

## *At-a-Glance*

- **Proposal to Add a Valuable Consideration Disclosure to the Bylaws**
- **Affected 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 Transplantation**
- **Living Donor Committee**
- Under this proposal, transplant centers would be required to document that potential living organ donors have been informed that the sale or purchase of human organs (kidney, liver, heart, lung, pancreas and any other human organ) is a federal crime.

- **Affected Groups**

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

## **Proposal to Add a Valuable Consideration Disclosure to the Bylaws**

**Affected 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 Transplantation**

### **Living Donor Committee**

#### **Summary and Goals of the Proposal:**

Under this proposal, transplant centers would be required to document that potential living organ donors have been informed that the sale or purchase of human organs (kidney, liver, heart, lung, pancreas and any other human organ) is a federal crime.

#### **Background and Significance of the Proposal:**

In 1984, Congress passed the National Organ Transplant Act (NOTA)<sup>1</sup> which prohibits the sale or purchase of human organs in the United States. Violations are punishable with five years in prison or a \$50,000 fine.<sup>2</sup>

Today, there is a disparity between demand for and the supply of organs available for transplantation. The plight of those awaiting potentially lifesaving organ transplants is a probable contributing factor in the recent and highly publicized case of the illegal sale and purchase of living donor organs.

For the first time since Congress passed NOTA, federal authorities charged an individual with violating the federal law prohibiting the sale or purchase of human organs in July 2009. Publicized reports state that the accused offered to obtain a living donor kidney for an undercover FBI agent. In this reported violation, the accused offered to obtain a living unrelated kidney from a donor in another country for \$160,000.

Upon notification of this case, the OPTN/UNOS Living Donor Committee questioned what actions could be taken to limit or prevent the illegal sale and purchase of living donor organs in the future. After examining the issue, Committee members opined that existing bylaws for kidney and liver transplant programs performing living donor transplantation should be modified to require centers to document that potential living organ donors understand that the sale or purchase of human organs is a federal crime. Human organs are the kidney, liver, heart, lung, and pancreas, as defined in the OPTN Final Rule.<sup>3</sup>

In September 2007, the Board of Directors modified the bylaws to establish additional minimum criteria for granting designated program status to transplant programs that perform living donor liver

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<sup>1</sup> 42 U.S.C. § 273 et seq.

<sup>2</sup> On March 28, 2007, the U.S Department of Justice issued a statement that clarifying that kidney paired donation does not violate the National Organ Transplant Act and is not considered valuable consideration. On December 6, 2007, Congress passed H.R. 710, the Charlie W. Norwood Living Organ Donation Act, which amended NOTA to state that kidney paired donation did not constitute valuable consideration. President George W. Bush signed this bill into law on December 21, 2007.

<sup>3</sup> 42 U.S.C. § 274e.

transplants. The intent of these additional bylaws was to require that transplant programs had essential elements in place for the evaluation, consent and follow-up of living donors.

The new 2007 bylaws required that transplant centers develop and, once developed, comply with written protocols for the informed consent and medical evaluation of potential living donors. Some of the elements required for all consent protocols included disclosing the medical, psychological and financial risk associated with living donation, disclosing that the donor has the right to opt out of the donation process at any time, and the disclosure that the transplant center is required to submit follow-up forms on each living donor at 6 months, one-year and two-years post donation.

The Committee and UNOS staff considered several ways to address the issue of valuable consideration for living donor organs. One option is to add a disclosure element in the bylaws that would require transplant centers to document that potential living donors understand that the purchase or sale of human organs is illegal. A second option would be to require that potential living donors attest that they are not participating in the sale or purchase of human organs. A third potential approach would be to add a requirement that the transplant center have both the potential living donor and candidate attest that they are not participating in the sale or purchase of human organs. The Committee and UNOS staff decided that the second and third options require more analyses and input from the transplant community before they can be considered. The Living Donor Committee, along with other Committees, will continue to investigate these approaches.

The Committee recommends that the consent requirements in the bylaws be modified to require transplant centers disclose 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. Additionally, the Committee recommends that transplant centers be required to document that each potential donor understands 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.

#### **Supporting Evidence:**

To date, the Committee is only aware of this single case of alleged sale of human organs. However, reported statements by the individual accused in this case indicate he had arranged the sale of numerous living donor organs in the past.

#### **Expected Impact on HHS Program Goals and the Strategic Plan:**

- Patient Safety
  - The proposed modification to the bylaws would promote safe, high quality care for potential living donors through an improved living donor consent process.
- Operational Effectiveness
  - Preventing the sale or purchase of human organs would be a system improvement that would best support critical network functions.

**Plan for Evaluating the Proposal:**

To the extent possible, the Committee will monitor any credible disclosures of the sale or purchase of human organs.

**Additional Data Collection:**

Additional data collection is permitted if used to help determine if institutional members are complying with policies. Under this proposal, the transplant center would be required to document that potential living organ donors understand that the sale or purchase of human organs is a federal crime. The transplant center is required to maintain the documentation and make it available to the OPTN contractor if requested. This proposal does not require any additional data collection in the UNet<sup>SM</sup> system.

**Expected Implementation Plan:**

Based on public comment, this proposed modification to the bylaws may be considered by the OPTN/UNOS Board of Directors at its June 21-22, 2010 meeting. If ultimately considered and approved by the Board, the bylaw would become effective on August 22, 2010. This date would be 30 days after the transplant community receives notification of the OPTN/UNOS Board of Director’s approval of the bylaw.

This proposal does not require any programming in UNet<sup>SM</sup>.

**Communication and Education Plan:**

Communication Activities			
Type of Communication	Audience(s)	Deliver Method(s)	Timeframe
Policy Notice	Living Donors Organ Candidates Transplant Administrators Transplant Coordinators Independent Donor Advocates Transplant Physicians/Surgeons Donor Family Members General Public Members	E-mail	30 days after Board approval

**Monitoring and Evaluation:**

UNOS Department of Evaluation and Quality (DEQ) staff will evaluate member compliance with the Bylaws.

*How members are expected to comply:*

As an element of their informed consent protocols, transplant programs must include documentation that potential living donors have been informed that the sale or purchase 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. Transplant programs must provide this documentation to the OPTN contractor upon request.

**Policy or Bylaw Proposal:**

**Proposed Modification to Bylaws, Appendix B, Attachment I, Section XIII, C (2), Designated Transplant Program Criteria.**

**XIII. Transplant Programs.**

**(1) Kidney Transplant [No Changes]**

**(2) Kidney Transplant Programs that Perform Living Donor Kidney Transplants**

**a-b (iii) (4) [No Changes]**

(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 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 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;
- (6) the telephone number that is available for living donors to report Concerns or grievances to the OPTN
- (7) documentation of disclosure by the 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.

- (8) documentation that each potential donor understands 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.

**Proposed Modification to Bylaws, Appendix B, Attachment I, Section XIII, C (4), Designated Transplant Program Criteria.**

**XIII. Transplant Programs.**

**(3) Liver Transplantation [No Changes]**

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

**a-b (iii) (4) [No Changes]**

- (iv) Informed Consent. Liver transplant programs that perform living donor liver transplants must develop, and once developed, must comply with written protocols for the Informed Consent for the Donor Evaluation Process and for the Donor Hepatectomy, 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 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 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;
  - (6) the telephone number that is available for living donors to report Concerns or grievances to the OPTN
  - (7) documentation of disclosure by the 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.

- (8) documentation that each potential donor understands 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.