

# Living Donor Committee Action Item

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Chair

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# Proposal to Improve the Packaging, Labeling and Shipping of Living Donor Organs, Vessels and Tissue Typing Materials

Policy 12.7 (Responsibility for the Transport of  
Living Donor Organs)

Living Donor Committee

## Background and Significance

- The majority of living donor organs recovered for transplant are not shipped or transported outside the recovery center, and therefore would not be affected by this proposal.
- However, the packaging and shipping of living donor organs is increasing, especially as “kidney paired” donation increases throughout the country.

# Background and Significance

- Changes to the policies for the packaging and shipping of **deceased** donor organs, vessels, and tissue typing materials were approved by the OPTN/UNOS Board in November 2010, and took effect in January 2011.
- The implementation of those policies created a situation where **the rules for packaging, labeling and shipping deceased donor organs are more stringent than policies for the packaging, labeling and shipping of living donor organs.**

## Background and Significance

- In response, this proposal would update living donor policy to more closely align with policy requirements for the packaging, labeling and shipment of deceased donor organs, vessels and tissue typing materials.
- The proposal also clarifies procedures when the living donor organ is not packaged, shipped or transported.
- Because OPOs sometimes assist with the packaging and shipping of living donor organs, both OPOs and transplant should benefit from the standardization of packaging and shipping requirements for all organs.

# Background and Significance

- If adopted, the Living Donor Committee anticipates that the proposed policy changes will increase the safety of living donors that are transported.
- The proposal would **not preclude transplant centers from entering into an agreement with an OPO** to coordinate the packaging and shipping of living donor organs, vessels and tissue typing materials.

## Background and Significance

- Prior to June 2009, requirements for the transport of all organs (both deceased and living donor organs) were located in Policy 2.0 and/or 5.0.
- At that time, Policies 2.0 and 5.0 contained requirements that OPOs should follow in the packaging and shipment of **deceased** donor organs, and similarly provided requirements that transplant programs should follow for the packaging and shipment of **living** donor organs.

# Background and Significance

- Over the past two years, the OPO Committee proposed revisions through three public comment proposals to Policies 2.0 and 5.0. Each of the proposals was approved by the OPTN/UNOS Board.
- The three proposals clarified policy requirements, eliminated redundant language and gave OPOs guidance on how to package, label and ship **deceased donor** organs, vessels and tissue typing materials.
- The OPTN now has different requirements for the packaging and labeling of deceased donor organs (Policy 5.0) and the packaging and labeling of living donor organs (Policy 12.0).



## Background and Significance

- Under this proposal, when appropriate, the packaging and shipping requirements for living donor organs, vessels and tissue typing materials will match the recently approved packaging and shipping requirements for deceased donor organs, vessels and tissue typing materials.
- As proposed, the recent OPTN/UNOS Board approved requirements from Policy 5.0 are being copied virtually intact and relocated to Policy 12.7 and would replace all previous policy content in Policy 12.7.

## Background and Significance

- The primary difference between Policy 5.0 and the new proposed requirements in Policy 12.7 is that OPOs maintain responsibility for the packaging, labeling, and shipping of deceased donor organs and transplant centers will have the responsibility for the packaging, labeling, and shipping of living donor organs.

# Supporting Evidence

Living Kidney & Liver Donors Recovered at a Center  
other than the Transplanting Center (as of 1/28/11)  
Includes Living Donors with Validated LDR Forms

<b>Kidney</b>	<b>Kidney</b>	<b>Liver</b>	<b>Total</b>
2000-2004	537	124	661
2005	95	26	121
2006	94	24	118
2007	83	33	116
2008	134	23	157
2009	204	21	225
All	1247	251	1498

# Policy Proposal

- Please note that the starting point for these proposed changes are OPTN/UNOS Board approved updates to Policy 5.0 (now in effect). Those updates to the packaging and shipping requirements for deceased donor organs are now being proposed for living donor organs.
- Some policy language being copied and duplicated in Policy 12.7 is not applicable to living donation, and consequently is proposed to be modified or deleted for the packaging and shipping of living donor organs.

# Policy Proposal

Since the proposed changes would be difficult to read with numerous strikethroughs and underlines typically seen in policy proposals, the proposed changes are being presented differently.

For this proposal, strikeouts and underlines are used to identify how current language from Policy 5.0 would be changed to make it applicable for the packaging and shipping of living donor organs

# Public Comment Response Tally

Comment Type	Response Total	In Favor	Opposed	No Comment
Individual	20	13 (65%)	1 (5%)	6 (30%)
Regional	11	11 (100%)	0 (%)	0 (%)
Committee	8*	7 (87.5%)	0 (%)	0 (%)

\*One Committee commented but did not vote on the proposal.