

## **IMPORTANT POLICY NOTICE**

**To:** Transplant Professionals

**From:** James B. Alcorn  
Director, Policy

**RE:** Impending Changes to OPTN/UNOS Policy, Bylaws, and Kidney Paired Donation Pilot Program Operation Guidelines

**Date:** May 29, 2012

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The attached report summarizes three separate changes that transplant professionals need to be aware of: the implementation date for the OPTN/UNOS Bylaws that pertain to OPO performance metrics that the OPTN/UNOS Board of Directors adopted at its June 2011 meeting; a change in the OPTN Kidney Paired Donation Pilot Program Operation Guidelines regarding waiting time accrual; and clarification of OPTN Policy 12.7.9 that the OPTN/UNOS Executive Committee adopted at its May 24<sup>th</sup> teleconference.

Thank you for your careful review of this policy notice. It, and those policy notices reviewing changes from previous Board of Directors meetings, can be found at [optn.transplant.hrsa.gov](http://optn.transplant.hrsa.gov) (click on “News,” and then select “View all Policy Notices”). If you have any questions about a particular Board of Directors or Executive Committee action, please contact your regional administrator at (804) 782-4800.

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## Model for Assessing the Effectiveness of Individual OPOs in Key Measures of Organ Recovery and Utilization

**Sponsoring Committees:** Membership and Professional Standards Committee (MPSC) & Organ Procurement Organization (OPO) Committee

**Bylaws Affected:** Appendix B to the OPTN Bylaws, Section I. Organ Procurement Organizations, F. Performance; and Appendix B to the UNOS Bylaws, Section I. Organ Procurement Organizations, G. Performance

**Distributed for Public Comment:** January 2011

**Amended After Public Comment:** Yes

**Effective Date:** July 1, 2012

Problem Statement
The OPTN does not have a robust method for reviewing OPO performance. To address this, the OPTN/UNOS Board of Directors approved <a href="#">these bylaw changes</a> at its June 2011 meeting. These changes will help the MPSC review OPO performance as it relates to aggregate and organ specific yield. Before these changes become effective, the Scientific Registry of Transplant Recipients (SRTR) must develop a report, and the members must then be notified of the exact implementation date.

Changes
These bylaws become effective on July 1, 2012. The MPSC will begin evaluating OPO performance during its July 2012 meeting.
The bylaw changes allow the MPSC to systematically review OPOs and identify opportunities for improvement when an OPO's observed performance falls below an expected performance threshold. The MPSC will identify an OPO for review (for all organs, as well as each organ type) if the OPO meets <i>all three</i> of the following criteria: <ul style="list-style-type: none"><li>• Observed organ yield per 100 donors - expected organ yield per 100 donors &lt; -10;</li><li>• A ratio of observed to expected yield is less than 0.90; and</li><li>• A two-sided p-value less than 0.05.</li></ul>

Action Required
Be aware that these bylaw changes will be implemented on July 1, 2012. Members should review and become familiar with the bylaw changes.

## Clarification of the Applicability of Policy 12.7.9

**Sponsoring Committee:** Executive Committee

**Policy Affected:** 12.7 (Standardized Packaging, Labeling and Transporting Of Living Donor Organs, Vessels, and Tissue Typing Materials)

**Distributed for Public Comment:** No

**Effective Date:** July 1, 2012

Problem Statement
Current policy states that, "Policy 12.7 and its subsections apply only to living donor organs, tissue typing specimens, and vessels which are transported outside the recovery facility." However, a subsection of the policy (Policy 12.7.9) creates confusion because it states that it applies to organs that remain in the same recovery facility as the intended candidate.

Changes
Policy 12.7 has been revised to state that the subsections apply only to living donor organs, tissue typing specimens and vessels that leave the facility, <i>unless otherwise stated</i> .

Action Required
Members should note that unless policy explicitly states otherwise, the requirements outlined in Policy 12.7 and its subsections only apply to living donor organs, tissue typing specimens, and vessels which are transported outside the recovery facility. For example, members must follow the existing verification requirements in Policy 12.7.9 when living donor organs do not leave the procurement facility.

## Revision to How Waiting Time Points Accrue in the OPTN KPD Pilot Program

**Sponsoring Committee:** Kidney Transplantation Committee

**OPTN KPD Pilot Program Operational Guidelines Affected:** Prioritization Points

**Distributed for Public Comment:** No

**Effective Date:** June 13, 2012

Problem Statement
The Kidney Paired Donation (KPD) Work Group and participating centers would prefer for KPD matches to be run more frequently. The current method of assigning waiting time points is based on the number of match runs and not calendar time, which means more frequent match runs will yield inconsistent KPD waiting time accrual across candidates. Candidates' KPD waiting time points would depend on the number of matches run after they are entered into the KPD pilot program, not necessarily how long they had been waiting.
Changes
<p>The accrual of KPD waiting time points has changed from 2 points per match run to 0.07 points per day (approximately 2 points per 30 days) in order to keep the relative value of KPD waiting time points the same if the match is run more often than once a month.</p> <p>KPD waiting time will begin when a candidate is added to the KPD system and accrues when a candidate is active or inactive.</p>
Action Required
Members participating in the KPD Pilot Program should make themselves familiar with the systematic change pertaining to how KPD waiting time points will be accrued.

**Affected Bylaw Language:**

**OPTN Bylaws:**

## **APPENDIX B TO BYLAWS**

### **Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership**

#### **I. Organ Procurement Organizations.**

**A. General.** [No change to content, only to numbering convention.]

**B. Key Personnel.** [No change to content, only to numbering convention.]

**C. Plan for Public Education on Organ Donation.** [No change to content, only to numbering convention.]

**D. Communication of Information for Organ Distribution.** [No change to content, only to numbering convention.]

**E. Donation After Cardiac Death:** [No change to content, only to numbering convention.]

**F. Performance:** The Membership and Professional Standards Committee (MPSC) will evaluate all OPOs to determine if the difference in observed and expected organ yield can be accounted for by some unique aspect of the Donation Service Area and/or OPO in question. The evaluation may include a peer visit to the OPO at the OPO's expense.

Those OPOs whose observed organ yield rates fall below the expected rates by more than a specified threshold will be reviewed. The absolute values of relevant parameters in the formula may be different for different organs, and may be reviewed and modified by the MPSC after distribution to the transplant community and subsequent Board approval.

The initial criteria used to identify OPOs with lower than expected organ yield, for all organs as well as for each organ type, will include all of the following:

- More than 10 fewer observed organs per 100 donors than expected yield (observed per 100 donors - expected per 100 donors < -10)
- A ratio of observed to expected yield less than 0.90.
- A two-sided p-value is less than 0.05.

All three criteria must be met for an OPO to be identified for MPSC review.

If an OPO's organ yield rate cannot be explained by donor mix or some other unique clinical aspect of the OPO or Donation Service Area in question, the Member, in cooperation with the MPSC, will adopt and promptly implement a plan for performance improvement. The Member's failure to do so will constitute a violation of OPTN requirements.

APPENDIX B TO BYLAWS

Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership

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**F. Inactive Status.** An organ procurement organization that is voluntarily inactive, declared inactive or withdrawn will no longer be allowed to list patients on the UNOS recipient list or to maintain a local recipient list in any form, and will not be allowed to provide organs to UNOS member transplant centers.

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If an OPO's organ yield rate cannot be explained by donor mix or some other unique clinical aspect of the OPO or Donation Service Area in question, the Member, in cooperation with the MPSC, will adopt and promptly implement a plan for performance improvement. The Member's failure to do so will constitute a violation of UNOS requirements.

To read the complete UNOS bylaw language visit [www.unos.org](http://www.unos.org) and select “UNOS bylaws” in the “I am looking for:” box in the upper left hand corner. To read the complete OPTN bylaw language visit [optn.transplant.hrsa.gov](http://optn.transplant.hrsa.gov), select the “Policy Management” tab, then select “OPTN Bylaws.”

**Affected Policy Language:**

**12.7 Standardized Packaging, Labeling and Transporting Of Living Donor Organs, Vessels, and Tissue Typing Materials**

Unless otherwise stated, Policy 12.7 and its subsections apply only when organs, tissue typing specimens, or vessels are recovered from living donors and transported outside the recovery facility. The purpose of Policy 12.7 is to: ~~and its subsections apply only to living donor organs, tissue typing specimens and vessels which are transported outside the recovery facility and:~~

- state requirements for packaging and labeling living donor organs (when applicable), tissue typing specimens, and (when applicable) vessels; to prevent wastage (and/or to promote safe and efficient use);
- define terms and responsibilities related to packaging, labeling, and transporting ~~organs~~ of living donor organs, and if applicable living donor tissue typing specimens, and vessels; and
- state requirements for recovering, storing, and using (when applicable) living donor vessels.

The responsibility for packaging and labeling living donor organs is assigned to the donor recovery transplant center. If a living donor organ ever requires repackaging by a transplant center for transport, the transplant center will package, label and ship the organ in accordance with this policy.

To read the complete policy language visit [www.unos.org](http://www.unos.org) or [optn.transplant.hrsa.gov](http://optn.transplant.hrsa.gov). From the UNOS website, select "Policies" from the "I am looking for:" box in the upper left hand corner. From the OPTN website, select the "Policy Management" tab, then select "Policies."

## Affected OPTN KPD Pilot Program Operational Guidelines Language:

### Prioritization Points

1. **Purpose:** To describe the candidate characteristics and the match characteristics that receive priority or additional points in the Kidney Paired Donation Pilot Program
2. **Procedures:**
  - a. Each match between a candidate and potential living donor receives a base of 200 points.
  - b. Zero antigen mismatches between a potential living donor and a candidate receive an additional 200 points.
  - c. Highly sensitized (e.g., probability of positive crossmatch  $\geq$  80%) candidates receive an additional 125 points.
  - d. Candidates who are prior living organ donors receive an additional 150 points.
  - e. Pediatric (i.e., age < 18 years) candidates receive an additional 100 points.
  - f. ~~Candidates who have participated in previous match runs but did not receive a transplant receive an additional 2 points per match run.~~ Candidates entered in the OPTN KPD Pilot Program receive 0.07 points per day beginning on the day the candidate is added to the OPTN KPD Pilot Program.
  - g. Matches between candidates and potential living donors who are in the same region receive 25 points in addition to the base number of points.
  - h. Matches between candidates and potential living donors who are in the same donation service area (DSA) receive 50 points in addition to the base number of points.
  - i. Matches between candidates and potential living donors who are located at the same center receive 75 points in addition to the base number of points.
  - j. Matches between candidates and donors who have one or more of the candidate's other antibody specificities receive -5 points.
  - k. The waiting list candidate and the non-directed donor in a donor chain will be assigned no points.

To read the complete OPTN Kidney Paired Donation Pilot Program Operational Guidelines visit [optn.transplant.hrsa.gov](https://optn.transplant.hrsa.gov), select the "Resources" tab, then select "Kidney Paired Donation Pilot Program." On this page, select [KPDPP Operational Guidelines](#).