

At-a-Glance

Proposal to Clarify Requirements for Independent Donor Advocates at Living Kidney Donor Recovery Centers

- **Affected and New Policies:** 12.4 (Independent Donor Advocate), 12.4.1 (IDA Role), 12.4.2 (IDA Responsibilities), and 12.4.3 (IDA Protocols).

- **Sponsoring Committee:** Living Donor Committee

This proposal would clarify existing requirements for independent donor advocates at living kidney donor programs, and would require living kidney donor programs to develop and follow new hospital-specific protocols addressing the qualifications, training and responsibilities of their independent donor advocates.

- **Affected Groups**

Transplant Administrators
Transplant Data Coordinators
Transplant Physicians/Surgeons
PR/Public Education Staff
Transplant Program Directors
Transplant Social Workers
Organ Candidates
Living Donors
Living Donor Advocates
Donor Family Members
General Public

- **Number of Potential Living Donors and Candidates Affected**

In 2011 there were 5,770 living kidney donors. The proposal would impact all potential living donors undergoing evaluation for donation.

- **Compliance with OPTN Strategic Goals**

The proposal meets strategic plan goals as it will:

- Optimize a safe environment for living donor transplantation by clarifying the requirements for and the responsibilities of living donor advocates.
- Improve living donation through development and enactment of policies to enhance patient safety and preserve the public trust.

Proposal to Clarify Requirements for Independent Donor Advocates at Living Kidney Donor Recovery Centers

Affected and New Policies: 12.4 (Independent Donor Advocate), 12.4.1 (IDA Role), 12.4.2 (IDA Responsibilities), and 12.4.3 (IDA Protocols)

Sponsoring Committee: Living Donor Committee

Public Comment Response Period: March 15, 2013 – June 14, 2013

Summary and Goals of the Proposal:

This proposal would clarify existing requirements for independent donor advocates at living kidney donor programs, and would require living kidney donor programs to develop and follow new hospital-specific protocols addressing the qualifications, training and responsibilities of their independent donor advocates.

Background and Significance of the Proposal:

History of OPTN/UNOS Requirements

In September 2007, the OPTN/UNOS Board of Directors (Board) approved new bylaw requirements¹ for living liver donor and living kidney donor programs. These requirements established minimum mandatory elements for the living donor evaluation, consent, and follow-up. The new bylaws required living donor programs to develop and follow written protocols for the responsibilities of the independent donor advocate (IDA). The bylaws required that the IDA must:

- 1) not be involved with the potential recipient evaluation,
- 2) be independent of the decision to transplant the potential recipient, and
- 3) be a knowledgeable advocate for the potential donor.

The bylaws directed that the goals of each transplant center's IDA protocols should be:

- 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.

¹ Originally located at OPTN/UNOS 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).

During its April 2012 meeting, the Committee received an annual report on the results of the 2011 living kidney donor program site surveys. The surveys revealed that non compliance with IDA requirements was common and specifically:

- 1) only 2 of 15 transplant centers were fully compliant with all IDA requirements;
- 2) one transplant center was compliant with documenting benefit and need for follow-up, but had minimal documentation discussing the evaluation process; and
- 3) the benefit and need for follow-up was the most common element not discussed or documented by the IDA.

This same report identified variability in transplant center's IDA protocols addressing:

- 1) Training;
- 2) Qualifications;
- 3) Required documentation;
- 4) IDA function within the living donor evaluation process; and
- 5) Individual IDA versus donor advocate teams.

Based on this report, the Committee determined that existing IDA requirements (in effect since 2007) should be updated to address independent donor advocate teams and to provide guidance on IDA and IDA team roles and responsibilities.

In June 2012, the Board approved changes to the bylaws structure, which included moving the IDA requirements for living kidney and liver donor programs out of the bylaws and into OPTN policy (Policies 12.10 and 12.11), while relocating other IDA requirements to Bylaws Appendices E.5.C, E.5.G and F.6.D. The bylaw requirements remain in effect for living kidney and liver donor programs, and are not impacted by this proposal.

In November 2012, the Board approved a new policy for the informed consent of living kidney donors. This action by the Board included moving IDA requirements from Policy 12.10 to Policy 12.4.

During 2012, 48 routine living donor program site surveys were completed. To date, the Membership and Professional Services Committee (MPSC) has reviewed 23 of the 48 routine site surveys completed last year. The MPSC determined that 20 of the 23 living donor program site surveys reviewed (86%) had compliance issues related to IDA requirements, and required additional audits.

The living donor program site audits are conducted through UNOS' Department of Evaluation and Quality (DEQ). DEQ observed trends that may explain the reasons a high percentage of programs are out of compliance with current IDA requirements including:

- 1) different interpretations of vague policy language by different programs;
- 2) difficulty monitoring policies in a consistent and valid manner; and
- 3) member difficulty understanding how to comply with the policy.

Under this proposal, the IDA policy would be updated to outline specific elements which will be evaluated during site surveys and it is hoped that this clarification will aid members' compliance with policy. For example:

- 1) The proposed language offers specificity on what the IDA must discuss with the potential living donor and document in reference to his or her psychosocial evaluation and medical evaluation. Current policy does not offer the same level of specificity.
- 2) The new proposed language offers specificity on what the member program must document in their own internal protocols in regards to the required qualifications of the IDA, their duties and responsibilities and their grievance processes to be used by the IDA if needed. The current policy offers no such direction.

Goals of the Proposal

In January 2013, the Committee met and approved the proposal to be distributed for public comment. The proposed policy would require living kidney donor programs to develop and follow hospital-specific protocols addressing IDA qualifications and training, duties and responsibilities, and how it will address and handle any grievance raised by an IDA concerning the rights and best interest of a living donor. The proposed new IDA requirements are based on CMS requirements and are supported in NATCO's Kidney Independent Living Donor Advocacy Training Documentation Manual (2012).

- **Collaboration:** The Committee asked the Transplant Administrators, Transplant Coordinators, and Patient Affairs Committees to review the proposal and provide feedback prior to the public comment period.
- **Alternatives considered:** The proposed policy would clarify the role, requirements, and responsibilities of living donor advocates. These clarifications should help standardize IDA practice across the transplant community and contribute to better care of all potential donors. To the extent possible, the proposed requirements mirror related CMS requirements to simplify compliance for transplant hospitals.
- **Description of unintended consequences:** If the proposed policy is ultimately approved and takes effect, the IDA requirements for living kidney donor and living liver donor programs would be different. Kidney living donor programs would be required to follow existing and new requirements found in Policy 12.4. Liver living donor programs would continue to follow their own centerspecific protocols for independent donor advocates as defined in the Bylaws and Policy 12.11.

Supporting Evidence:

**Table 1. Living Kidney Donors in the US²
January 1, 2005 – December 31, 2011**

Year of Donation	Transplanted Living Donor Kidneys
2005	6,570

² Based on OPTN data as of May 31, 2012. Data subject to change based on future data submission or correction

Year of Donation	Transplanted Living Donor Kidneys
2006	6,434
2007	6,043
2008	5,968
2009	6,387
2010	6,277
2011	5,770

Published literature has supported the need for clear guidelines regarding IDA and IDA team roles and responsibilities (LaPointe Rudow & Brown, 2005³, LaPointe Rudow, 2009⁴; Steel et al., 2012⁵). A recent survey of 120 independent donor advocates from living donor programs in the United States reported that there was considerable variability in independent donor advocate selection, training, and clinical responsibilities and activities regarding potential living donors (Steel et al., 2012). The authors concluded that this variability could have a negative impact on potential and actual donors because it could affect screening, selection, and preparation of living donor candidates for donation

Expected Impact on Living Donors or Living Donation:

In 2011, there were 5,770 living kidney donors. The proposed policy modifications should improve the care of all potential living donors being evaluated for donation.

Expected Impact on Specific Patient Populations:

The proposed policy modifications should improve the care of all potential living donors being evaluated for donation.

Plan for Evaluating the Proposal:

³ LaPointe Rudow D & Brown RS Jr. Role of the independent donor advocacy team in ethical decision making. *Progress in Transplantation* 2005; 15(3):298-302.

⁴ LaPointe Rudow D. The living donor advocate: a team approach to educate, evaluate, and manage donors across the continuum. *Progress in Transplantation* 2009; 19(1):64-70

⁵ Steel, J., Dunlavy, A., Friday, M., Kingsley, K., Brower, D., Unruh, M., Tan, H., Shapiro, R., Peltz, M., Hardoby, M., McCloskey, C., Sturdevant, M. and Humar, A. (2012), A National Survey of Independent Living Donor Advocates: The Need for Practice Guidelines. *American Journal of Transplantation*. doi: 10.1111/j.1600-6143.2012.04062.x

The proposal should lead to increased standardization in IDA practice among living kidney donor programs. The Committee will continue to request annual reports on the results of living donor program site surveys, and will use the reports to evaluate whether variability in IDA practice is reduced and whether the number of IDA policy violations identified during living kidney donor program site surveys is reduced.

Additional Data Collection:

No additional data collection is required under this proposal.

Expected Implementation Plan:

If the proposal receives favorable public comment it could be considered by the OPTN/UNOS Board as early as November 2013. If ultimately approved by the Board, transplant centers would be required to follow new and revised IDA policy requirements (Policy 12.4).

Communication and Education Plan:

The policy is intended to clarify and provide additional detail for existing requirements. There are also similar IDA requirements established by the Centers for Medicare and Medicaid Services (CMS). As a result, there would be two goals for member communication/education efforts:

- to create awareness of the specific responsibilities and clarifications
- to highlight areas of similarity and difference with CMS requirements

Educational webinars are already in process to educate members about new and enhanced OPTN requirements for living donor programs. The new policy would be included in these webinars, either as a single topic or in combination with other requirements.

The new policy would also be referenced in a future update to an existing "[crosswalk](#)" resource document that outlines CMS and OPTN requirements on areas of common interest.

In addition, notification of the policy would be included in the following routine communication vehicles:

- Policy notice
- System notice
- UNOS Update article
- Transplant Pro/Member Communications archive article
- Presentation at Regional meetings

Compliance Monitoring:

During site reviews of living kidney donor recovery hospitals, the Department of Evaluation and Quality (DEQ) staff will verify the presence and accuracy of evidence that all required elements are met in the care of potential living kidney donors. Evidence examined will include documentation in the donor's medical record, internal (site-specific) policies and procedures or internal written protocols, and interviews with the living donor team, including the IDA or IDA

team. DEQ staff will examine this evidence to verify that the recovery hospital's IDA is fulfilling all required elements for IDA roles and responsibilities, including:

- Designating a key IDA contact for each potential living kidney donor
- Functioning independently from the transplant candidate's team
- Advocating for the living donor and the potential living donor
- Demonstrating the required knowledge
- Discussing with each donor, the:
 - Informed consent process
 - Evaluation process
 - Surgical procedure
 - Medical and psychosocial risks
 - Follow-up requirements and the benefit and need for participating in the follow-up

DEQ staff will review the hospital's clinical protocols and supporting documentation to verify that they include:

- IDA team composition (if an IDA team is used)
- Required qualifications and training of IDA(s), and proof that the IDA meets the requirements
- IDA duties and responsibilities
- Grievance processes provided for the IDA

In its review of a sample of donor medical records, DEQ will assess whether the documentation satisfies the requirements of this policy and the hospital's policies, procedures and protocols.

DEQ staff will request a corrective action plan if they are unable to verify compliance with the requirements of these policies. Results of the review and any corrective action plans submitted will be forwarded to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for review.

Policy Proposal:

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

12.4. Independent Donor Advocate (IDA)

12.4.1 IDA Role

For any potential living kidney donor who is undergoing evaluation for donation, the living kidney donor recovery hospital must designate and provide an independent donor advocate (IDA) who is not involved with the potential recipient evaluation and is independent of the decision to transplant the potential recipient. The IDA may be one person or an independent living donor advocate team with multiple members. An IDA team must designate one person from the team as the key contact for each potential living donor.

12.4.2 IDA Responsibilities

~~12.4.1 The IDA must assist the potential living kidney donor with the evaluation process and focus on their needs and questions. The IDA must be knowledgeable about risks and benefits associated with all phases of the donation process. The IDA responsibilities include, but are not limited to the following must:~~

1. Function independently from the transplant candidate's team
~~Promote the best interests of the potential living donor~~
2. Advocate for the potential living donor rights of and the living donor
3. Demonstrate knowledge of living organ donation, transplantation, medical ethics, informed consent, and the potential impact of family or other external pressures on the potential living donor's decision about whether to donate
4. Discuss each of the following areas with the potential living donor, and assist the potential donor in obtaining information regarding the:
 - o Informed Consent process as described in policy 12.2 and its subsections
 - o Evaluation process as described in policies 12.2.1, 12.3.3, and 12.3.4 and its subsections
 - o Surgical procedure;
 - o Medical and psychosocial risks as described in policy 12.2.1
 - o Follow-up requirements, and the Bbenefit and need for participating in follow-up as described in policies 7.2, 12.8.2, 12.8.3 and 12.8.4.

12.4.3 IDA Protocols

The living kidney donor recovery hospital must develop, and once developed must comply with, written protocols for:

1. The composition of the IDA team, if the hospital uses a team
2. The qualifications and training (both initial and ongoing) required for the IDA or the IDA team. Minimum qualifications must include knowledge of living organ donation, transplantation, medical ethics, informed consent, and the potential impact of family or other external pressures on the potential living donor's donation decision.
3. The duties and responsibilities of the IDA, which must include at least the functions and duties listed throughout Policy 12.4
4. The process the living donor recovery hospital will provide for the IDA to file a grievance when necessary to protect the rights or best interests of the living donor.
5. The process the living donor recovery hospital will use to address any grievance raised by the IDA concerning the rights or best interests of the living donor.

