

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

*Living Donor Committee*

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# The Problem

- IDA requirements do not reflect current practice—last updated in 2007
- Living donor program site surveys since 2011 have revealed:
  - Non compliance with IDA requirements is common
  - Variability in IDA practice

# Goal of the Proposal

- Standardize and improve IDA practice across the transplant community
- Contribute to better care of all potential living kidney donors

# How the Proposal will Achieve its Goal

Require living kidney donor programs to develop and follow protocols

- IDA qualifications and training, duties and responsibilities
- IDA grievances concerning the rights and best interest of a living donor

# What Members Will Need to Do

Fulfill all required elements for IDA roles and responsibilities, including:

- Functioning independently from the transplant candidate's team
- Advocating for the living donor and the potential living donor
- Fulfilling qualifications and training requirements specified by hospital's protocols
- Discussing with each donor all phases of the donation process

# What Members Will Need to Do

Develop and document clinical protocols to 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
- Duties and responsibilities
- Grievance processes provided for the IDA

# Public Comment

## OPTN Committees

- 14 supported - 2 opposed

## OPTN Regions

- 6 supported - 5 opposed

## Public comments

- 44 responses:
- 57% supported - 36% opposed - 7% no opinion

# Public Comment

## AST

- Opposed – commented language created more questions

## ASTS

- Opposed - supported concept opposed some language

## NATCO & American Nephrology Nurses Assoc

- Supported

# Public Comment

## Major recurring themes

- Not clear what is meant by/encompassed by demonstrating knowledge of living organ donation, transplantation, medical ethics, informed consent...”
- Not clear how an IDA could be expected to “discuss surgical procedure as well as medical risks...”

## Other comments

- Not clear where IDAs can receive training
- Policy may not be prescriptive enough; centers want guidance

## 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.

*[no changes post public comment]*

## 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~~

*[no changes post public comment]*

## 12.4.2 IDA Responsibilities (continued)

3. Fulfill the qualifications and training requirements specified in the hospital's protocols regarding 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. Documentation that each requirement has been met must be made available to the OPTN Contractor upon request.

## 12.4.2 IDA Responsibilities (continued)

4. Review whether the potential donor has received information on each of the following areas, and assist the potential donor in obtaining additional information as needed regarding the:

- Informed Consent process as described in policy 12.2 and its subsections
- Evaluation process as described in policies 12.2.1, 12.3.3, and 12.3.4 and its subsections
- Surgical procedure;
- Medical and psychosocial risks as described in policy 12.2.1
- Follow-up requirements, and the benefit and need for participating in follow-up as described in policies 7.2, 12.8.2, 12.8.3 and 12.8.4.

Document that each topic was reviewed.

## 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 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.

### 12.4.3 IDA Protocols (cont)

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.

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- Questions

# CMS requirements for the IDA

- (1) The living donor advocate or living donor advocate team must not be involved in transplantation activities on a routine basis.
- (2) The independent living donor advocate or living donor advocate team must demonstrate:
  - (i) Knowledge of living organ donation, transplantation, medical ethics, and informed consent; and
  - (ii) Understanding of the potential impact of family and other external pressures on the prospective living donor's decision whether to donate and the ability to discuss these issues with the donor.

# CMS requirements for the IDA

- (3) The independent living donor advocate or living donor advocate team is responsible for:
  - (i) Representing and advising the donor;
  - (ii) Protecting and promoting the interests of the donor; and
  - (iii) Respecting the donor's decision and ensuring that the donor's decision is informed and free from coercion.

# Pre public comment version

The IDA must

- 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
- Discuss each of the following areas with the potential living donor, and assist the potential donor in obtaining information regarding the:
  - .....