At-a-Glance

- **Proposal to Modify the Requirements for Transplant Hospitals that Perform Living Donor Kidney Recoveries**

- **Affected Bylaw:** Bylaws, Appendix B, Attachment I, Designated Transplant Program Criteria, Section XIII. Transplant Programs.

- **Membership and Professional Standards Committee (MPSC)**

- The proposal recognizes that surgeons who are designated and qualified to perform laparoscopic living donor nephrectomies, are also designated and qualified to perform open donor nephrectomies. The goal of the proposal is to provide an additional means for meeting the open donor nephrectomy qualifications. The revisions also eliminate the requirement for approving kidney transplant programs to be specifically designated to perform open donor nephrectomies since the majority of donor surgeries are performed laparoscopically. These proposed revisions more closely align the bylaws with current practice.

- **Affected groups**
  Kidney Transplant Administrators
  Kidney Transplant Physicians/Surgeons
  Kidney Transplant Program Directors
  Kidney Transplant Surgery Fellows
  Living Kidney Donors
  Potential Living Kidney Donors

- **Number of Potential Candidates Affected**
  Approximately 6000 living donor kidney recoveries take place each year. The proposed changes revise current requirements in a way that should not affect candidate access or directly affect the donor pool.

- **Compliance with OPTN Strategic Goals and Final Rule**
  The proposal is supported by the OPTN Strategic Goal to promote safe, high-quality care for transplant candidates, transplant recipients, and living donors. The Final Rule Section §482.98 addresses transplant surgeon requirements.

- **Specific requests for comment**
  Do the proposed changes related to surgical experience better align the requirements with current practice?
  - Are expectations clearly articulated and easy to understand?
  - Are there strengths or weakness?
  - Do you foresee any unintended consequences?

Please note, additional modifications to this section of the Bylaws are also out for public comment. The proposed language does not reflect suggested modifications relating to the "Proposal to Clarify which Transplant Program has Responsibility for Elements of the Living Donation Process and to Reassign Responsibility for Living Donation from the Recipient Transplant Program to the Transplant Program Performing the Living Donor Nephrectomy or Hepatectomy."

Proposal to Modify the Requirements for Transplant Hospitals that Perform Living Donor Kidney Recoveries

Affected Bylaw: Bylaws, Appendix B, Attachment I, Designated Transplant Program Criteria, Section XIII. Transplant Programs.

Membership and Professional Standards Committee (MPSC)

Summary and Goals of the Proposal:

The proposal recognizes that surgeons who are designated and qualified to perform laparoscopic living donor nephrectomies, are also designated and qualified to perform open donor nephrectomies. The goal of the proposal is to provide an additional means for meeting the open donor nephrectomy qualifications. The revisions also eliminate the requirement for approving kidney transplant programs to be specifically designated to perform open donor nephrectomies since the majority of donor surgeries are performed laparoscopically. These proposed revisions more closely align the bylaws with current practice.

Background and Significance of the Proposal:

Several issues arose over the past few years that have made it apparent that the current bylaws and policies pertaining to program requirements for living donor transplantation were in need of review.

The initial bylaws were developed through the committee and public comment process during 2002-2003; and ultimately approved by the board of directors in June 2004. During subsequent years, the area of living donation has continued to evolve and some of the requirements no longer correspond with current practice. These changes became most apparent when the MPSC was reviewing the hospital's applications for living donor kidney transplantation in 2009. The percentage of cases performed laparoscopically increased from 69.7% to 92.4% between 2002 and 2008 and many hospitals are no longer performing open nephrectomies.

As a result, the MPSC Chair appointed a joint work group comprised of members of the Kidney, Liver and Intestine, Living Donor and Membership and Professional Standards Committees to review the living donor bylaws. The charge given to the work group was to determine whether the bylaws remain current, relevant, and effective in specifying requirements for programs to care for living donors and/or the recipients of living donor transplants. The MPSC asked the work group to address the two key areas relevant to kidney programs that perform living donor recoveries - currency in regards to current practice; and certification related to donation surgical competencies.

- Currency in regards to Current Practice: The current bylaws, while relevant at the time they were developed, no longer reflect current expectations for experience or the trend towards the majority of living donors undergoing laparoscopic rather than open donor nephrectomies. The following proposed changes will make the requirements more relevant to the current practice of living kidney donation:

    - The proposal recommends removing the requirement that programs demonstrate expertise and receive separate approval to perform open nephrectomies, in order to also be approved to perform laparoscopic recoveries. If the proposal to amend the bylaws is approved it means that programs will not be required to have individuals designated to perform open donor procedures when the hospital only intends to perform laparoscopic procedures. This

would result in programs not needing to submit applications or key personnel change applications for a procedure they do not intend to perform. The committee agreed that this change was appropriate because performing 10 open nephrectomies is not relevant training for doing a conversion from laparoscopic to open procedure. Surgeons can already demonstrate experience through deceased donor nephrectomies in the current bylaws.

- The proposal recommends removing the requirement that the open donor recovery surgeon have performed 10 open donor nephrectomies within the 5-year period prior to their designation as a primary surgeon in an application. Removing the five-year currency requirement will allow senior surgeons who have experience, but who have not performed living donor recoveries in the last 5 years, to qualify.

- The proposal recommends removing the language that specifies that if laparoscopic and open nephrectomy expertise resides within different individuals then the program must demonstrate how both individuals will be available to the surgical team. Time is of the essence when converting from a laparoscopic to an open nephrectomy procedure. The recovery team is not likely to seek the involvement of the second surgeon, who may already be engaged in performing the recipient surgery.

- The laparoscopic expertise requirement currently states that the surgeon must have acted as primary surgeon or first assistant on at least 15 laparoscopic nephrectomies within the prior 5-year period. The proposed amendment will further specify that seven (7) of the procedures must have been performed as a primary surgeon. Some programs may only have one individual who has the training/experience to perform the donor recovery. For this reason, the committee agreed that it was important for that surgeon to have functioned as the primary in at least seven (7) of the 15 required cases. Recognizing that a transplant surgery fellow may not be listed as the primary/attending surgeon on the operative note for billing reasons, the committee proposed adding a requirement for submission of a letter from the fellowship program director, which could document the actual role of the transplant fellow in the donor operation.

- This proposal adds language that specifies that the donor procedure log that is included in applications for primary surgeons must include the type of procedure (open or laparoscopic). This information is already requested in the OMB approved application forms so this change should not result in additional burden.

- Certification related to Donation Surgical Competencies: The living donor requirements largely specify the program components and surgeon experience appropriate for hospitals that care for living donors and that perform living donor recoveries. As currently written the bylaws apply to the transplant hospital that performs living donor kidney transplants rather than the hospital that actually provides the donor care and surgery. The MPSC has encountered situations where the living donor care and recovery surgery are provided in one fully approved program and the transplant itself is performed in another transplant hospital. The MPSC asked the work group to consider bylaw revisions that would clarify that the living donor requirements apply to the member hospital providing the donor care and performing the donor recovery operation.

  In response, the committee considered amending the bylaws to place the requirements on member hospital performing the living donor recovery operation. The transplant hospital should not be responsible for meeting the requirements for a procedure that is not performed there and/or for surgeons who do not work at that hospital. This issue is a particularly valid

concern in light of the expected advances in kidney-paired donation (KPD). Ultimately, a second work group was created to explore both of these issues. The MPSC agreed that the proposed changes to the donor recovery surgeon requirements needed a timely resolution and they could be revised while discussion on this larger topic of certification and data submission responsibility continued in the other work group.

In summary, this proposal will align the requirements with current practice by:

- Eliminating the need for a kidney program to have separate designation to perform open donor nephrectomies since the majority of donor recovery surgeries are performed laparoscopically; and
- For laparoscopic procedures, it will specify that at least seven (7) of the 15 required cases used to demonstrate experience must be performed as the primary surgeon.

A proposal to amend the bylaws pertaining to the responsibility of the recovery hospital will be circulated for public comment separately.

Supporting Evidence and/or Modeling:

The Committee reviewed UNet[sm] data showing the number of open donor procedures had steadily declined since time the bylaws were enacted in 2004 (see Table 1). In 2008, laparoscopic nephrectomies were performed 92.4% of the time in living kidney donors.

Table 1. United Network for Organ Sharing, Kidney Report 1A: Open versus Laparoscopic Recoveries for Living Donor Kidney Transplants, by Year, 2000-2008

	Procedure Type						
	Missing		Open		Laparoscopic		Total
	N	%	N	%	N	%	N
Date Organ Recovered							
2000	18	0.3	2,804	51.0	2,677	48.7	5,499
2001	31	0.5	2,343	38.8	3,668	60.7	6,042
2002	24	0.4	1,868	29.9	4,348	69.7	6,240
2003	35	0.5	1,529	23.6	4,909	75.8	6,473
2004	122	1.8	1,171	17.6	5,354	80.5	6,647
2005	71	1.1	953	14.5	5,547	84.4	6,571
2006	3	0.0	754	11.7	5,679	88.2	6,436
2007	6	0.1	574	9.5	5,462	90.4	6,042
2008	2	0.0	451	7.6	5,517	92.4	5,970
Total	312	0.6	12,447	22.3	43,161	77.2	55,920

Expected Impact on Living Donors or Living Donation
Refer to background section above.

Expected Impact on Specific Patient Populations

The proposal addresses requirements for surgeons who perform living donor recoveries so this proposal most directly relates to potential living donors. The proposal involves changing existing requirements to make them more relevant with current practices. The committee does not anticipate that patient access will be impacted since no new requirements are being introduced.

Expected Impact on Program Goals, Strategic Plan, and Adherence to OPTN Final Rule:

Final Rule Reference

§ 482.98 Condition of participation: Human resources. The transplant hospital must ensure that all individuals who provide services and/or supervise services at the hospital, including individuals furnishing services under contract or arrangement, are qualified to provide or supervise such services.

(a) Standard: Director of a transplant center. The transplant center must be under the general supervision of a qualified transplant surgeon or a qualified physician-director. The director of a transplant center need not serve full-time and may also serve as a center's primary transplant surgeon or transplant physician in accordance with § 482.98(b). The director is responsible for planning, organizing, conducting, and directing the transplant center and must devote sufficient time to carry out these responsibilities, which include but are not limited to the following: (

1) Coordinating with the hospital in which the transplant center is located to ensure adequate training of nursing staff and clinical transplant coordinators in the care of transplant patients and living donors.
(2) Ensuring that tissue typing and organ procurement services are available.
(3) Ensuring that transplantation surgery is performed by, or under the direct supervision of, a qualified transplant surgeon in accordance with § 482.98(b).

(b) Standard: Transplant surgeon and physician. The transplant center must identify to the OPTN a primary transplant surgeon and a transplant physician with the appropriate training and experience to provide transplantation services, who are immediately available to provide transplantation services when an organ is offered for transplantation.

(1) The transplant surgeon is responsible for providing surgical services related to transplantation.
(2) The transplant physician is responsible for providing and coordinating transplantation care.

Plan for Evaluating the Proposal:

The Committee is recommending these changes to the bylaws because the current requirements are no longer reflective of current practice. This is most notable when reviewing the number of open versus laparoscopic donor nephrectomies being performed today.

The Committee will evaluate the effectiveness of the changes during the course of its routine reviews of programs applying to conduct live donor transplants, through the review of applications for changes in key personnel, and through the review of live donor adverse events.

The Committee continuously reviews the bylaws to ensure that they reflect current practice.

Additional Data Collection:

This proposal does not require additional data collection.

Expected Implementation Plan:

Transplant Hospitals that perform or intend to perform living donor kidney recoveries will need to review the credentials of their primary recovery surgeons to ensure that they meet the new requirements. Based on this review, the hospitals may need to modify their program coverage plan or succession plan for key personnel.

The current proposal should not require any changes to the Membership Database or its associated reports. If the proposal is modified post public comment it will be necessary to consider the impact of those changes on the database.

Changes will also be required in the OMB Approved application forms (OMB No. 0915-0184), which are scheduled for reissue in February 2011.

Communication and Education Plan:

The following table proposes how and to whom these policy changes would be communicated if they are approved.

Communication Activities			
Type of Communication	**Audience(s)**	**Deliver Method(s)**	**Timeframe**
Policy Notice	Transplant Administrators, Coordinators, Program Directors, Surgeons, Physicians, Social Workers, Data Coordinators, IDA's at Programs that perform LDK	Email	Distributed 30 days after Board approval
UNOS Update announcement	Staff at programs that perform or intend to perform LDK transplants. Potential living donors.	Electronic, Paper	Next edition of Update after passage by the Board of Directors

Education/Training Activities			
Education/Training Description	**Audience(s)**	**Deliver Method(s)**	**Timeframe and Frequency**
General update	Transplant Professionals	Regional Meeting – MPSC Regional Representative	Next meeting after Board Approval

Monitoring and Evaluation:

The Committee will monitor compliance with these bylaws during the course of its routine reviews of programs applying to conduct live donor recoveries, and through the review of applications for changes in key personnel. Transplant Hospitals document compliance on the OMB Approved application form (OMB No. 0915-0184).

The Committee continuously reviews the bylaws to ensure that they reflect current practice.

Bylaw Proposal:

Living Donor Program Requirements- Kidney

ATTACHMENT I
TO APPENDIX B OF UNOS BYLAWS

Designated Transplant Program Criteria

XIII. Transplant Programs.

(1) No Changes

(2) Kidney Transplant Programs that Perform Living Donor Kidney Recoveries ~~Transplants~~: Kidney transplant programs that perform living donor kidney transplants must demonstrate the following:

a. **Personnel and Resources:** Kidney transplant programs that perform living kidney transplants must demonstrate the following regarding personnel and resources:

(i) That the ~~center~~ hospital meets the qualifications of a kidney transplant program as set forth above; and

(ii) In order to perform open donor nephrectomies, a qualifying kidney donor surgeon must be on site and must meet ~~either~~ one of the criteria set forth below:

(1) Completed an accredited ASTS fellowship with a certificate in kidney; or

(2) Performed no fewer than 10 open donor 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.~~ or

(3) Qualified under the section below (iii)(1) to perform laparoscopic donor nephrectomies.

(iii) If the ~~center~~ hospital wishes to perform laparoscopic donor nephrectomies, a qualifying kidney donor surgeon must be on site and must have:

(1) Acted as primary surgeon or first assistant in performing no fewer than 15 laparoscopic nephrectomies within the prior 5-year period, seven (7) of which were performed as a primary surgeon. Role of the surgeon could be document by a letter from fellowship program director.

~~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 hospital ~~center~~ that is distinct from the approved transplant hospital ~~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, and the type of procedure (open or laparoscopic).

(iv) The Hospital ~~center~~ must have the resources available to assess the medical condition of and specific risks to the potential living donor;

(v) The psychosocial assessment should include an assessment of the potential donor's capacity to make an informed decision and confirmation of the voluntary nature of proceeding with the evaluation and donation; and

(vi) That the Hospital ~~center~~ has an independent donor advocate (IDA) who is not involved with the potential recipient evaluation, is independent of the decision to transplant the potential recipient and, consistent with the IDA protocol referred to below, is a knowledgeable advocate for the potential living donor. The goals of the IDA are:

(1) to promote the best interests of the potential living donor;

(2) to advocate the rights of the potential living donor; and

(3) to assist the potential living donor in obtaining and understanding information regarding the:

(a) consent process;
(b) evaluation process;
(c) surgical procedure; and
(d) benefit and need for follow-up.

b. Protocols: Kidney transplant programs that perform living donor kidney transplants must demonstrate that they have the following protocols:

(i) Living Donation Process: Kidney transplant programs that perform living donor kidney transplants 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 care, and

submission of required follow-up forms at 6 months, one-year, and two-years post donation.

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

(ii) Independent Donor Advocate: Kidney transplant programs that perform living donor kidney transplants must develop, and once developed, must comply with written protocols for the duties and responsibilities of Independent Donor Advocate (IDA) that include, but are not limited to, the following elements:

(1) a description of the duties and primary responsibilities of the IDA to include procedures that ensure the IDA:

(a) promotes the best interests of the potential living donor;
(b) advocates the rights of the potential living donor; and

(c) assists the potential donor in obtaining and understanding information regarding the:
(i) consent process;
(ii) evaluation process;
(iii) surgical procedure; and
(iv) benefit and need for follow-up.

(iii) Medical Evaluation: Kidney transplant programs that perform living donor kidney transplants must develop, and once developed, must comply with written protocols for the medical evaluation of the potential living donors that must include, but are not limited to, the following elements:

(1) a thorough medical evaluation by a physician and/or surgeon experienced in living donation to assess and minimize risks to the potential donor post-donation, which shall include a screen for any evidence of occult renal and infectious disease and medical co-morbidities, which may cause renal disease;

(2) 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) to determine decision making capacity, screen for any pre-existing psychiatric illness, and evaluate any potential coercion;

(3) screening for evidence of transmissible diseases such as cancers and infections; and

(4) anatomic assessment of the suitability of the organ for transplant purposes.

(iv) Informed Consent: Kidney transplant programs that perform living donor kidney transplants must develop, and once developed, must comply with written protocols for the Informed Consent for the Donor Evaluation Process and for the Donor Nephrectomy, which include, at a minimum, the following elements:

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

(2) assurance that all communication between the potential donor and the Transplant ~~center~~ Hospital will remain confidential;

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

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

(5) disclosure by the member hospital ~~transplant center~~ that it is required, at a minimum, to submit Living Donor Follow-up forms addressing the health information 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; and

(6) the telephone number that is available for living donors to report concerns or grievances through the OPTN.

(7) documentation of disclosure by the Member Hospital ~~Transplant center~~ to potential donors that the sale or purchase of human organs is a federal crime and that it is unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation. This documentation must be maintained in the potential donor's official medical record.