

**OPTN/UNOS MEMBERSHIP AND PROFESSIONAL STANDARDS COMMITTEE REPORT**  
**September 17-18, 2007**  
**SUMMARY**

**I. Action Items for Board Consideration:**

- The Board of Directors is asked to approve one new transplant center (Item 1, Page 3).
- The Board of Directors is asked to approve for designated program status three new programs in existing member centers. The Board is also asked to approve three liver transplant programs to perform living donor transplants. (Item 1, Page 3).
- The Board of Directors is asked to approve continued membership for 11 organizations and Individual members. (Item 1, Page 3).
- The Board of Directors is asked to grant full approval to two liver programs that perform live donor liver transplants. The Board is also asked to grant one-year extensions of conditional status to five programs that perform living donor liver transplants as permitted in the Bylaws. (Item 1, Page 3).
- The Board of Directors is asked to approve modifications to Bylaws, Appendix B, Attachment I, Section XIII, C (2) Kidney Transplant Programs that Perform Living Donor Kidney Transplantation and Appendix B, Attachment I, Section XIII, C (4) Liver Transplant Programs that Perform Living Donor Liver Transplants. (Item 3, Pages 5-15).

**II. Other Significant Items:**

- Annual Committee Goals: During its August meeting, the Committee was presented with the Goals that had been approved for the year and the progress that had been made on each. (Item 2, Pages 3-5).
- Due Process Proceedings and Presentations: The Committee conducted four interviews, one hearing, and held one informal discussion with member organizations. (Item 4, Page 15).
- Offer/Organ Acceptance Rate Modeling: The Committee was updated on the Process Improvement Working Group's progress in the development of an agreeable methodology for collecting and analyzing organ acceptance/turndown rates and deaths on the waiting list, which can be used to evaluate program performance. (Item 5, Pages 15-6).
- Update on enforcement of mandatory Donation after Cardiac Death (DCD) protocols: The Committee was updated on UNOS staff efforts to solicit and obtain certification statements from all member OPOs and transplant hospitals attesting that they have and employ a mandatory DCD organ recovery protocol, which was effective July 1, 2007, and required as a condition for OPTN/UNOS membership. (Item 6, Pages 16-17).
- Program Related Actions and Personnel Changes: The Committee reviewed 62 key personnel change applications during its August meeting. (Item 7, Pages 17-18).

- Proposed Modification to Bylaws Appendix B, Section II, Paragraphs B and C: The Committee considered a proposal delineating when “informal discussions” may be held with an Institutional Member and determined that the proposal should be circulated for public comment. (Item 8, Page 18).
- Proposed Modification to Bylaws Appendix A, Section 3.01A Paragraphs (1) and (3) and Section 5.05A, Addition of Section 5.07A: A draft proposal was considered by the MPSC at its August 1-2, 2007, meeting. The purpose of the proposal is two-fold - to better define how a Member may be considered for restoration of full membership privileges, and to clarify the way to move from “Member Not in Good Standing” to a lesser action, such as probation. The Committee is requesting input from the Executive Committee prior to issuing a proposal for public comment (Item 9, Pages 18-19).
- Proposed Modifications to Policy 7.4 “*Submission of Organ-Specific Transplant Recipient Follow-up Form.*” The proposed modifications require transplant centers to report all recipient deaths that occur in the first year after transplant. After centers are notified of a recipient death, they have two working days to report this information to the OPTN using the UNet<sup>sm</sup> system. The Committee discussed this proposal and suggested that the Operations Committee consider revising the proposal to from two days to 72 hours to provide uniformity/consistency between other places in the Data Submission policies. (Item 10, Page 19).
- Review of Active Programs with Inactive Wait Lists: The Data Subcommittee discussed the potential to review active programs with inactive wait lists. Because of the extensive discussions, the Subcommittee formed a work group to further evaluate and codify a process for reviewing this metric. (Item 12, page 20).
- UNOS Actions: During the August meeting, 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 17, Page 22).

**REPORT OF THE  
OPTN/UNOS MEMBERSHIP AND PROFESSIONAL STANDARDS COMMITTEE  
TO THE  
BOARD OF DIRECTORS  
Los Angeles, CA  
September 17-18, 2007**

**Robert S. D. Higgins, M.D., Chair  
Carl L. Berg, M.D., Vice Chair**

I. Regular Committee Meetings. The Membership and Professional Standards Committee's (MPSC) met on July 31 – August 2, 2007. On July 31, the staff conducted a half-day training session for the Committee. The training session was followed by meetings of the Policy Compliance and Data Subcommittees. The full Committee met on August 1-2, and its deliberations and recommendations are provided below.

1. Membership Application Issues: The Committee recommends that the Board of Directors approve one new transplant center, three new programs in existing member centers, and three liver programs to perform live donor transplants.

In addition to considering applications for institutional membership, the Committee reviewed applications for continued medical/scientific and public organization membership, and applications for new Business and Individual Membership (two-year terms).

Reports from Conditionally Approved Programs: During its August 2007 meeting, the Committee approved a change in status of one liver program that performs live donor transplants and one pancreas program from 12-month conditional approval to full approval. The liver program was initially conditionally approved pending performance of seven live donor hepatectomies by the second primary surgeon. The pancreas program was initially conditionally approved pending acquisition of additional clinical experience on an active pancreas transplant service by the primary physician.

The Committee also reviewed five living donor liver programs that had requested an additional year of conditional status as allowed by the Bylaws, and agreed that the programs had demonstrated adequate progress to qualify for extensions.

Additionally, the Committee reviewed a kidney transplant program that had previously voluntarily inactivated and approved reinstatement of the program's active status.

The Committee reviewed bimonthly progress reports for three transplant programs (one kidney and two heart programs) that were conditionally approved for 12 months to provide time for the primary physician to meet the full primary physician criteria or to allow the program to recruit a physician who fully meets primary physician criteria. The Committee also reviewed a progress report from a kidney program whose primary surgeon was approved under the pediatric pathway with bi-monthly reporting stipulations.

2. Overview of Annual Committee Goals: During its August meeting, an update was provided to the Committee on the goals that were approved for the year and the progress that had been made on each. A summary of the goals and the progress made on each is described below:

- Goal: Develop the process for action on referrals made to MPSC as a result of the new policy requiring notification of death or listing for transplant of a living donor.  
Progress: Members were informed of the requirement and have begun to use the new online reporting option in the Patient Safety System that was activated on January 3, 2007.
- Goal: Partner with Living Donor Committee to determine what policies are needed to provide oversight of living donor programs (donor safety and patient outcomes).  
Progress: A Working Group was formed to develop changes to the bylaws that would further ensure living donor safety. Proposed changes to the Bylaws were distributed for public comment on July 13, 2007 (See Section 3 of this report for additional details).
- Goal: Participate in the working group to be established by the OPO Committee to develop the required elements of the mandated DCD protocols.  
Progress: MPSC members participated in the DCD Working Group to develop protocol guidelines. The Board approved modifications to the Bylaws that establish model elements to be included in DCD protocols, during its December 2006 meeting.
- Goal: Consider any policy or procedures that need to be put in place to support violations of the newly passed policy that requires all DCD procurements to be done in accordance with an established protocol.  
Progress: During the October Meeting of the MPSC, a DCD Policy Subcommittee was established and charged with developing policy and methods for monitoring and enforcing compliance as it pertains to the oversight of approved DCD protocols. The MPSC was given a progress report during its August meeting. (See Section 7 below for additional details).
- Goal: Continue work with SRTR to develop organ specific acceptance rate metrics of center performance.  
Progress: The SRTR provided acceptance rate data factoring in a couple of newly identified variables. The MPSC Process Improvement Work Group 1 continues to meet by conference call to discuss this issue and has recommended a pilot study through the Data Subcommittee. The MPSC was given a progress update during its August meeting. (See Section 5 below for additional details).
- Goal: Provide a 6-month update to Board on progress or changes made in implementing the 2006 MPSC improvement project.  
Progress: A report was included in the June 2007 report to the Board of Directors as well as this document.
- Goal: Provide to the Finance Committee prior to the March 2007 Board meeting, an update on budgetary needs for next financial year.  
Progress: Developed budgetary needs and presented them to the Finance Committee.

The Committee was also given a tentative list of the Goals for 2007-2008. This list includes the following items:

- Rewrite the Bylaws with an updated format and plain language.
- Performance Measures: Complete a retrospective review of current processes and implementation of new performance measures.
- Initiate the application process for live donor kidney transplantation.

- Initiate and complete the audit of transplant surgeons and physicians and update the database accordingly to indicate which individuals meet the new criteria for “additional” surgeon/physician.
  - Collect and process Program Coverage Plans from all existing transplant programs.
  - Review transplant centers and OPOs that are not in compliance with the new DCD Bylaws requiring that they have protocols to facilitate the recovery of organs from DCD donors.
  - Work with Research staff to develop General OPTN System Metrics that address areas such as donors, waiting list, outcomes, and life years and net benefit.

The Committee also discussed its work in terms of the HHS Program Goals and the Strategic Plan Goals. While the goals are not necessarily specific to the work of the Committee, the Committee agreed that it has a role with increasing DCD.

3. Proposed Modifications to the Living Donor Requirements: A proposal for changes to the Bylaws is being presented to the Board for approval. The modifications will establish additional minimum criteria for granting designated program status to programs that perform living donor kidney and liver transplants. These revised bylaws will further ensure that living donor kidney and liver transplant programs have essential elements in place for the evaluation, consent, and follow-up of living donors. The proposed modifications were circulated for public comment as separate kidney and liver proposals but for the purposes of this report and the attached briefing paper (Exhibit M-1) they have been combined. Except for the Medical Evaluation section, the language in these proposals is nearly identical. Many of the comments submitted were identical for each proposal. Based on the Committee’s opinion that it is important to highlight the background and significance of the development of these proposed modifications, the following information is provided:

Background and Significance: The transplant community recognizes its responsibility to make the process of living donation as safe and effective as possible for all involved. Donors make a tremendous sacrifice by assuming the risk of possible physical harm and/or death when they undergo actual donation. The Bylaws presently focus on the general qualifications of a transplant center requesting to be designated to perform the transplant procedure. These proposed changes to the bylaws require transplant programs to have basic resources and protocols that will help ensure that a prospective living donor has all the information needed to make an informed decision. While the proposed bylaws do not dictate medical practice, they provide a framework that each program must incorporate into their current living donation protocols, while at the same time providing the OPTN with the basic tools that are needed to evaluate performance and respond to complaints.

The following guiding principles were used by the Committee as it developed the proposed modifications to the Bylaws:

- The potential living donor must be competent to make a decision.
- The potential living donor must be free to withdraw at any time from the process without consequence.
- The potential living donor must be free from coercion.
- The potential living donor is given appropriate information necessary to make a decision for or against donation, including medical risk, social consequences, and financial consequences.

- Assurance is given that information about the living donor will not be disclosed to other individuals (except as mandated by law and good medical practice) without the consent of the individual.
- The potential living donor is given enough time to make a good decision and that an independent advocate is available to help with the decision.
- The procedure will be performed by people with appropriate training and experience.
- The living donor will be given appropriate medical care until recovered from the donation procedure.

Background: The Bylaws currently establish extensive membership criteria for deceased donor transplantation programs as well as transplant programs that perform living donor kidney and liver transplants. These proposed requirements are considered an important step to further protect the health and safety of all living donors and are being proposed in response to a directive from HRSA (see below). The requirements will help create a standardized level of quality among the growing number of programs that perform living donor transplants.

In 2002, the Ad Hoc Living Donor Committee was formed and began the process of developing requirements for programs that perform living donor transplants. The Committee developed, with input from other OPTN committees, minimum standards for programs that perform living kidney and liver donor transplants. The requirements were circulated for public comment and approved by the OPTN Board of Directors in 2003. Until 2003, OPTN policies predominately focused on issues related to deceased organ donation and transplantation. Several widely publicized living donor deaths and the increased incidence of altruistic living donation prompted concern that this area of transplantation may not have sufficient oversight. Additionally, the Living Donor Committee developed, through the same committee and public comment process, guidelines for living donor evaluation. The Board of Directors approved these guidelines in June 2004.

Authority to Develop Living Donor Requirements: The authority for the OPTN to develop and implement policies and standards is described in an October 29, 2004, letter from James S. Burdick, M.D., Director, Health Resources and Services Administration, Department of Health and Human Services (HHS). That letter states the following:

*“However, the Final Rule also provides that the OPTN shall be responsible for developing policies on a variety of topics, including ‘policies on such other matters as the Secretary directs. ‘In accordance with the authority, HRSA, HSB, DoT is directing the OPTN to develop allocation guidelines for organs from living donors. These guidelines should be limited to the allocation of organs from living donors made to an anonymous pool, and not to organs procured in connections with directed donations. The DoT also is directing the OPTN to develop other voluntary policies/guidelines (not pertaining to organ allocation) it believes necessary and appropriate to promote the safety and efficacy of living donor transplantation for the donor and the recipient.’”*

On January 23, 2006, a notice was issued in the Federal Register soliciting comments regarding whether criteria developed by the OPTN addressing living donation should be given the same status, and be subject to the same enforcement actions, as other OPTN policies. After considering public comment on this issue, the Department of Health and Human Services determined that OPTN living donor guidelines should be given the same status of other OPTN policies. Further, the Secretary directed the OPTN to develop policies regarding living organ donors and living organ donor recipients, including policies for the equitable allocation of living donor organs. The

final directive was published in the Federal Register, Vol. 71, No. 116 on June 16, 2006, and stated the following:

*“HRSA has reviewed and considered each aspect of each comment and has determined that OPTN living donor guidelines should be given the same status of other OPTN policies as discussed in the Federal Register Notice published on January 23, 2006. Under 42 CFR 121.4(a)(6), the Secretary directs the OPTN to develop policies regarding living organ donors and living organ donor recipients, including policies for the equitable allocation of living donor organs, in accordance with section 121.8 of the final rule. Thus, the OPTN shall develop such policies in the same manner, and with the same public comment process, that it does for policies on deceased organ donors and deceased organ donor recipients. Non-compliance with such policies shall subject OPTN members to the same consequences as noncompliance with policies concerning deceased organ donors and deceased organ donor recipients developed under the final rule.”*

A copy of the full text of this section of the Federal Register is provided as Attachment 3 to Exhibit M-1.

Relationship to CMS Conditions of Participation: While the OPTN Committees were working on the proposed Bylaws, the Medicare Conditions of Participation (CoPs) were also under development. These requirements were published in the Federal Register, Vol. 72, No. 61, Friday, March 30, 2007. The roles of CMS and the OPTN are addressed in the comments section for the regulations. It states the *“OPTN’s primary responsibilities are to ensure the effectiveness, efficiency, and equity of organ allocation, increase the supply of transplantable organs, collect and disburse data, and designate transplant programs.”* CMS is *“responsible for establishing minimum standards to protect patient health and safety, and for implementing oversight mechanisms to ensure that transplant centers provide quality transplant and living donor care to Medicare beneficiaries through the development of health and safety requirements.”* The OPTN’s role can be described as that of a facilitator, not a regulator while HHS has regulatory oversight responsibilities. By facilitating organ transplantation, the OPTN provides services and conducts medical peer review for the purposes of continuous quality and performance improvement. This issue of the Federal Register further summarizes the focuses of CMS and OPTN requirements as shown below:

Main Focuses of CMS Requirements

- *Regulatory oversight of transplant centers.*
- *Patient care & transplant services furnished to beneficiaries.*
- *Relationship with transplant centers based on Provider Agreement & Medicare reimbursement.*
- *Medicare approval & re-approval based on compliance with Conditions of participation (CoPs).*
- *Provider responsibilities.*

Main focuses of OPTN Policies/Bylaws.

- *Organ allocation.*
- *Credential of transplant surgeons/physicians.*
- *Relationship with transplant hospital members is collegial with the goal to help them to improve performance.*
- *OPTN Membership application reviewed by peer reviewers.*
- *Member obligations.*

Bylaw Development Process: Based on the 2004 directive from HRSA, the Membership and Professional Standards Committee (MPSC) began evaluating living donor liver transplant program applications in 2005. This review was conducted using the Bylaws that were approved in 2003, and in March 2006, amended to include a conditional approval option. While conducting these reviews the Committee became concerned that the requirements did not go far enough to ensure the safety of the living donor in accordance with the HRSA mandate.

The MPSC placed on hold the process of reviewing and approving approximately 240 programs that perform living donor kidney transplants until these proposed requirements could be developed and approved. The Committee wanted to ensure that centers not only have in place experienced key personnel, but the other essential elements to be approved as a living donor center as well. To minimize the burden placed on the members, the Committee agreed that the application process should be delayed so that the currently proposed changes could be incorporated into the forms and a single review process could be conducted.

While the MPSC was evaluating living donor liver transplant program applications, the Living Donor Committee was simultaneously addressing a multitude of issues in living donation, including the consent process, medical evaluation, and follow-up of living donors. In order to prevent duplication of efforts between the two committees, a Living Donor Policy Advisory Work Group was formed in October 2006, and included members from both the MPSC and the Living Donor Committee. The Living Donor Policy Advisory Work Group began their work based on the principles listed on the preceding page as well as the following objectives:

1. Further develop the minimum set of criteria for granting designated program status to centers performing living donor transplants.
2. Ensure adequate donor education/informed consent.
3. Work-up of potential donors: Determine whether there should be guidelines or a minimum set of required elements?

Endorsed by the MPSC and the Living Donor Committee, the Work Group proposed modifications to the Bylaws pertaining to programs that perform living donor kidney and liver transplants. The issues discussed by the MPSC during its initial review included:

- What are the key elements for programs that perform living donor transplants?
- It is important for the Bylaws to be monitorable, but not overly proscriptive.
- Independent Donor Advocate (IDA):
  - What is the specific function of a donor advocate?
  - How do you measure the adequacy of the IDA or of the proposals?
  - Independent Donor Advocate (IDA) or IDA team? The Committee agreed that there should be an IDA member who is a physician and who is not involved with the evaluation and decision to transplant a potential recipient. The Committee agreed that the use of an IDA or IDA team should be flexible since different centers have different approaches. They incorporated their suggestions into the proposal.
  - Concern about identifying a person who can be completely uninvolved in transplant yet be knowledgeable and able to advise living donors.
  - Should a guideline be developed for the committee to use when evaluating a center's performance relative to the IDA?

- The Committee agreed that the Bylaws should delineate what a program must have in order to receive initial approval to perform living donor transplants, and the requirements that must be met to maintain approval once it has been granted.

The Work Group met by conference call and held electronic discussions. They reviewed and incorporated certain recommendations from the Advisory Committee on Organ Transplantation (ACOT), Centers for Medicare and Medicaid Services (CMS), the American Society of Transplantation (AST), and the State of North Carolina living donor statutes in the development of these guidelines. The Work Group also considered other papers such as the “*Report of the Amsterdam Forum on the Care of the Live Kidney Donor: Data and Medical Guidelines. Transplantation*” and “*The Ethics Statement of the Vancouver Forum on the Live Lung, Liver, Pancreas, and Intestine Donor. Transplantation.*” The Committee was particularly aware of the need to develop proposals that are complemented the CMS requirements.

During the May 18, 2007, Executive Committee meeting, Dr. McDiarmid requested that a Living Donor Committee (LDC)/MPSC Task force be formed to reconcile the proposed LDC and MPSC living donor bylaws and guidelines. Dr. Robert Higgins was asked to lead this task force. After further debate and discussion, the task force agreed to distribute for public comment the proposed modifications to OPTN/UNOS Bylaws, Appendix B, Attachment I, Sections XIII, C (2) and (4).

The proposed requirements for centers that perform living donor transplant included the following concepts:

- Program must have an independent donor advocate (IDA) or an IDA team.
- Program must develop and comply with written protocols to address all phases of the living donation process.
- Program must have written protocols that include the following elements:
- Description of duties and primary responsibilities of the IDA or IDA team members.
- A thorough medical evaluation by a physician and/or surgeon experienced in living donation.
- Program must have written protocols for informed consent for the donor evaluation process and informed consent for the donor nephrectomy.

Final Proposal: The MPSC met on August 1-2, 2007, and considered the input received to date from individuals, the Regions, associations, and other OPTN/UNOS Committees. The public comment period would not end until August 11; therefore, the Committee was unable to make final recommendations on the proposals, but they did agree that the IDA language in the proposal could be amended and asked the working group to finalize the language. The Committee agreed, by a vote of 22 For, 0 Against, and 2 Abstentions, to empower the working group to finalize the language in the proposals.

The MPSC/Living Donor Policy Working Group convened by conference call on August 13, 2007, to discuss the comments that had been received. The Work Group took under consideration comments received from individuals, the regions, and from other Committees and has recommended modifications to the proposal that was circulated for public comment.

The Work Group observed that the comments for the most part fell into one of the following categories:

- The transplant community does not fully appreciate the OPTN’s mandate to develop living donor policies.

- The Bylaws and guidelines proposals are viewed as dictating medical practice, and are too prescriptive.
- The transplant community believes that implementing the Bylaws and guidelines will increase costs.
- The transplant community believes the Bylaws should be more closely aligned with the Medicare Conditions of Participation (COP) for Medicare approved programs.

Responses to the specific comments can be found in the “Summary of Comments” section in Exhibit M-1.

Summary of Modifications Recommended Following the Public Comment Period: In response to the comments, the proposals have been amended to state that the center must have an Independent Donor Advocate (IDA) who is not involved with the evaluation and decision to transplant the potential recipient. The initially proposed language indicating that if a center has a single IDA it must be a physician, has been removed. The changes made to the IDA language more closely align with the Medicare COP for Medicare approved programs.

Additionally, language has been added to further clarify that the center must have personnel and resources available to assess the medical condition and risks for the potential donor; and to conduct a thorough psychosocial assessment.

Changes have been proposed to the sections on informed consent to clarify that the center is responsible for having a written protocol for notifying donors of the plan for collecting follow up information for the donor on the Living Donor Follow-up form. This language restates the reporting schedule that is delineated in Policy 7.3.2 (Submission of Organ Specific Transplant Recipient Registration Forms and Submission of Living Donor Registration Forms).

The medical evaluation section of the proposal for living donor liver transplantation has been modified. The proposed bylaw for the radiographic assessment has been made less prescriptive by removing the requirement for vascular and biliary imaging.

The Working Group agreed to amend the proposals in response to the comments that had been received and the direction provided by the MPSC. Based on this recommendation the following resolution is presented to the Board of Directors for their consideration.

**\*\* RESOLVED that the Bylaws, Appendix B, Sections III, C(2) and C(4) shall be modified as set forth below and shall be effective upon approval by the Board of Directors, and pending notice to the members.**

Following the conclusion of the conference call meeting on August 13, the Work Group members reviewed the final proposed language by electronic means. The members suggested some additional minor modifications to the language but there was not time to circulate these recommended changes for additional consideration prior to the due date for this report. Additionally, the Kidney Transplantation Committee met on August 14 and reconsidered the proposed modifications. The Kidney Transplantation Committee made a recommendation to amend the language in Kidney Section 2, b,ii(d) and Liver Section 4, 2, ii(d). This recommendation was accepted by the MPSC Chair.

*(The final version of the Bylaws, as approved by the Board of Directors at its September meeting, will be posted on [www.unos.org](http://www.unos.org) and [www.optn.org](http://www.optn.org) ).*

The proposed modifications to the Bylaws that were made following public comment are shown below as double underlines and ~~double~~ strikeouts. Further recommendations received after the committee conference call but without time for a final vote are shown as double underline, bold, and in *italics*.

**Final – Proposal**  
**Proposed Modifications to Bylaws, Appendix B, Attachment I, Section XIII, C (2),**  
**Designated Transplant Program Criteria**

**XIII. Transplant Programs.**

- A. No changes
- B. No changes
- C (1) No changes

**(2) ~~Living Donor~~ Kidney Transplant Programs that Perform Living Donor Kidney Transplantation.**

~~A. Living Donor Kidney Transplant Programs~~

1. Kidney Transplant Programs that Perform Living Donor Kidney Transplantation ~~A Living living donor kidney transplant program~~ must demonstrate the following regarding personnel and resources:

- (a) That the center meets the qualifications of a renal transplant program as set forth in (Section (1) above; and)
- (b) In order to perform open donor nephrectomies, a qualifying renal donor surgeon must be on site and must meet the criteria of (i) and/or (ii) below:
  - (i) Completed an accredited ASTS fellowship with a certificate in kidney, or
  - (ii) Performed no fewer than 10 open nephrectomies (to include deceased donor nephrectomy, removal of polycystic or diseased kidneys, etc.) as primary surgeon or first assistant within the prior 5-year period.
- (c) If the center wishes to perform laparoscopic donor nephrectomies, a qualifying renal donor surgeon must be on site and must have:
  - (i) Acted as primary surgeon or first assistant in performing no fewer than 15 laparoscopic nephrectomies within the prior 5-year period.

If the laparoscopic and open nephrectomy expertise resides within different individuals then the program must demonstrate how both individuals will be available to the surgical team. It is recognized that in the case of pediatric living donor transplantation, the Living organ donation may occur at a center that is distinct from the approved transplant center.

All surgical procedures identified for the purpose of surgeon qualification must be documented. Documentation should include the date of the surgery, medical records identification and/or UNOS identification number, and the role of the surgeon in the operative procedure.

- d) The center must have the resources available to assess the medical condition *of and any* risks for the individual for potential *living* donation;
  - e) The psychosocial assessment should include the *potential donor's* capacity to make an informed decision and to affirm the voluntary nature of proceeding with the evaluation and donation; and
  - f) That the center has ~~either an independent donor advocate (IDA) who is a physician, or an independent donor advocate team, which includes at least one member who is a physician and at least one member who is not involved with the evaluation and decision to transplant the potential recipient and who fulfills the duties listed in Section 2 (b) below.~~
2. Kidney Transplant Programs that Perform Living Donor Kidney Transplantation must demonstrate that they have the following ~~regarding~~ protocols:
- a) Living Donor Transplant centers must develop, and once developed must comply with written protocols to address all phases of the living donation process. Specific protocols shall include the evaluation, pre-operative, operative, post-operative and two-year follow-up period after donation.

Transplant centers must document that all phases of the living donation process were performed in adherence to the center's protocol. This documentation must be maintained and made available upon request.
  - b) Written protocols must include, but are not limited, to the following elements:
    - i) a description of the duties and primary responsibilities of the IDA ~~or IDA Team members as described in 1 (d) above,~~ to include procedures that:
      - (a) protect and promote the best interests of the potential living donor;
      - (b) ensure protection of the rights of the living donor; and
      - (c) provide the potential donor with information regarding the:
        - (i) consent process;
        - (ii) evaluation process;
        - (iii) surgical procedure; and
        - (iv) benefit and need for follow-up.
    - (ii) a thorough medical evaluation by a physician and/or surgeon experienced in living donation including:
      - (a) a screen for any evidence of occult renal and infectious disease or medical comorbidities which may cause renal disease;
      - (b) age appropriate cancer screening;
      - (c) a radiographic assessment to evaluate vascular anatomy and any congenital malformation; and
      - (d) a psychosocial evaluation of the potential living donor by a psychiatrist, psychologist, or social worker with experience in transplantation (criteria defined in Appendix B, Attachment I, ~~Section C (17))~~ to determine *decision making capacity competency*, screen for any pre-existing psychiatric illness, and/or any potential coercion.

- c) The center shall have written protocols for the Informed Consent for the Donor Evaluation Process and Informed Consent for the Donor Nephrectomy, which include, at a minimum, the following elements:
- (i) discussion of the potential risks of the procedure including the medical, psychological and financial risks associated with being a living donor.
  - (ii) assurance that all communication between the *potential* donor and the transplant center will remain confidential;
  - (iii) discussion of the donor's right to opt out at any time during the donation process;
  - (iv) discussion that the medical evaluation or donation may impact the donor's ability to obtain health, life and disability insurance; *and*
  - (v) disclosure by the transplant center that it is required, at a minimum, to *submit contact and obtain follow up* Living Donor Follow-up forms addressing the health information on of each living donor at 6 months, one-year, and two-years post donation. The protocol must include a plan to collect the information about each donor.

**(3) No changes**

**(4) Liver Transplant Programs that Perform Liveing Donor Liver Transplants.**

1. ~~A live donor liver transplant center must demonstrate the following:~~ Liver Transplant Programs that Perform Living Liver Transplants~~ation~~ must demonstrate the following regarding personnel and resources:
  - a) That the center meets the qualifications of a liver transplant center as set forth ~~in UNOS Bylaws, Appendix B, Attachment I, Section XIII~~~~(=and)~~,
  - b) That the center has on site no fewer than two surgeons who qualify as liver transplant surgeons under UNOS Bylaws Appendix B, Attachment I, Section XII(C)(2)(a) and who have demonstrated experience as the primary surgeon or first assistant in 20 major hepatic resectional surgeries (to include living donor operations, splits, reductions, resections, etc.), 7 of which must have been live donor procedures within the prior 5-year period. These cases must be documented. Documentation should include the date of the surgery, medical records identification and/or UNOS identification number, and the role of the surgeon in the operative procedure. It is recognized that in the case of pediatric living donor transplantation, the live organ donation may occur at a center that is distinct from the approved transplant center;
  - c) The center must have the resources available to assess the medical condition of and any risks for the individual for potential *living* donation;
  - d) The psychosocial assessment should include the *potential donor's* capacity to make an informed decision and to affirm the voluntary nature of proceeding with the evaluation and donation; and
  - e) ~~That the center has either an independent donor advocate (IDA) who is a physician, or an independent donor advocate team, which includes at least one member who is a physician and at least one member who is not involved with the evaluation and decision to transplant the potential recipient and who fulfills the duties listed in Section 2 (b) below.~~

2. Liver Transplant Programs that Perform Living Liver Transplantation must demonstrate that they have the following protocols:

- a) Living Donor Transplant centers must develop, and once developed must comply with written protocols to address all phases of the living donation process. Specific protocols shall include the evaluation, pre-operative, operative, post-operative and two-year follow-up period after donation.

Transplant centers must document that all phases of the living donation process were performed in adherence to the center's protocol. This documentation must be maintained and made available upon request.

- b) Written protocols must include, but are not limited, to the following elements:

- i) a description of the duties and primary responsibilities of the IDA ~~or IDA Team members as described in 1 (d) above~~, to include procedures that:

(a) protect and promote the best interests of the potential living donor;

(b) ensure protection of the rights of the living donor; and

(c) provide the potential donor with information regarding the:

(i) consent process;

(ii) evaluation process;

(iii) surgical procedure; and

(iv) benefit and need for follow-up.

- (ii) a thorough medical evaluation by a physician and/or surgeon experienced in living donation including:

(a) a screen for any evidence of occult liver disease;

(b) age appropriate cancer screening;

(c) a radiographic assessment to ensure adequate ~~graft and remnant liver~~ volume ~~as well as vascular and biliary imaging to ensure and inflow and outflow is preserved in~~ of the graft and the remnant liver; and

(d) a psychosocial evaluation of the potential living donor by a psychiatrist, psychologist or social worker with experience in transplantation (criteria defined in Appendix B, Attachment ~~I-X~~) must also be provided to assess decision making capacity competency, screen for any pre-existing psychiatric illness, and any potential coercion.

- c) The center shall have has written protocols for Informed Consent for the Donor Evaluation Process and Informed Consent for the Donor Hepatectomy, which include at a minimum the following elements:

(i) discussion of the potential risks of the procedure including the medical, psychological and financial risks associated with being a living donor;

(ii) assurance that all communication between the potential donor and the transplant center will remain confidential;

(iii) discussion of the donor's right to opt out at any time during the donation process;

(iv) discussion that the medical evaluation or donation may impact the donor's ability to obtain health, life and disability insurance; and

(v) disclosure by the transplant center that it is required, at a minimum, to submit contact and obtain follow-up Living Donor Follow-up forms addressing the health information on of each living donor at 6 months, one-year, and two-years post donation. The protocol must include a plan to collect the information about each donor.

3.2. Conditional Approval Status: If the transplant center does not have on site a second surgeon who can meet the requirement for having performed 7 live donor liver procedures within the prior 5-year period, but who has completed the requirement for obtaining experience in 20 major hepatic resection surgeries (as described above), as well as all of the other requirements to be designated as a primary liver transplant surgeon, the program may be eligible for Conditional Approval Status. The transplant program can be granted one year to fully comply with applicable membership criteria with a possible one year extension. This option shall be available to new programs as well as previously approved programs that experience a change in key personnel. During this period of conditional approval, both of the designated surgeons must be present at the donor's operative procedure.

The program shall comply with such interim operating policies and procedures as shall be required by the Membership and Professional Standards Committee (MPSC).

This may include the submission of reports describing the surgeon's progress towards meeting the requirements and such other operating conditions as may be required by the MPSC to demonstrate ongoing quality and efficient patient care. The center must provide a report prior to the conclusion of the first year of conditional approval, which must document that that the surgeon has met or is making sufficient progress to meet the objective of performing 7 live donor liver procedures or that the program is making sufficient progress in recruiting and bringing to the program a transplant surgeon who meets this criterion as well as all other criteria for a qualified live donor liver surgeon. Should the surgeon meet the requirements prior to the end of the period of conditional approval, the program may submit a progress report and request review by the MPSC.

The transplant program must comply with all applicable policies and procedures and must demonstrate continuing progress toward full compliance with Criteria for Institutional Membership.

The program's approval status shall be made available to the public.

4. Due Process Proceedings and Informal Discussions: The Committee conducted four interviews, one hearing, and held one informal discussion with member organizations. Summaries of the proceedings are provided below.
5. Offer/Organ Acceptance Rate Modeling: The Committee received an update on the Process Improvement Working Group's efforts in developing an agreeable methodology for collecting, analyzing, and applying organ acceptance/turndown rates and deaths on the waiting list, which can be used to evaluate program performance. This working group was formed following the November 2005 Board meeting, where the Executive Committee and the Board of Directors directed the Membership and Professional Services Committee (MPSC) to form a working group composed of members of the MPSC and the Board of Directors to identify improvements for, and propose changes to, the membership review processes and standards. Ultimately, the larger working group split into three smaller groups that each worked on specific initiatives that are described in Section 13 of this report. Work Group 1 was tasked with this effort.

Background: The intended purpose of the metric is to identify programs that are inappropriately inactive and may pose a risk to patient safety. The Working Group agreed that each analysis will have to be organ specific to account for unique clinical and logistical characteristics, and requested that the Scientific Registry of Transplant Recipients (SRTR) create multi-variable models comparing actual to expected acceptance rates (looking at both offers and organs offered) for each organ starting with kidney, liver, and then the other organs.

Progress: A timeline was presented, which provided a chronology of the work beginning in January 2006 to this point. The “good organ” criterion was presented by staff member, David Kappus, UNOS Assistant Director of Membership, and commented upon by SRTR staff. “Good organ” criteria are defined as kidney or livers transplanted within 50 offers and/or by one of the first 3 centers receiving an offer. Both offer acceptance and organ acceptance are measured. The acceptance rate information for kidney and liver programs had been placed by SRTR on the programs’ private sites for review. A couple of criteria for data inclusion in the analysis were discussed between the Working Group and SRTR. The SRTR was scheduled to publicly release this center specific data to the public on January 11, 2007, but was delayed after some discussion regarding possible variances in acceptance practices by region, which may affect the results at certain centers. A SRTR reanalysis of the calendar year 2006 acceptance rate data for both kidney and liver was given to the Working Group in June 2007.

The profiles of the programs, which were identified in the analysis, are currently being reviewed so the Working Group can convene in August 2007 to discuss the next recommendation regarding the use of this metric. The acceptance rate model was developed as a tool for identifying programs whose observed acceptance rates fell significantly below their expected and has identified four programs that subsequently closed, so it is capturing useful information and needs to be evaluated further. Some discussion has occurred regarding delaying further development of any acceptance rate model until “better” turn down data are collected through DonorNet<sup>®</sup> 2007.

The presented results using this current methodology for the period calendar year 2006 showed that of the 242 kidney programs analyzed there were 26 programs identified for review (11percent). Next, of the 121 liver programs analyzed, 15 programs were identified for review (12.4 percent) because both their offer and organ observed acceptance rates fell significantly below the expected on a national adjusted scale. Again, these programs are now being profiled with respect to other factors, which may be associated with overall program transplant performance. The current analysis is yielding findings that reported aberrant acceptance rate behavior may be due to regional and organ donor source factors previously not identified. The Working Group will continue to assess what is now available; make recommendations for improvement to SRTR; and report its recommendations at future MPSC meetings.

6. Verification of the Presence of Donation after Cardiac Death (DCD) Organ Recovery Protocols at Organ Procurement Organizations (OPO) and Transplant Centers: Staff updated the Committee regarding its efforts to solicit and obtain Certification statements from all member OPOs and transplant hospitals attesting that they have and employ a mandatory DCD organ recovery protocol. The requirement was effective July 1, 2007, and is required as a condition for OPTN/UNOS membership.

Background: the Committee first discussed this issue during its February 2006, meeting. During the its October 2006, meeting the MPSC appointed members to participate along with OPO Committee appointees in a DCD Policy Working Group. The Working Group was charged with developing policy as it pertains to the oversight of DCD protocols. Bylaws regarding the need for

OPOs and transplant centers to have and use DCD organ recovery protocols were passed in December 2006. These DCD protocols needed to address Model Elements, which were identified by an OPO Subcommittee, but were rejected the December 2006 Board of Directors meeting as being too specific.

The DCD model elements were revised and approved by the Board in March 2007. At the March meeting, the Board took the position that every transplant hospital and OPO adopts and follows a DCD organ recovery protocol, which addresses the model elements. If members could not comply, then assistance would be provided by an expert UNOS Advisory group offering resources and guidance on how to adopt and implement the needed DCD protocol with model elements. The DCD policy notice, with an effective date of July 1, 2007, was sent out to the members on May 9, 2007.

Update: The DCD Policy Working Group met on May 15, 2007, and discussed how to verify the existence of the mandatory DCD organ recovery protocol; how to monitor the continued presence and adherence to the protocol; and what violations need to be reported to UNOS. The Chief Executive Officer or equivalent at each OPO and transplant center is asked to sign a certification statement attesting that his or her organization has and adheres to a DCD organ recovery protocol, which addresses the model elements. If a certification statement is not received by UNOS, the institution's name and contact information will be given to an OPO advisory group, which will try to address the reasons why the DCD protocol is not in place and through assistance try to resolve issues, which may be preventing compliance with the requirement. As of August 1, 68.7 percent (219 of 319) of all programs had sent in certification statements. The breakdown is 45 of 58 OPOs and 174 of 261 transplant centers. A second request is being sent to non-responders who then will be then be contacted with a phone call if they still are uncertified. A response is required of each member OPO and transplant center. The continued monitoring of DCD protocols is not considered necessary at this time. That may be readdressed in the future. The reporting of DCD protocol violations was preliminarily discussed. The group agreed that the OPO should be required to report to UNOS within 72 hours of its knowledge any incident when a member of the organ recovery team or OPO staff participates in the guidance or administration of palliative care, or the declaration of death for a DCD patient. In addition, OPO and donor hospital staffs are requested to report any DCD protocol violations needing MPSC review to UNOS through the policy compliance reporting hot line. The DCD Policy Working Group will meet in September to discuss the issues relating to the DCD organ recovery protocol and prepare recommendations for the MPSC to consider.

7. Program Related Actions and Personnel Changes: During its August meeting, the Committee reviewed and accepted programs changing status by voluntarily inactivating or withdrawing from designated program status. Additionally, the Committee reviewed 62 Key Personnel Changes and approved 56. Four applications for change in primary histocompatibility laboratory directors remain in process.

The Committee received a request for a Member to add an intestinal transplant program to its membership. The program was initially recorded as active in UNOS records but it had been done when UNOS first started tracking intestinal transplant programs. At that time all programs that had performed a transplant or wait listed a patient were set to active in the membership database. Subsequently, UNOS has requested written notification from centers initiating intestinal transplant programs so that appropriate effective dates and contact information can be set in both the Membership Database and UNet<sup>sm</sup>. The center submitted the needed information to formalize the status of this program.

The Committee also reviewed a report of three transplant programs that had not submitted an application for a change in key personnel by the deadline. Each of these programs had experienced a departure of a primary surgeon or physician. The Committee was notified that one of the individuals had not actually left their program after all and the personnel change was retracted. A second program had sent in their application by the meeting date. The third program will be sent a second notice letter should the application not be received within 15 days of the primary individual's departure. This second notice letter would be sent in accordance with a standard protocol established by the Committee at its May 2006, meeting.

8. Proposed Modification to Bylaws Appendix B, Section II, Paragraphs B and C. This proposal was considered by the MPSC at its August 1-2, 2007 meeting. The purpose of the proposal is to delineate when "informal discussions" may be held with an Institutional Member. The Bylaws provide that a Member is entitled to an interview as part of its due process rights when the MPSC is considering taking specified actions against the members. However, the Committee found that it is useful to engage in discussions with the Member in other circumstances. This proposal clarifies that the Data Subcommittee of the MPSC can use an informal discussion with the Member when conducting its review of survival rates and activity at a program. The intent is to continue fact-finding, and at the same time encourage an open dialogue with the Member about its program. The informal discussion established by the proposal is not an element of due process, nor is it a right of the Member.

The Committee approved the following resolution:

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

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

9. Proposed Modification to Bylaws Appendix A, Section 3.01A Paragraphs (1) and (3) and Section 5.05A, Addition of Section 5.07A. This proposal was considered by the MPSC at its August 1-2, 2007 meeting. The purpose of the proposal is two-fold: to better define how a Member may be considered for restoration of full membership privileges, and to provide a way to move from "Member Not in Good Standing" to a lesser action, such as probation.

The proposal provides that in order to be released from "Member Not in Good Standing" or "Probation" the Member must demonstrate that it is in (i) substantial compliance with OPTN requirements; (ii) its approved corrective action plan has been fully implemented; and (iii) the root cause of the violation that was the basis for the adverse of action of "Member Not in Good Standing" has been corrected or eliminated. The proposal does not provide a set time period for the adverse action to be in effect. Rather, it provides the flexibility for the MPSC and the Board to consider each Member's specific circumstances. The proposal does provide that the Member may request that the MPSC reconsider its status six months after approval of its corrective action plan.

The proposal also provides a means for the MPSC to consider changing the adverse action of "Member Not in Good Standing" to a "Provisional Reinstatement" of membership status. In order to accomplish this, the Member must demonstrate to the MPSC that it is in substantial compliance with OPTN requirements, that the root cause of the violations has been substantially corrected, and that the Member is in the process of implementing its approved corrective action plan. The proposal allows the MPSC to consider such requests three months after it has approved the Member's corrective action plan. This provision of the proposal specifies that there is no

additional due process for the Member. Ordinarily a new adverse action would result in some sort of additional due process. This proposal establishes that there is no additional due process for the Member unless the MPSC is “arbitrary and capricious” in its decision to deny the change from “Member Not in Good Standing” to “Provisional Reinstatement.”

The Committee recognized that this proposal would change how the MPSC and the Board of Directors manage adverse actions, and wanted to be sure that the proposal is in accord with the Board of Directors’ thoughts. Thus, the Committee supported the following resolution:

\*\* RESOLVED, that the Committee supports the language in the proposal, but requests that the Executive Committee review the language, and provide an opinion before the proposal is issued for public comment.

10. Proposed Modifications to Policy 7.4 “Submission of Organ-Specific Transplant Recipient Follow-up Form.” (Sponsored by the Operations Committee) The proposed modifications require transplant centers to report all recipient deaths that occur in the first year after transplant. After centers are notified of a recipient death, they have two working days to report this information to the OPTN using the UNet<sup>sm</sup> system. These data will complement the existing Patient Safety System data and allow for early monitoring of post-transplant deaths that may be donor-specific in nature.

The Committee discussed this proposal and suggested that the Operations Committee consider revising the proposal to from reporting within two working days to within 72 hours in order to provide more consistency within the Data Submission policies (such as reporting living donor adverse events).

11. Pancreas Outcome Analysis Model: During the July 12, 2006, meeting, the Data Subcommittee discussed the issue of pancreas (including kidney/pancreas and pancreas after kidney) transplant program outcome monitoring. A number of committee members suggested that the Committee consider implementation of pancreas outcome monitoring. In turn, the Committee asked the SRTR to evaluate potential models and possibilities available for increasing the sample size so the analytical model could be applied to pancreas programs. Currently the SRTR does publish outcome data for kidney/pancreas programs but there is no model for the evaluation of pancreas alone or pancreas after kidney one year outcomes. The Committee understood that some pancreas programs may still fall below the 10 or more transplants performed threshold, in which case the Subcommittee will follow the process currently utilized for small volume outcome reviews for other organs.

During the October 11, 2006, meeting, the Committee was informed that the SRTR was prepared to begin work to create the model. However, the Committee believed that the Pancreas Transplantation Committee needed to review the variables, including recipient and donor risk factors, before the model is developed. The Committee asked the Pancreas Transplantation Committee to discuss the variables to be included in an outcome analysis model for pancreas alone, pancreas after kidney, and simultaneous kidney/pancreas transplantation.

Update: During the July 31 – August 2, 2007, meeting, the MPSC was informed that the Pancreas Transplantation Committee formed a subcommittee to begin discussions with SRTR representatives regarding the pancreas outcome analysis model.

12. Number of Days a Program has its Wait List Inactive (But not Membership): During its January/February meeting, staff presented the Committee with an overview of the programs that

had periods when the Wait List Program Status field was set to “temporarily inactive” during 2006, but the program had not inactivated its membership status. There were 21 programs (representing all organs) that had their waitlist set to “temporarily inactive” for 15 or more days. Seven of these programs had a cumulative waitlist inactive time of greater than 100 days.

The Committee agreed that further review of this data should be performed by the Data Subcommittee as part of its review of functionally inactive programs. They also recommended that letters be sent to those programs that currently have their waitlist default set to temporarily inactive and 15 or more consecutive days have passed. The letter should explain the bylaws relating to functional inactivity and seek information on the status of the program and its future plans.

Update: During the July 31, 2007, meeting, the Data Subcommittee discussed the potential to review active programs with inactive wait lists. Because of the extensive discussions, the Subcommittee formed a work group to further evaluate and codify a process for reviewing this metric. The work group includes Drs. Voigt, Steadman, Reyes, and Mr. Gleason. The work group will convene prior to the next DSC meeting.

13. MPSC Process Improvement Initiatives: Staff provided the Committee a status report on the MPSC Process Improvement Initiatives. During the November 2005 Board meeting, the Executive Committee and the Board of Directors directed the MPSC to form a work group composed of members of the MPSC and the Board of Directors to identify improvements for, and propose changes to, the membership review processes and standards. This Work Group, in conjunction with the MPSC, has met now completed five of its six goals as outlined below.

Completed:

- The establishment of a confidential communication line directly to UNOS for individuals wishing to divulge sensitive information;
- Consideration of procedures that would improve the timeliness of required compliance with corrective action, site visit action plans, and MPSC review, along with requirements that failure of a center to meet timelines would prompt immediate consideration of adverse action; and the same would apply to instances of dishonesty in the provision of information or failure to adhere to representations in documents submitted;
- A Bylaw requiring members to notify the OPTN of reviews and adverse actions taken against them by other organizations;
- A Bylaw requirement specifically defining what constitutes onsite availability of transplant surgeon and physician coverage;
- Consideration of a bylaw that would prohibit a physician or surgeon who has been a primary focus in assessing activity leading to an adverse action, which involves loss of membership of a program or a center to not be permitted to be primary physician or surgeon at another UNOS approved program.

Still under Development:

- Bylaws that enable the MPSC to determine how organ acceptance/turn-down rates and deaths on the waiting list will be evaluated and incorporated into the standard elements of center performance in addition to patient and graft survival (work on this proposal continues in development and an update is provided in Item 5 above.)

14. Goals for Bylaws Rewrite: Staff updated the Committee on one of the new goals established for the committee by the President: the re-write of the existing Bylaws. The purpose of the revision

is to improve clarity regarding member rights and responsibilities, and OPTN/UNOS responsibilities. Clarity will be achieved by the use of plain language and logical organization of the content.

15. Review of Event under Policy 7.3.3 (Submission of Living Donor Death and Organ Failure Data):

The Committee was updated on the status of events surrounding a live donor death that was reviewed under Policy 7.3.3. This Policy requires these reviews to ensure that there are no patient safety concerns or associated policy violations when a living organ donation results in an adverse outcome for the donor. If corrective actions are required, they would be stated in the findings, and reported to the Board of Directors.

Utilizing the Committee Management System, a Subcommittee of the MPSC initially reviewed a case involving the death of a living kidney. They concluded that no further action was required in this case as there was not any evidence of policy violations and patient safety issues were not exposed. This issue was placed on the consent agenda for the August MPSC meeting. There being no request to remove this issue from the consent agenda the full Committee supported the findings of the Subcommittee. The report will also be disseminated to the Living Donor Committee and to the center where the event occurred.

16. Content of Patient Acceptance Letters: During its February 2007 meeting, the Committee recommended that the Board approved changes to the Bylaws that further described program coverage. The Committee agreed to ask the Patient Affairs Committee to explore the feasibility of implementing the oversight component relating to program coverage, by having the OPTN provide a letter for the transplant patients, that the center will in turn provide to each patient when they are wait listed, along with the acceptance letter. The Committee envisioned that this letter would reference the web sites to find center data, state the patient's ability to seek care at other centers, and include the patient hotline number and information about patient rights. It was suggested that the letter should come from the OPTN/UNOS as an oversight organization rather than the center itself and that the acceptance letter must reference the OPTN letter as an enclosure. The Committee agreed that this project should be referred to the Patient Affairs Committee for further development since it parallels a similar Committee project regarding patient notification.

Update: During its August meeting, the Committee was informed that the Patient Affairs Committee had considered the Committee's request. An excerpt of its response is provided below:

*"... The Committee agreed that the OPTN/UNOS letter should be written clearly and simply to accommodate the needs of a wide variety of literacy levels. Members also supported articulating the role of the OPTN/UNOS and the type of assistance provided by UNOS Patient Services staff.*

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

17. UNOS Actions: During the August meeting, 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.

\*\* 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.

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

**Attendance at the Membership and Professional Standards Committee Meeting  
July 31 – August 2, 2007**

| <b>NAME</b>                          | <b>POSITION</b> | <b>ATTENDED</b> |
|--------------------------------------|-----------------|-----------------|
| Robert S Higgins MD,MSHA             | Chair           | X               |
| Carl Berg MD                         | Vice Chair      | X               |
| Paul Morrissey MD                    | Regional Rep.   | X               |
| Lynt Johnson MD                      | Regional Rep.   | X               |
| George Loss Jr., MD, PhD             | Regional Rep.   | X               |
| John Goss MD                         | Regional Rep.   |                 |
| Chris Freise MD                      | Regional Rep.   | X               |
| Jorge Reyes MD                       | Regional Rep.   | X               |
| Yolanda Becker MD, FACS              | Regional Rep.   | X               |
| Michael Voigt MD                     | Regional Rep.   | X               |
| Patricia Sheiner MD                  | Regional Rep.   | X               |
| Lynn Driver CPTC                     | Regional Rep.   | X               |
| Tim Brown                            | At Large        | X               |
| Jonathan Chen MD                     | At Large        |                 |
| Niloo Edwards MD                     | At Large        | X               |
| James Gleason                        | At Large        | X               |
| Julie Heimbach MD                    | At Large        | X               |
| John Herre MD                        | At Large        | X               |
| Donald Hricik MD                     | At Large        | X               |
| John Lake MD                         | At Large        | X               |
| Geoffrey Land PhD                    | At Large        | X               |
| Richard Luskin MPA                   | At Large        | X               |
| Jill Maxfield RN, CPTC               | At Large        | X               |
| Patricia McDonough RN, CPTC,<br>CCTC | At Large        | X               |
| Brendan McGuire MD                   | At Large        | X               |
| Jennie Perryman RN, PhD              | At Large        | X               |
| Fuad Shihab MD                       | At Large        |                 |
| Randall Starling MD, MPH             | At Large        | X               |
| Randolph Steadman M.D.               | At Large        | X               |
| David Weill MD                       | At Large        |                 |
| James Burdick MD                     | Ex Officio      |                 |
| Renee Dupee Esq.                     | Ex Officio      | X               |
| Christopher McLaughlin               | Ex Officio      | X               |
| Charlotte Arrington MPH              | SRTR Liaison    | X               |
| Douglas Schaubel Ph.D.               | SRTR Liaison    |                 |
| Tempie Shearon                       | SRTR Liaison    |                 |
| Robert Wolfe Ph.D.                   | SRTR Liaison    | X               |

| <b>NAME</b>                 | <b>POSITION</b>   | <b>ATTENDED</b> |
|-----------------------------|-------------------|-----------------|
| Sally Aungier               | Committee Liaison | X               |
| Doug Heiney                 | Support Staff     | X               |
| Elizabeth Coleburn          | Support Staff     | X               |
| Jerry DeSanto               | Support Staff     | X               |
| Rosey Edmunds               | Support Staff     | X               |
| Leah Edwards, Ph.D.         | Support Staff     | X               |
| Mary D. Ellison, Ph.D.      | Support Staff     | X               |
| Alex Garza                  | Support Staff     | X               |
| Suzanne Gellner JD, CHC     | Support Staff     | X               |
| Walter K. Graham            | Support Staff     | X               |
| David Kappus MAS            | Support Staff     | X               |
| Karl McCleary Ph.D., M.P.H. | Support Staff     | X               |
| Joel Newman                 | Support Staff     | X               |
| Jacqueline O'Keefe MBA      | Support Staff     | X               |
| John Persons Esq.           | Support Staff     | X               |
| John Rosendale              | Support Staff     |                 |
| Deanna Sampson Esq., CHC    | Support Staff     | X               |
| Leah Slife                  | Support Staff     | X               |

**EXHIBIT M- 1**  
**Proposed Modifications to the Living Donor Requirements**

**BRIEFING PAPER**

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1. **Proposed Modifications to Bylaws, Appendix B, Attachment I, Section XIII, C (2) Kidney Transplant Programs that Perform Living Donor Kidney Transplantation. (Membership and Professional Standards and Living Donor Committees).**
2. **Proposed Modifications to Bylaws, Appendix B, Attachment I, Section XIII, C (4) Liver Transplant Programs that Perform Living Donor Liver Transplants (Membership and Professional Services and Living Donor Committees).**

For the purposes of this document Proposals 1 and 2 have been combined into a single briefing paper. Except for the Medical Evaluation section, the language in these proposals is nearly identical. Many of the commenter's submitted the same comment on each proposal or commented on one with a reference to the other.

**I. SUMMARY/PERFORMANCE OBJECTIVE - AIM**

These proposals will establish additional minimum criteria for granting designated program status to programs that perform living donor kidney and liver transplants. These revised bylaws will further ensure that living donor kidney and liver transplant programs have essential elements in place for the evaluation, consent, and follow-up of living donors.

**II. BACKGROUND AND SIGNIFICANCE**

**GOALS:**

The transplant community recognizes its responsibility to make the process of living donation as safe and effective as possible for all involved. Donors make a tremendous sacrifice by assuming the risk of possible physical harm and/or death when they undergo actual donation. The Bylaws presently focus on the general qualifications of a transplant center requesting to be designated to perform the transplant procedure. These proposed changes to the bylaws require transplant programs to have basic resources and protocols that will help ensure that a potential living donor has all the information needed to make an informed decision. While the proposed bylaws do not dictate medical practice, they provide a framework that each program must incorporate into their current living donation protocols, while at the same time providing the OPTN with the tools that are needed to evaluate performance and respond to complaints.

The following guiding principles were used by the Committee as it developed the proposed modifications to the Bylaws:

- The potential living donor must be competent to make a decision.
- The potential living donor must be free to withdraw at any time from the process without consequence.
- The potential living donor must be free from coercion.
- The potential living donor is given appropriate information necessary to make a decision for or against donation, including medical risk, social consequences, and financial consequences.
- Assurance is given that information about the living donor will not be disclosed to other individuals (except as mandated by law and good medical practice) without the consent of the individual.
- The potential living donor is given enough time to make a good decision and that an independent advocate is available to help with the decision.
- The procedure will be performed by people with appropriate training and experience.
- The living donor will be given appropriate medical care until recovered from the donation procedure.

## **BACKGROUND:**

The Bylaws currently establish extensive membership criteria for deceased donor transplantation programs as well as transplant programs that perform living donor kidney and liver transplants. These proposed requirements are considered an important step to further protect the health and safety of all living donors and are being proposed in response to a directive from HRSA (see below). The requirements will help create a standardized level of quality among the growing number of programs that perform living donor transplants.

In 2002, the Ad Hoc Living Donor Committee was formed and began the process of developing requirements for programs that perform living donor transplants. The Committee developed, with input from other OPTN committees, minimum standards for programs that perform living kidney and liver donor transplants. The requirements were circulated for public comment and approved by the OPTN Board of Director's in 2003. Until 2003, OPTN policies predominately focused on issues related to deceased organ donation and transplantation. Several widely publicized living donor deaths and the increased incidence of altruistic living donation prompted concern that this area of transplantation may not have sufficient oversight. Additionally, the Living Donor Committee developed, through the same committee and public comment process, guidelines for living donor evaluation. These guidelines were approved by the Board of Director's in June 2004.

### **Authority to Develop Living Donor Requirements**

The authority for the OPTN to develop and implement policies and standards is described in an October 29, 2004, letter from James S. Burdick, M.D., Director, Health Resources and Services Administration, Department of Health and Human Services (HHS). That letter states the following:

*“However, the Final Rule also provides that the OPTN shall be responsible for developing policies on a variety of topics, including ‘policies on such other matters as the Secretary directs.’ In accordance with the authority, HRSA, HSB, DoT is directing the OPTN to develop allocation guidelines for organs from living donors. These guidelines should be limited to the allocation of organs from living donors made to an anonymous pool, and not to organs procured in connections with directed donations. The DoT also is directing the OPTN to develop other voluntary policies/guidelines (not pertaining to organ allocation) it believes necessary and appropriate to promote the safety and efficacy of living donor transplantation for the donor and the recipient.”*

On January 23, 2006, a notice was issued in the Federal Register soliciting comments regarding whether criteria developed by the OPTN addressing living donation should be given the same status, and be subject to the same enforcement actions, as other OPTN policies. After considering public comment on this issue, the Department of Health and Human Services determined that OPTN living donor guidelines should be given the same status of other OPTN policies. Further, the Secretary directed the OPTN to develop policies regarding living organ donors and living organ donor recipients, including policies for the equitable allocation of living donor organs. The final directive was published in the **Federal Register**, Vol. 71, No. 116 on June 16, 2006, and stated the following:

*HRSA has reviewed and considered each aspect of each comment and has determined that OPTN living donor guidelines should be given the same status of other OPTN policies as discussed in the **Federal Register** Notice published on January 23, 2006. Under 42 CFR 121.4(a)(6), the **Secretary directs the OPTN to develop policies regarding living organ donors and living organ donor recipients, including policies for the equitable allocation of living donor organs**, in accordance with section 121.8 of the final rule. Thus, the OPTN shall develop such policies in the same manner, and with the same public comment process, that it does for policies on deceased organ donors and deceased organ donor recipients. Non-compliance with such policies shall subject OPTN members to the same consequences as noncompliance with policies concerning deceased organ donors and deceased organ donor recipients developed under the final rule.*

A copy of the full text of this section of the Federal Register is provided as Attachment 4 to this Exhibit.

### **Relationship to CMS Conditions of Participation:**

While the OPTN Committees were working on the proposed Bylaws, the Medicare Conditions of Participation (CoPs) were also under development. These requirements were published in the Federal Register, Vol 72, No. 61, Friday, March 30, 2007. The roles of CMS and the OPTN are addressed in the comments section for the regulations. It states the *“OPTN’s primary responsibilities are to ensure the effectiveness, efficiency, and equity of organ allocation, increase the supply of transplantable organs, collect and disburse data, and designate transplant*

programs.” CMS is “responsible for establishing minimum standards to protect patient health and safety, and for implementing oversight mechanisms to ensure that transplant centers provide quality transplant and living donor care to Medicare beneficiaries through the development of health and safety requirements.” The OPTN’s role can be described as that of a facilitator, not a regulator. HHS has regulatory oversight responsibilities. By facilitating organ transplantation, the OPTN provides services and conducts medical peer review for the purposes of continuous quality and performance improvement. This issue of the Federal Register further summarizes the main focuses of CMS and OPTN requirements as shown below:

Main Focuses of CMS Requirements

- *Regulatory oversight of transplant centers.*
- *Patient care & transplant services furnished to beneficiaries.*
- *Relationship with transplant centers based on Provider Agreement & Medicare reimbursement.*
- *Medicare approval & re-approval based on compliance with Conditions of participation (CoPs).*
- *Provider responsibilities.*

Main focuses of OPTN Policies/Bylaws.

- *Organ allocation.*
- *Credential of transplant surgeons/physicians.*
- *Relationship with transplant hospital members is collegial with the goal to help them to improve performance.*
- *OPTN Membership application reviewed by peer reviewers.*
- *Member obligations.*

**Bylaw Development Process:**

Based on the 2004 directive from HRSA, the Membership and Professional Standards Committee (MPSC) began evaluating living donor liver transplant program applications in 2005. This review was conducted using the Bylaws that were approved in 2003, and in March 2006, amended to include a conditional approval option. While conducting these reviews the Committee became concerned that the requirements did not go far enough to ensure the safety of the living donor in accordance with the HRSA mandate.

The MPSC placed on hold the process of reviewing and approving approximately 240 programs that perform living donor kidney transplants until these proposed requirements could be developed and approved. The Committee wanted to ensure that centers not only have in place experienced key personnel, but the other essential elements to be approved as a living donor center as well. To minimize the burden placed on the members, the Committee agreed that the application process should be delayed so that the currently proposed changes could be incorporated into the forms and a single review process could be conducted.

While the MPSC was evaluating living donor liver transplant program applications, the Living Donor Committee was simultaneously addressing a multitude of issues in living donation, including the consent process, medical evaluation, and follow-up of living donors. In order to prevent duplication of efforts between the two committees, a Living Donor Policy Advisory Work Group was formed in October 2006, and included members from both the MPSC and the Living Donor Committee. The Living Donor Policy Advisory Work Group began their work based on the principles listed on the preceding page as well as the following objectives:

1. Further develop the minimum set of criteria for granting designated program status to centers performing living donor transplants.
2. Ensure adequate donor education/informed consent.
3. Work-up of potential donors: Determine whether there should be guidelines or a minimum set of required elements?

Endorsed by the MPSC and the Living Donor Committee, the Work Group proposed modifications to the Bylaws pertaining to programs that perform living donor kidney and liver transplants. The issues discussed by the MPSC during its initial review included:

- What are the key elements for programs that perform living donor transplants?
- It is important for the Bylaws to be monitorable, but not overly prescriptive.
- Independent Donor Advocate (IDA):
  - What is the specific function of a donor advocate?
  - How do you measure the adequacy of the IDA or of the proposals?
  - Independent Donor Advocate (IDA) or IDA team? The Committee agreed that there should be an IDA member who is a physician and who is not involved with the evaluation and decision to transplant a potential recipient. The Committee agreed that the use of an IDA or IDA team should be flexible since different centers have different approaches. They incorporated their suggestions into the proposal.
  - Concern about identifying a person who can be totally uninvolved in transplant yet be knowledgeable and able to advise living donors.
  - Should a guideline be developed for the committee to use when evaluating a center's performance relative to the IDA?
- The Committee agreed that the Bylaws should delineate what a program must have in order to receive initial approval to perform living donor transplants, and the requirements that must be met to maintain approval once it has been granted.

The Work Group met by conference call and held electronic discussions. They reviewed and incorporated certain recommendations from the Advisory Committee on Organ Transplantation (ACOT), Centers for Medicare and Medicaid Services (CMS), the American Society of Transplantation (AST), and the State of North Carolina living donor statutes in the development of these guidelines. The Work Group also considered other papers such as the *“Report of the Amsterdam Forum on the Care of the Live Kidney Donor: Data and Medical Guidelines. Transplantation”* and *“The Ethics Statement of the Vancouver Forum on the Live Lung, Liver, Pancreas, and Intestine Donor. Transplantation.”* The Committee was particularly aware of the need to develop proposals that are complemented the CMS requirements.

During the May 18, 2007, Executive Committee meeting, Dr. McDiarmid requested that a Living Donor Committee (LDC)/MPSC Task force be formed to reconcile the proposed LDC and MPSC living donor bylaws and guidelines.. Dr. Robert Higgins was asked to lead this task force. After further debate and discussion, the task force agreed to distribute for public comment the proposed modifications to THE Bylaws, Appendix B, Attachment I, Sections XIII, C (2) and (4) for public comment.

### **III. POLICY PROPOSAL**

The proposed requirements for centers that perform living donor transplant included the following concepts:

- Program must have an independent donor advocate (IDA) or an IDA team.
- Program must develop and comply with written protocols to address all phases of the living donation process.
- Program must have written protocols that include the following elements:
  - Description of duties and primary responsibilities of the IDA or IDA team members.
  - A through medical evaluation by a physician and/or surgeon experienced in living donation.
- Program must have written protocols for informed consent for the donor evaluation process and informed consent for the donor nephrectomy.

The proposed modifications to the Bylaws are shown below as single underlines and strikeouts.

**Proposed Modifications to Bylaws, Appendix B, Attachment I, Section XIII,  
C (2), Kidney Transplant Programs that Perform Living Donor Kidney Transplantation.**

**XIII. Transplant Programs.**

- A. No changes**
- B. No changes**
- C(1) No changes**

**(2)- ~~Living Donor Kidney Transplant Programs~~ that Perform Living Donor Kidney Transplantation.**

~~A. Living Donor Kidney Transplant Programs~~

1. Kidney Transplant Programs that Perform Living Donor Kidney Transplantation ~~A Living living donor kidney transplant program~~ must demonstrate the following regarding personnel and resources:

- (a) That the center meets the qualifications of a renal transplant program as set forth in (Section (1) above; and)
- (b) In order to perform open donor nephrectomies, a qualifying renal donor surgeon must be on site and must meet the criteria of (i) and/or (ii) below:
  - (i) Completed an accredited ASTS fellowship with a certificate in kidney, or
  - (ii) Performed no fewer than 10 open nephrectomies (to include deceased donor nephrectomy, removal of polycystic or diseased kidneys, etc.) as primary surgeon or first assistant within the prior 5-year period.
- (c) If the center wishes to perform laparoscopic donor nephrectomies, a qualifying renal donor surgeon must be on site and must have:
  - (i) Acted as primary surgeon or first assistant in performing no fewer than 15 laparoscopic nephrectomies within the prior 5-year period.

If the laparoscopic and open nephrectomy expertise resides within different individuals then the program must demonstrate how both individuals will be available to the surgical team. It is recognized that in the case of pediatric living donor transplantation, the Living organ donation may occur at a center that is distinct from the approved transplant center.

All surgical procedures identified for the purpose of surgeon qualification must be documented. Documentation should include the date of the surgery, medical records identification and/or UNOS identification number, and the role of the surgeon in the operative procedure.

- d) That the center has either an independent donor advocate (IDA) who is a physician, or an independent donor advocate team, which includes at least one member who is a physician and at least one member who is not involved with the evaluation and decision to transplant the potential recipient.

2. Kidney Transplant Programs that Perform Living Donor Kidney Transplantation must demonstrate the following regarding protocols:

- a) Living Donor Transplant centers must develop, and once developed must comply with written protocols to address all phases of the living donation process. Specific protocols shall include the evaluation, pre-operative, operative, post-operative and two-year follow-up period after donation.

Transplant centers must document that all phases of the living donation process were performed in adherence to the center's protocol. This documentation must be maintained and made available upon request.

- b) Written Protocols must include, but are not limited, to the following elements:

- i) a description of the duties and primary responsibilities of the IDA or IDA Team members as described in 1 (d) above, to include procedures that:

(a) protect and promote the best interests of the potential living donor;

(b) ensure protection of the rights of the living donor; and

(c) provide the potential donor with information regarding the:

(i) consent process;

(ii) evaluation process;

(iii) surgical procedure; and

(iv) benefit and need for follow-up.

- ii) a thorough medical evaluation by a physician and/or surgeon experienced in living donation including:

(a) a screen for any evidence of occult renal and infectious disease or medical comorbidities which may cause renal disease;

b) age appropriate cancer screening;

(c) a radiographic assessment to evaluate vascular anatomy and any congenital malformation; and

(d) a psychosocial evaluation of the potential living donor by a psychiatrist, psychologist, or social worker with experience in transplantation (criteria defined in Appendix B, Attachment I, Section C (17)) to determine competency, screen for any pre-existing psychiatric illness, and/or any potential coercion.

- c) The center shall have written protocols for the Informed Consent for the Donor Evaluation Process and Informed Consent for the Donor Nephrectomy, which include, at a minimum, the following elements:

(i) discussion of the potential risks of the procedure including the medical, psychological and financial risks associated with being a living donor.

(ii) assurance that all communication between the donor and the transplant center will remain confidential;

(iii) discussion of the donor's right to opt out at any time during the donation process;

- (iv) discussion that the medical evaluation or donation may impact the donor's ability to obtain health, life and disability insurance;
- (v) disclosure by the transplant center that it is required, at a minimum, to contact and obtain follow-up health information on each living donor at 6 months, one-year, and two-years post donation.

**2. Proposed Modifications to Bylaws, Appendix B, Attachment I, Section XIII, C (4) Liver Transplant Programs that Perform Living Donor Liver Transplants**

**XIII. Transplant Programs.**

- A. No changes**
- B. No changes**
- C (1) – (3) No changes**

**(4) Liver Transplant Programs that Perform Liveing Donor Liver Transplants.**

~~1. A live donor liver transplant center must demonstrate the following:~~

1. Liver Transplant Programs that Perform Living Liver Transplantation must demonstrate the following regarding personnel and resources:

- a) That the center meets the qualifications of a liver transplant center as set forth (in UNOS Bylaws, Appendix B, Attachment I, Section XIII; and)
- b) That the center has on site no fewer than two surgeons who qualify as liver transplant surgeons under UNOS Bylaws Appendix B, Attachment I, Section XIII(C)(2)(a) and who have demonstrated experience as the primary surgeon or first assistant in 20 major hepatic resectional surgeries (to include living donor operations, splits, reductions, resections, etc.), 7 of which must have been live donor procedures within the prior 5-year period. These cases must be documented. Documentation should include the date of the surgery, medical records identification and/or UNOS identification number, and the role of the surgeon in the operative procedure. It is recognized that in the case of pediatric living donor transplantation, the live organ donation may occur at a center that is distinct from the approved transplant center.
- c) That the center has either an independent donor advocate (IDA) who is a physician, or an independent donor advocate team, which includes at least one member who is a physician and at least one member who is not involved with the evaluation and decision to transplant the potential recipient.

2. Liver Transplant Programs that Perform Living Liver Transplantation must demonstrate the following protocols:

- a) Living Donor Transplant centers must develop, and once developed must comply with written protocols to address all phases of the living donation process. Specific protocols shall include the evaluation, pre-operative, operative, post-operative and two-year follow-up period after donation.

Transplant centers must document that all phases of the living donation process were performed in adherence to the center's protocol. This documentation must be maintained and made available upon request.

- b) Written Protocols must include, but are not limited, to the following elements:

- i) a description of the duties and primary responsibilities of the IDA or IDA Team members as described in 1 (d) above, to include procedures that:
    - (a) protect and promote the best interests of the potential living donor;
    - (b) ensure protection of the rights of the living donor; and
    - (c) provide the potential donor with information regarding the:
      - (i) consent process;
      - (ii) evaluation process;
      - (iii) surgical procedure; and
      - (iv) benefit and need for follow-up.
  - ii) a thorough medical evaluation by a physician and/or surgeon experienced in living donation including:
    - (a) a screen for any evidence of occult liver disease;
    - (b) age appropriate cancer screening;
    - (c) a radiographic assessment to ensure adequate graft and remnant liver volume as well as vascular and biliary imaging to ensure inflow and outflow is preserved in the graft and the remnant liver.
    - (d) a psychosocial evaluation of the potential living donor by a psychiatrist, psychologist or social worker with experience in transplantation (criteria defined in Appendix B, attachment I-X) must also be provided to assess competency, screen for any pre-existing psychiatric illness, and any potential coercion.
- b) The center shall have has written protocols for Informed Consent for the Donor Evaluation Process and Informed Consent for the Donor Hepatectomy, which include at a minimum the following elements:
- (i) discussion of the potential risks of the procedure including the medical, psychological and financial risks associated with being a living donor.
  - (ii) assurance that all communication between the donor and the transplant center will remain confidential;
  - (iii) discussion of the donor’s right to opt out at any time during the donation process;
  - (iv) discussion that the medical evaluation or donation may impact the donor’s ability to obtain health, life and disability insurance;
  - (v) disclosure by the transplant center that it is required, at a minimum, to contact and obtain follow-up health information on each living donor at 6 months, one-year, and two-years post donation.
3. Conditional Approval Status: If the transplant center does not have on site a second surgeon who can meet the requirement for having performed 7 live donor liver procedures within the prior 5-year period, but who has completed the requirement for obtaining experience in 20 major hepatic resection surgeries (as described above), as well as all of the other requirements to be designated as a primary liver transplant surgeon, the program may be eligible for Conditional Approval Status. The transplant program can be granted one year to fully comply

with applicable membership criteria with a possible one year extension. This option shall be available to new programs as well as previously approved programs that experience a change in key personnel. During this period of conditional approval, both of the designated surgeons must be present at the donor's operative procedure.

The program shall comply with such interim operating policies and procedures as shall be required by the Membership and Professional Standards Committee (MPSC).

This may include the submission of reports describing the surgeon's progress towards meeting the requirements and such other operating conditions as may be required by the MPSC to demonstrate ongoing quality and efficient patient care. The center must provide a report prior to the conclusion of the first year of conditional approval, which must document that the surgeon has met or is making sufficient progress to meet the objective of performing 7 live donor liver procedures or that the program is making sufficient progress in recruiting and bringing to the program a transplant surgeon who meets this criterion as well as all other criteria for a qualified live donor liver surgeon. Should the surgeon meet the requirements prior to the end of the period of conditional approval, the program may submit a progress report and request review by the MPSC.

The transplant program must comply with all applicable policies and procedures and must demonstrate continuing progress toward full compliance with Criteria for Institutional Membership.

The program's approval status shall be made available to the public.

## **POLICY PERFORMANCE MEASURES**

Transplant hospitals that intend to perform living donor transplants will need to complete an application that demonstrates how the applicant center meets the requirements. The applicant will also be responsible for submitting an application whenever there is a change in key personnel. The questions in the existing applications and surveys (e.g. applications for new programs, reactivation, and key personnel changes, staffing surveys, and Outcomes and Activity Surveys) that are relative to living donor programs will be changed to incorporate the concepts outlined in the modified Bylaws. The staff and the MPSC will review the responses as part of the evaluation process.

Hospitals that do not already have written protocols for the all phases of the living donation process including medical evaluation and informed consent will need to formalize their protocols in writing. These protocols will need to address at a minimum the elements specified in the final proposal.

## **RESOURCE ANALYSIS**

OPTN policy development and implementation focuses on cost and resource efficiency. To give the Board of Directors reasonable expectations regarding the resources that will be required by policy proposals, we need to assess the resources associated with the implementation, compliance, and maintenance of a policy.

During the public comment process input was sought to help determine how the proposed policy will affect the following groups:

- OPTN/UNOS Committee(s)
- Transplant Hospitals, OPOs, and Histocompatibility Laboratories
- Candidates, Recipients, and Donors

Members were also asked to consider how the policy will affect the staff involved in policy development and implementation. Such effects might include changes in data submission obligations and changes in operational and/or staffing needs that will occur as a result of the policy. The change could be either an increase or decrease in

these obligations or needs, depending upon the particular proposal and its objective. Understanding expected change in both directions is important.

This information is used to prepare the resource assessment that will be presented to the Committee(s) originating the proposal, Policy Oversight Committee, and Board of Directors.

#### IV. SUMMARY OF PUBLIC COMMENTS

##### Proposal 1

##### **Proposed Modifications to THE Bylaws, Appendix B, Attachment I, Section XIII, C (2) Kidney Transplant Programs that Perform Living Donor Kidney Transplantation.**

###### **A. Individual Comments:**

As of 8/11/2007, 48 responses have been submitted to UNOS regarding this policy proposal. Of these, 33 (68.75%) supported the proposal, 8 (16.67%) opposed the proposal, and 7 (14.58%) had no opinion. Of the 41 who responded with an opinion, 33 (80.49%) supported the proposal and 8 (19.51%) opposed the proposal. Comments on the proposal received to date are as follows:

###### **Comment 1:**

*Vote: Oppose*

*Date Posted: 07/23/2007*

Our center takes great pains to make sure the donor physicians/RNs/MSWs are NOT the persons who saw the recipient BUT the recip may have been evaluated months or years prior to a donor coming forward...and the donors' physicians very well may have been at our selection committee and heard the recipient being presented. It will be logistically difficult to make sure they were not in that portion of the process. Unless you insist on an internist or family practice MD seeing the donor...and we feel a nephrologist and transplant specialist know better than anyone the risks the donor is taking

Committee Response: The intent of the proposed bylaw modification is to ensure the independent donor advocate (IDA) or IDA team (IDAT) serves the best interest of the potential donor and is someone who is "not involved with the evaluation and decision to transplant the potential recipient." We did not intend that the IDA/IDAT have no knowledge of a potential recipient, but rather that they not be involved directly with the care of the potential recipient. The proposal has been amended to say that the center must have an IDA who is not involved with the evaluation and decision to transplant the potential recipient. The initially proposed language indicating that if a center has a single IDA it must be a physician, has been removed. The changes made to the IDA language more closely align with the Medicare Conditions of Participation (COP) for Medicare approved programs that were issued in March 2007, by the Department of Health and Human Services (DHHS).

###### **Comment 2:**

*Vote: Oppose*

*Date Posted: 07/13/2007*

That the IDA team, who in most cases I have only minimal and preoperative contact with the donor would be a better protector of the potential donor's interests and health than the donor surgeon who commits to care for the donor in perpetuity and the transplant program that commits to follow the donor, also in perpetuity, is hard to imagine. If this provision is intended to address a specific problem, it could probably be done better at some other way. If this is felt to be a good idea in principle only, I respectfully disagree. Under circumstances in which any of the participants -- donor, recipient, physicians, surgeons, coordinators, social workers, psychiatrists, etc. -- have concerns, they showed, as we have done in the past, take the council over the hospital ethics committee.

Committee Response: as above, the policy is intended to serve the best interest of the potential donor and was developed considering many existing documents, such as the ACOT guidelines to ensure at least one member of the team is not also primarily responsible for the care of the potential recipient and therefore may have issues of objectivity. The subcommittee is not responding to any specific event, but rather to amend existing bylaws in order to facilitate OPTN/UNOS oversight of living donor transplantation in accordance with the HRSA directive.

The proposal has been amended to say that the center must have an IDA who is not involved with the evaluation and decision to transplant the potential recipient. The initially proposed language indicating that if a center has a single IDA it must be a physician, has been removed.

**Comment 3:**

*Vote: Oppose*

*Date Posted: 08/08/2007*

These comments were compiled by Benjamin Hippen, M.D., on behalf of the Division of Transplantation, Carolinas Medical Center and the Metrolina Transplant Clinic in Charlotte, North Carolina. We have several concerns about the proposals regarding the evaluation and follow-up of living donors. Please note that the comments that follow refer to and apply to all of the proposed modifications.

1. There is insufficient justification for the proposed regulations. The proposed regulation is predicated on the assumption that safeguards for donors under the current system are inadequate. The assumption begs the central question. System failure to provide adequate donor protection must be proved, not assumed. No data are provided to support an argument for system-wide inadequacy.

2. There is insufficient justification for an independent donor advocate (IDA), or independent donor advocate team (IDAT). Section 1(d) requires that an Independent Donor Advocate Team be formed, and that at least one of the members be a physician who is "...not involved with the evaluation and the decision to transplant the potential recipient." Typically, transplant centers present donor and recipient evaluations to a transplant conference. Formally or informally, every physician and surgeon a transplant center is "involved," however tangentially in the decision to accept every recipient. Section 1 (d) does not specify what constitutes "involvement." Should 1 (d) require a physician who otherwise does not currently serve on the transplant team, it might require service from a willing, former (perhaps retired?) transplant physician or a physician whose area of expertise does not include the medical, surgical or psychological evaluation of living donors. Up-to-date competence and willingness may be problematic in either case. Requiring a third-party not trained and experienced in the nuances of the evaluation of donors from a medical, surgical and/or psychosocial perspective, notwithstanding whether or not the third-party is a licensed physician, is no service at all to living donors.

3. On what basis would the IDA/IDAT determine what is in the best interest of a living donor? Would it do its own independent medical, surgical, social, psychological, assessment? If not, how could its judgment reasonably rival, in quality and competence, the detailed assessment made by the transplant center? Suppose that the donor and the evaluating transplant physicians disagree with the judgment of the IDA team, how would the disagreement be managed w/o making the IDA a judge in its own quarrel? It would appear that beyond fulfilling the (to be determined!) regulations governing the abstract requirements of 2(b)(i) (a) – (c), the IDA team has absolutely no accountability.

4. Section 2 (b)(i)(c)(iv) affirms the general principle that "...the donor is doing this [donating] voluntarily and for no personal medical benefit." But this conflicts with requiring the Center to "...provide the potential donor with information regarding the (personal) benefit and (personal) need for follow-up." In so far as the Center emphasizes personal benefit from follow-up, it is a prima facie violation of the proscription of "valuable consideration" for donation elucidated in the National Organ Transplant Act.

5. Section 2 (c) (v) stipulates that the transplant center "...is required, at a minimum, to contact and obtain follow-up health information at 6 months, 1 year, and 2 years post-donation." Section O. under "Donor evaluation" (p. 29) seems to require that donors agree to post-donation follow-up as a condition of permission by the IDA to be a donor. These sections place an obligation not only on transplant centers, but by extension on the donor's primary care physician (assuming the donor's PCP does not work for the transplant center, a common occurrence) and the donor. In addition to the costs in the donor's time,

physician's time, laboratory testing, reporting and tracking, this Bylaw presumes that the donor will not decline to present for such evaluations or ongoing testing. UNOS has no moral or regulatory authority to require donors to undergo testing/evaluations if the donors choose not to engage it, and transplant centers cannot plausibly be held accountable for the autonomous, competent choices of donors post-donation. 6. The mandated time frame of 2 years follow-up is arbitrary and without foundation in either evidence or common sense: The salient concerns regarding the outcomes of living donors are hardly foreclosed after examining two years of follow-up.

If UNOS desires data about the practice of living donation, it should request funding for a well-designed, adequately powered study, which provides for the voluntary, lifelong follow-up of living donors, preferably by a general or transplant nephrologist.

See also comments under Proposals 3 and 4.

#### Committee Response:

Item 1. The justification for the proposed modifications to the Bylaws was published in the **Federal Register**, Vol. 71, No. 116 on June 16, 2006, and stated the following:

*HRSA has reviewed and considered each aspect of each comment and has determined that OPTN living donor guidelines should be given the same status of other OPTN policies as discussed in the Federal Register Notice published on January 23, 2006. Under 42 CFR 121.4(a)(6), the Secretary directs the OPTN to develop policies regarding living organ donors and living organ donor recipients, including policies for the equitable allocation of living donor organs, in accordance with section 121.8 of the final rule. Thus, the OPTN shall develop such policies in the same manner, and with the same public comment process, that it does for policies on deceased organ donors and deceased organ donor recipients. Non-compliance with such policies shall subject OPTN members to the same consequences as noncompliance with policies concerning deceased organ donors and deceased organ donor recipients developed under the final rule.*

Item 2 & 3: See response to Comment 2 above. Additionally, it should be noted that the requirement is for the program to develop a protocol that includes the minimal elements. It will be up to each center to develop specific protocols for addressing the questions raised in this comment.

Item 4: The Committee disagrees. Providing “the potential donor with information regarding the (personal) benefit and (personal) need for follow-up” is not same as valuable consideration. Centers would be expected to provide standard post-operative care to patients who were living donors.

On September 18, 2006 UNOS issued a position statement: “Kidney Paired Donations, Kidney List Donations and NOTA § 301,” which addressed the interpretation of “valuable consideration.”

*“Valuable consideration” under NOTA § 301 is a monetary transfer or a transfer of valuable property between donor, recipient and/or organ broker in a sale transaction. It is not familial, emotional, psychological or physical benefit to the organ donor or recipient, all of which attach equally to the “living-related kidney transplants” in yesterday’s terminology and to the multi-party kidney paired donations, kidney list donations and similar innovative and highly beneficial living donation arrangements of today and tomorrow. There is no “valuable consideration” under NOTA § 301 in any of these living donation arrangements. The donor receives none, the recipient gives none and none is transferred to a broker. In fact, there is no “consideration” at all in a living organ donation arrangement because the donation is a “gift” as will be explained below...*

A complete copy of this position statement can be found at [http://www.unos.org/living\\_donation.asp](http://www.unos.org/living_donation.asp)

Item 5: The Committee disagrees with that statement that the proposal “requires that donors agree to post-donation follow-up as a condition of permission by the IDA to be a donor.” The proposal states that the center must have a protocol for informing the patient of its obligation to report follow up health information but does not describe any specific protocol for obtaining the information. The Committee has modified the language in this element to make it clearer that this information correlates to the Living Donor Follow-up Form which is required in the Data Submission Policies.

In response to this commenter's concerns regarding scope of data submitted, the Committee pointed out that following a period of development and public comment, the Board of Directors approved modifications to the following Data Submission Policies in June 2007:

- Policy 7.1.5 (Reporting Definitions). The follow-up period for living donors was changed from one year to *a minimum of two years*.
- Policy 7.3.2 (Submission of Organ Specific Transplant Recipient Registration Forms and Submission of Living Donor Registration Forms) was amended to state that the *"The recipient transplant center must submit LDF forms for each living donor at six months, one year and two years from the date of donation."*

Options for living donor status on the LDF form are as follows:

- (1) Living: Donor seen at transplant center;
- (2) Living: Donor status updated by verbal or written communication between transplant center and donor;
- (3) Living: Donor status updated by other health care facility;
- (4) Living: Donor status updated by transplant recipient
- (5) Living: Donor contacted, declined follow up with transplant center;
- (6) Dead;
- (7) Lost: No attempt to contact donor; and
- (8) Lost: Unable to contact donor (document)

If item 8 (Lost: Unable to contact donor) is selected, the transplant center will be asked to document their efforts to contact the donor.

Changes to the LDR form will provide:

- (1) the date of and the living donor's status during the most recent contact between the donor and the recipient transplant center; and
- (2) whether living donor organ recovery and transplant of that organ occurred at the same center.

These policies fulfill an OPTN contractual obligation to collect information on all living donors at the time of donation and for at least two years after the donation. The two-year Living Donor Follow-up (LDF) form includes the same data elements that have been collected at one-year post donation. The longer follow-up period will provide valuable information on the experience, safety, and health implications for living donors. Transplant center compliance with living donor follow-up is especially important since no alternative source of data exists.

This additional data collection is in accordance with the OPTN Principle of Data Collection to "ensure patient safety when no alternative sources of data exist." The "operational statements for data collection" approved by the Board in December 2006, also state that (1) the OPTN will only collect data that is contracted by HRSA, and (2) that data for specific populations (e.g., Living Donors) may constitute exceptions to the Principles of Data Collection. There are currently no other sources of data for living donors that would allow the OPTN to meet this contractual requirement.

**Comment 4:**

*Vote: Oppose*

*Date Posted: 07/13/2007*

To mandate a IDA for a procedure that has been performed since 1954 is unwarranted. The documentation required is excessive and will be very expensive. Who pays for it??

Committee Response: See response to Comment 1

**Comment 5:**

*Vote: Oppose*

*Date Posted: 08/10/2007*

Too prescriptive. Need to follow due process. See ASTS comments

Committee Response: See Response to Comment 16

**Comment 6:**

*Vote: Support*

*Date Posted: 08/07/2007*

First of all, would like to thank the MPSC and the Living Donor Committee members who worked on these proposals--especially the living donors who served as the 'voice' for donors and persisted in completion of this work. In light of the 2007, CMS Rules and Regulations for Transplant Programs; the Final Rule, the primary goal for all programs doing any type of living donor surgery should be to set forth policies and procedures consistent with the new federal legislation including the mandate for an independent donor advocate or an independent donor advocate team. The CMS Final Rule established lines for authority from the Sec to CMS to the OPTN noted as a membership organization whose role is to establish policy and monitor for policy compliance. If the goal is to establish minimum criteria for the surgeon(s) performing living donor nephrectomy,

I do not expect that all 240 programs will meet the requirements. However, this policy is needed to create 'standard level of quality' and be consistent with the Bylaws. Failure to develop living donor policies not only violates the HRSA mandate for the OPTN to develop policy on behalf of living donors, but would fail to ensure adequate donor care and demonstrate surgical expertise. As the policy reads "The proposed requirements for centers that perform living donor transplants (kidneys) include the following: 1. IDA--this is not duplication since is mandated under new CMS Rules and Regulations for Transplant Programs 2. Develop and comply with written protocols not only for the medical evaluation but the informed consent--again not duplication since CMS surveyors will audit for this information. This is consistency in expectations and policy language.

I support the changes and modifications to the designated transplant program criteria. In good conscience, not sure how any program could disagree. In order to be consistent with the 2004 Board vote, centers performing Living Donor Kidney Transplantation need to complete their application to demonstrate how will comply. The proposal is clear--this is not new information. This proposal puts forth the steps needed to be a designated Live Donor Kidney Program--and is consistent with the CMS Regs. CMS will look to the OPTN for leadership as a membership organization; and for policies & procedures and data as they stated on the Federal Register. As a living donor advocate group, we educate potential donors. This information is invaluable in that it does set a community standard (even if at a minimum.) Not only have the new CMS Rules & Regs put forth language on behalf of donors, so has the OPTN> Thank you.

Committee Response:

No Committee response; comment in support of proposal.

**Comment 7:**

*Vote: Support*

*Date Posted: 07/16/2007*

I strongly support all parts of this proposal that are designed to protect the rights of our patients.

Committee Response: No Committee response; comment in support of proposal.

**Comment 8:**

*Vote: Support*

*Date Posted: 07/13/2007*

Most of proposal is already in place with CMS guidelines, and is acceptable. I do question the usefulness of requiring the donor advocate to be a physician who is experienced in living donation, but not part of the transplant team?! We educated an internist on the donor evaluation, contraindications, etc to assist in this process and found that NOT very useful- they approved individuals who were clearly not suitable by the standards used by transplant team. I do not favor requiring a physician because I believe the transplant physicians are best qualified to make the determination- it will add nothing.

Committee Response:

The committee recognizes the deviation from CMS certificate of participation in requiring that centers who have only a single independent donor advocate (rather than a team) have a physician in that role. This concept was initially proposed due to the recognition that some small centers may not have enough members to constitute a team (of which, under the proposed policy, only one member must be independent of the decision to transplant the potential recipient). The proposal has been amended to say that the center must have an IDA who is not involved with the evaluation and decision to transplant the potential recipient. The initially proposed language indicating that if a center has a single IDA it must be a physician, has been removed.

**Comment 9:**

*Vote: Support*

*Date Posted: 07/13/2007*

Need to clarify if the Psychosocial eval can be done by the same person that does the recipient eval?

Committee Response: The psychosocial evaluation for the donor and recipient can be done by the same person, as long as that person is not serving as a member of the IDA team, and is independent of the evaluation and decision to transplant the potential recipient.

**Comment 10:**

*Vote: Support*

*Date Posted: 07/14/2007*

The bylaws in effect are on point. Evaluation, consent, and follow-up play a major role in transplant activity.

Committee Response:

No Committee response; comment in support of proposal.

**Comment 11:**

*Vote: Support*

*Date Posted: 08/10/2007*

The requirements related to the IDA team is very confusing and problematic especially a physician and a person not connected to the transplant. It is hard to have someone who is not connected to the Transplant to have the adequate knowledge to participate in any decision making process. Their impact on the process may therefore be minimal. The guidelines related various assessments are clearly laid out and I don't see the additional contribution made by this person. Besides this also adds another expense to the TX hospital. Re: qualifications of donor surgeon: - they should perform 10 donor nephrectomies. Nephrectomies for other causes due to diseased kidneys should not be acceptable

Committee Response: See response to Comment 1 regarding the IDA. The Committee pointed out that the donor surgeon requirements were approved in June 2004, and are not newly proposed Bylaw amendments.

**Comment 12:**

*Vote: Support*

*Date Posted: 07/21/2007*

Will renal programs currently performing LD transplants be required to reapply or will they be grandfathered in?

Committee Response: Existing renal programs that perform living donor transplants will be required to apply and document they have the existing components of the Bylaws, Appendix B, Attachment I. The process will be similar to the process undertaken during the last 2 years by existing liver programs that also perform living donor transplants. The proposed modifications to the Bylaws new elements that would also be required for centers to be approved to perform living donor transplants.

**Comment 13:**

*Vote: Support*

*Date Posted: 08/10/2007*

XIII C (2) a (1) d living donor transplant "at least one member who is not involved with the transplant evaluation" member should be physician.

Committee Response:  
See response to Comment 11.

**Comment 14:**

*Vote: Support*

*Date Posted: 08/11/2007*

XIII. C. 2. c) Please consider adding as a minimum requirement that a "plain language" description of the written description of the donor evaluation and nephrectomy will provided. Also, perhaps as a consideration for the future, UNOS could provide sample templates for the required written protocols to further ensure consistency and quality of living donor programs across the US.

Committee Response: This comment has been referred to the Living Donor Committee which is developing the "Guidelines for the Consent of Living Donors."

**Comment 15**

*Vote: Oppose*

*Date Received: 8/10/2007*

The additional donor follow up and testing is a great idea and we currently recommend that all of our living donors have annual follow up, however, there is no financial support for this follow-up 6 month after donation. Of note, we currently have difficulty getting living donors to come back after their 2 week check, and anticipate even more difficulty with compliance as outlined in the guidelines, particularly if it's the donors financial responsibility. [Proposals 1, 2, &4]

Committee Response: See response to Comment 3, Item 5

**Comment 16**

*Vote- not stated*

*Date Received: 8/10/2007*

See attached letter from ASTS. Only those comments that relate to the Proposal 1 and/or 2 are addressed in this Briefing Paper.

Concerns related to Process:

- Principles of Data Submission were not considered in the development of these proposals:

Committee Response: These policies fulfill an OPTN contractual obligation to collect information on all living donors at the time of donation and for at least two years after the donation. The two-year Living Donor Follow-up (LDF) form includes the same data elements that have been collected at one-year post donation. The longer follow-up period will provide valuable information on the experience, safety, and health implications for living donors. Transplant center compliance with living donor follow-up is especially important since no alternative source of data exists.

This additional data collection is in accordance with the OPTN Principle of Data Collection to "ensure patient safety when no alternative sources of data exist." The "operational statements for data collection" approved by the Board in December 2006, also state that (1) the OPTN will only collect data that is contracted by HRSA, and (2) that data for specific populations (e.g., Living Donors) may constitute exceptions to the Principles of Data Collection. There are currently no other sources of data for living donors that would allow the OPTN to meet this contractual requirement.

- OPTN members did not have an opportunity to comment on the current living donor requirements.

Committee Response: The original requirements were developed by the Living Donor Committee with input from the MPSC, Kidney Transplantation Committee, and the Liver and Intestinal Organ Transplantation Committee. The current requirements were initially circulated for public comment March 14, 2003, through April 30, 2003. After reconsideration by the committee, the liver requirements were approved by the Board of Directors in November 2003, and the kidney requirements were approved in June 2004. Additional amendments to the living donor liver bylaws were considered in a public comment period lasting from May 19 – July 18, 2006. These changes, which instituted a conditional pathway, were approved by the Board of Directors in September 2006.

- Duplication and Differences with CMS Regulations:  
Committee Response: OPTN requirements apply to all transplant programs whereas CMS requirements only pertain to those that are Medicare certified or seeking Medicare certification. Programs that are not Medicare certified should not have to meet lesser standards. The Committees recommended aligning the requirements wherever possible.
  - IDAT – See response to comment 3 above
  - Required 2 year follow up for living donors – See response to comment 3 above.

In addition to the concerns raised in the ASTS letter dated August 9, 2007, the Living Donor Work Group considered the comments that were shared by ASTS Committee members (who also sit on this Work Group) regarding living donor kidney transplantation qualifications with respect to laparoscopic and open donor nephrectomies. Dr. Andy Klein, a member of the Work Group, as well as the Chair of newly formed ASTS Ad hoc Committee on Living Donation, accepted the Work Group’s response that it would be happy to entertain recommendations from the ASTS regarding this issue once they are developed by the ASTS committee. The Work Group observed that any such recommendation would need to be considered by the appropriate OPTN/UNOS Committees and that proposed modifications to the bylaws would then need to be circulated for public comment.

**Comment 17**

Vote: Not specified in letter  
Date Received: 8/10/2007

See attached letter from UPenn.  
Only those comments that relate to the Proposal 1 and/or 2 are addressed in this Briefing Paper.

Institution supports the proposals that require “each center to develop and comply with its own living donor protocol(s) in order to ensure donor safety.” The center further indicates that it supports the adoption of “required model elements.” Furthermore, the institution supports “a policy that mandates that centers have a detailed protocol for evaluation, and that the protocol be followed, but not to require specific tests or studies.”

Committee Response: The Committee believes that the proposed Bylaw language accomplishes these recommendations.

**Comment 18:**

vote: Support  
Date Posted: 08/13/2007

These minimum standards, if uniformly applied and enforced, will resolve long standing challenges to wider and deeper public acceptance of and confidence in living donor transplantation in the United States.

Committee Response:  
No Committee response; comment in support of proposal.

**Comment 19:**

*vote: Oppose*

*Date Posted: 08/13/2007*

The IDA team is onerous, particularly for simultaneous kidney pancreas. While you say it can be a physician alone, every kidney donor will see a social worker for the psycho-social evaluation. That person either must be a member of the IDA team. On page 26 you then stipulated “it least one member or the IDAT team must be entirely independent of the transplant provider. That’s a [...] concept, but where are providers supposed to find such individuals to devote hours of their time to advocate for living donors? If they request compensation who will pay?

Committee Response: See response to Comment 1

## SUMMARY OF PUBLIC COMMENTS – PROPOSAL 2

### Proposed Modifications to Bylaws, Appendix B, Attachment I, Section XIII, C (4) Liver Transplant Programs that Perform Living Donor Liver Transplants

#### Individuals Comments:

As of 8/11/2007, 47 responses have been submitted to UNOS regarding this policy proposal. Of these, 30 (63.83%) supported the proposal, 5 (10.64%) opposed the proposal, and 12 (25.53%) had no opinion. Of the 35 who responded with an opinion, 30 (85.71%) supported the proposal and 5 (14.29%) opposed the proposal. Comments on the proposal received to date are as follows:

#### **Comment 1:**

*Vote: Oppose*

*Date Posted: 08/13/2007*

Should be more strict with safety. Section c, 4, 2, b, ii focuses on liver, cancer, competency. A whole evaluation must be done of cardiovascular and pulmonary because this is a major endeavor.

#### Committee Response:

The minimal elements that must be addressed in the protocol are delineated in the Bylaws; however, the center may develop more detailed medical evaluation requirements.

#### **Comment 2:**

*Vote: Oppose*

*Date Posted: 07/13/2007*

To mandate an IDA for a procedure that has been performed since 1954 is unwarranted. The documentation required is excessive and will be very expensive. Who pays for it??

#### Committee Response:

Same comment as #4 under the kidney proposal. See that Committee Response.

#### **Comment 3:**

*Vote: Oppose*

*Date Posted: 08/10/2007*

Too prescriptive. Need to follow due process. See ASTS comments

#### Committee Response:

Same comment as #5 under the kidney proposal. See that Committee Response.

#### **Comment 4:**

*Vote: Support*

*Date Posted: 08/07/2007*

Again, support since it is meant to mirror the language of Live Donor Programs. Support these additional bylaws to ensure essential elements for the liver lobe donor. The committee members obviously saw this information as 'essential'--I would expect the same from the transplant community at large.

#### Committee Response:

No Committee response; comment in support of proposal.

#### **Comment 5:**

*Vote: Support*

*Date Posted: 08/10/2007*

Similar to what I said above (Comment 11)

Committee Response:  
See Committee response to Comment 11 under the Kidney proposal

**Comment 6:**

*Vote: Support*

*Date Posted: 07/14/2007*

The bylaws in effect are agreeable to protocol.

Committee Response:  
No Committee response; comment in support of proposal.

**Comment 7:**

*Vote: Support*

*Date Posted: 08/11/2007*

XIII. C. 4. b) Please consider adding as a minimum requirement that a "plain language" description of the written description of the donor evaluation and surgical procedure will provided. Also, perhaps as a consideration for the future, UNOS could provide sample templates for the required written protocols to further ensure consistency and quality of living donor programs across the US.

Committee Response:  
Committee Response: Same as Comment 14 in the Kidney Proposal. This comment has been referred to the Living Donor Committee which is developing the "Guidelines for the Consent of Living Donors."

*Comment 8:*

*vote: Support*

*Date Posted: 08/13/2007*

These minimum standards, if uniformly applied and enforced, will resolve long standing challenges to wider and deeper public acceptance of and confidence in living donor transplantation in the United States.

Committee Response:  
No Committee response; comment in support of proposal. (Same as Comment 18 in Proposal 1)

**B. COMMENTS FROM OTHER COMMITTEES:**

Kidney and Pancreas Transplantation Committees- Proposal 1

The Kidney and Pancreas Committees met jointly via conference call in July 2007 to discuss this proposal. Both Committees expressed that the scope of this proposal is too large for an expedited public comment cycle of only 30 days. This timeframe has not allowed for adequate discussion or consideration during in-person Committee meetings. While the Committees believe that there needs to be coverage of living donation in the by-laws and policy, they are unable to approve this proposal at this time due to the concerns described below.

The Committees were primarily concerned with the methods used to develop these by-law recommendations. Sixteen large transplant programs were surveyed and requirements were gleaned from their practices. The Committee expressed that smaller transplant programs may be unable to abide by the recommended by-laws due to staffing or other resource limitations. Larger centers will have larger staffs and more flexibility for staffing an independent donor advocate team.

The Committees did not formally vote on this proposal and instead decided to continue the discussion at the upcoming in person meetings in August and September 2007.

The Kidney Transplantation Committee again reviewed the bylaws proposal to set requirements for transplant programs that perform living donor kidney transplants during its May 15, 2007, meeting. The Committee understands the need for the OPTN to have bylaws in place for the protection of living donors.

The Committee appreciates the Membership and Professional Standards and Living Donor Committees efforts to further align the proposed bylaws with the recently released CMS requirements. This alignment will mitigate the compliance burden on transplant centers while still accomplishing the goals of putting protections in place. The Kidney Committee recommends, at the behest of its ethicist members, that the bylaws be changed from assessing the competence of the potential living donor to assessing the decision-making ability of the potential living donor.

Committee response: The methods used to develop this proposed amendment to the OPTN and UNOS Bylaw were not based upon a survey of 16 large transplant centers but rather by reviewing existing documents such as the NY and SC state regulations, the ACOT guidelines and the CMS Certificate of Participation. Proposals 3 and 4 (guidelines regarding consent and medical evaluation) were developed in part using the above referenced survey method. The Committee understands the difficulty in reaching consensus on an accelerated schedule. However, the joint working group is responding to the very high priority placed upon the issue of living donor oversight by the OPTN/UNOS Board of Directors, as well as the community at large, and remains highly motivated to proceed. To facilitate this discussion, the proposed that a subcommittee member be present for any required clarification to discussion of the proposed policy at the next scheduled meeting of the Kidney Transplantation Committee meeting on August 14-15 2007. Dr. Pruett attended the meeting and provided clarification.

The recommendation to amend the language in Kidney Section 2, b,ii(d) and Liver Section 4, 2, ii(d) was received after the last Living Donor Work Group conference call meeting, however, this recommendation was accepted by the MPSC Chair.

#### Ad Hoc International Relations Committee – Proposals 1 and 2

The Ad Hoc International Relations Committee met via telephone conference call on August 7, 2007, and discussed this proposal as part of its full committee meeting. Since the scope of this proposal falls outside of its purview, the Committee decided to submit a “No Comment” as feedback for the MPSC and Living Donor Committee (4-No Comment; 0-Support; 0-Oppose; 0-Abstain).

Committee Comment: No response required.

#### Thoracic Organ Transplantation Committee – Proposals 1 and 2

The Thoracic Organ Transplantation Committee conducted an online review of this proposal, and voted to support it (9-Support, 0-Oppose, and 3-Abstain). There were no additional comments submitted for this proposal.

Committee Comment: No Committee response; comment in support of proposal.

#### Liver and Intestinal Transplant Committee – Proposal 2- Liver Proposal

There was some concern about the two year follow-up period for living donors and the Committee was reminded that it is now an OPTN contract requirement to follow living donors for two years. Under the previous OPTN contract, the follow-up period was one year. The information collected at two years is the same information that is collected on the one year follow-up form.

The Committee discussed the requirement for biliary imaging as part of the donor evaluation. This testing has previously been “suggested” but never required like other tests such as volumetrics and vascular imaging. There was no objection to this requirement although it was noted that the OPTN has always tried to avoid getting involved with the specifics of how medical professionals practice medicine. The individual transplant programs should be allowed to decide what tests are needed to properly evaluate potential donors. It was noted by a Committee member who was involved in the development of this proposal that the Committees tried to avoid being too prescriptive with these requirements.

The Committee discussed the requirement to have written protocols for informed consent for the donor evaluation process and the donor hepatectomy. There was some confusion about whether this requires two separate written consent forms, whether verbal communication is acceptable, and what sort of documentation is required during the process?

Motion: The Committee supports the proposal as written but requests that the MPSC and Living Donor Committee clarify how the communications and discussions required in section 4.2.b (regarding informed consent for evaluation and donor hepatectomy) need to be documented by the transplant centers.

Committee vote: 18 in favor, 0 opposed, and 0 abstentions.

Committee response:

The consent of the potential living donor must include a discussion of both the risks of the evaluation of the donor (such as the diagnosis of malignancy, occult liver disease, etc...) and the risks of the surgical procedure. The proposed amendment does not specify that this requires two separate signed consent forms, but rather has left it to the purview of the individual center to determine the best protocol for to ensure documentation of this discussion (including making this discussion a standardized part of the IDA visit, or a standardized part of the initial medical evaluation visit.)

Additionally, the Committee reconsidered the inclusion of specific types of imaging and is recommending that the language for the radiographic assessment be amended as shown in this document under Final Proposal.

Transplant Coordinators Committee – Proposals 1 and 2

The TCC did not support the proposed change by a vote of 1-4-4.

The TCC has several concerns:

- clinical practice should not be dictated,
- cost of donor follow-up,
- responsibility for the donor follow-up costs,
- responsibility for medical and disability insurance,
- cost of donor follow-up when insurance coverage ends.

Committee response: See Background and Significance Section of this document as well as the Committee responses to Comment 3 in the Kidney Proposal. The Committee pointed out that medical & disability insurance are addressed in Proposal 4, “Guidelines for the Consent of Living Donors, Donor Evaluation,” which is sponsored by the Living Donor Committee.

Minority Affairs Committee – Proposals 1 and 2

The Minority Affairs Committee met via conference call on August 3, 2007 to discuss the proposals. All four living donor proposals were reviewed and discussed as a unit.

The committee supports the principles and intent behind the proposals submitted by the Membership and Professional Standards (MPSC) and Living Donor Committees. However, it believes that the guidelines, as written, are overly prescriptive and detailed and appear to mandate specific elements of a protocol, without allowing enough flexibility in medical decision making for individual patients, cases, etc. Although the proposals are presented as guidelines, there is also concern that they could be used as a model against which all programs would be measured. The committee believes that the principles of good practices should be reflected in the guidelines, rather than mandated functions of procedures and staff.

The committee is very supportive of the concept of the independent donor advocate (IDA), provided there is flexibility in how the position and team is defined. The committee recognizes the difficulty in assembling an IDA team which would be totally independent of the donation process; however, the committee agrees that programs should have at least one team member who is relatively independent of the process at that level. The committee also supports centers assisting donors with obtaining medical and disability insurance, as the donation procedure could potentially impact the donor’s ability to obtain future employment and insurance.

The committee did not formally vote on the proposals.

Committee response: The Committee appreciates these comments from the Minority Affairs Committee and notes that the proposed IDA requirements have been amended as shown in the Final Proposal section of this report. Comments regarding the Guidelines in Proposals 3 and 4 will be considered by the Living Donor Committee.

OPO Committee - Proposals 1 and 2

Members agreed that these controls are necessary to protect the living donor. Reporting members supported all of these proposals put forth by the Living Donor Committee with a vote of 7-0-0.

Committee response: No Committee response; comment in support of proposal.

Patient Affairs Committee- Proposal 1

Concern was expressed regarding the lack of consistency between CMS regulations and the proposed policy regarding the following elements: specified personnel to conduct the psychosocial evaluation; and the defined role and responsibilities of the IDA/IDAT. Overall, Members supported the Living Donor Committee's effort to standardize minimum criteria for kidney transplant programs that perform living donor kidney transplants and unanimously supported this proposal by a vote of 11-0-0.

Committee response: The Committee recognizes the deviation from CMS Certificate of Participation in requiring that centers who have only a single independent donor advocate (rather than a team) have a physician in that role. This concept was initially proposed due to the recognition that some small centers may not have enough members to constitute a team (of which, under the proposed policy, only one member must be independent of the decision to transplant the potential recipient). The proposal has been amended to state that the center must have an IDA who is not involved with the evaluation and decision to transplant the potential recipient. The initially proposed language indicating that if a center has a single IDA it must be a physician, has been removed.

Patient Affairs Committee – Proposal 2

Concern was expressed regarding the lack of consistency between CMS regulations and the proposed policy regarding the following elements: specified personnel to conduct the psychosocial evaluation; and the defined role and responsibilities of the IDA/IDAT. Overall, Members supported the Living Donor Committee's effort to standardize minimum criteria for liver transplant programs that perform living donor liver transplants and unanimously supported this proposal by a vote of 11-0-0.

Committee response:  
See Response to Comment 1

Pediatric Transplantation Committee – Proposal 1 and 2

Upon review, a member noted that this proposal aligns OPTN policies with CMS requirements. It was suggested that the word "independent" when used in Independent Donor Advocate (IDA) is controversial and not well understood in this context. Neither CMS nor UNOS has offered a specific definition, but it is assumed that, as referenced, it is implied that the IDA have no perceived conflict of interest in advocating for a donor. The Committee unanimously supports these modifications and asks that the Living Donor Committee consider formalizing a definition for the term IDA. (Committee vote: 17-0-0)

Committee response:  
The proposal has been amended to state that the center must have an IDA who is not involved with the evaluation and decision to transplant the potential recipient. The initially proposed language indicating that if a center has a single IDA it must be a physician, has been removed. The amended language will read "...That the center has an independent donor advocate (IDA) who is not involved with the evaluation and decision to transplant the potential recipient.

Operations Committee – Proposals 1 and 2  
The committee did not review the proposal.

Thoracic Organ Transplantation Committee – Proposal 1 and 2  
No Comment.

Transplant Administrators Committee – Proposal 1 and 2  
No Comment.

Pancreas Transplantation Committee – Proposal 2  
No comment.

Organ Availability Committee – Proposal 2  
The Committee has no comment on this proposal.

Histocompatibility Committee – Proposal 1 & 2  
No Comment

**C. REGIONAL COMMENT SUMMARY – PROPOSAL 1**

**Proposed Modifications to Bylaws, Appendix B, Attachment I, Section XIII, C (2) Kidney Transplant Programs that Perform Living Donor Kidney Transplantation**

| Region | Live Meeting Date | Motion to Approve as Written | Approved as Amended         | Did not Consider |
|--------|-------------------|------------------------------|-----------------------------|------------------|
| 1      | 8/3/07            | 8 yes, 0 no, 2 abstentions   |                             |                  |
| 2      | 8/8/07            |                              | 24 yes, 0 no, 4 abstentions |                  |
| 3      | 8/9/07            | 4 yes, 11 no, 2 abstentions  |                             |                  |
| 4      | 7/30/07           | 0 yes, 22 no, 0 abstentions  |                             |                  |
| 5      | 7/26/07           | 8 yes, 3 no, 1 abstentions   |                             |                  |
| 6      | 8/10/07           | 19 yes, 2 no, 1 abstentions  |                             |                  |
| 7      | 7/24/07           | 11 yes, 1 no, 1 abstentions  |                             |                  |
| 8      | 7/26/07           | 13 yes, 0 no, 3 abstentions  |                             |                  |
| 9      | 8/8/07            | 10 yes, 0 no, 1 abstentions  |                             |                  |
| 10     | 8/7/07            | 2 yes, 9 no, 6 abstentions   |                             |                  |
| 11     | 8/9/07            | 6 yes, 7 no, 3 abstentions   |                             |                  |

**Region 1:** The region felt strongly that the IDA should be a transplant physician. In addition, the proposed IDA language is not compatible with the CMS definition of an IDA. The region is interested in reviewing models from other transplant centers that currently have an IDA or IDAT. The members also raised concern regarding the transplant center paying an IDA when the physician is supposed to be an independent advocate.

**Committee Response:**

The Committee recognizes the deviation from CMS certificate of participation in requiring that centers who have only a single independent donor advocate (rather than a team) have a physician in that role. This concept was initially proposed due to the recognition that some small centers may not have enough members to constitute a team (of which, under the proposed policy, only one member must be independent of the decision to transplant the potential recipient). The proposal has been amended to state that the center must have an IDA who is not involved with the evaluation and decision to transplant the potential recipient. The initially proposed language indicating that if a center has a single IDA it must be a physician, has been removed.

**Region 2:** Region 2 approved the proposal with the following comments and language modification:

- There was concern that it would be very difficult to find an IDA who was completely independent from transplant recipients. The region agreed that the IDA should not be involved with the specific recipient being evaluated, but that this person may have involvement with other recipients.
- The region agreed that the language in OPTN/UNOS Bylaws, Appendix B, Attachment I, Section XIII, C (2) should be modified to read: *d) That the center has either an independent donor advocate (IDA) who is a physician, or an independent donor advocate team, which includes at least one member who is a physician and at least one member who is not involved with the evaluation and decision to transplant the that specific recipient.*

**Committee Response:**

See Response to Region 1 comment.

**Regions 3 and 11:** This Bylaw Proposal was not approved.

Some of the concerns raised included:

- The proposed Bylaws for the IDA are stricter than the CMS Regulations.
- The wording for the IDA is unclear. What is the intent?
- There should be some consistency between CMS Regulations and the OPTN/UNOS Bylaws.

Committee Response:

See Response to Region 1 comment.

**Region 4:** The region was strongly opposed to the proposal for the following reasons:

- UNOS is dictating medical practice.
- 2 year follow-up is difficult to get and there is no funding. Living donors usually have problems in the first year post donation or many years post donation. Follow-up after year two will provide little, if any, valuable data.
- IDA: Transplant centers would have to pay someone to take on this role.

Committee Response:

See responses to Comment 3 in the Kidney Proposal as well as Region 1 above.

**Region 6:** Region 6 approved the proposal but asked the committee to clarify the definition of “independent” in reference to the IDA.

Committee Response:

See response to Comment 1 in the Kidney Proposal

**Region 8:** The motion was approved with the following comments:

- Criteria should include appropriate requirements for disease identification to ensure that state of the art testing is being used.
- 2 year follow-up is difficult to get and there is no funding. Living donors usually have problems in the first year post donation or many years post donation. Follow-up after year two will provide little, if any, valuable data.
- These criteria should be in parallel with CMS Conditions of Participation.

Committee Response:

See responses to Comments 3 and 16 in the Kidney Proposal.

**Region 10:** The region opposed this proposal and they feel that any Bylaw requirements put forth by UNOS should mirror the CMS guidelines. They also commented that if a transplant program is CMS approved to perform living kidney transplants than that transplant center should automatically be approved as an OPTN/UNOS living kidney donor program. Transplant centers should not be asked to submit the same/similar sets of information/application to two government agencies.

Committee Response: The role of OPTN Bylaws and Policies and CMS regulations are not the same as described in the Background and Significance section of this document.

**REGIONAL COMMENT SUMMARY - PROPOSAL 2:**

**Proposed Modifications to Bylaws, Appendix B, Attachment I, Section XIII, C (4) Liver Transplant Programs that Perform Live Donor Liver Transplants**

| Region | Live Meeting Date | Motion to Approve as Written | Approved as Amended         | Did not Consider |
|--------|-------------------|------------------------------|-----------------------------|------------------|
| 1      | 8/3/07            | 7 yes, 0 no, 3 abstentions   |                             |                  |
| 2      | 8/8/07            |                              | 21 yes, 0 no, 7 abstentions |                  |
| 3      | 8/9/07            | 4 yes, 7 no, 5 abstentions   |                             |                  |
| 4      | 7/30/07           | 0 yes, 15 no, 3 abstentions  |                             |                  |
| 5      | 7/26/07           | 7 yes, 3 no, 6 abstentions   |                             |                  |
| 6      | 8/10/07           | 16 yes, 2 no, 4 abstentions  |                             |                  |
| 7      | 7/24/07           | 12 yes, 0 no, 1 abstentions  |                             |                  |
| 8      | 7/26/07           | 11 yes, 0 no, 4 abstentions  |                             |                  |
| 9      | 8/8/07            | 9 yes, 0 no, 0 abstentions   |                             |                  |
| 10     | 8/7/07            | 2 yes, 5 no, 13 abstentions  |                             |                  |
| 11     | 8/9/07            | 7 yes, 2 no, 6 abstentions   |                             |                  |

**Region 1:** Region 1 approved the proposal with the following comments:

The region felt strongly that the IDA should be a transplant physician.

In addition, the proposed IDA language is not compatible with the CMS definition of an IDA.

The region is interested in reviewing models from other transplant centers that currently have an IDA or IDAT.

The members also raised concern regarding the transplant center paying an IDA when the physician is supposed to be an independent advocate, but finding someone to serve as an IDA without compensation is highly unlikely.

Committee Response: See Committee Response to Region 1 in the kidney proposal.

**Region 2:** Region 2 approved the proposal with the following comments and language modification:

There was concern that it would be very difficult to find an IDA who was completely independent from transplant recipients. The region agreed that the IDA should not be involved with the specific recipient being evaluated, but that this person may have involvement with other recipients.

The region agreed that the language in OPTN/UNOS Bylaws, Appendix B, Attachment I, Section XIII, C (4) should be modified to read: *c) That the center has either an independent donor advocate (IDA) who is a physician, or an independent donor advocate team, which includes at least one member who is a physician and at least one member who is not involved with the evaluation and decision to transplant ~~the~~ that specific recipient.*

Committee Response: See Committee Response to Region 2 in the kidney proposal.

**Regions 3 and 11:** This Bylaw Proposal was not approved by Region 3.

Some of the concerns raised by members of both regions included:

- The proposed Bylaws for the IDA are stricter than the CMS Regulations.
- The wording for the IDA is unclear.
- There should be some consistency between CMS Regulations and the OPTN/UNOS Bylaws.

Committee Response: See Committee Response to Region 3 in the kidney proposal.

**Region 4:** The region was strongly opposed to the proposal for the following reasons:

- UNOS is dictating medical practice.
- 2 year follow-up is difficult to get and there is no funding. Living donors usually have problems in the first

year post donation or many years post donation. Follow-up after year two will provide little, if any, valuable data.

- IDA: Transplant centers would have to pay someone to take on this role.

Committee Response: See Committee Response to Region 4 in the kidney proposal.

**Region 6:** Region 6 approved the proposal but asked the committee to clarify the definition of “independent” in reference to the IDA.

Committee Response: See Committee Response to Region 1 in the kidney proposal.

**Region 10:** The region opposed this proposal and they feel that any Bylaw requirements put forth by UNOS should mirror the CMS guidelines. They also commented that if a transplant program is CMS approved to perform living liver transplants than that transplant center should automatically be approved as an OPTN/UNOS living liver donor program. Transplant centers should not be asked to submit the same/similar sets of information/application to two government agencies

Committee Response: See Committee Response to Region 10 in the kidney proposal.

## V. FINAL PROPOSALS

These proposals were issued to a mailing list of approximately 13,100 individuals and organizations for a comment period of 30 days beginning on July 13, 2007 and ending August 11, 2007. Notifications of all policy and bylaw proposals issued for public comment are either mailed to the distribution list in hard copy form, or via electronic mail with website link by request.

The MPSC met on August 1-2, 2007, and considered the input received to date from individuals, the Regions, associations, and other OPTN/UNOS Committees. The public comment period would not end until August 11; therefore the Committee was unable to make final recommendations on the proposals, but they did agree that the IDA language in the proposal could be amended and asked the working group to finalize the language. The Committee agreed, by a vote of 22 For, 0 Against, and 2 Abstentions, to empower the working group to finalize the language in the proposals.

The MPSC/Living Donor Policy Working Group convened by conference call on August 13, 2007, to discuss the comments that had been received. The Committee took under consideration all of the comments that had been received and has recommended modifications to the original proposal.

The Work Group observed that the comments for the most part fell into one of the following categories:

- The transplant community does not fully appreciate the OPTN's mandate to develop living donor policies.
- The Bylaws and guidelines proposals are viewed as dictating medical practice, and are too prescriptive.
- The transplant community believes that implementing the Bylaws and guidelines will increase costs.
- The transplant community believes the Bylaws should be more closely aligned with the Medicare Conditions of Participation (COP) for Medicare approved programs.

Responses to these comments can be found in the "Summary of Comments" section of this document.

### Summary of Modifications Recommended Following the Public Comment Period:

In response to the comments, the proposals have been amended to state that the center must have an Independent Donor Advocate (IDA) who is not involved with the evaluation and decision to transplant the potential recipient. The initially proposed language indicating that if a center has a single IDA it must be a physician, has been removed. The changes made to the IDA language more closely align with the Medicare COP for Medicare approved programs.

Additionally, language has been added to further clarify that the center must have personnel and resources available to assess the medical condition and risks for the potential donor; and to conduct a thorough psychosocial assessment.

Modifications have been proposed to the sections on informed consent to clarify that the center is responsible for having a written protocol for notifying donors of the plan for collecting follow up information for the donor on the Living Donor Follow-up form. This language restates the reporting schedule that is delineated in Policy 7.3.2 (Submission of Organ Specific Transplant Recipient Registration Forms and Submission of Living Donor Registration Forms).

The medical evaluation section of the proposal for living donor liver transplantation has been modified. The proposed bylaw for the radiographic assessment has been made less prescriptive by removing the requirement for vascular and biliary imaging.

The Working Group agreed to amend the proposals in response to the comments that had been received and the direction provided by the MPSC. Based on this recommendation the following resolution is presented to the Board of Directors for their consideration.

- \*\* RESOLVED that the Bylaws, Appendix B, Sections III, C(2) and C(4) shall be modified as set forth in below and upon approval by the Board of Directors and pending notice to the members.**

Following the conclusion of the conference call meeting on August 13, the Work Group members reviewed the final proposed language by electronic means. The members suggested some additional minor modifications to the language but there was not time to circulate these recommended changes for additional consideration prior to the due date for this report. Additionally, the Kidney Transplantation Committee met on August 14 and reconsidered the proposed modifications. The Kidney Transplantation Committee made a recommendation to amend the language in Kidney Section 2, b,ii(d) and Liver Section 4, 2, ii(d). This recommendation was accepted by the MPSC Chair.

**The proposed modifications to the Bylaws that were made following public comment are shown below as double underlines and ~~double~~ strikeouts. Further recommendations received after the committee conference call but without time for a final vote are shown as double underline, bold, and in *italics*.**

### Proposed Modifications to the Living Donor Requirements

#### Final - Proposal 1

#### Proposed Modifications to THE Bylaws, Appendix B, Attachment I, Section XIII, C (2), Designated Transplant Program Criteria

### XIII. Transplant Programs.

- A. No changes
- B. No changes
- C (1) No changes

(2) ~~Living Donor Kidney Transplant Programs~~ that Perform Living Donor Kidney Transplantation.

~~A. Living Donor Kidney Transplant Programs~~

1. Kidney Transplant Programs that Perform Living Donor Kidney Transplantation ~~A Living living donor kidney transplant program~~ must demonstrate the following regarding personnel and resources:
  - (a) That the center meets the qualifications of a renal transplant program as set forth in (Section (1) above; and)
  - (b) In order to perform open donor nephrectomies, a qualifying renal donor surgeon must be on site and must meet the criteria of (i) and/or (ii) below:
    - (i) Completed an accredited ASTS fellowship with a certificate in kidney, or
    - (ii) Performed no fewer than 10 open nephrectomies (to include deceased donor nephrectomy, removal of polycystic or diseased kidneys, etc.) as primary surgeon or first assistant within the prior 5-year period.
  - (c) If the center wishes to perform laparoscopic donor nephrectomies, a qualifying renal donor surgeon must be on site and must have:

- (i) Acted as primary surgeon or first assistant in performing no fewer than 15 laparoscopic nephrectomies within the prior 5-year period.

If the laparoscopic and open nephrectomy expertise resides within different individuals then the program must demonstrate how both individuals will be available to the surgical team. It is recognized that in the case of pediatric living donor transplantation, the Living organ donation may occur at a center that is distinct from the approved transplant center.

All surgical procedures identified for the purpose of surgeon qualification must be documented. Documentation should include the date of the surgery, medical records identification and/or UNOS identification number, and the role of the surgeon in the operative procedure.

- d) The center must have the resources available to assess the medical condition *of* and *any* risks for the individual for potential *living* donation;
- e) The psychosocial assessment should include the *potential donor's* capacity to make an informed decision and to affirm the voluntary nature of proceeding with the evaluation and donation; and
- f) That the center has ~~either an independent donor advocate (IDA) who is a physician, or an independent donor advocate team, which includes at least one member who is a physician and at least one member who is not involved with the evaluation and decision to transplant the potential recipient and who fulfills the duties listed in Section 2 (b) below.~~

2. Kidney Transplant Programs that Perform Living Donor Kidney Transplantation must demonstrate that they have the following ~~regarding~~ protocols:

- a) Living Donor Transplant centers must develop, and once developed must comply with written protocols to address all phases of the living donation process. Specific protocols shall include the evaluation, pre-operative, operative, post-operative and two-year follow-up period after donation.

Transplant centers must document that all phases of the living donation process were performed in adherence to the center's protocol. This documentation must be maintained and made available upon request.

- b) Written protocols must include, but are not limited, to the following elements:
  - i) a description of the duties and primary responsibilities of the IDA ~~or IDA Team members as described in 1 (d) above~~, to include procedures that:
    - (a) protect and promote the best interests of the potential living donor;
    - (b) ensure protection of the rights of the living donor; and
    - (c) provide the potential donor with information regarding the:
      - (i) consent process;
      - (ii) evaluation process;
      - (iii) surgical procedure; and
      - (iv) benefit and need for follow-up.
  - (ii) a thorough medical evaluation by a physician and/or surgeon experienced in living donation including:

- (a) a screen for any evidence of occult renal and infectious disease or medical co-morbidities which may cause renal disease;
  - (b) age appropriate cancer screening;
  - (c) a radiographic assessment to evaluate vascular anatomy and any congenital malformation; and
  - (d) a psychosocial evaluation of the potential living donor by a psychiatrist, psychologist, or social worker with experience in transplantation (criteria defined in Appendix B, Attachment I, ~~Section C (17)~~ to determine **decision making capacity** ~~competency~~, screen for any pre-existing psychiatric illness, and/or any potential coercion.
- c) The center shall have written protocols for the Informed Consent for the Donor Evaluation Process and Informed Consent for the Donor Nephrectomy, which include, at a minimum, the following elements:
- (i) discussion of the potential risks of the procedure including the medical, psychological and financial risks associated with being a living donor.
  - (ii) assurance that all communication between the **potential** donor and the transplant center will remain confidential;
  - (iii) discussion of the donor's right to opt out at any time during the donation process;
  - (iv) discussion that the medical evaluation or donation may impact the donor's ability to obtain health, life and disability insurance; **and**
  - (v) disclosure by the transplant center that it is required, at a minimum, to submit contact and ~~obtain follow-up~~ Living Donor Follow-up forms addressing the health information on of each living donor at 6 months, one-year, and two-years post donation. The protocol must include a plan to collect the information about each donor.

**Final – Proposal 2**  
**Proposed Modifications to UNOS Bylaws, Appendix B, Attachment I, Section XIII,**  
**C(4), Designated Transplant Program Criteria**

**XIII. Transplant Programs.**

- A. No changes**
- B. No changes**
- C. (1) No changes**
  - (2) See above**
  - (3) No changes**

**(4) Liver Transplant Programs that Perform Living Donor Liver Transplants.**

1. ~~A live donor liver transplant center must demonstrate the following:~~ Liver Transplant Programs that Perform Living Liver Transplants~~ation~~ must demonstrate the following regarding personnel and resources:
  - a) That the center meets the qualifications of a liver transplant center as set forth ~~in UNOS Bylaws, Appendix B, Attachment I, Section XIII~~~~(=and)~~.
  - b) That the center has on site no fewer than two surgeons who qualify as liver transplant surgeons under UNOS Bylaws Appendix B, Attachment I, Section XII(C)(2)(a) and who have demonstrated experience as the primary surgeon or first assistant in 20 major hepatic resectional surgeries (to include living donor operations, splits, reductions, resections, etc.), 7 of which must have been live donor procedures within the prior 5-year period. These cases must be documented. Documentation should include the date of the surgery, medical records identification and/or UNOS identification number, and the role of the surgeon in the operative procedure. It is recognized that in the case of pediatric living donor transplantation, the live organ donation may occur at a center that is distinct from the approved transplant center;
  - c) The center must have the resources available to assess the medical condition of and any risks for the individual for potential *living* donation;
  - d) The psychosocial assessment should include the *potential donor's* capacity to make an informed decision and to affirm the voluntary nature of proceeding with the evaluation and donation; and
  - e) ~~That the center has either an independent donor advocate (IDA) who is a physician, or an independent donor advocate team, which includes at least one member who is a physician and at least one member who is not involved with the evaluation and decision to transplant the potential recipient and who fulfills the duties listed in Section 2 (b) below.~~
2. Liver Transplant Programs that Perform Living Liver Transplants~~ation~~ must demonstrate that they have the following protocols:
  - a) Living Donor Transplant centers must develop, and once developed must comply with written protocols to address all phases of the living donation process. Specific protocols shall include the evaluation, pre-operative, operative, post-operative and two-year follow-up period after donation.

Transplant centers must document that all phases of the living donation process were performed in adherence to the center's protocol. This documentation must be maintained and made available upon request.

- b) Written protocols must include, but are not limited, to the following elements:
- i) a description of the duties and primary responsibilities of the IDA ~~or IDA Team members as described in 1 (d) above,~~ to include procedures that:
    - (a) protect and promote the best interests of the potential living donor;
    - (b) ensure protection of the rights of the living donor; and
    - (c) provide the potential donor with information regarding the:
      - (i) consent process;
      - (ii) evaluation process;
      - (iii) surgical procedure; and
      - (iv) benefit and need for follow-up.
  - ii) a thorough medical evaluation by a physician and/or surgeon experienced in living donation including:
    - (a) a screen for any evidence of occult liver disease;
    - (b) age appropriate cancer screening;
    - (c) a radiographic assessment to ensure adequate ~~graft and remnant liver~~ volume ~~as well as vascular and biliary imaging to ensure and inflow and outflow is preserved in~~ of the graft and the remnant liver; and
    - (d) a psychosocial evaluation of the potential living donor by a psychiatrist, psychologist or social worker with experience in transplantation (criteria defined in Appendix B, Attachment I-~~X~~) must also be provided to assess decision making capacity competency, screen for any pre-existing psychiatric illness, and any potential coercion.
- c) The center shall have has written protocols for Informed Consent for the Donor Evaluation Process and Informed Consent for the Donor Hepatectomy, which include at a minimum the following elements:
- (i) discussion of the potential risks of the procedure including the medical, psychological and financial risks associated with being a living donor;
  - (ii) assurance that all communication between the potential donor and the transplant center will remain confidential;
  - (iii) discussion of the donor's right to opt out at any time during the donation process;
  - (iv) discussion that the medical evaluation or donation may impact the donor's ability to obtain health, life and disability insurance; and
  - (v) disclosure by the transplant center that it is required, at a minimum, to submit contact and obtain follow up Living Donor Follow-up forms addressing the health information on of each living donor at 6 months, one-year, and two-years post donation. The protocol must include a plan to collect the information about each donor.

3.2. Conditional Approval Status: If the transplant center does not have on site a second surgeon who can meet the requirement for having performed 7 live donor liver procedures within the prior 5-year period, but who has completed the requirement for obtaining experience in 20 major hepatic resection surgeries (as described above), as well as all of the other requirements to be designated as a primary liver transplant surgeon, the program may be eligible for Conditional Approval Status. The transplant program can be granted one year to fully comply with applicable membership criteria with a possible one year extension. This option shall be available to new programs as well as previously approved programs that experience a change in key personnel. During this period of conditional approval, both of the designated surgeons must be present at the donor's operative procedure.

The program shall comply with such interim operating policies and procedures as shall be required by the Membership and Professional Standards Committee (MPSC).

This may include the submission of reports describing the surgeon's progress towards meeting the requirements and such other operating conditions as may be required by the MPSC to demonstrate ongoing quality and efficient patient care. The center must provide a report prior to the conclusion of the first year of conditional approval, which must document that the surgeon has met or is making sufficient progress to meet the objective of performing 7 live donor liver procedures or that the program is making sufficient progress in recruiting and bringing to the program a transplant surgeon who meets this criterion as well as all other criteria for a qualified live donor liver surgeon. Should the surgeon meet the requirements prior to the end of the period of conditional approval, the program may submit a progress report and request review by the MPSC.

The transplant program must comply with all applicable policies and procedures and must demonstrate continuing progress toward full compliance with Criteria for Institutional Membership.

The program's approval status shall be made available to the public.

*(The final version of the Bylaws, as approved by the Board of Directors will be posted on [www.unos.org](http://www.unos.org) and [www.optn.org](http://www.optn.org) )*

Attachment 1 to Exhibit M-1



Penn Transplant Institute

August 11, 2007

Public Comment Coordinator  
 United Network for Organ Sharing  
 700 North 4<sup>th</sup> Street  
 Richmond, VA 23218  
 Via Facsimile: 804-782-4896

To Whom It May Concern:

We are writing on behalf of the PENN Transplant Institute and the Hospital of the University of Pennsylvania to submit our formal comments related to the current policy proposals and guidelines on living donation.

The current guidelines developed by the Living Donor Committee, while laudable, are overly prescriptive, both from the standpoint of clinical practice and transplant operations. We understand that these are meant as "guidelines" and not policy, but there is a real concern that these guidelines are not all evidence-based, have the potential to be interpreted as policy and may compromise transplant center accreditation by regulatory agencies, such as CMS and JCAHO.

This institution is in full support of a UNOS mandate that requires each transplant center to develop and comply with its own living donor protocol(s) in order to ensure donor safety. We believe this mandate can be accomplished through the adoption of required model elements, similar to the process UNOS recently set forth for donation after cardiac death, rather than setting forth very specific guidelines that may be subjective, not universally accepted, and evolve over time.

We would like to highlight a few examples with suggested changes:

#### Living Donor Evaluation

We support the need for transplant centers to include standard elements in the donor evaluation process, however some of the suggested tests are certainly not routinely done at many transplant centers. For example, while birthweight of potential donor and their offspring may have some potential benefit, this inquiry should not be considered a routine screening question, and is not known by many patients. In another example, TSH may be performed as indicated in select patients, but does not necessarily need to be a routine screening for donor evaluations. We would be in support of a policy that mandates that centers have a detailed protocol for evaluation, and that the protocol be followed, but not to require specific tests or studies.

#### Independent Donor Advocate (IDA)

The current language may confuse the very separate role of the IDA with some routine functions of donor evaluation and coordination. The current language also states an IDA " ... should not be involved in the care of the potential transplant recipient". We are in full support of an independent

advocate for each donor, but recognize that many transplant centers may not have the resources necessary to support a separate IDA in this context. We suggest the language be modified to "should not be involved in the decision to transplant of *specific recipient for the potential donor*". Such a modification would help to satisfy the requirement that the IDA has "requisite knowledge of transplant" but be unattached from the determination to transplant the specific recipient. This would also provide transplant centers with more flexibility to allocate resources. Centers with multiple organ programs would be free to utilize cross-coverage services to meet the IDA requirements.

#### Consent of Living Donors

Our center is well aligned with the need to fully inform the potential donor regarding the risks associated with donation, and we also support the need for legal consent. We are also well aligned with the need to inform and consent the potential donor in their native language. Again, we feel that each transplant center be left to develop and implement their own parameters to inform and consent living donors. We also propose that the "suggested questions" for the psychosocial evaluation be shared with transplant centers as a "tool" versus a guideline, allowing each transplant center to incorporate at their discretion.

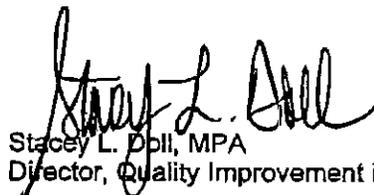
#### Health and Disability Coverage

We firmly believe that it is the obligation of each transplant center to provide care to living donors throughout the donation process, and it is imperative that this obligation applies if donation-related complications arise. It is also critical that each donor be made aware of the transplant center's obligation, as well as the limits of the center's responsibility. We strongly believe it to be unreasonable, and unfeasible, that transplant centers provide living donors with health and disability insurance, which is unduly cost-prohibitive.

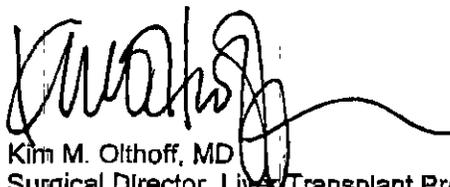
Sincerely,



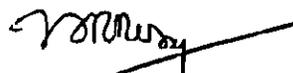
Diane S. Jakobowski, MSN, CRNP  
Administrator, PENN Transplant Institute



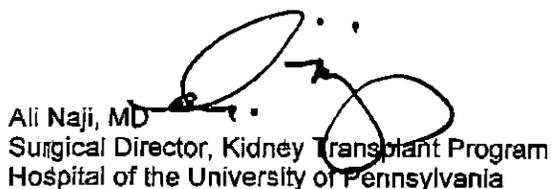
Stacey L. Dill, MPA  
Director, Quality Improvement in Transplantation



Kim M. Olthoff, MD  
Surgical Director, Liver Transplant Program  
Hospital of the University of Pennsylvania



K. Rajender Reddy, MD  
Medical Director, Liver Transplant Program  
Hospital of the University of Pennsylvania



Ali Naji, MD  
Surgical Director, Kidney Transplant Program  
Hospital of the University of Pennsylvania



Roy D. Bloom, MD  
Medical Director, Kidney Transplantation  
Hospital of the University of Pennsylvania

/sld

cc: Abraham Shaked, MD, PhD  
Clyde Barker, MD



American Society of Transplant Surgeons

By email on 8/9/07  
RECEIVED AUG 14 2007

August 9, 2007

Timothy L. Pruett, MD  
President  
Organ Procurement Transplant Network  
United Network for Organ Sharing  
P.O. Box 2484  
700 North 4<sup>th</sup> Street  
Richmond, VA 23219

Dear Dr. Pruett,

As President of the American Society for Transplant Surgeons (ASTS), I am delighted to have the opportunity to submit these comments on the "Proposed Modifications to OPTN/UNOS Bylaws, Appendix B, Attachment I, Section XIII, C(2), Designated Transplant Program Criteria (the "Proposed Changes"). The Proposed Changes consist of two proposed modifications of UNOS Bylaws and two proposed sets of guidelines. All of these changes apparently arose as the result of a mandate that the OPTN received from the Secretary of HHS directing the OPTN "to develop allocation guidelines for organs from living donors and other policies necessary and appropriate to promote safety and efficacy of living donor transplants for recipients and donors". ASTS is delighted to have the opportunity to comment on the Proposed Changes.

Preliminarily, however, we wish to express two concerns related to process. First, we wish to express our continuing concern that the Principles of Data Submission (the "Principles") (Attachment A) that were developed with the painstaking involvement of the ASTS and the AST apparently were not considered by the Board or by the relevant Committees in developing the Proposed Changes. This same apparent indifference to the administrative burden imposed on Transplant Centers was evident when the "Modifications to Data Elements on the Recipient Follow-up Form" was subject to comment in December, 2006.

**National Office**  
2461 South Clark Street  
Suite 640  
Arlington, VA 22202  
Phone: 703 414-7870  
Fax: 703 414-7874  
Email: asts@asts.org  
www.asts.org

**President**  
Goran B. Klintmalm, MD, PhD  
Baylor Regional Transplant Inst.  
3500 Gaston Avenue  
Dallas, TX 75246  
Phone: 214 820-2050  
Fax: 214 820-4527  
Email: gorank@baylorhealth.edu

**President-Elect**  
John P. Roberts, MD  
Univ. of California San Francisco  
Division of Transplantation  
505 Parnassus Ave  
Box 0780, Room M896  
San Francisco, CA 94143-0780  
Phone: 415 353-1888  
Fax: 415 353-8709  
Email: robertsj@surgery.ucsf.edu

**Secretary**  
Robert M. Merion, MD  
University of Michigan  
315 West Huron, Suite 240  
Ann Arbor, MI 48103-4262  
Phone: 734 936-7336  
Fax: 734 998-6620  
Email: merionb@umich.edu

**Treasurer**  
Michael M. Abecassis, MD, MBA  
Northwestern University  
Division of Transplantation  
675 N. St. Clair Street, #17-200  
Chicago, IL 60611  
Phone: 312 695-0359  
Fax: 312 695-9194  
Email: mabecass@nmh.org

**Immediate Past President**  
Arthur J. Matas, MD

**Past President**  
A. Benedict Cosimi, MD

**Councilors-at-Large**  
Mitchell L. Henry, MD  
Kim M. Olthoff, MD  
Robert L. Kormos, MD  
Alan N. Langnas, DO  
Richard B. Freeman, Jr., MD  
Dixon B. Kaufman, MD, PhD

**Executive Director**  
Katrina Crist, MBA  
Email: katrina.crist@asts.org

After the considerable time and effort that went into the initiative to reduce the data submission burdens on Transplant Centers (TCs), we are extremely concerned that new administrative burdens are now being imposed once again without a clearly articulated rationale supported by one or more of the Principles. This is not a propitious start to the goal of maintaining data submission requirements at reasonable levels. Prior to adopting any of the proposed changes, we request that the Board instruct the relevant Committees to identify which of the Principles support each of the Proposed Changes. We particularly request that any new application form required of living donor transplant programs be designed in a manner that is consistent with the Principles.

Second, we note that even the current living donor guidelines were adopted in a manner that is inconsistent with the notice and comment requirements required by the governing regulations. As we stated in our response to the HRSA's proposal to expand its enforcement authority with respect to living donor transplants, it does not appear that the OPTN Membership had the opportunity comment on the current living donor guidelines, as required by 42 CFR Section 121.4(b)(1). Therefore, the current solicitation of public comments should encompass not only the Proposed Changes, but the current guidelines themselves. In addition, we believe that the Proposed Changes are the type of "significant" proposed policy changes that are required to be published in the Federal Register for comment, under 42 C.F.R. Section 121.4(b)(2).

On a more substantive note, we offer the following comments on the Proposed Changes:

A. Proposed Changes to Bylaws related to Requirements for Kidney and Liver Transplant Programs that Perform Living Donor Kidney Transplantation ("Proposed Bylaws Changes")

The proposed Bylaws changes for kidney and liver living donor programs appear to be virtually identical. First, these proposed Bylaws changes include new requirements for an independent donor advocate (IDA) for both kidney and liver living donors. Second, the proposed Bylaws changes for both kidney and liver living donor programs would require the development and implementation of numerous new protocols, including a description of the duties and primary responsibilities of the IDA; a protocol for the medical evaluation of potential living donors by a physician and/or surgeon experienced in living donation; a protocol for the informed consent for the donor evaluation; and a protocol for informed consent for the donor organ excision. The content of each of the required protocols is set forth with considerable specificity.

ASTS' views regarding mandated protocols for IDAs, informed consent, and living donor management are set forth in detail in the attached comments, submitted to CMS in response to that agency's Notice of Proposed Rulemaking on Transplant Center Medicare certification standards (Attachment B). We are particularly struck by the detail in these proposals, since living donor kidney transplants have been performed since 1954 and living donor kidney transplantation has become a well functioning established practice. We are unaware of any problem with this practice that warrants the type or scope of the changes suggested in this proposal.

We also note that a number of the proposed Bylaws changes appear to be duplicative of requirements set forth in the Transplant Center certification regulations recently adopted by CMS—although the OPTN requirements are considerably more detailed and specific. However, we note at least two areas where CMS and the OPTN appear to have different requirements: (1) While the CMS regulations do not require that the IDA be a physician, the proposed Bylaws changes specifically require that a physician fulfill this function. In addition, while the CMS regulations require the development of "written donor management policies for the donor evaluation, donation, and discharge phases of living organ donation if it performs living donor

transplants” the proposed OPTN Bylaws require the development of specific protocols that include the “evaluation, pre-operative, operative and two-year follow-up after donation.” (Emphasis added).

It is precisely this type of duplication and inconsistency that we believe is most likely to undermine effective enforcement of Transplant Center standards. The IDA should not be required to be a physician, consistent with the CMS Transplant Center regulations, this should be a decision made by the transplant centers. Again, it is potentially onerous and confusing for Transplant Centers to have different requirements imposed by different regulatory bodies.

And, we strongly object to the proposed two year follow-up requirement for living donors. From a clinical perspective, living donor risks generally occur either early or late in the process: Intermediate follow-up-- such as two years-- is unhelpful to the living donors themselves and does not advance the field of living donor transplantation by providing data necessary to minimize the risks to future living donors.

Furthermore, the goals for living donor follow-up need to be clearly identified. If the goal is to understand the common risks of donation to better inform the potential donors, it is unlikely that two year follow data will result in substantial improvement over what is known from the clinical literature on kidney donation and from what may become available in the future from NIH sponsored studies (for example, with respect to liver transplantation, the Adult-to-Adult Living Liver Cohort Study). If the goal is to monitor transplant centers for compliance with quality assurance (QA) protocols and to institute a system for corrective action, the rarity of events make the collection of two year follow up data a crude tool to achieve the objective, due to the rarity of complications. The OPTN will end up collecting data on a number of serious complications, such as death, pulmonary embolus and returns to the Operating Room that are uncommon events—events that occur at centers that provide high quality care as well as those that do not. The OPTN needs to be clear about how these events would be investigated and how changes in care would be recommended. It is also imperative that the OPTN provide adequate funding to provide these audits in a complete and competent fashion.

Additionally, in reality, it is exceedingly difficult to even obtain a one year follow-up of living donors for several reasons. For example, the donor may not be motivated to take off from work for a clinical evaluation which may include long travel and related expenses; the donor may have moved and can not be found; neither the donor’s insurance nor the recipient’s may cover the evaluation; and numerous other problems may arise.

As set forth in ASTS’ recent correspondence to Senator Grassley on this issue (Attachment C), what is needed is a well-designed and adequately funded research study addressing the long-term health consequences of living donation, not the ad-hoc imposition of clinical follow-up requirements that are unlikely to yield benefits either for current or for future living donors—follow-up requirements that entail the provision of clinical services that are covered by neither living donors’ health insurance nor by the Government.

#### B. Proposed Guidelines for the Medical Evaluation of Living Kidney Donors

The “Proposed Guidelines for the Medical Evaluation of Living Kidney Donors” are detailed patient evaluation and management guidelines that appear to incorporate every possible component of clinical care. We do not believe that the OPTN’s policy-making authority should be extended to areas, such as the evaluation of potential living donors, that involve the practice of

medicine, especially where, as in the area of living donor evaluation, there is no clear clinical consensus regarding the practices and standards that should be followed. We strongly urge the OPTN to withdraw this proposal. OPTN could make general recommendations of what areas need to be included in a living donor work up. However, recommendations for the practice of medicine should come from specialty societies.

C. Guidelines for the Consent of Living Donors

The proposed “Guidelines for the Consent of Living Donors” constitute detailed procedures and requirements relating to the informed consent process. Significantly, while the document is offered as a “guideline,” it is written as a minimum standard, setting forth informed consent requirements that “must” and “shall” be met. ASTS believes that the informed consent process is one that can—and necessarily should—vary by institution and by individual clinical circumstance. We respectfully suggest that the level of specificity set forth in the proposed guidelines far exceeds the appropriate role of the OPTN. In addition, it is unclear what sanction might be applied to a Transplant Center that departs from the suggested “guidelines” –for example, by instituting an informed consent process that it believes to be more effective in communicating to the living donor the potential risks involved. Again, dictating the practice of medicine and surgery is not the role of the OPTN, let alone in the best interests of patients.

We hope that these comments are helpful to you and look forward to future discussion of these important issues.

Sincerely yours,



Goran B. Klintmalm, MD, PhD, FACS  
President  
American Society of Transplant Surgeons

RECEIVED AUG 14 2007

OPTN/UNOS Board of Directors  
December 12, 2006  
Data Collection Principles Resolution

\*\*RESOLVED, that the OPTN/UNOS Board approves the following principles for data collection:

Institutional members must provide sufficient data to OPTN to allow it to:

- a) Develop transplant, donation and allocation policies
- b) Determine if Institutional Members are complying with policy
- c) Determine Member-specific performance
- d) Ensure patient safety when no alternative sources of data exist
- e) Fulfill the requirements of the OPTN Final Rule

\*\* FURTHER RESOLVED, that the OPTN/UNOS Board approves the following operational statements for data collection:

1. The OPTN will only collect data that is contracted by HRSA.
2. Data collected and submitted by Institutional Members to the OPTN may differ in nature and character for specific populations, forming exceptions to Guiding Principles above (e.g. Pediatrics, Living Donors). For these exceptions to the foregoing principles, alternative sources of information must be explored and supported, duplication of existing efforts (e.g. registries) avoided, and sample data collection considered. The need and purpose of any such exceptions must be clearly articulated and subject to Policy Oversight Committee and Board approval, and public comment.
3. All future data requests by OPTN committees must be justified in the context of the above guiding principles and new data collection will require approval by the Policy Oversight Committee and the Board of Directors of the OPTN, and be subject to public comment.

RECEIVED AUG 14 2007

May 18, 2005

Mark McClellan, M.D., Ph.D.  
Administrator  
Center for Medicare and Medicaid Services  
7500 Security Blvd  
C5-11-24  
Baltimore, Maryland 21244-1850

**Re: Requirements for Approval and Re-approval of Transplant Centers to Perform Organ Transplantation; CMS – 3835-P**

Dear Dr. McClellan:

The American Society of Transplant Surgeons (ASTS), the American Society of Transplantation (AST), and the International Society for Heart and Lung Transplantation (ISHLT) are pleased to have this opportunity to respond to the proposed rules establishing requirements for approval and re-approval of transplant centers, as published in the February 4, 2005 Federal Register.

ASTS is an organization comprised of over 1000 transplant surgeons, physicians and scientists dedicated to excellence in transplantation surgery through education and research with respect in all aspects of organ donation and transplantation so as to save lives and enhance the quality of life of patients with end stage organ failure.

AST is an organization of more than 2,200 transplant professionals dedicated to research, education, advocacy and patient care in transplantation, whose goal is to offer a forum for the exchange of knowledge, scientific information and expertise in the field of transplantation.

ISHLT is an organization comprised of over 2200 cardiothoracic surgeons, cardiologists, pulmonologists, transplant coordinators, and other medical professionals dedicated to the advancement of the science and treatment of end-stage heart and lung diseases.

**Introduction and Summary of Concerns**

We are pleased that CMS has moved forward to update the standards for Medicare-approved transplant centers and to codify the standards for extra-renal organs in the Medicare regulations, and we commend the agency for its commitment to improving transplantation care for Medicare beneficiaries. We share CMS' interest in ensuring that transplant recipients and living donors receive the best possible care.

However, we are concerned that certain aspects of the proposed rules will be counterproductive to the achievement of these objectives. It is important to point out that the field of transplantation and transplant centers, in particular, are already subject to substantial regulatory requirements through the Organ Procurement and Transplantation Network (OPTN). We believe it is essential that the OPTN oversight and compliance process and Medicare conditions of participation work in tandem. We are very concerned that the proposed rule would create parallel processes for review of transplant center quality with potentially inconsistent standards of review and decisions.

While we appreciate CMS' efforts to implement data and outcomes standards that are consistent with OPTN requirements, we do not believe that the proposed regulations go far enough in ensuring that CMS and OPTN review processes are implemented in a manner that eliminates duplicative and potentially conflicting regulatory requirements. Because we believe that the OPTN requirements and oversight processes are highly effective in assuring quality, we propose that CMS review a center for potential termination from the Medicare Program only if the Secretary has been notified of a final decision of the OPTN Board to take an adverse action against the center such as probation, member not in good standing or suspension of member privileges.

As discussed during the meeting held with CMS during the initial comment period, ASTS and AST believe that if CMS decides not to modify the Proposed Rules to reflect this view, substantial changes should be made. ASTS and AST both very much appreciate CMS' receptivity to our concerns as expressed during the meeting. It was our impression from the comments that were made that the more specific our recommendations are, the more helpful they will be to CMS. For this reason, in an effort to eliminate any potential ambiguity in our comments and to facilitate CMS' consideration of our recommendations, we have incorporated our suggested changes in proposed regulatory language, which is included as Attachment 1 to these comments. We offer this mark-up as an illustration of how our suggestions might be incorporated into the Proposed Rules, and hope that CMS finds it helpful. The sections of the comment letter that address each of the proposed changes are cross-referenced for ease of reference, and our concerns are summarized immediately below.

\* \* \*

First, we are extremely concerned about the standards and process to be used for initial approval of transplant centers. In this regard, we note that while the Proposed Rule describes a process of "initial approval," for several hundred centers that have been approved under the current standards, the process is in fact a process of re-approval, and the denial of initial approval is in fact a termination that may have extremely significant repercussions for Medicare transplant and prospective transplant patients. Moreover, termination of Medicare approval may well trigger termination of approval by non-Medicare payers, which often follow Medicare's lead.

Yet, the proposed initial approval process appears to deny any opportunity for explanation, remediation, or survey for those centers that fail to meet the proposed data

submission and outcomes standards. This is especially troublesome since neither the data submission nor the outcomes standards were intended to be used in this manner, but rather were intended solely as a “trigger” for further investigation by the OPTN. See Attachment 1, Proposed Sec. 482.80(b)(3) and Sec 482.82 (b)(3). In fact, utilizing the OPTN data submission and outcomes measures in this manner—as a “bright line” test for initial approval—is completely inconsistent with the way that these standards were intended to be used and are in fact used by the OPTN itself. We believe that the misuse of the OPTN data submission and outcomes standards as bright line tests for initial approval likely would result in extraordinary disruption of care for the Nation’s transplant (and potential transplant) patients.<sup>1</sup>

Second, in the event that CMS decides not to rely upon the OPTN’s review and remediation process to address potential data submission and outcomes deficiencies (as we suggest), the Proposed Rules should be modified to provide an alternative process of review and remediation with respect to alleged data submission and outcomes deficiencies. See Attachment 1, Proposed Sec. 488.61( c)(4).

Third, if CMS continues to believe that Medicare conditions of approval for transplant centers should be independently enforced through state survey agencies prior to the OPTN Board reporting to the Secretary its final decision to take an adverse action against the center, a number of changes should be made in the proposed process regulations to assure consistency between CMS and OPTN requirements to the extent practicable and to better coordinate the two processes, as described in further detail below.

Fourth, the Proposed Rules fail to set forth the standards for re-approval with sufficient specificity. It is our understanding that, under the Proposed Rules, if a center does not meet the data submission and outcomes requirements, CMS (through the state survey agencies) conducts a survey to determine if it is in compliance with the “process” requirements. The preamble suggests that that the Medicare status of a center that has an acceptable survey with respect to the process requirements may not be terminated and further suggests that the Secretary may consider special circumstances that may explain the center’s failure to meet data submission and outcomes requirements. However, these provisions are not reflected in the Proposed Rules, nor is there any other provision setting forth clear standards for the Secretary to make termination decisions. We believe that the Proposed Rules should be modified to address these issues. See Attachment 1, Proposed Sec 488.61( c)(5)-(7).

Finally, the Proposed Regulations do not set forth the center’s rights to appeal with specificity. See Attachment 1, proposed Sec. 488.61(g)

Our comments on specific aspects of the proposed rule are set forth below.

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<sup>1</sup> Conversely, the proposed process for initial approval calls for on-site surveys of centers that do meet the data submission and outcomes requirements—on-site surveys that we do not believe are necessary.

**I. CMS should defer any decision regarding data submission or outcomes requirements until OPTN review procedures have been concluded and should only consider termination of a center if the OPTN Board reports to the Secretary that it has made a final decision to take an adverse action against the center.**

We appreciate CMS' efforts to establish meaningful standards with respect to data submission and outcomes for transplant centers. In particular, we believe the current approach with respect to outcomes is at least conceptually an improvement over existing standards, which focus on volume and achievement of a fixed survival rate.<sup>2</sup> We also commend the agency for its efforts to achieve consistency with OPTN standards. We believe these are all steps in the right direction. We also realize the complexity surrounding the development of meaningful outcome measures.

While we agree that transplant centers must submit data and be measured by their outcomes, and that centers with poor outcomes should not participate in the Medicare program, we note that the current OPTN outcome and data submission standards, which CMS would use to determine compliance with Medicare conditions of participation, were developed by the OPTN for quite a different purpose - **as a tool for identifying centers with potential problems.** Centers that do not meet these standards are flagged for investigation and remediation if necessary. The purpose of the OPTN outcome standards is to identify, investigate, and correct, if appropriate. **The standards were not designed as a test for whether a center should qualify for participation in Medicare, or even as a proxy for determining that a center is providing substandard care.** A center that fails the outcomes measures still may be providing high quality care. For that reason, we believe use of the OPTN standards as a bright line test for Medicare approval is entirely inappropriate.

One possible consequence of such an approach is that transplant centers, worried about their outcome statistics, will become increasingly unwilling to use expanded criteria donors and deceased cardiac donors (ECDs and DCDs) because use of these organs could negatively impact a center's one-year patient and graft survival rates. Although the SRTR methodology is designed to risk adjust for this, the risk adjustment models are still evolving. Consequently, centers may be discouraged from using ECDs and DCDs. The result will be a reduction in the number of transplants and more limited access for waiting candidates.<sup>3</sup>

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<sup>2</sup> We note that outcomes standards have not been developed by the OPTN for certain transplants, including, for example, heart-lung, pancreas, islet and intestinal transplants. Because outcomes standards ultimately may be applicable to these transplant procedures and because new transplant procedures may be developed in the future, we recommend that the proposed regulatory language be modified to automatically authorize the application of outcomes measures by CMS once such measures are developed by the OPTN, rather than providing a permanent exception from outcomes requirements for these procedures. See Attachment 1, Sec. 482.68(a).

<sup>3</sup> We are also concerned about the potential effect the proposed OPO standards will have on transplant center outcomes. Specifically, the proposed outcome standards for OPOs create an incentive to increase an OPO's conversion rate by procuring more ECDs and DCDs (at the expense of DBDs) which are associated

We also note that, under the proposed regulations, compliance with the outcomes requirements will be based on a single data point that may be up to three and a half years old. Since the time of the submission of this data, a transplant center may have made significant changes in its program—changes which may have ameliorated or largely eliminated quality concerns. In light of the unavoidable lag between outcomes, the reporting of outcomes, analysis of any potential issue flagged through such reports, and amelioration, we believe that it would be entirely inappropriate to use failure to meet outcomes measures as grounds for termination, without the opportunity for explanation or remediation.

The OPTN has a rigorous and well-established procedure for enforcing its data submission and outcome standards (the same measures that CMS is proposing would apply to Medicare) and for identifying centers that do not meet those standards. The OPTN conducts ongoing and periodic reviews, site visits, and evaluations of each Member Transplant Center for compliance with the OPTN policies. (See OPTN Bylaws, Appendix A and Appendix B (Attachment 2)). If a center is found to be out of compliance with standards, it is referred to the Member Professional Standards Committee (MPSC) for investigation to determine if the low outcome rate may be accounted for by patient mix or some other unique clinical aspect of the transplant program in question. If a center's performance cannot be explained by such factors, a corrective action plan may be imposed. If a center cannot meet the standards after a reasonable opportunity to correct, then the OPTN implements sanctions against the center and informs the Secretary of the center's failure to meet OPTN requirements.

Unless Medicare review of outcomes is coordinated with ongoing OPTN oversight, the integrity of both review mechanisms will be undermined. ASTS and AST strongly recommend that OPTN policies and standards should first be interpreted and enforced by the OPTN. Without such coordination, there is a very real risk that centers will be subject to inconsistent interpretations of the OPTN outcome standard. For example, a center under investigation by the OPTN for poor outcomes would be given an opportunity to explain the reason for its poor outcomes or implement a corrective action plan under OPTN oversight. At the same time, based on the same evidence, CMS could deny Medicare approval or re-approval. The OPTN may subsequently conclude that there was a reason for the poor outcomes unrelated to quality or the center may be able to demonstrate that the cause of the poor outcomes has been ameliorated. However, that center would have already lost its Medicare approval.

If CMS believes that the OPTN outcome standards are the best outcomes standards available at this time, it is contradictory to apply those standards to terminate a center while the OPTN is still evaluating the center.<sup>4</sup> If CMS pursues an independent process, it would not be using the OPTN measures as they were intended to be used.

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with poorer graft and patient survival rates, especially for extra-renal organs. We address this issue in separate comments submitted in response to the OPO proposed regulation.

<sup>4</sup> For this reason, we believe it would be inappropriate for CMS to grant initial approval to a transplant center that at the time is under review by the OPTN for failure to meet OPTN outcome measures. See Attachment 1, Proposed Sec. 482.82(b)(2)(iii).

Our organizations believe that the goal of ensuring that transplant centers meet Medicare data submission and outcome requirements could be best achieved by first allowing the OPTN to complete its process for enforcing those requirements through its existing well-established policies and procedures with CMS taking action to deny approval or re-approval only after the OPTN process has concluded. This approach would allow the OPTN to do what it is already doing successfully, and would also provide for corrective action and remediation. Failure to meet OPTN data submission standards should not be a basis for denial of approval or re-approval unless and until OPTN enforcement mechanisms have not been successful.

### **Recommendation**

Since the OPTN is already identifying and investigating centers that do not comply with its standards and has the expertise necessary to properly interpret complex center outcomes data and evaluate that data in relation to expected outcomes, ASTS and AST recommend that CMS coordinate its review of center outcomes with the OPTN process. Specifically, we recommend that CMS not take action to deny approval or re-approval of a center based on failure to meet Medicare data submission or outcome standards while the OPTN is investigating that center. If a center is under OPTN review, CMS should defer any conclusion regarding outcomes or data submission until the OPTN has concluded its investigation and remediation. If the OPTN determines that the center still does not meet standards, the OPTN is required by regulation to report this to the Secretary. 42 C.F.R. § 121.10. Upon such reporting, CMS could then initiate action to deny approval or re-approval.

## **II. Initial Approval**

We have serious concerns about the process CMS would use for granting initial approval of transplant centers. Those concerns would be largely addressed if our recommendation above regarding coordination with the OPTN were followed. However, if they are not, we believe the process for initial approval should be modified substantially.

The Proposed Rules provide that each transplant center that seeks Medicare approval must submit an application within 180 days of the effective date of the final rule. Data submission and outcome standards would be treated as threshold requirements and failure to meet either would result in automatic denial of approval. Only a center that meets the threshold requirements would be surveyed for compliance with the process requirements and only if that center complies with process requirements would the center be approved.

We believe using OPTN data submission and outcome standards as the sole basis for denial of an initial application is simply inappropriate. As discussed in more detail above, these standards were not intended to be used for such a purpose. Rather, these measures are used to identify centers with possible quality issues, and failure to meet the standards triggers an investigation and remediation process by the OPTN. It is completely inappropriate to use these standards as a bright line test for Medicare approval. If CMS believes, as it apparently does, that the OPTN standards are the best available measures of quality, then it should use them in a manner consistent with their purpose.

We strongly urge that CMS not deny an initial application based on these threshold requirements without providing for any opportunity for waiver or process for further review. As the agency has stated in the preamble, there may be reasons unrelated to quality of care that could result in failure to meet the outcome requirements. It is important to remember that most centers that will be seeking initial approval are already approved by Medicare under its previous rules.<sup>5</sup> Thus, denial of initial approval would result in termination of a center that is currently participating in Medicare, and substantial disruption for transplant patients as well as those on the waiting list.

We believe it is more logical and more consistent with the goals of the rulemaking to survey the centers that do not meet the threshold requirements, but that file a plan of correction setting forth the actions that they will take to do so. See Attachment 1, Proposed Sec. 488.61(c). This is, in fact, what the agency has proposed for centers seeking re-approval. We see no reason for creating a distinction between centers seeking initial approval and those seeking re-approval. In either case, problems meeting the data submission or outcome standards may or may not indicate quality problems: Such a failure is the beginning, not the end, of the inquiry into quality.

In contrast, we do not see the purpose of surveying centers that do meet outcome and data submission standards. If CMS is trying to conserve scarce resources, it is eminently more sensible to survey centers that may have problems and not survey the ones that do not.

Consequently, we strongly urge that centers seeking initial approval be treated the same as those in the re-approval stage: They should be surveyed for compliance with the process requirements and should be denied initial approval only if they fail to meet the same standards that are applied to centers seeking re-approval. At the very least, they should be given an opportunity to explain or remediate potential outcome or data submission problems before denial of their application. Without such a process, centers providing high quality care may be terminated from the program. For programs with high volume Medicare transplants (e.g. most kidney, liver and heart programs) this could result in closure of the program. The consequences of this could be devastating for patients, including Medicare beneficiaries, on that center's waiting list as well as for patients who are receiving pre and post-transplant care at that center.

### **III. Review and Corrective Action**

If CMS does not adopt our recommendation to refrain from terminating a center on the basis of outcomes unless that center is reported to the Secretary by the OPTN, then it is critical that the agency create its own review and corrective action process to ensure that centers are not inappropriately terminated based on the data submission and outcomes standards. Without such a process, a center could be denied initial approval based on perceived data submission or outcome deficiencies without any opportunity to explain or correct. This could have a devastating affect on centers that perform a large number of transplants on Medicare beneficiaries. Terminating a center's Medicare participation (for

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<sup>5</sup> For this reason, we believe that centers that already have been approved at the effective date of the final regulations should be subject to re-approval procedures, rather than to initial approval procedures. See *Proposed Sec. 482.70 (Definitions)*; *Proposed Sec. 482.80*; and *Proposed Sec. 482.82*.

that is what denial of initial approval really is for an existing center) without any opportunity to explain or correct is too harsh a penalty and would not advance the goals of this proposal.

Although this issue is of particular concern at the initial approval stage, we note that even at the re-approval stage, it would appear that CMS could revoke approval based on outcomes or data submission standards following a survey for compliance with process requirements. Although Medicare survey and certification procedures would apply, including the corrective action policy set forth in 42 CFR § 488.18, the proposed rule specifically makes that process inapplicable to data submission and outcome requirements. See proposed 42 CFR § 488.61. Therefore, under the Proposed Rules, there is no opportunity at any stage for review or corrective action with respect to data submission and outcomes.

There may be quite reasonable explanations for a center's failure to meet both the data submission and the outcomes requirements set forth in the Proposed Rules. Significantly, the reliability of the SRTR outcome measures by which all centers are to be judged is solely dependent on the quality and completeness of the data submitted. Ironically, if Medicare eligibility is tied to the strict adherence to 90 day deadline for the submission of 95% of all OPTN-required data, the quality of the data collected is likely to be reduced as the result of transplant centers' efforts to submit the required data on a timely basis. For example, transplant centers today sometimes fail to meet the 90 day deadline because they are reluctant to provide less than complete patient follow-up data. If Medicare eligibility were at stake, centers may resort to marking individual data elements to "unknown" and whole patient follow-ups to "lost to follow up" much more often than is currently done, which would reduce the overall quality of follow-up data available to the OPTN, and may well affect the reliability of the OPTN outcomes measures.

Likewise, there may be quite acceptable reasons for a center's failure to meet the outcomes requirements set forth in the Proposed Rules—reasons that are unrelated to any ongoing quality problems. As CMS has observed, participation in an IRB could have a negative impact on graft or patient survival rates. Or it is possible that problems reflected in the most recent SRTR report no longer exist. For example, a center that replaces its transplant team and is able to demonstrate good results for a year with the new team should not be denied approval based on the poor results of the departed team even though those poor results would be reflected in the most recent SRTR center-specific report. The time lag between the SRTR reporting period and the present makes the opportunity to demonstrate correction critical. Otherwise, good centers will be denied approval based on conditions that may no longer exist.

For all of the above reasons, it is critical that centers be given the opportunity to explain or correct problems related to data submission or outcomes before a decision is made to deny approval or re-approval.

### **Recommendation**

We recommend that the final rule provide for review and corrective action mechanism for the data submission and outcome standards similar to that set forth in 42 CFR § 488.18. Specifically, assuming that the data submission requirements are modified to require only the submission of the data necessary for application of the outcomes

measures (as proposed in Section III of these comments, below), if CMS believes that a center is out of compliance, CMS should be required to provide to the transplant center involved a plain language description of the data whose unavailability precludes application of the outcomes standards, and should provide the center with a reasonable period (e.g. 30 days) to provide such data. Only after such notice and opportunity to respond should a center be found to be out of compliance with the data submission requirements.

Likewise, the Proposed Rules should be modified to require that CMS provide a plain language explanation of the methodology used by the SRTR to determine actual and expected outcomes (including the nature and weight of the various risk factors that are taken into account), as well as a complete list of the transplant patients whose one-year outcomes were considered in the calculation. The center should be provided an opportunity to submit a written response, which should be subject to review by a CMS designee with experience in the field of transplantation involved. In the event that the response is unacceptable, the center should be given the opportunity to develop a plan of correction that would be approved by CMS and would be given 180 days<sup>6</sup> in which to correct the deficiency. If the OPTN is investigating the center's failure to meet outcomes measures at the time the written response is submitted to CMS, the regulations should specifically state that any explanation or corrective action plan that is considered acceptable by the OPTN shall be deemed to be acceptable by CMS.

#### **IV. Data Submission: Section 484.80(a)**

We are pleased that CMS is not proposing that transplant centers submit data beyond that required by the OPTN. However, we believe that the scope of the data required to be submitted for Medicare certification purposes should be defined and limited as set forth below. Failure to meet data submission requirements should be grounds for denying approval or re-approval only if a transplant center fails to provide the data necessary to determine compliance with the final rule's outcomes requirements, and only after the center has been provided sufficient opportunity to remediate, either as described above or in accordance with OPTN data submission remediation procedures. We also believe that the proposed regulation should be modified to clarify the 95% criterion.

##### **A. Scope of data should be limited to data needed to calculate one-year outcomes.**

ASTS and AST strongly support the data collection activities of the OPTN. However, we believe that OPTN data collection beyond that which is necessary for CMS to determine compliance with Medicare outcomes requirements should not be enforceable through termination of Medicare participation.<sup>7</sup>

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<sup>6</sup> In this case, given the fact that the SRTR reporting period is every 6 months, we recommend that centers have 180 days to demonstrate corrective action.

<sup>7</sup> Of course, if CMS adopts the position proposed in Section I of these comments, a center's Medicare participation could be terminated if the OPTN reports that center to the Secretary as a center that is not in good standing with OPTN requirements based on the center's non-compliance with data submission requirements.

We see no reason why Medicare conditions of participation should require compliance with OPTN data submission standards that have no relationship to the calculation of the Medicare one-year outcomes standard.<sup>8</sup> OPTN data submission standards were not developed for the sole purpose of monitoring the quality of services provided by transplant centers. The OPTN collects a wide variety of data related to donor and recipient characteristics and post-transplant follow-up care that is used for long-term follow-up and other purposes but is not used in the determination of one-year outcomes.

Since the Medicare outcome requirements are (appropriately) limited to one-year outcomes, it would be inappropriate for a transplant center to be denied approval or re-approval for failure to meet the 95% requirement for OPTN follow-up data beyond one year post-transplant. We therefore recommend that the 95% standard for data submission be based only on OPTN data used in calculating the center's one-year outcomes. We recommend that CMS confer with the OPTN and the SRTR regarding which forms and which data fields relate to the Medicare one-year outcome calculation.

This would in no way impact on the obligations of a center, as an OPTN member, to meet the rest of the OPTN data submission standards. ASTS and AST strongly support the data collection activities of the OPTN; however, unless CMS decides to rely completely on OPTN standards and processes to determine compliance with the data submission and outcomes requirements (as suggested in Section I of these comments), we believe that compliance with OPTN data submission requirements that are unrelated to the more limited data set necessary to determine compliance with the one-year outcomes measures should not be enforceable through termination of Medicare participation.

#### **B. The Timeliness of Submissions Should be Determined Based on the CMS Review Cycle.**

OPTN rules require that 95% of all required data be submitted within 90 days of the due date established by the OPTN, and the Proposed Rule would incorporate this requirement for Medicare approval and re-approval purposes. See Proposed Section 482.80(a) (initial approval) and Proposed Section 482.82(a)(re-approval) under the Proposed Rules, a center may be denied initial approval if it does not obtain from the OPTN a statement that it “has complied with” all data submission requirements (Proposed Section 488.61(i)(iii)). With respect to re-approval, the Proposed Rule provides that:

To determine compliance with the data submission requirements [including the 90 day deadline], CMS or its designee will request data submission data from the OPTN for the previous 3 calendar years.

Proposed Section 488.61(b)(1)(i).

A literal interpretation of the Proposed Rules would suggest that if a center **ever** missed the 90 day deadline for submission of data to the OPTN, it may be denied initial approval, since it is unclear whether, under these circumstances, the OPTN could state that the center “has complied with” all data submission requirements. (And, as discussed above, such a center would have no opportunity to remediate or seek a waiver). Moreover, a center that fails to meet the 90 day deadline at any time during the three year

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<sup>8</sup> Under the Proposed Rules, the required data includes, “but are not limited to” submission of transplant candidate registration, transplant recipient registration, and recipient follow-up forms.

review period, it ostensibly could be found to be out of compliance with the data submission requirements when it seeks re-approval.

We believe that these proposed standards are unnecessarily harsh. Again, while we strongly support the OPTN's data collection activities, the imposition of the 90 day deadline is not necessary for CMS to determine compliance with the applicable outcome criteria: It should be sufficient if 95% of the required one-year data is submitted in time to be included in the SRTR report (or reports<sup>9</sup>) that CMS reviews to ensure compliance with the outcomes standards. Again, data submission requirements alone should not be the basis for denial of approval (or re-approval), unless the lack of data precludes application of the outcomes measures.

**C. The 95% data submission standard should be clarified.**

The 95% standard needs further explanation. As stated above, we believe the standard should be defined to require submission of 95% of those forms necessary to determine Medicare outcome standards. *See Attachment 1, Sec. 482.80(a) and Sec. 482.82(a)*. Fields on the form that are not used by the SRTR to calculate outcomes should not be counted toward compliance with the 95% rate. However, regardless of whether our recommendation is adopted, in light of the serious consequences of not meeting this standard, it is essential that the standard be clear and unambiguous. For example, does 95% compliance mean 95% of forms? 95% of patients? 95% of data fields? We request that CMS confer with the OPTN to clarify exactly what level of compliance is necessary to assure reliable application of the outcome measures and that this standard be set forth with specificity in the final regulations.

**D. If no opportunity for remediation is provided, the 95% submission requirement should be modified for Medicare certification purposes.**

As discussed above, we believe that it is crucial for centers to have an opportunity for explanation and remediation with respect to both the data submission and the outcomes requirements. If CMS decides not to adopt this recommendation, then we believe that the proposed data submission standard should be modified to require a data submission standard lower than 95% for compliance. We recommend that CMS confer with the OPTN to establish a more appropriate threshold, and urge both agencies to keep in mind that there is no evidence linking failure to submit OPTN-required data with poor outcomes.

**V. Outcomes Measures: Section 482.80(b) and Section 482.82(b)**

**A. Outcomes requirements should be based on outcome trends, rather than a single SRTR report. [See Attachment 1, Proposed Section 482.82(b)].**

CMS states that in assessing compliance with outcome standards it will look at the most recent SRTR report. While use of the most recent report may be appropriate for OPTN

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<sup>9</sup> As discussed below, we believe that one-year outcomes from more than a single SRTR report should be considered, and that the 95% standard ideally should be met for any SRTR report that it considered during the review process.

purposes to identify centers for further investigation, we do not believe it should be the only outcomes measure used if denial of Medicare participation is at stake. Rather, we recommend that, for Medicare approval purposes, CMS should consider trends, rather than the single “snapshot” reflected in one SRTR report. Since the SRTR publishes center-specific reports every 6 months, we recommend that the outcome standard be based on review of two consecutive reports or two out of the most recent three reports. Reviewing a center at a single point in time, especially where the outcomes data may be up to 3.5 years old, can result in a significantly distorted impression of a center’s overall quality and performance.

**B. CMS should modify the proposed rules to assure automatic adoption of future changes to SRTR/OPTN outcomes measures and data submission requirements.** *[See Attachment 1, Proposed Sec. 482.80(b)(3) and Sec. 482.82(b)(3)].*

We believe that the methodology used by the SRTR/OPTN should be flexible, in order to meet the rapidly changing field of scientific and medical knowledge in transplantation. The SRTR/OPTN methodology and risk adjustment models are continuously evolving in response to changes in clinical practice and innovations in treatments. It is essential that changes in OPTN outcome standards be automatically incorporated by CMS into the regulations without substantial lag time; however, CMS states in the preamble to the Proposed Rule that any changes in the OPTN methodology or thresholds would be considered by CMS and could be adopted through notice and comment rulemaking, which could result in delays of a year or more in CMS’s adoption of changes in SRTR/OPTN methodologies.

If CMS regulations lag behind OPTN standards, the SRTR (or another CMS designee) would have to calculate two observed vs. expected one-year outcomes models for each center – one using the outdated CMS methodology and the other using the updated OPTN methodology. Such a result would be inconsistent with the best interests of Medicare beneficiaries, the Medicare Program, and the transplant community generally. It is crucial that the OPTN incorporate new risk adjustments in the outcomes models by which transplantation quality is judged: A lag between CMS and OPTN measures may provide a disincentive for the OPTN to update the models as expeditiously as possible, since doing so may increase the OPTN workload in producing the six month reports. Inconsistent outcomes methodologies for OPTN and CMS purposes would also subject transplant centers to conflicting standards, making them reluctant to provide transplant services to patients whose risk factors are taken into account under the OPTN (but not the CMS) outcomes methodologies.<sup>10</sup> And double standards may result in the termination of centers that meet the updated outcomes standards used for OPTN purposes but not the outmoded standards used for CMS certification purposes.

**Recommendation**

We recommend that Section 482.80(b) cross reference to standards set by the OPTN/SRTR for center specific report of observed and expected one-year patient and

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<sup>10</sup> In this regard, it is important to note that the methodology and thresholds used by Medicare will affect care provided to all transplant patients since outcome measures used to qualify for Medicare reimbursement will be based on results for all candidates – not just Medicare beneficiaries.

graft survival. We further recommend that the final regulations explicitly provide the Secretary with authority to update the requirements through Program Notices (and without notice-and comment rulemaking), in the event of changes in the SRTR/OPTN outcomes methodology.

**C. Outcomes standards should be tightened only if they are used solely as a trigger for further investigation by the OPTN.**

CMS has specifically requested comments on whether a center must fail all three tests in section 482.80(b)(3) in order to be considered out of compliance with the outcomes standard. If the outcomes standards are used *solely* as a trigger for further investigation and remediation pursuant to OPTN processes, as recommended above, rather than as a “bright line” test authorizing termination of Medicare certification, then it may be appropriate to adopt a stricter standard for identifying centers with possibly substandard outcomes. However, so long as the outcomes standards are used as a “bright line” to deny Medicare approval (or re-approval), we believe that the outcomes standards set forth in the proposed Rules are appropriate.

**D. The Criteria for Approving New Transplant Centers with Experienced Transplant Teams Should be Revised.** [*See Attachment 1, proposed Sec. 482.80(b)(5)*].

ASTS and AST support the proposal to permit a new center to request application of different outcome criteria if the key members of the center’s transplant team performed transplants at a Medicare approved center for at least one year prior to the opening of the new center. However, we believe there should be a definition of “key members” which should include at least the transplant surgeon.

However, we do not believe that the assessment should be based on one-month post-transplant data. Rather, we believe that the assessment should be based on up-to-date outcome data available on transplants performed during the previous year. Based on this data, the OPTN should calculate the center’s projected one year outcomes, which should be compared with expected one-year outcomes to determine compliance with the outcome measures. [*See Attachment 1, Proposed Section 482.80(5)*].

**E. Confidentiality of OPTN Data** [*See Attachment 1, Proposed Section 488.61(f)*].

The proposed rule is not clear as to how CMS would obtain outcomes data from the OPTN. We are concerned lest the sharing of data between CMS and the OPTN jeopardize the confidentiality of transplant centers’ data submissions to the OPTN under applicable laws and regulations protecting peer review processes, and request that the regulation be clarified to state that the regulation is not intended to affect the confidentiality of the process in any manner. These issues have important implications for the OPTN compliance monitoring and privileged peer review process employed by the OPTN committees.

**Recommendation**

CMS should clarify, in the preamble to the final rule, that nothing in the final rule changes existing OPTN rules and policies with respect to confidentiality of data obtained from centers as part of its oversight and compliance obligations.

## VI. Process and Other Requirements Subject to State Survey

### A. CMS Should Rely On The OPTN Standards and Surveys and Should Not Impose Independent Process Requirements.

While we strongly support CMS' goal of ensuring the highest quality care for transplant recipients and living donors, we are concerned that many of the process requirements either duplicate current OPTN requirements (and thus create the potential for inconsistent requirements in the event that OPTN requirements are modified in the future), or impose additional paperwork burdens without improving quality.

As noted above, the OPTN already approves centers for membership in the OPTN and conducts site visits to centers on a regular basis as part of its compliance activities. It has years of expertise and experience in evaluating transplant centers. In addition, although the proposed Medicare process requirements are not the same as those of the OPTN, many of the areas covered by the OPTN standards overlap with those in the proposed regulations. For example, OPTN standards include the following areas: personnel, patient notification and wait list management, organ procurement, management and protection of living donors, as well as many others. The additional process requirements outlined in the Proposed Rules are not likely to improve the quality of the services provided by transplant centers.

Transplant centers are already subject to enormous recordkeeping and data collection requirements under OPTN rules.<sup>11</sup> Further, most of the costs associated with these requirements are not reimbursed by Medicare or other payers. Therefore, while we understand the need to document compliance, we are very concerned that the proposed regulations will create even more paperwork for centers.

Further, we question whether state survey agencies have the experience and the resources to properly survey transplant centers for compliance with at least some of the more technical standards, such as those pertaining to wait list management and organ allocation. The OPTN has experience with these issues, while state survey agencies do not.

#### Recommendation

Any center that does not have in effect appropriate processes is already required to be reported to the Secretary under 42 C. F.R. Section 121.10 for potential termination. For this reason, we recommend that Medicare refrain from adopting independent process requirements, but rather rely on the OPTN to assure compliance with proper processes as part of the OPTN survey, review, and remediation procedures. In this manner, transplant centers can be assured that they will not be subject to inconsistent or duplicative requirements pertaining to the same subject areas.

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<sup>11</sup> According to a recent study, annual personnel costs associated with SRTR and OPTN data collection at one large transplant center were \$143,026 and required 2.46 FTEs. The average number of forms submitted per year over a 3-year period was 5,245. Roberts J, Nikolai B, Tomlanovich S. *Cost of Organ Procurement and Transplantation Network Data Collection for a Large Transplant Center*. Am. J. Tr. 2003; 3:1316-1317.

**B. If CMS does impose independent process requirements potential inconsistencies with OPTN requirements should be minimized and other changes should be made.**

If CMS decides that process requirements separate from those required by the OPTN are needed, we have the following recommendations:

**1. Notification to CMS.** *[Attachment 1, Proposed Sec. 482.74].*

The requirement that a center notify CMS of any changes that might affect its approval or re-approval requires clarification. An unusually large number of early deaths may or may not affect a center's one-year outcomes depending on the number of subsequent successful transplants that are performed. For example, if a low volume liver transplant center experiences two sequential operative deaths this may have a dramatic effect on that center's one-year outcomes but may have little effect if the Center subsequently has an increase in liver transplant volume with good results. Centers would not be able to estimate the effect of deaths and graft losses on the SRTR center specific report without access to the methodology and it would be difficult to estimate the effect that the specific events would have on the three measures outlined in the proposed regulations. Further, any significant impact on one-year outcomes will be captured by the outcome measures.

We recommend that the scope of Section 482.74 be specifically limited to requiring notification of CMS of Adverse Events (as specifically defined)<sup>12</sup> and of the departure of key members of the transplant team, such as the Transplant Director or transplant surgeon(s), under the same circumstances as such notification is required for the OPTN. The regulation should also set forth with specificity the mechanism to be used for such notification. Also, good faith failure to comply with the notification requirement (regardless of its scope) should not by itself constitute grounds for termination, if the other conditions of participation are met.

**2. Pediatric Transplant.** *[Attachment 1, Proposed Section 482.76].*

It is unclear whether centers seeking approval to perform pediatric transplants must specify personnel different than those listed on the adult application or whether overlap is permitted. It may be a hardship for a center performing predominantly adult transplants to hire different personnel to administer its pediatric program. It is frequently the same core team that does adult and pediatric transplants and it is often impractical, if not impossible, to find qualified pediatric-only transplant surgeons. The OPTN rules allow the same individuals who provide care to adults to provide care to pediatric patients, so long as such individuals are qualified. We recommend that CMS clarify Section 482.76 to authorize the use of shared personnel for adult and pediatric transplant programs, consistent with existing OPTN requirements for pediatric transplants. In addition, we recommend that the Medicare approval status of pediatric and adult transplant programs run by the same center impact each other only if substantially the same transplant team is involved in performing both pediatric and adult transplants.

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<sup>12</sup> Please note in this regard that the term "Adverse Event" should be restricted to transmittal of infectious disease that is both unintended and unexpected. In some cases, a transplant may be clinically appropriate even if there is a calculated risk of transmittal of an infectious disease. So long as there is proper patient consent, transmittal of an infectious disease under this circumstance should not be considered an "Adverse Event" that is subject to reporting requirements. See Attachment 1, Proposed Sec.482.70 (Definitions).

### 3. Patient and Living Donor Selection. [Attachment 1, Proposed Sec 482.90].

**a. Written Selection Criteria:** The OPTN has patient listing criteria that centers are already required to follow. Although these are technically different than patient selection criteria, from a functional standpoint there is no reason for CMS to require the establishment of selection criteria that are different and separate than the OPTN listing criteria. Moreover, the field of transplantation is constantly changing, and any written selection criteria would have to be constantly updated, resulting in additional paperwork burdens. We disagree with CMS that centers already maintain such written criteria. This would be a new recordkeeping burden with associated costs – costs which have not been included in the Regulatory Impact Analysis.

**b. Selection Criteria for Living Donors:** With respect to selection criteria for living donors, the OPTN's *ad hoc* Living Donor Committee has developed living donor transplant care and management guidelines that have been approved by the OPTN board (Attachment 3). Therefore, we do not believe it is necessary for transplant centers to develop their own written selection criteria for living donors for Medicare purposes and suggest that OPTN monitoring of adherence to its policies provides sufficient means for evaluating living donor program quality.

**c. Confidentiality of Medical Records:** We also question the requirement that the living donor's suitability for donation be documented in the recipient's medical records. This raises confidentiality issues, such as how much of the donor's private medical information can be documented in another patient's record.

**d. General Medical Ethics:** The requirement that living donor selection must be consistent with general medical ethics is extremely vague. For example, there is a significant divergence of opinion as to whether selection of a living donor via an Internet solicitation is ethical. We suggest that this language be eliminated.

**e. Psychosocial Evaluation:** We support the requirement that transplant candidates and living donors receive a psychosocial evaluation and that the center determine the patient's blood type.

### 4. Organ Recovery and Receipt. [Attachment 1, Proposed Sec. 482.92].

While we support CMS' objective of decreasing organ wastage and increasing the number of successful transplants, we are very concerned that the requirements in proposed Section 482.92 represent serious impediments to the timely placement and transplantation of deceased donor organs and could dramatically increase ischemia times.

**a. Requirement that Transplant Surgeon Ensure Medical Suitability of Organ:** We are concerned about the possible interpretation of the requirement that the “transplanting surgeon at the transplant center is responsible for ensuring the medical suitability of donor organs for transplantation into the intended recipient.” While we agree that the transplanting surgeon is ultimately responsible for the decision to proceed with the transplant, it is the OPO that is responsible for collecting accurate information and communicating it properly to the surgeon. In many cases, information such as blood tests, cultures, final pathology reports and autopsy data are not known during the window

of transplantation. In order for a transplanting surgeon to be capable of “ensuring” the medical suitability of a donor organ, he or she would have to oversee all of the OPO’s collection and recording of the donor data and possibly interview the family of the potential donor to verify the medical history of the donor. This may also involve waiting for the OPO data to be complete and communicated to the surgeon. If this is required, otherwise acceptable organs will not be transplanted because the surgeon cannot “ensure” their suitability without such data. We strongly urge that this language be modified, for example, to state that the transplanting surgeon is “responsible for ensuring, to the extent possible, based on information available at the time, the medical suitability of the donor organs . . .”

**b. Review of Data Before Organ Recovery:** Proposed section 482.92(a) requires that a transplant center’s organ recovery team “review and compare the donor data with the recipient blood type and other vital data before organ recovery takes place.” (Emphasis supplied). Again, this will greatly jeopardize timely procurement and placement of viable organs and will result in increased organ wastage. In many cases, the procuring team is not the accepting team, and organs are procured before accepting transplant centers are notified of the organ’s availability. Requiring a center to review donor data before recovery takes place will delay organ recovery efforts, increase the time required to place organs, increase organ ischemia times, and, if Medicare participation is at stake, will result in many centers’ refusing otherwise acceptable organs because their team did not review the donor data before the procurement procedure started. Further, with respect to kidneys, many times the recipient has not yet been identified at the time of organ removal from a deceased donor. We suggest, as an alternative, that the rule require that the accepting transplant team must review the donor data with the recipient blood type and other vital data before accepting the organ.

**c. Protocols for Deceased Organ Recovery:** We believe that the proposed requirement that centers have written protocols for deceased organ recovery should be clarified. It is not clear whether this means that there must be criteria for acceptable donors or that there must be protocols for recovery of organs from deceased donors. Strict delineation of acceptable donors would have to entail every possible scenario of donor risk vs. recipient need for every transplant type within a center. Since it is not possible to anticipate all of these scenarios, this requirement is impractical and has little impact on quality. Further more, outcome measures will reflect the adequacy of a center’s organ acceptance criteria. We also note that in large multi-center OPOs, protocols for recovery of deceased donor organs would be determined to a considerable extent by the OPO and not the transplant center.

**d. Verification of Blood Type:** We agree with the requirement in proposed 482.92 (b) that, upon arrival of the organ, the transplanting surgeon and at least one other individual verify blood type, intended recipient and other vital data. This is routine for the transfusion of blood products in most centers and is a reasonable requirement. However, there should be an exception for intended ABO incompatible transplants.

**5. Patient and Living Donor Management.** [Attachment 1, Proposed Sec. 482.

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Again, we are concerned that the requirement for written policies does little to advance quality of care and poses significant bureaucratic and administrative burdens on centers.

**a. Center responsibility for pre- and post-transplant care:**

Subsection(a) of proposed section 482.94 requires that each transplant patient be under the care of a patient care team coordinated by a physician through the pre-transplant and discharge phases of transplantation. In many cases, waiting potential recipients are not managed by transplant centers but by local specialists. In the case of kidney transplantation, patients are frequently cared for at dialysis centers that are far away from the transplant centers, sometimes hundreds of miles.

Further, many recipients are returned to their referring physicians after a transplant, where they are managed with little input from the transplant center. In fact, some Medicare intermediaries require that care be returned to the referring physician in cases where the center is not located in the patient's home state. It is not possible for centers to oversee such patients. Thus, pre-transplant and post-transplant care is not always within the control of the center, and it is impossible for the center to "ensure" the manner in which that care is delivered. For this reason, we suggest that the proposed regulations be modified to require that pre and post transplant care for organ recipients be provided in conjunction with the local team.

**b. Waitlist Management:** Proposed section 482.94(b) sets forth requirements related to wait list management. Wait list management is an extremely complex area and is already subject to substantial oversight by the OPTN, which examines a center's waitlist practices and determines if it has an excessive turn-down rate. Most of the proposed waitlist management requirements are, in fact, already part of OPTN policy. Consequently, we do not believe the additional requirements in this section are necessary. Moreover, to the extent that OPTN policies in this complex area change, and CMS policies lag behind due to formal notice and comment requirements, there is a possibility for a transplant center to be subject to inconsistent requirements.

**c. Notification of Waitlist Status:** Proposed section 482.94 relates to patient records and requires notification to the patient or his or her placement status on the center's waitlist. We support the requirement that a transplant candidate (and dialysis center where appropriate) should be notified about his or her placement on the waiting list and if he or she is removed from the waitlist. However additional yearly notification of a patient's place on the waitlist is not practical. The waitlist is extremely fluid and dynamic, particularly for extra renal organs. Yearly notification of a patient's place on the list would be meaningless since waitlist status can change rapidly during the course of a year. Moreover, the first come, first served system for extra-renal organs has been eliminated so notifying a patient of his or her place on the list at one point in time has little bearing on that patient's place on the list at future points in time.

Further, it is impossible for a center to ensure that a patient receives notification of his status. In our experience, despite their best efforts, centers are often unable to reach patients. Some patients move away without notifying their center; sometimes they have died; and some choose not to answer. The center should be found to be in compliance with this requirement if it documents that it made a reasonable attempt to notify a patient rather than requiring that a center actually succeed in notifying a patient.

**d. Care by Multidisciplinary Team:** OPTN policy stipulates personnel requirements for transplant centers. Centers in compliance with OPTN requirements should be deemed to be in compliance with CMS requirements: Additional regulations relating to the composition of teams is likely to be either duplicative of or inconsistent with OPTN requirements.

**Nutritional Services:** Regarding proposed section 482.94(e) related to nutritional services, we note that living donors are healthy, by definition. Requiring that they receive a specific dietary prescription is burdensome, not medically indicated, and adds expense without improving outcomes.

**Transplant Pharmacologist:** A much more reasonable requirement would be the inclusion of a transplant pharmacologist. Given the complexity of today's immunosuppressive regimens and multiple drug interaction, a dedicated pharmacist or pharmacologist with expertise in transplant care would contribute to increased patient and graft survival rates.

## **6. Quality Assessment and Performance Improvement.** *[Attachment 1, Proposed Sec. 482.96].*

The requirement for a "written, comprehensive data-driven QAPI program" should be eliminated. In this regard, we note that QAPI programs are required under Medicare conditions of participation for hospitals and by JCAHO. To the extent that a Medicare-approved transplant center is necessarily associated with a Medicare –approved, the center will necessarily be part of an ongoing QAPI program.

The monitoring of outcome measures should adequately identify centers that are not keeping pace with advancing standards of care and should ensure that centers are improving over time. And while we agree that centers should address adverse events. However this is already a JCAHO standard and Medicare standard for hospitals generally and does not need to be duplicated. Implementation of a formal QAPI program might be appropriate as an aspect of remediation for a center that does not meet outcome standards.

## **7. Human Resources.** *[Attachment 1, Proposed Section 482.98].*

**Director of Transplantation:** The director of the transplant center is not well defined. It is unclear whether an individual meeting the OPTN's definition of transplant surgeon or transplant physician would qualify to hold this position. We suggest that either a

physician or surgeon meeting the OPTN requirements for a designated transplant physician or surgeon would qualify as a transplant center director.

**Transplant Physician:** The requirement that there be a transplant physician “responsible for providing and coordinating transplantation care” is vague. This should be coordinated with existing OPTN requirements for transplant physicians, by cross-referencing the OPTN definition. If CMS does not cross-reference the OPTN definition, provision should be made to update the CMS requirements for transplant physicians to be consistent with any modifications made by the OPTN, without compliance with notice and comment rulemaking.

**Transplant Surgeon:** We recommend that the final regulations cross-reference the OPTN definition, and if CMS does not cross-reference the OPTN definition, provision should be made to make the CMS requirements consistent with the OPTN requirements, without compliance with notice and comment rulemaking.

**Certified Transplant Coordinator:** Proposed section 482.98(c) requires a clinical transplant coordinator certified by the American Board of Transplant Coordinators. The requirement of a clinical transplant coordinator is a reasonable one. However, many highly experienced, excellent transplant coordinators do not have ABTC certification; nor do we believe such certification is necessary or would improve transplant care. Rather, we suggest that the Transplant Director be responsible for training transplant coordinators and ensuring that they have the necessary knowledge and skills.

## **8. Patient and Living Donor Rights.** *[Attachment 1, Proposed Sec. 482.102].*

**Written Informed Consent Policies:** The requirement of written policies for informed consent is burdensome and unnecessary. Documentation in the medical record that informed consent was obtained, including the specifics of the discussion with each patient or donor should be sufficient evidence that such a policy exists. We agree that such discussions should include use of ECD or DCD donors, transmission of disease from donor to recipient, potential outcomes, risks, benefits, alternatives, and the like, but we do not believe this needs to be written down as a separate policy.

**Informing Transplant Candidates of Risk:** Informing transplant candidates about potential risks should be done in general terms well before an actual organ is offered. This can be done by describing scenarios where disease could be transmitted, where a donor may have high risk behaviors but has tested negative for diseases, and by general descriptions of ECD characteristics. It is reasonable to require documentation of these discussions; however it is impossible to cover all the potential scenarios. At the time of an actual organ offer, known donor information can be discussed in the context of these initial discussions without disclosing donor identify. Documentation of these last minute discussions will be extremely difficult because often they are done over the phone, in the middle of the night and under rapid decision-making conditions.

**Informing Living Donors of Risks:** The proposed rule states that living donors must be informed of medical risks. In addition, CMS states, in the preamble, that potential donors should be informed of the long-term risks associated with kidney donation, such as renal failure. This requirement is impractical since there is no long-term living donor registry with which to provide such information. The OPTN has developed a plan for such a registry, but it has not been funded. We strongly support the concept of informing not only potential kidney donors but all living donors of the short- and long-term risks; however a living donor registry must be funded and implemented before this will be possible. We also question the statement in the preamble that mortality risk of living liver donation has been estimated at 1%. There is no citation for this estimate and we are not aware of peer-reviewed clinical literature supporting this estimate.

**Informing Patients of Unavailability of Transplant Surgeon:** We support the requirement that patients be informed of the potential unavailability of a transplant surgeon or physician and the impact this may have on the patient's ability to receive a transplant should an organ become available.

**Living Donor Advocate:** CMS has asked for comments on whether it should require an independent living donor advocate to ensure protection of donor rights. This is an issue that has been debated by ACOT, the ASTS Ethics Committee and the OPTN's *ad hoc* committee on living donors as well as the NY State Task Force on Living Liver Donation, among others. While there is a general consensus that some form of donor advocate is desirable, the debate centers on the issue of independence. Many believe that a completely independent advocate without any transplantation knowledge cannot accurately assess the risks and benefits for a potential donor. In addition, while some believe that the advocate should have veto power over the wishes of the potential donor or transplant team, it currently appears to be the predominant view the donor advocate should advise but not necessarily veto the procedure.

Specifying the credentials for an individual advocate is also problematic. In order to provide educated advice to the donor, the advocate should have a thorough knowledge of the risks and benefits of the donation procedure. This might indicate a physician or surgeon. However, those best qualified are likely to be less independent from the transplant team.

We do not advocate requiring a specific donor advocate at this time. However, we believe it would be appropriate for the transplant center to be required to offer the services of a transplant-educated health care worker who is not directly involved in the transplant procedure.

Further, an independent advocate probably is not necessary for living kidney donors, since the living donor and transplant procedures are often performed by the same team. This has been the standard of care and routine practice in many centers for over fifty years.

**VII. The Proposed Rules should be modified to include explicit standards for denial of approval or re-approval. [Attachment 1, Proposed Sec. 488.61].**

Clarification is needed regarding the standards to be used in determining whether a center meets Medicare conditions of participation. Specifically, the proposed rule states that a center that does not meet data submission or outcome standards will be surveyed for compliance with the process requirements in accordance with the procedures described in 42 CFR section 488, subpart A and that “a successful survey may under certain circumstances make up for a center’s failure to meet one or more of the quantitative requirements.” 70 Fed. Reg. 6167.

But while the procedures described in 42 CFR § 488.18 provide for corrective action of deficiencies, it is not clear whether a “successful survey” means that the center ultimately corrects any deficiencies in the process requirements as provided for in §488.18 or whether it must be in compliance with all the process requirements at the time of the survey. Further, it appears that a “successful survey” (however that is defined) will only compensate for failure to meet data submission and outcomes requirements in “certain circumstances” however, those circumstances are not described. We believe that more specificity is crucial.

We believe that a transplant center should be denied approval (or re-approval) for failure to meet data submission requirements if, but only if, the OPTN refuses to provide a letter indicating that the center has complied with the data submission requirements; the center fails to produce independent evidence that it has submitted such data, and the failure to produce the necessary data is not attributable to unique circumstances that are unlikely to recur.

We propose that a transplant center be subject to termination for failure to meet the outcomes standards if, after exhaustion of the notice and remediation process described in Section III of these comments, the center fails to submit an acceptable plan of correction (as determined by CMS through a designee that has experience in the field of transplantation involved). If the center submits an acceptable plan of correction with respect to its compliance with the outcomes measures, it should be eligible for a process survey. If, upon survey, it is either in compliance with the applicable conditions or submits an acceptable plan of correction, it should be approved or re-approved.

Transplant centers for which there are no OPTN outcomes measures should be approved or re-approved if, upon survey, they are found to be in compliance with the process requirements or if they submit an acceptable plan of correction with respect to any deficiency.

We also believe that the Proposed Rules should be modified to explicitly authorize the Secretary to delay a determination with respect to a center’s compliance with data submission and outcomes requirements if the center is under active review by the MPSC/OPTN.

## **VIII. Hearing and Appeals**

CMS has stated in the preamble that it intends that transplant centers be able to appeal denials of approval or re-approval. However, because transplant centers do not fit cleanly into the definition of either a provider or a supplier, as those terms are defined in the Medicare statute, it is unsure how to apply existing appeal requirements to transplant centers. Further, there is nothing in the proposed regulation that indicates that centers can appeal adverse decisions.

It is critical that transplant centers be given the same appeal rights as other entities providing services to Medicare beneficiaries, regardless of whether they are considered providers or suppliers. We believe transplant centers should have all of the due process and appeal rights set forth in section 498 of Title 42 of the Code of Federal Regulations and believe there is little difference between providers and suppliers when it comes to appeal rights. However, since transplant centers are part of hospitals which are considered providers under the Medicare statute, it would seem more logical to apply the same appeal rights that apply to hospitals. In any event, we believe CMS has the authority, through regulation, to apply the procedures set forth in section 498 to transplant centers and the final rule should contain such a provision. We also believe that the final regulations should explicitly state that a transplant center shall remain eligible for participation in the Medicare program pending the exhaustion of any appeals, so long as it has in place an acceptable QAPI program and that its continued treatment of Medicare patients does not jeopardize such patients' health and safety.

In addition, we request that CMS clearly state that denial of initial approval as well as re-approval is an "initial determination" that triggers the appeal rights under section 498.

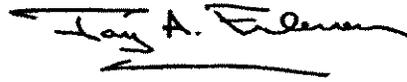
## **Conclusion**

We appreciate the opportunity to comment on these complex and important regulations. We recognize the difficulty involved in striking an appropriate balance between protecting potential transplant donors and recipients and imposing unnecessary, duplicative, and potentially conflicting requirements on transplant centers, which are already among the most heavily regulated of providers. We would appreciate the opportunity to meet with you and would suggest that, perhaps, once the issues requiring further discussion are delineated, it also may be appropriate for the transplant community, CMS, and representatives of the OPTN to meet together to coordinate Medicare approval and OPTN requirements to achieve the necessary balance. Please contact Katrina Crist at 703-684-5990 to coordinate a meeting or if you have any questions regarding these comments.

Sincerely,



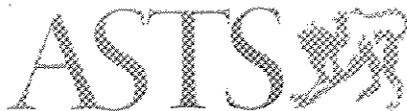
Richard J. Howard, M.D., Ph.D  
President  
American Society of Transplant Surgeons



Jay A. Fishman, M.D.  
President  
American Society of Transplantation



Mark L. Barr, M.D.  
President  
International Society for Heart and Lung Transplantation



American Society of Transplant Surgeons

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Via Electronic Transmission  
thomas\_novelli@finance-re.senate.gov

June 25, 2007

The Honorable Charles E. Grassley  
Ranking Member  
Committee on Finance  
United States Senate  
Washington, DC 20510-63200

Dear Senator Grassley:

The American Society of Transplant Surgeons is the organization that represents transplant surgeons throughout the country. Our mission, in part, is to foster and advance the practice and science of transplantation for the benefit of patients and society. We share your concerns regarding the long-term outcome of both donors and recipients. A major part of our activity is to promote education and studies to improve outcomes.

Our membership has been active in studying and improving short- and long-term outcomes for donors. Laparoscopic kidney donor nephrectomy was developed, implemented, studied, and refined by ASTS members. With laparoscopic nephrectomy, there is less pain and a quicker recovery time than after the previously used conventional open nephrectomy. In addition, the ASTS has been actively involved in the NIH-sponsored "A2ALL" study – a study of long-term follow-up of living liver donors. The ASTS has partnered with the NIH to provide additional funds for this study so that more centers could be funded to enroll participants.

We recognize that there are numerous unanswered questions about short- and long-term donor outcome. We believe that the answers will best be provided by designing the appropriate studies. But, before designing studies, we believe it is appropriate to: 1) prioritize the questions; 2) think about the costs of collecting and analyzing the data.

National Office  
2461 South Clark Street  
Suite 642  
Arlington, VA 22202  
Phone: 703 414-7870  
Fax: 703 414-7874  
Email: [asts@asts.org](mailto:asts@asts.org)  
[www.asts.org](http://www.asts.org)

President  
Goran B. Khintmalin, MD, PhD  
Baylor Regional Transplant Inst.  
3500 Chestnut Avenue  
Dallas, TX 75246  
Phone: 214 820-2050  
Fax: 214 820-4527  
Email: [g.krank@baylorhealth.edu](mailto:g.krank@baylorhealth.edu)

President-Elect  
John P. Roberts, MD  
Univ. of California San Francisco  
Division of Transplantation  
305 Parnassus Ave  
Box 2780, Room M096  
San Francisco, CA 94143-0780  
Phone: 415 353-1888  
Fax: 415 353-8709  
Email: [robertj@surgery.ucsf.edu](mailto:robertj@surgery.ucsf.edu)

Secretary  
Robert M. Merion, MD  
University of Michigan  
315 West Huron, Suite 240  
Ann Arbor, MI 48103-4262  
Phone: 734 936-7336  
Fax: 734 998-6620  
Email: [merionh@umich.edu](mailto:merionh@umich.edu)

Treasurer  
Michael M. Abecassis, MD, MBA  
Northwestern University  
Division of Transplantation  
675 N. St. Clair Street, #17-200  
Chicago, IL 60611  
Phone: 312 695-0359  
Fax: 312 695-9194  
Email: [mabecass@northwestern.edu](mailto:mabecass@northwestern.edu)

Immediate Past President  
Arthur J. Mutas, MD

Past President  
A. Benedict Costin, MD

Councillors-at-Large  
Mitchell L. Henry, MD  
Kim M. Offhoff, MD  
Robert L. Karimas, MD  
Alan N. Langnas, DO  
Richard B. Freeman, Jr., MD  
Dixon B. Kaufman, MD, PhD

Executive Director  
Katriina Crist, MBA  
Email: [katriina.crist@asts.org](mailto:katriina.crist@asts.org)

It is critical to note that the type of data gathered may depend on the questions being asked. For example, if the priority is to compare donor outcome at individual transplant centers, then we should be developing a "short-term" registry to study critical events like deaths, reoperations, perioperative infections, readmissions within 30 days, organ failure and other similar items. Donor demographics, etc., would have to be collected and reports could be generated studying center-specific outcome. Such studies would not provide data on long-term donor health-related issues. However, the costs of doing these studies would be less than the costs of long-term studies. Separate studies would be required for kidney, liver, and lung donors. (And, for cost-efficiency, it would be of benefit to not replicate the A2ALL study).

Alternatively, if the priority is to study long-term donor outcome, then the decision needs to be made as to whether it is necessary to study long-term outcome at all centers (which would be extraordinarily expensive) or outcome in a representative sample from a smaller number of centers. In addition, it is important to decide whether to study long-term outcome for today's donors (it will take up to 50 years to get the results), or collect data on previous donors. Of note, the NIH (through its grant mechanism) has just begun a study of long-term kidney donor outcome; donors from three transplant centers will be studied. Studying a representative sample will clearly be less costly than studying the entire donor population. (And, as discussed above, the A2ALL study is following liver donors).

For kidney donors, we believe that the questions that need to be answered include:

- 1) What is the long-term ( $\geq 15$  years) outcome of donor nephrectomy? Most published studies have a mean follow-up of  $< 15$  years, and those with longer follow-up times have incomplete information. It is important to determine whether or not the incidence of hypertension, proteinuria, and renal dysfunction is higher in living donors than in their siblings or than in the age-matched general nondonor population.
- 2) Does proteinuria (protein in the urine) or mild renal dysfunction in living donors herald the development of renal failure? Previous studies have noted both proteinuria and mild renal dysfunction in some former donors. However, sequential studies have not been done and it is unknown whether either the proteinuria or renal dysfunction are progressive.
- 3) In the general population, both proteinuria and mild renal dysfunction have been noted to be risk factors for cardiovascular disease. Is the proteinuria or mild renal dysfunction (seen in some living donors) associated with an increased risk of cardiovascular disease or mortality?
- 4) Is the use of laparoscopic nephrectomy and expanded-criteria living donors (those who are obese or who have mild hypertension) associated with an increased incidence of surgical and perioperative complications, proteinuria, or renal dysfunction?
- 5) If living donors develop native kidney disease or another disease that might affect their remaining kidney (particularly type 2 diabetes), will they suffer an accelerated course to renal failure?
- 6) Is quality of life affected by laparoscopic nephrectomy?
- 7) Is donor outcome affected by donor ethnicity or other demographic variables?

For liver donors, we believe that the important questions to be answered are:

- 1) What is the long-term ( $\geq 15$  years) outcome of donor hepatectomy? There are no data on this currently although A2ALL has started to collect these data.
- 2) What is the incidence of the known complications of living donor hepatectomy?

- 3) What is the significance of these complications (i.e. what is the impact on the donors?)
- 4) Are there social and financial complications that occur such as inability to secure health insurance, life insurance, etc.?
- 5) Are there psychological complications? Is quality of life affected following live donor hepatectomy?

Clearly developing studies to answer these questions will require some type of research funding. However, this is not only about data collection. The donors are not currently seen and any visit for the sake of the requested follow-up incur significant costs for clinic time, laboratory work, other potential investigations such as radiology, and physician time. These costs are not reimbursed by the donors health insurance or the organ recipients health insurance that paid for the evaluation and organ donation surgery. This is true for Medicare as well as for third party payers.

Transplant centers do not have the personnel to collect and analyze these kinds of data. And, the number of donors at any one center is not sufficient to provide an adequate answer. Thus, multi-center studies or a registry will be necessary (with the attendant costs). Moreover, current reimbursement schemes do not allocate funds for research purposes. As the number of live donor cases increases, the financial burden of this type of necessary follow-up must be addressed and the required funding should be made available, but to reiterate, we should not advocate for unnecessary data collection, but rather we should insist on focused and meaningful data collection and analysis.

Additionally, there are other inherent difficulties with living donor follow-up. We know from decades of experience that once the early postoperative phase is over and the donor feels well, his/her interest to come back to see the doctor quickly fades. The reasons for this are many including not wanting to take time away from work for a doctors appointment (i.e. financial), not wanting to receive more needle sticks – "I feel good," living far away necessitating long distance travel which demands more time and may require hotel accommodations and even airfare. Donors relocate just like everybody else. Reasons like these and many others make long term follow-up inherently difficult. These difficulties rapidly escalate with time. This needs to be understood and kept in mind as one discusses this topic.

We would be glad to meet with you or your representatives to discuss how best to move these types of initiatives forward. We would also be happy to make arrangements for other interested parties to participate in such discussions. Please feel free to contact me directly at 214.820.1730 or you may contact Katrina Crist, ASTS Executive Director, at 703.414.7870.

Yours truly,



Goran B. Klintmalm, MD, PhD, FACS  
President

Cc: Sue V. McDiarmid, MD, OPTN/UNOS

IND effective date was July 24, 1992, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act:* December 8, 2000. The applicant claims December 7, 2000, as the date the new drug application (NDA) for Symlin (NDA 21-332) was initially submitted. However, FDA records indicate that NDA 21-332 was submitted on December 8, 2000.

3. *The date the application was approved:* March 16, 2005. FDA has verified the applicant's claim that NDA 21-332 was approved on March 16, 2005.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,586 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by August 15, 2006. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by December 13, 2006. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 17, 2006.

**Jane A. Axelrad,**

*Associate Director for Policy, Center for Drug Evaluation and Research.*

[FR Doc. E6-9414 Filed 6-15-06; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Response to Solicitation on Organ Procurement and Transplantation Network (OPTN) Living Donor Guidelines

**AGENCY:** Health Resources and Services Administration (HRSA), HHS.

**ACTION:** Response to solicitation of comments.

**SUMMARY:** A notice was published in the **Federal Register** on January 23, 2006 (Vol. 71, No. 14, pages 3519-3520). The purpose of this notice was to solicit comments to assist HRSA in determining whether criteria developed by the Organ Procurement and Transplantation Network (OPTN) concerning organs procured from living donors, including those concerning the allocation of organs from living donors, should be given the same status, and be subject to the same enforcement actions, as other OPTN policies.

**FOR FURTHER INFORMATION CONTACT:** James F. Burdick, M.D., Director, Division of Transplantation, Healthcare Systems Bureau, Health Resources and Services Administration, Parklawn Building, Room 12C-06, 5600 Fishers Lane, Rockville, Maryland 20857; telephone (301) 443-7577; fax (301) 594-6095; or e-mail: [jburdick@hrsa.gov](mailto:jburdick@hrsa.gov).

**SUPPLEMENTARY INFORMATION:** Congress has provided specific authority under sections 372 of the Public Health Service (PHS) Act, as amended, 42 U.S.C. 274 for the creation of a national OPTN, which is, among other things, to facilitate a donor and recipient matching system; establish membership criteria and medical criteria for allocating donated organs; and provide opportunities to members of the public to comment with respect to proposed criteria.

The OPTN Final Rule (42 CFR part 121) governs the operations of the OPTN and is intended to help achieve the most equitable and medically effective use of human organs that are donated in trust for transplantation. Under the final rule, the OPTN is to develop policies on a variety of issues, including "[p]olicies for the equitable allocation of cadaveric organs [now referred to as deceased donor organs]." 42 CFR 121.4(a)(1). Under the final rule, allocation policies developed by the OPTN under section 121.8 of the final rule will be considered enforceable when and if the Secretary approves the policies as such. Enforceable OPTN policies are subject

to the sanctions described in section 121.10(c)(1) of the final rule. Non-enforceable OPTN policies may still be subject to lesser sanctions by the OPTN (e.g., an OPTN member being designated a Member Not in Good Standing).

Although the authorizing statute does not distinguish between transplants using organs from living donors and those using organs from deceased donors, the final rule does not include a requirement that the OPTN develop policies concerning the equitable allocation of living donor organs. Until recently, OPTN policies have predominantly focused on issues related to organ donation and transplantation of deceased donor organs.

However, several widely publicized living donor deaths have caused the OPTN to implement new practices of reviewing and approving, on an advisory basis, the qualifications of living donor transplant programs. Additionally, the increased incidence of altruistic living donations has prompted the OPTN to consider policies that are patient-focused yet address the unique circumstances pertaining to the recovery and transplantation of living donor organs. Section 121.4(a)(6) of the final rule provides that the OPTN shall be responsible for developing policies on a variety of topics, including "[p]olicies on such matters as the Secretary directs." In accordance with that authority, the Healthcare Systems Bureau directed the OPTN to develop allocation guidelines for organs from living donors and other policies necessary and appropriate to promote the safety and efficacy of living donor transplantation for the donor and recipient. It further advised the OPTN that all living donation policies (other than data reporting policies) should be considered as best practices or voluntary guidelines and not subject to regular OPTN sanctions (even those available with respect to violation of non-enforceable policies) until the public has had an opportunity to comment on the matter.

In the January 23, 2006, **Federal Register** notice, comments were requested to assist HRSA in determining whether OPTN living donor guidelines should be given the same status of other OPTN policies, *i.e.*, be treated as policies developed in accordance with 42 CFR 121.8, and be subject to the same enforcement actions. The Secretary explained that if he decided these questions in the affirmative, OPTN policies relating to living donors would be treated the same as other OPTN policies developed in accordance with section 121.8 of the final rule. In other words, OPTN policies concerning living

donors would not be considered enforceable policies under section 121.10 of the final rule, and violations of such policies would not be subject to the sanctions described in section 121.10(c)(1), unless and until the Secretary approved such policies as enforceable.

During the comment period, HRSA received 29 comments from individuals affiliated with or representing universities, hospitals, professional associations, and living donation advocacy organizations; a healthcare accreditation organization; transplant recipients; and family members of donors, recipients and candidates. Twenty of these comments explicitly referenced changing the status of OPTN living donor guidelines. The remaining nine comments expressed views about various aspects of the national transplant system not directly related to the solicitation of comments.

HRSA thanks the respondents for the quality and thoroughness of their comments. The comments and HRSA's decision are discussed below.

### **I. Living Donor OPTN Policies Consistent With Other OPTN Policies**

The majority of respondents indicated that OPTN living donor guidelines should be given the same status of other OPTN policies. Of the 20 comments that explicitly referenced changing the status of OPTN living donor guidelines, 17 were supportive of giving OPTN living donor guidelines the same status, and subjecting these to the same enforcement actions, as other OPTN policies. Supportive comments were received from representatives of academia, transplant surgeons, living donors who had positive donation experiences, living donors who had negative donation experiences, family members of living donors who died or who experienced complications as a result of the donation, living donation advocacy organizations, transplant administrators, the professional societies representing transplant surgeons and transplant physicians, transplant candidate/recipient advocacy organizations, the organization serving as the current OPTN contractor, and an organization that accredits hospitals.

Supportive comments cited the appropriateness of OPTN involvement in policies relating to living donors, including donor evaluation, informed consent, evaluation of surgical outcomes and complications, protection of living donors, peri-operative care, organ allocation, qualifications of transplant programs, and transplant program compliance with living donor policies.

A few comments indicated opposition to giving OPTN living donor guidelines the same status as other OPTN policies. A family member of two kidney transplant candidates who died on the waiting list is now an advocate of potential living donors and recipients meeting on the Internet and is opposed to the OPTN's involvement in living donor policy making because of the perception that the OPTN discourages living donor transplants resulting from such meetings. Another opponent of OPTN involvement is waiting for a liver transplant and does not trust the OPTN policymaking process because of the perception that wealthier candidates receive priority for donor organs. One data manager from a large transplant program commented that mandating data collection on living donors was unlikely to increase donor follow-up form completion rates unless the donors' insurance companies can be persuaded to pay for follow-up visits. HRSA appreciates each of these comments.

### **II. OPTN Living Donor Policy Making Authority—Organ Allocation**

Comments supportive of OPTN involvement in living donor policy making expressed varying views regarding the scope of policies the OPTN should consider. Of the 17 comments that were supportive of OPTN involvement, five suggested areas in which the OPTN should not become involved. One comment did not advocate an intrusive role for the OPTN in the allocation of living donor organs or ethical review of local living donor practices. A transplant administrator offered the similar caution that altruistic living donors may feel a sense of connection to their local transplant center and may not want their organs allocated to a distant center. A representative of the professional society for transplant surgeons offered a comment to HRSA that the OPTN Final Rule does not authorize the OPTN to establish policies for living donor organ allocation. In response to this, HRSA emphasizes that its authority to direct the OPTN to develop living donor organ allocation policies is granted in § 121.4(a)(6) of the OPTN Final Rule which permits the Secretary to develop policies on such other matters as the Secretary directs. The wording in § 121.8(a) of the final rule referring to policies "for the equitable allocation of cadaveric organs" should not be construed as a limitation of the Secretary's policy making authority over living donation.

A representative of a living donor advocacy organization commented that

OPTN policies should not interfere with the right of an altruistic living donor to direct their organ to a specific individual. We agree. Section 121.8(h) of the OPTN Final Rule permits the allocation of an organ to a recipient named by those authorized to make the donation. Because we are directing the OPTN to develop living donor allocation policies under section 121.8 of the final rule, section 121.8(h) will apply to living donation equally as it applies to deceased donation.

### **III. OPTN Living Donor Policy Making Authority—Donor Evaluation**

Supportive comments varied in their level of support for OPTN involvement in developing policies for living donor evaluation. Of the 17 comments that were supportive, two were opposed to OPTN policymaking in this area. One comment from a representative of the professional organization for transplant surgeons and another from a transplant surgeon asserted that the OPTN should not develop policy in the area of donor evaluation because there is no clear clinical consensus regarding the policies or standards that should be followed. HRSA believes it is very likely that should the OPTN consider policy making in the area of living donor evaluation that members of OPTN committees and the Board of Directors will consider this perspective and abandon policy making in the absence of clear clinical consensus. Additionally, through its public comment process transplant professionals also have the opportunity to advise the OPTN of the lack of clear clinical consensus, should it exist.

### **IV. OPTN Living Donor Policy Making—Living Donor Follow-up**

Several comments stated greater attention should be given to understanding the impact of donation on living donors. One commenter who represents the professional organization for transplant professionals recommended more Federal funding for a live organ donor database. A comment from a living donor who is a healthcare professional and living donor advocate asserted that there should be mandatory policies to protect living donors and a central source of outcome data via a living donor registry. A comment from a transplant surgeon supports more OPTN involvement in living donor data collection and monitoring living donor outcomes. A comment from a representative of a healthcare accreditation organization stated it is appropriate for the OPTN to establish additional policies to promote the safety of living donor transplantation. A

comment from the mother of a living donor and recipient who both experienced post-transplant complications asserted that stronger policies should be developed to ensure living donor safety.

### Conclusion

HRSA has reviewed and considered each aspect of each comment and has determined that OPTN living donor guidelines should be given the same status of other OPTN policies as discussed in the **Federal Register** Notice published on January 23, 2006. Under 42 CFR 121.4(a)(6), the Secretary directs the OPTN to develop policies regarding living organ donors and living organ donor recipients, including policies for the equitable allocation of living donor organs, in accordance with section 121.8 of the final rule. Thus, the OPTN shall develop such policies in the same manner, and with the same public comment process, that it does for policies on deceased organ donors and deceased organ donor recipients. Non-compliance with such policies shall subject OPTN members to the same consequences as noncompliance with policies concerning deceased organ donors and deceased organ donor recipients developed under the final rule.

Dated: June 9, 2006.

**Elizabeth M. Duke,**  
Administrator.

[FR Doc. E6-9401 Filed 6-15-06; 8:45 am]

**BILLING CODE 4165-15-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Human Genome Research Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Human Genome Research Institute Special Emphasis Panel; Sequencing Centers Review.

*Date:* July 13, 2006.

*Time:* 8 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* The Hotel Rouge, 1315 16th Street, NW., Washington, DC 20036.

*Contact Person:* Rudy O. Pozzatti, PhD, Scientific Review Administrator, Office of Scientific Review, National Human Genome Research Institute, National Institutes of Health, Bethesda, MD 20892. 301-402-0838. (Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: June 12, 2006.

**Anna Snouffer,**

*Acting Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 06-5471 Filed 6-15-06; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Child Health and Human Development; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Child Health and Human Development Special Emphasis Panel; Gonadotropin Inhibitors: A Structural Biology Approach To Immunoneuroendocrinology.

*Date:* July 6, 2006.

*Time:* 10 a.m. to 11 a.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6100 Executive Boulevard, Room 5B01, Rockville, MD 20852 (Telephone Conference Call).

*Contact Person:* Jon M. Ranhand, PhD, Scientist Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, NIH, 6100 Executive Boulevard, Room 5B01, Bethesda, MD 20892. (301) 435-6884. [ranhandj@mail.nih.gov](mailto:ranhandj@mail.nih.gov).

*Name of Committee:* National Institute of Child Health and Human Development Special Emphasis Panel; Global Profiling of Molecular Errors Associated With Human Spermatogenic Disorder.

*Date:* July 6, 2006.

*Time:* 2 p.m. to 3 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6100 Executive Boulevard, Room 5B01, Rockville, MD 20852 (Telephone Conference Call).

*Contact Person:* Jon M. Ranhand, PhD, Scientist Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, NIH, 6100 Executive Boulevard, Room 5B01, Bethesda, MD 20892. (301) 435-6884. [ranhandj@mail.nih.gov](mailto:ranhandj@mail.nih.gov).

*Name of Committee:* National Institute of Child Health and Human Development Special Emphasis Panel; Immunodominant Ovarian Antigens Involved in Premature Ovarian Failure.

*Date:* July 7, 2006.

*Time:* 10 a.m. to 11 a.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6100 Executive Boulevard, Room 5B01, Rockville, MD 20852 (Telephone Conference Call).

*Contact Person:* Jon M. Ranhand, PhD, Scientist Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, NIH, 6100 Executive Boulevard, Room 5B01, Bethesda, MD 20892. (301) 435-6884. [ranhandj@mail.nih.gov](mailto:ranhandj@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: June 12, 2006.

**Anna Snouffer,**

*Acting Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 06-5470 Filed 6-15-06; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose

## Implementation Package

Proposed Modifications to OPTN/UNOS Bylaws, Appendix B, Attachment I, Section XIII, C (2) Kidney Transplant Programs that Perform Living Donor Kidney Transplantation and

OPTN/UNOS Bylaws, Appendix B, Attachment I, Section XIII, C (4) Liver Transplant Programs that

### Proposal Summary

These proposed modifications will establish additional minimum criteria for granting designated program status to transplant programs that perform living donor kidney and liver transplants. These revised bylaws will ensure living donor programs have essential elements in place for the evaluation, consent, and follow-up of living kidney donors.

For review by Board of Directors

Membership and Professional Standards and Living Donor Committees

Author(s) - *Sally Aungier, Administrator, Membership Services*

Date: August 21, 2007



United Network for Organ Sharing  
700 N. 4<sup>th</sup> Street  
Richmond, Virginia 23219

## Executive Summary

Proposed Modifications to OPTN/UNOS Bylaws, Appendix B, Attachment I, Section XIII, C (2) Kidney Transplant Programs that Perform Living Donor Kidney Transplantation and  
OPTN/UNOS Bylaws, Appendix B, Attachment I, Section XIII, C (4) Liver Transplant Programs that Perform Living Donor Liver Transplants  
Membership and Professional Standards and Living Donor Committees

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## Executive Summary

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 Membership and Professional Standards and Living Donor Committees

## Section 1: Information to be provided to the POC

### 1 Summary/Background

| Proposal Summary   |   |
|--|---|
| Subject  | Description   |
| Brief summary of proposed Policy                               | These proposed modifications will establish additional minimum criteria for granting designated program status to transplant programs that perform living donor kidney and liver transplants. |
| Primary goal(s) of Policy as set forth by sponsoring Committee | These revised bylaws will ensure living donor programs have essential elements in place for the evaluation, consent, and follow-up of living kidney donors.                                   |
| Primary metric(s) identified to assess policy                  | Transplant programs will be asked to submit applications that describe how they meet the requirements for living donor transplantation.   |

### 2 Checklist for Analytic Modeling

| 5-Point Checklist for Analytic Modeling  |                        |
|--|------------------------|
| Component  | Assessed by Committee? |
| Statement of the Objectives of the Proposed Policy   | Not applicable         |
| Building the Models  | Not applicable         |
| Testing the Models   | Not applicable         |
| Testing the Consequences of the Formulated Proposed Policy Prior to Implementation (Simulation Modeling) | Not applicable         |
| Evaluation of the Effectiveness of the Policy  | Not applicable         |

## Executive Summary

Proposed Modifications to OPTN/UNOS Bylaws, Appendix B, Attachment I, Section XIII, C (2) Kidney Transplant Programs that Perform Living Donor Kidney Transplantation and  
 OPTN/UNOS Bylaws, Appendix B, Attachment I, Section XIII, C (4) Liver Transplant Programs that Perform Living Donor Liver Transplants  
 Membership and Professional Standards and Living Donor Committees

Additional supporting data/analyses

See Attached Briefing Paper from September 2007 MPSC Report to the Board of Directors.

### 3 Program Goals, Strategic Plan and Relationship to OPTN Final Rule

| Goals  |  |
|--|--|
| Program Goal   | Impact   |
| Increase number of deceased donor transplants  | Not Applicable   |
| Increase number of DCD donors  | Not Applicable   |
| Increase number of non-DCD donors  | Not Applicable   |
| Increase life years gained   | Not Applicable   |
| Increase organs transplanted/donor - non-DCD   | Not Applicable   |
| Increase organs transplanted/donor - DCD   | Not Applicable   |
| Strategic Plan   | Impact   |
| Increase donors and transplants in support of HHS Program Goals  | Not Applicable   |
| Refine allocation policies, incorporating concepts of: <ul style="list-style-type: none"> <li>• donor risk</li> <li>• recipient benefit, and</li> <li>• net benefit</li> </ul> | Not Applicable   |
| Reduce variation of death on the waiting list across the country   | Not Applicable   |
| Optimize a safe environment for living donor transplantation   | These changes will help to fulfill the goal by promoting donor safety. |

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| Goals  |   |
|--|---|
| Improve compliance with policies to protect patient safety and preserve public trust | These Bylaw changes will provide additional minimal requirements that programs performing living donor transplants must meet. All OPTN policies regarding performance are considered member obligations and compliance is monitored and addressed when necessary through the peer review process. This approach is necessary because the OPTN Bylaws have not been approved by HHS as federal regulations and are considered voluntary. |
| Improve the OPTN data system   | Data Submission policies for living donors are already in place. The information collected will be contained in the applications submitted by programs that perform or wish to perform living donor transplants. This information will predominantly identify the staff, their training/experience, and document that the program's have developed the appropriate protocols as required in the proposed modifications to the bylaws.   |

| Comportment with the Final Rule  |  |
|--|--|
| <p>These changes will help to ensure transplant center compliance with Section §121.8 and the Secretary's statement issued on June 16, 2006, that stated the following:</p> <p><i>Under 42 CFR 121.4(a)(6), the Secretary directs the OPTN to develop policies regarding living organ donors and living organ donor recipients, including policies for the equitable allocation of living donor organs, in accordance with section 121.8 of the final rule. Thus, the OPTN shall develop such policies in the same manner, and with the same public comment process, that it does for policies on deceased organ donors and deceased organ donor recipients. Non-compliance with such policies shall subject OPTN members to the same consequences as noncompliance with policies concerning deceased organ donors and deceased organ donor recipients developed under the final rule.</i></p> |  |

## 4 New/Modified Data Collection Requirements

| Data Collection Requirements                                   |  |
|--|--|
| Data Collection Principle                                      | Details  |
| Develop transplant, donation, and allocation policies          | Not applicable.  |
| Determine if institutional members are complying with policies | Transplant hospitals that perform or intend to perform living donor transplants will need to complete an application that demonstrates how the applicant center meets the requirements. The applicant will also be responsible for submitting an application whenever there is a change in key personnel.<br>The questions in the existing applications and surveys (e.g. applications for new programs, reactivation, and key |

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| Data Collection Requirements                                    |   |
|---|---|
| Data Collection Principle                                       | Details   |
|   | <p>personnel changes, staffing surveys, and Outcomes and Activity Surveys) that are relative to living donor programs will be changed to incorporate the concepts outlined in the modified Bylaws.</p> <p>OMB approval of the new application forms will be required. New and revised forms will be submitted to the OMB following approval of the proposed bylaws by the Board of Directors.</p> <p>The staff and the MPSC will review the applications and other responses as a part of the evaluation process.</p>   |
| Determine member-specific performance                           | Data can be used to analyze performance of programs that perform living donor transplants.  |
| Ensure patient safety when no alternative sources of data exist | Data collection for living donors is in accordance with the OPTN Principle of Data Collection to “ensure patient safety when no alternative sources of data exist.” The “operational statements for data collection” approved by the Board in December 2006, also state that (1) the OPTN will only collect data that is contracted by HRSA, and (2) that data for specific populations (e.g., Living Donors) may constitute exceptions to the Principles of Data Collection. There are currently no other sources of data for living donors that would allow the OPTN to meet this contractual requirement.  |
| Fulfill the requirements of the OPTN Final Rule                 | <p>The final directive was published in the Federal Register, Vol. 71, No. 116 on June 16, 2006, and stated the following:</p> <p><i>HRSA has reviewed and considered each aspect of each comment and has determined that OPTN living donor guidelines should be given the same status of other OPTN policies as discussed in the Federal Register Notice published on January 23, 2006. Under 42 CFR 121.4(a)(6), the Secretary directs the OPTN to develop policies regarding living organ donors and living organ donor recipients, including policies for the equitable allocation of living donor organs, in accordance with section 121.8 of the final rule. Thus, the OPTN shall develop such policies in the same manner, and with the same public comment process, that it does for policies on deceased organ donors and deceased organ donor recipients. Non-compliance with such policies shall subject OPTN members to the same consequences as noncompliance with policies concerning deceased organ donors and</i></p> |

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| Data Collection Requirements   |  |
|--|--|
| Data Collection Principle  | Details  |
|  | <i>deceased organ donor recipients developed under the final rule.</i> |
| *For specific populations (e.g. Pediatrics, Living Donors) if exceptions to the foregoing principles, have alternative sources of information been explored? | NA   |

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### 5 Public Comment Summary - Proposals 1 and 2

#### Public Comment Distribution

Has the proposal been distributed for public comment? YES

Date of distribution: 7/13/2007

Public comment end date: 8/11/2007

| Public Comment Response Tally |                  |                                    |                             |                              |
|-------------------------------|------------------|------------------------------------|-----------------------------|------------------------------|
| Type                          | Response Total   | In Favor                           | Opposed                     | No Comment                   |
| Individual Comments           | 48 KI<br>47 LI   | 33/ 68.75% KI<br>30 63.83% LI      | 8/16.67% KI<br>5/ 10.64% LI | 7/14.58% KI<br>12/ 25.53% LI |
| Regional Comments             | 188 KI<br>173 LI | *105 / 55.85% KI<br>*87 / 50.28 LI | 55/29.29% KI<br>34/19.65 LI | 28/14.89% KI<br>52/30.05 LI  |

\*KI 24 votes for approval with amendment.

\*LI 21 votes for approval with amendment

#### Primary Public Comment Concerns/Questions

- The transplant community does not fully appreciate the OPTN's mandate to develop living donor policies.
- The Bylaws and guidelines proposals are viewed as dictating medical practice, and are too prescriptive.
- The transplant community believes that implementing the Bylaws and guidelines will increase costs.
- The transplant community believes the Bylaws should be more closely aligned with the Medicare Conditions of Participation (COP) for Medicare approved programs.

### 6 Estimated UNOS Resource Utilization

(See Appendix A for further details on departmental resources.)

| UNOS Resource Estimates for Implementation |  |
|--|--|
| Area                                       | Impact   |
| Resource Impact                            | Membership Staff:<br>See Appendix A.<br><br><i>Department of Evaluation and Quality (DEQ) Staff: See Appendix A.</i> |
| Estimated FTEs                             | 2.25 for KI and .75 for LI   |

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## 7 Implementation Strategy

| Implementation Plan Status                       |           |   |
|--|-----------|---|
| Documentation/Plan                               | Complete? | Status Comments   |
| Functional and Technical Specification Documents | N         | Membership Database modifications are in process and additional enhancements will be evaluated in conjunction with the System Redesign  |
| Resource Analysis Assessment                     | Y         | See Appendix A  |
| Communications and Education Plan                |           | A policy notice mailing will be sent to the members that describe the changes to the Bylaws and how they will be implemented.<br><br>In conjunction with Implementation Live Meeting Training on the application form for programs that perform living donor kidney transplant will be offered. |
| Monitoring Plan                                  | Y         | See Appendix C  |

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## Section 2: POC RECOMMENDATIONS to Board of Directors

### 8 Policy Oversight Committee (POC) Recommendations

Date(s) proposal reviewed by POC:

POC Policy Scorecard

Not Applicable

Summary of Recommendations

Not Applicable

### 9 Board of Directors Review

Date(s) proposal submitted to Board of Directors: 9/17-18/2007

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### 10 Appendix A: Resource Analysis Plan

(Note: Level of detail subject to further internal discussion!)

| UNOS Staff Resources: Policy Development and Implementation |   |                              |                         |
|---|---|------------------------------|-------------------------|
| Department  | Brief Detail  | Annual Staff Hour Percentage | Cost Estimate           |
| Communications  |   |                              |                         |
| Corporate Counsel   |   |                              |                         |
| Evaluation and Quality                                      | DEQ staff will need to modify its site survey process to incorporate a review of living donor/recipient records.  | 47 KI<br>47 LI               | \$1,497 KI<br>\$1497 LI |
| Information Technology                                      | <p>Business Systems Analysts</p> <ul style="list-style-type: none"> <li>Initial analysis</li> <li>Functional spec doc (includes design)</li> <li>Seek approvals (internal and external)</li> <li>Project management</li> <li>Update Match Documentation</li> <li>Spec doc revisions<sup>4</sup></li> </ul> <p>Graphic Designers - Create Comps</p> <p>Project management:</p> <ul style="list-style-type: none"> <li>Assisting with functional spec doc</li> <li>Technical spec doc</li> <li>Seek approvals</li> <li>Coding</li> <li>Dev unit testing (Individual + Peer)</li> <li>Revise coding</li> <li>Implementation plan &amp; deploy</li> </ul> | 41 KI                        | 0.04% KI                |
| Membership /Regional Administration                         | <p>The primary new work effort for the Membership staff will be initiating the review process for programs that currently perform living donor transplants. This effort includes the following tasks:</p> <ul style="list-style-type: none"> <li>Assemble program applications</li> <li>Develop strategy for handling identified database changes</li> <li>Solicit &amp; send out applications</li> <li>Receive, process, review &amp; post</li> </ul>  | 4567 KI<br>1195 LI           | 18.49% KI<br>4.84% LI   |

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|                       |  |             |                  |
|-----------------------|--|-------------|------------------|
|                       | applications<br>Committee approval/determination and program notification <ul style="list-style-type: none"> <li>• Program database entry</li> <li>• Developing and conducting Live Meeting Training</li> <li>• Project 17 hours application team work per each live kidney program added</li> </ul> Regional Administration: <ul style="list-style-type: none"> <li>• Communicate with Regional Representative(s)</li> <li>• Disseminate information to regions</li> <li>• Coordinate/participate in calls/meetings to hash out requirements</li> <li>• Policy voted on by Region and summarize discussion for sponsoring committee</li> <li>• Provide Regional input to BOD</li> </ul> |             |                  |
| Policy                |  |             |                  |
| Professional Services |  |             |                  |
| Research              |  |             |                  |
| <b>Total</b>          |  | <b>5897</b> | <b>\$308,876</b> |

| Community and Membership Impact |   |
|---------------------------------|---|
| Community/Member/Organization   | Impact Description  |
| Transplant Centers              | <p>Transplants programs that presently perform living donor transplants will be required to submit an application that demonstrates that they meet the minimal requirements that are specified in the proposed bylaws. Programs that perform Living Donor transplants have already undergone this process but the kidney programs will be entering the initial phase of the process.</p> <p>Hospitals that are not currently performing living donor transplants will need to submit an application to the OPTN and receive approval prior to performing any living donor transplants</p> |

## UNOS Staff Resources: Continual Support

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| Department                          | Brief Detail  | Annual Staff Hour Percentage | Annual Resource Percentage |
|-------------------------------------|---|------------------------------|----------------------------|
| Communications                      | Article in UNOS Update  |                              |                            |
| Corporate Counsel                   |   |                              |                            |
| Evaluation and Quality              | Reviewing living donor/recipient records during the site survey process will require additional continual effort.                                 | 110 KI<br>110 LI             | 0.19% KI<br>0.19% LI       |
| Information Technology              | Development of application tracking tools.  |                              |                            |
| Membership /Regional Administration | Communicate with members and general public subsequent to implementation. Service and process existing program key personnel change applications. | 2704 KI<br>764 LI            | 10.95% KI<br>3.09% LI      |
| Policy                              |   |                              |                            |
| Professional Services               |   |                              |                            |
| Research                            |   |                              |                            |
| <b>Total</b>                        |   | <b>3688</b>                  | <b>14.41%</b>              |

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### 11 Appendix B: Communication and Education Plan

| Communication Responsibilities and Outcomes |   |                                     |                                  |
|---|---|-------------------------------------|----------------------------------|
| Type of Communication                       | Audience(s)   | Delivery Method(s)                  | Timeframe                        |
| Article in UNOS Update Magazine             | Transplant Centers  | Print                               | Preceding implementation         |
| Policy Notice                               | Transplant Directors, surgeons, physicians and administrators | Electronic                          | Within 30 days of Board approval |
| Summary update at Reg. Mtg.                 | Attendees of regional mtgs.                                   | Agenda item during regional meeting | As scheduled                     |
|   |   |                                     |                                  |
|   |   |                                     |                                  |

| Education / Training Responsibilities and Outcomes |                            |  |   |
|--|----------------------------|--|---|
| Education / Training Description                   | Audience(s)                | Delivery Method(s)                     | Timeframe                                     |
| Live Meeting                                       | Transplant Administrators. | Microsoft Live Mtg. Online application | Within 2 wks of the application mailing date. |
|  |                            |  |   |
|  |                            |  |   |
|  |                            |  |   |

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## 12 Appendix C: Monitoring Plan

| Member Expectations      |   |
|--------------------------|---|
| Member Description/Group | Action  |
| Transplant Center        | <p>Each kidney or liver transplant program that performs living donor transplants will be required to:</p> <ul style="list-style-type: none"> <li>• Submit an application to the OPTN/UNOS;</li> <li>• Develop, implement, and comply with written protocols that address all phases of living donation outlined in the Bylaws; and</li> <li>• Document that all phases of the living donation process were performed according to protocols, maintain this documentation, and make this documentation available upon request.</li> </ul> |

| Monitoring Effort Summary |   |  |
|---------------------------|---|--|
| #                         | Monitoring Action Planned                                 | Plan Detail  |
| 1                         | Staff review the individual Applications                  | The applications for living donor programs will be reviewed by staff to ensure that the applications are complete.   |
| 2                         | MPSC or an MPSC Subcommittee review of Applications       | Following a staff review applications will be forwarded to the Committee/Subcommittee for their evaluation and recommendation.   |
| 3                         | Site Surveys of Transplant Centers Conducted by DEQ Staff | During site surveys of transplant centers with approved living donor programs, DEQ staff will review the program's written protocol and a sample of living donor/recipient records. DEQ staff will review the documentation in the record to verify that all phases of the living donation process were performed according to the program's protocol. |