre-transplant outcomes, with an emphasis on detecting and preventing severe problems in a program's ability to serve its waitlisted patients. The Composite Pre-transplant Metric (CPM) takes into account risk-adjusted mortality rates, transplant rates and acceptance (organ and offer based) rates provided by the SRTR. Programs are ranked based on a single composite score that is a weighted sum of their pre-transplant observed-to-expected ratio of all four metrics, accounting for varying sample sizes across institutions. A working group will consider the merits of this approach for monitoring of pre-transplant performance.

17. OPO Committee Response Concerning Scanning Donor Serologies: The Committee requested that the OPO Committee consider requiring that OPOs scan serology source documents (as PDFs) into DonorNet® so that source documents may be viewed by the staff at potential recipients' transplant centers and OPOs during the organ offer process. The MPSC reviewed the OPO Committee's response during its July 2009 meeting.

    The OPO Committee agreed with the concept of providing source documents (when possible and available) and agreed that doing so would promote patient safety through accurate reporting of serology results. The OPO Committee further agreed that individual OPOs and centers should rely more on source documents as opposed to results that are transcribed. Unfortunately, many serology results, if not most, are not available when organs are offered and placed electronically through DonorNet, therefore it would be impossible to require them to be in the system for all organ offers. Many organ offers are accepted pending serology results and the recovery itself may occur without serologies being available. While the OPO Committee shares the MPSC's concern regarding accurate record keeping, members do not believe that faxing the source document at the time of making the organ offer is going to solve the record keeping issue. In terms of the patient safety issue, the source document should be provided to the team with the organ.

18. Data Coordination Responsibilities and Guidelines: The Committee sent a memo to the OPO, Histocompatibility, Transplant Administrators, and Transplant Coordinators committees requesting feedback on codifying the responsibilities and expectations for primary data coordinators in the bylaws. Feedback was not provided to the Committee in time for the July meeting.

19. Voting Status of Hospital Based OPOs and Laboratories: The Committee reviewed a June 26, 2009, letter that was co-signed by the executive directors of the eight hospital based organ procurement organizations (OPOs). In the letter they asked the MPSC to consider modifying the voting structure of the OPTN/UNOS to allow for hospital-based OPO's to have a vote on regional and national matters. Historically, these OPO's have been considered a part of the parent member (the transplant hospital) under which they applied, and they have shared a single institutional vote.

The Committee agreed that this request should be further reviewed and that at the same time the voting status of hospital-based laboratories should be examined. A work group was established to review this issue and report to the full Committee.

20. Patterns and Trends of Member Compliance and MPSC Actions: Staff presented a summary of trends of OPO and transplant center site survey results. Information included top policy violations found during site surveys, as well as the percentages of programs and centers that meet Committee thresholds for performance on routine and follow up surveys. Staff presented a possible path for future trend analysis to the Committee. The Committee agreed with the proposed path for continuing analysis.

21. Proposal to Include Non-Directed Living Donors and Donor Chains in the Kidney Paired Donation Pilot Program: The Committee reviewed the public comment proposal, which was sponsored by the Kidney Transplantation Committee. The proposal would allow non-directed (or altruistic) living donors to participate in the Kidney Paired Donation Pilot Program. In addition, this proposal would include donor chains as a matching option in the program in addition to two-way and three-way matching.

    The Committee agreed to support the proposal as written 18 For, 0 Against, 0 Abstentions.

22. Process for Letters of Reprimand, Probation, and Member not in Good Standing (MNGS): If the Committee considers recommending an adverse action such as Probation or Member Not in Good Standing or is considering issuing a Letter of Reprimand, the applicant or member is entitled to an interview. Historically, if a member waived its right to an interview for a proposed action, the department of evaluation and quality would, on behalf of the Committee, issue the proposed sanction without further committee deliberation. Staff requested that the Committee consider whether to formally standardize this practice in all cases where a member waives its right to an interview. The Committee decided that, when the Committee is considering issuing a Letter of Reprimand, if the member waives its right to an interview, the Committee would proceed to issue the Letter of Reprimand. If the Committee is considering recommending Probation or Member Not in Good Standing and the member waives its right to an interview, staff will inform the Committee that the member waived its right to an interview and ask the Committee to review the situation again in an expedited fashion for further consideration of the recommendation.

23. Organ Availability Committee (OAC) Memo Regarding Positive End-expiratory Pressure (PEEP) and SRTR Analysis: During the September 2009 conference call, the MPSC considered a request from the Organ Availability Committee (OAC) regarding a project to increase lung donor utilization. Programs that participate in a multi-center study regarding this project may be adversely affected by the current SRTR post-transplant survival analysis. The OAC requested that the MSPC not use the SRTR analysis flags for programs that are pursuing extended donor lung utilization.

    The Committee noted that the project was worthwhile, but that it could not exclude programs involved in the project from the outcomes analysis. The Committee will be mindful of programs that are identified and reminds the OAC that each program is provided the opportunity to disclose reasons for the exhibited lower than expected outcomes as identified. Additionally, the SRTR representatives to the Committee can provide additional analyses for the outcomes in these programs.

** RESOLVED, that the Committee supports the work of the OAC with regard to increasing lung donor utilization but cannot exclude these programs from the normal course of post-transplant survival reviews.

The Committee voted 22 For, 0 Against, 0 Abstention

24. Copying all Program Directors on Notices of Potential Adverse Actions: A Committee member asked the Committee to consider copying all program directors at an institution (each program specific director) when it is considering recommending an adverse action such as Probation or Member Not in Good Standing. This was recommended in several recent cases to ensure that all parties that may be affected by an institution-wide action be aware of the potential for adverse action.

    The Committee discussed the consequences to instituting this practice and agreed that all Program Directors should be copied when the Committee is considering an adverse action.

    ** RESOLVED, that the Committee recommends all Program Directors be copied on notices when the Committee is considering taking an adverse action against the member.

    The Committee voted 20 For, 2 Against, 1 Abstention

25. Data Subcommittee Name Change: The Data Subcommittee has been discussing changing its name to be more representative of the work it undertakes. The Data Subcommittee members voted on suggestions for new names using Survey Monkey. During the September 25, 2009, conference call, the MPSC considered and approved the new name.

    **RESOLVED, that the Committee agrees to change the name of the Data Subcommittee to the Performance Analysis and Improvement Subcommittee (PAIS).

    The Committee voted 22 For, 0 Against, 0 Abstentions

26. DCD Related Issues: The Committee had previously been tasked with reviewing transplant centers and OPOs to ensure that they were in compliance with the DCD Bylaws requiring that they have protocols to facilitate the recovery of organs from DCD donors. During the July meeting, the Committee was informed that one transplant hospital remains out of compliance with the policy requiring each approved transplant hospital to develop, implement and comply with a DCD organ recovery protocol. Center 25628D continues to address internal resistance with complying and intends on resolving the issues before the end of the year with the help of three new intensivists. These new staff members will be given the task of championing the DCD organ recovery effort and bringing the hospital into compliance. The Committee commented that reported progress is welcome news, but the resolution needs to be accomplished soon.

27. UNOS Actions: During the July meeting, the Committee members unanimously agreed that actions regarding Bylaws, Policy, and program-specific decisions made during the OPTN session would be accepted as UNOS actions.

    ** RESOLVED, that the Committee accepts those program specific determinations made during the meeting as UNOS recommendations. FURTHER RESOLVED, that the Committee also accepts the recommendations made relative to Bylaw and Policy changes.

During the September 25 conference call, the Committee unanimously approved the same resolution relative to actions taken during that meeting.

Participation at the Membership and Professional Standards Committee Meetings
July 22-23, 2009 and September 25, 2009

NAME	COMMITTEE POSITION	July 22-23, 2009	Sept 25, 2009 Conf Call
Charles Alexander RN, MSN, MBA, CPTC	Chair	X	X
David Mulligan, MD	Vice Chair	X	X
Elizabeth Pomfret, MD, PhD	Regional Rep.	X	X
David Klassen, MD	Regional Rep.	X	
Christopher Hughes, MD	Regional Rep.	X	X
David Nelson MD	Regional Rep.	X	X
Christopher Marsh MD	Regional Rep.	X	X
Karen Nelson Ph.D., D(ABHI)	Regional Rep.	X	X
Yolanda Becker MD, FACS	Regional Rep.	X*	X
Susan Dunn, MBA, RN, BSN	Regional Rep.	X	X
David Conti MD	Regional Rep.		X
Steven Rudich, MD, PhD	Regional Rep.	X*	X
Prabhakar Baliga, MD	Regional Rep.	X	X
Abbas Ardehali, MD	At Large	X	
Sharon Bartosh MD	At Large	X	X
Elaine Berg, MPA, FACHE	At Large	X	X
Jonathan Chen MD	At Large	X	X
Todd Dewey MD	At Large	X	
Udeme Ekong, MBBS, MRCP	At Large	X	
Barry Friedman RN, BSN, MBA, CPTC	At Large	X	X
Benjamin Hippen M.D.	At Large	X	X
Marjorie Hunter, ESQ	At Large	X	X
Ian Jamieson MBA, MHA	At Large	X	X
David Marshman, CPTC, BS	At Large	X	X
Jerry McCauley MD, MPH	At Large	X	X
Michael Mulligan MD	At Large	X	
Claus Niemann M.D.	At Large	X	
Todd Pesavento, MD	At Large	X	X
Shirley Schlessinger, MD	At Large	X	X
Roshan Shrestha, MD	At Large	X	
Betsy Walsh, JD, MPH	At Large	X	X
Mark Zucker, MD, JD	At Large	X	X
Christopher McLaughlin	HRSA	X	
Robert Walsh	HRSA	X	X
Charlotte Arrington MPH	SRTR Liaison	X	X

NAME	COMMITTEE POSITION	July 22-23, 2009	Sept 25, 2009 Conf Call
Jack Kalbfleisch	SRTR Liaison	X	
Robert Wolfe, Ph.D.	SRTR Liaison	X	
Sally Harris Aungier	Committee Liaison	X	X
David Kappus MAS	Committee Liaison	X	X
Elizabeth Coleburn	Support Staff	X	X
Rosey Edmunds	Support Staff	X	X
Erick Edwards Ph.D.	Support Staff	X	X
Mary D Ellison, Ph.D.	Support Staff	X	
Suzanne Gellner JD, CHC	Support Staff	X	X
Linda Gobis, BS, MN, JD	Support Staff	X	
Diana Marsh	Support Staff	X	
Karl McCleary Ph.D., M.P.H.	Support Staff	X	X
Kevin Myer	Support Staff	X	X
Heather Neil	Support Staff	X	
Jacqueline O'Keefe MBA	Support Staff	X	X
Ann Paschke	Support Staff	X	
Amy Putnam	Support Staff	X	
Leah Slife	Support Staff		X
Darren Stewart	Support Staff	X	
Robyn Zernhelt	Support Staff		X
Thomas Hamilton, CMS	Guest	X	

* Participated by conference call