At-a-Glance

Clarification of Multi-Organ Policies

- **Affected/Proposed Policy:** Policies 2.12.F (Multiple Organ Procurement), 3.4.C (Candidate Registrations), 3.4.F (Multi-Organ Candidate Registrations), 5.4.D (Multiple Organ Procurement and Offers), 5.8 (Allocation of Multi-Organ Combinations), and 6.4.A (Waiting Time for Multi-organ Candidates).

- **Policy Oversight Committee (POC)**

  Approximately 1,452 multi-organ transplants are performed each year. OPTN Policies regarding multi-organ procurement, allocation, and waiting time are unclear and sometimes inconsistent. The organ–specific Committees are addressing multi-organ allocation issues, but the POC identified general multi-organ policies that could be clarified to support the organ-specific Committees' work, yet not interfere with the allocation issues and related language that they are addressing.

- **Affected Groups**
  Directors of Organ Procurement
  OPO Executive Directors
  OPO Medical Directors
  OPO Coordinators
  Transplant Administrators
  Transplant Physicians/Surgeons
  Transplant Program Directors
  Organ Recipients
  Organ Candidates
  Living Donors
  Donor Family Members
  General Public

- **Compliance with OPTN Strategic Plan and Final Rule**
  By clarifying and reorganizing these policies, the proposal supports the strategic plan goal to promote the efficient management of the OPTN. Since it will also enhance understanding and compliance, the proposed improvements to policy language could increase patient safety.

- **Specific Requests for Comment**
  The Committee invites comment on whether the proposed language is more easily understood. Additional input on whether this proposal supports current clinical practices is welcome.

Clarification of Multi-Organ Policies

Affected/Proposed Policy:
Policies 2.12.F (Multiple Organ Procurement), 3.4.C (Candidate Registrations), 3.4.F (Multi-Organ Candidate Registrations), 5.4.D (Multiple Organ Procurement and Offers), 5.8 (Allocation of Multi-Organ Combinations), and 6.4.A (Waiting Time for Multi-organ Candidates).

Policy Oversight Committee (POC)

Public comment response period: September 29 – December 5, 2014

Summary and Goals of the Proposal:

Approximately 1,452 multi-organ transplants were performed in 2013. OPTN Policies regarding multi-organ procurement, allocation, and waiting time are unclear and sometimes inconsistent. The organ–specific Committees are addressing multi-organ allocation issues, but the POC identified general multi-organ policies that could be clarified to support the organ-specific Committees' work, yet not interfere with the allocation issues and related language that they are addressing. Specifically, the POC proposes these changes to policy language:

- Policy 2.12.F is edited for clarity and to better explain what is required when organs are recovered. This is *not* an issue of multi-organ procurement, but organ procurement in general, so the title is changed to reflect that. (Would appreciate thorough review from OPO folk in particular.)
- Information in Policy 3.4.F was similar in content with Policy 3.4.C therefore these two policies were combined. With these changes, Policy 3.4.C now includes the multi-organ candidate registration requirements so that all the information is in one place.
- Policy 5.4.D says the same thing as Policy 2.12.F and so it is deleted. The first sentence in the original language is vague— "OPO's medical judgment" and not a true requirement as written and therefore justifies deletion.
- The first sentence in Policy 5.8 is very similar to Policy 3.4.F and is not needed here.
- New section 5.8.A highlights different allocation scheme for Heart-Lung candidates and includes a cross-reference. This is not new, but it is moved out of the paragraph below for emphasis.
- New section 5.8.B clarifies multi-organ allocation and eliminates the language about paybacks that was not a true requirement and only "recommended" and is in keeping with the removal of paybacks once the new Kidney Allocation System (KAS) is implemented.
- Policy 6.4.A is better located in Policy 3.7 with the other waiting time modifications as new Policy 3.7.C. Table 6-4 is updated since most of these waiting time modifications cannot operationally be done since this is currently not programmed and there is currently no automated process to do these modifications. In addition, status to different organ types cannot transfer. For example, no way to equate a status 1a heart candidate's time to an LAS score, so these sorts of waiting time modifications do not logically make sense and have never been put into practice as currently written.

Background and Significance of the Proposal:

OPTN Policies regarding multi-organ procurement, allocation, and waiting time are unclear and sometimes inconsistent.

- **Collaboration:** The POC formed a multi-organ policies working group with representatives from the Thoracic, Kidney, Liver, and Pancreas Committees that drafted the new proposed policy language.

- **Alternatives considered:** The Committee explored the idea of waiting and addressing these issues as part of the projects the organ-specific Committees are working on to address multi-organ allocation issues. However, the POC recognized that having clearer and well-organized policies regarding multi-organ transplantation generally would help these Committees with their projects and therefore there was no need to wait.

- **Strengths and weaknesses:** This proposal's strength is that it clarifies these important policies that deal with multi-organ transplantation.

- **Description of intended and unintended consequences:** An intended consequence of the Committee is that these clarifies policies will support the organ-specific Committees in their projects concerning the specific multi-organ allocation policy issues that they are working to address.

Supporting Evidence and/or Modeling:

The 2013 OPTN Policies Plain Language Rewrite identified issues with the current multi-organ policies and highlighted the need to clarify these policies. While working to clarify the language in these policies, staff was able to identify improvements in organization as well.

Expected Impact on Living Donors or Living Donation:

This proposed policy change will not directly impact living donors or living donation.

Expected Impact on Specific Patient Populations:

This proposed policy change will not directly impact any specific patient population.

Expected Impact on OPTN Strategic Plan, and Adherence to OPTN Final Rule:

By clarifying the definition for organ transplant and the start and end of transplant, the proposal supports the strategic plan goal to promote the efficient management of the OPTN. Since it will also enhance reporting of transplant procedures and increase accuracy of reporting, the proposed improvements to policy language could increase patient safety.

Plan for Evaluating the Proposal:

The Committee will continue communication with UNOS staff to determine if members have questions or concerns about the new policy language.

Additional Data Collection:

There is no additional data collection required as a result of this policy change.

Expected Implementation Plan:

If public comment is favorable, this proposal will be submitted to the OPTN Board of Directors in June 2015 and, if approved, the clarified policies will become effective in September 2015.

Communication and Education Plan:

This proposal only clarifies and reorganizes current policy language and does not require that members change how they currently deal with multi-organ transplantation at their institutions. The following Communication & Education Activities will help notify members of the clarified policy language:

- Policy notice
- Presentation at Regional Meetings

Compliance Monitoring:

This proposal does not require any changes to the current compliance monitoring of these policy requirements.

Policy or Bylaw Proposal:

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

2.15.F ~~Multiple~~ Start Time for Organ Procurement

After ~~a member indicates its initial acceptance of an~~ organs have been offered and accepted, ~~the transplant hospitals and OPOs involved~~ recovery teams must agree on the time the ~~that multiple organ~~ procurement will begin. If ~~the members~~ they cannot agree on the ~~procurement~~ start time for the procurement, the host OPO has the authority to ~~may~~ withdraw the offer from the transplant hospital ~~or OPO~~ that cannot ~~unable to~~ agree on the start time for procurement ~~to begin~~.

3.4.C Candidate Registrations

Recipients of deceased and living donor organs must be registered as candidates on the waiting list prior to their transplant, including recipients receiving directed donations from deceased donors. All multi-organ candidates must be registered on the waiting list for each required organ.

Transplant programs must complete all candidate registrations, modifications, and removals in the waiting list.

3.4.D Candidate Human Leukocyte Antigen (HLA) Requirements

The candidate's transplant program must report to the OPTN Contractor complete human leukocyte antigen (HLA) information (at least 1A, 1B, and 1DR antigen) according to *Table 3-1* below:

Table 3-1: HLA Requirements

If the candidate is registered for a…	Then, HLA information is…
Kidney alone	Required
Kidney–pancreas	Required
Kidney with any other non-renal organ	Not required
Pancreas alone	Required

Transplant programs must report this HLA information using current World Health Organization (WHO) nomenclature when the candidate is registered on the waiting list.

3.4.E Inactive Status

If the candidate is temporarily unsuitable for transplant, then the candidate's transplant program may classify the candidate as inactive and the candidate will not receive any organ offers.

~~3.4.F Multi-organ Candidate Registrations~~

~~If a multi-organ transplant candidate requires a heart, lung, or liver the candidate must register on the waiting list separately for each required organ.~~

~~Multi-organ candidates who have been named as the recipient of a directed organ donation must appear on at least one of the deceased donor's match runs for at least one of the required organ types.~~

3.4.~~G~~F Multiple Transplant Program Registrations

Candidates may be registered for an organ at multiple transplant programs within the same Donation Service Area (DSA) or different DSAs. A transplant program may choose whether or not to accept a candidate seeking multiple registrations for an organ.

Transplant hospitals may access a report from the OPTN Contractor that identifies any candidates that have multiple registrations for the same organ. This report will not include the identities of the other hospitals where the candidates are registered.

Policy 3.7.C~~6.4.A~~ Waiting Time Modifications for Heart, Lung, and Heart-Lung Candidates

A transplant program may request that the OPTN Contractor modify a candidate's waiting time when a candidate has multiple registrations ~~qualifies to receive waiting time accrued from one waiting list to another waiting list~~ according to *Table ~~6-4~~* 3-6 below.

Table ~~6-4~~ 3-6: Waiting Time Modifications for Heart, Lung, and Heart-Lung Candidates

From this registration:	To this registration:
~~Heart~~	~~Lung~~
Heart	Heart-lung
~~Lung~~	~~Heart~~
~~Lung~~	~~Heart-lung~~
Heart-lung	Heart
Heart-lung	Lung

~~**5.4.D Multiple Organ Procurement and Offers**~~

~~If an OPO has permission to procure all organs from a deceased donor, that OPO must offer those organs unless, in the OPO's medical judgment, the organs are not suitable for transplant.~~

~~After the organs have been accepted, all receiving transplant hospitals must agree on when the multiple organ procurement will begin. If they cannot agree on a start time for the procurement, the host OPO may withdraw the offer from the transplant hospitals that accepted the organs.~~

5.4.~~E~~D Backup Organ Offers

OPOs may make backup offers for all organs. Transplant hospitals must treat backup offers the same as actual organ offers and must respond within one hour of receiving the required deceased donor information for an organ. If a transplant hospital refuses to consider or does not respond to a backup offer, the offer will be considered refused.

If a transplant hospital accepts a backup offer, it may later refuse to accept the organ based on medical or logistical criteria. Transplant hospitals should be promptly notified of any change in deceased donor status or organ availability.

5.4.~~F~~E Allocation to Candidates Not on the Match Run

When a candidate does not appear on at least one of the deceased donor's match runs for at least one organ type, the transplant hospital must document the reason the candidate does not appear and ensure that the organ is safe and appropriate for the candidate. Acceptable reasons for allocation to the candidate may include, but are not limited to, directed donations or to prevent organ waste.

In such an event, the transplant hospital must document *all* of the following:

1. The reason for transplanting an organ into a candidate who did not appear on the match run
2. The reason the candidate did not appear on the match run
3. Whether the transplant hospital is willing to accept a kidney from a deceased donor with a KDPI score greater than 85% or from a donation after circulatory death (DCD) donor, if applicable
4. That the transplant hospital verified the medical suitability between the deceased donor organ and recipient prior to transplant in at least, but not limited to, *all* the following areas according to organ type:

    - Blood type
    - Blood subtype, when used for allocation
    - Donor HLA and candidate's unacceptable antigens
    - Donor height
    - Donor weight
    - Infectious disease test results

The transplant hospital must maintain all related documentation.

5.4.~~G~~F Local Conflicts

If any member believes there is an inequity or has a conflict with an OPO policy regarding the allocation of organs that cannot be resolved, the member may submit the issue to the appropriate organ-specific committee and Board of Directors for review and a final decision.

Policy 5.8 Allocation of Multi-Organ Combinations

~~Candidates registered for multiple organs must appear on the heart, lung, or liver match run to be eligible to receive a heart, lung, or liver.~~

5.8.A Allocation of Heart-Lungs

Heart-lung combinations are allocated according to *Policy 6.5.E: Allocation of Heart-Lungs*.

5.8.B Other Multi-Organ Combinations

When multi-organ candidates ~~other than heart-lung candidates~~ are registered on the ~~eligible to receive a~~ heart, lung, or liver waiting list, the second required organ will be allocated to the multi-organ candidate from the same donor if the donor's DSA is the same DSA where the multi-organ candidate is registered. ~~Heart-lung combinations are allocated according to *Policy 6.5.E: Allocation of Heart-Lungs*.~~

If the multi-organ candidate is on a waiting list outside the donor's DSA, it is permissible to allocate the ~~voluntary sharing of the~~ second organ to the multi-organ candidate ~~is~~ receiving the first organ. ~~recommended. When the second organ is shared, the same organ of an identical blood type must be paid back to the host OPO from the next acceptable donor procured by the recipient OPO, unless the second organ is a kidney. If the second organ is a kidney, then there is no payback obligation.~~