

**SELECTED RECOMMENDATIONS OF THE
OPTN/UNOS OPERATIONS COMMITTEE TO THE
BOARD OF DIRECTORS**

SUMMARY

I. Action Items

- The Board of Directors is asked to approve modifications to Policies 3.5.3.5 (Organ Offer Limit), 3.8.1.7.1 (Time Limit), and 7.6.1.2 (Validation of Offers of Organs Placed through the Organ Center). (Item 1, Page 3)
- The Board of Directors is asked to approve clarifying modifications to Policy 5.5 (Standard Organ Package Specifications). (Item 2, Page 6)

II. Other Significant Items

- None

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OPTN/UNOS OPERATIONS COMMITTEE
TO THE BOARD OF DIRECTORS**

**Richmond, VA
June 19-20, 2008**

**Richard D. Hasz, M.F.S., Chair
Marwan Abouljoud, M.D., Vice-Chair**

The following report represents the selected recommendations of the Operations Committee to the Board of Directors.

1. Reconsideration of Modifications to Policies 3.5.3.5, 3.8.1.7.1, and 7.6.1.2 (Change Organ Time Limits to Organ Offer Limits for Zero Antigen Mismatched Kidneys, Pancreata, and Kidney/Pancreas Combinations) - Post Public Comment – The Committee reconsidered its proposed policy modifications and discussed public comment feedback. These policy modifications allow OPOs to make zero antigen mismatched organ offers through UNetsm instead of requiring OPOs to use the Organ Center to place all zero antigen mismatched organs. The modifications state that OPOs and the Organ Center must make a specified number of zero antigen mismatched organ offers instead of offering the zero antigen mismatched organs for a specified number of hours. The goal of these changes is to implement a process that can be applied consistently across OPOs, that is in line with DonorNet® advances, and that is monitorable by UNOS staff. Additionally, these modifications will bring policy in line with the Executive Committee’s May 2007 resolution to allow OPOs to make offers for zero antigen mismatched organs rather than using the Organ Center to make such offers. These policy modifications are intended to change how zero antigen mismatched offers are measured, not the amount or number of zero antigen mismatched offers that are made. The proposed policies modifications are fully outlined in the executive summary that includes public comment with accompanying Committee responses in Exhibit A. The proposed modifications will be recommended to the Board of Directors in June 2008. The Committee recommends the following for consideration by the Board:

**** RESOLVED, that the proposed modifications to Policies 3.5.3.5 (Organ Offer Limit), 3.8.1.7.1 (Time Limit), and 7.6.1.2 (Validation of Offers of Organs Placed through the Organ Center) as set forth below, having been distributed for public comment and subsequently reconsidered by the Operations Committee, are hereby approved effective pending distribution of notice to the Members:**

3.5.3.5 Organ Offer~~Time~~ Limit. Kidneys to be shared as zero antigen mismatches, either alone or with pancreata, must be offered to the appropriate recipient transplant centers through UNetsm or through the Organ Center ~~within 8 hours after organ procurement for standard donors and within 4 hours after organ procurement for expanded criteria donors (organ procurement is defined as cross clamping of the donor aorta).~~ For standard criteria donor (SCD) kidneys, offers must be made for at

~~least 10 zero antigen mismatched potential recipients¹ candidates, or all candidates. If fewer there are less than 10 zero antigen mismatched potential recipients appear on the match list, then offers must be made for all zero antigen mismatched potential recipients on the match list. For ~~extended~~ expanded criteria donor (ECD) kidneys, offers must be made for at least the first 5 zero antigen mismatched potential recipients candidates, or all candidates. If fewer there are less than 5 zero antigen mismatched potential recipients appear on the match list, then offers must be made for all zero antigen mismatched potential recipients on the match list. If these offers are turned down (either explicitly refused or the notification time or evaluation time is exceeded as defined in Policy 3.4.1), The Organ Center will attempt to place standard donor organ(s) for zero antigen mismatched candidates according to the national lists of candidates waiting for combined kidney/pancreas or isolated kidney transplantation, as applicable, for a period of four hours (starting from the time the Organ Center makes the first offer) after which time the Organ Center will notify the Host OPO that it may:~~

- ~~• allocate the organ(s) according to the standard geographic sequence of kidney allocation under Policy 3.5.6 and pancreas allocation under Policy 3.8.1 (first locally, then regionally, and then nationally); or~~
- ~~• allocate the organ(s) for the remaining zero antigen mismatched potential recipients.~~

~~If the Host OPO chooses to continue offering the kidney (s) for zero antigen mismatched potential recipients beyond the 10th potential recipient for a SCD or 5th potential recipient for an ECD, no obligation to pay back the kidney pursuant to Policy 3.5.5 (Payback Requirements) will be generated, even if the kidney is accepted for a zero antigen mismatched potential recipient. The period of time allowed for acceptance of zero antigen mismatched standard kidney offers made within the four hours permitted for placing these organs, but with less than an hour before the four hours will expire, shall equal the time remaining within the four hour period for placement of standard zero mismatched donor kidneys. In the event the Host OPO declines the opportunity to allocate standard donor organ(s) locally, then the Organ Center shall continue to attempt to place the organ(s) for zero antigen mismatched candidates according to the national lists of waiting candidates. Acceptance of organs declined by the Host OPO will not generate an obligation to pay back the kidney pursuant to Policy 3.5.5 (Payback Requirements) even if accepted for a zero antigen mismatched candidate. The Organ Center will attempt to place expanded criteria donor organ(s) for zero antigen mismatched candidates according to the national lists of candidates waiting for expanded criteria donor kidney transplantation for a period of two hours (starting from the time the Organ Center makes the first offer) after which time the Organ Center will notify the Host OPO that it may allocate the organ(s) according to the standard geographic sequence of kidney allocation under Policy 3.5.6 (first locally, then regionally, and then nationally) for candidates designated as eligible to receive expanded criteria donor kidneys. The period of time allowed for acceptance of zero antigen mismatched expanded criteria donor kidney offers made within the two hours permitted for placing these organs, but with less than an hour before the two hours will expire,~~

¹ For the purposes of Policy 3.5.3.5, zero antigen mismatched potential recipients are zero antigen mismatched potential recipients who appear in the zero antigen mismatch classification on the match run.

~~shall equal the time remaining within the two-hour period for placement of expanded criteria zero mismatched donor kidneys. Time available for organ acceptance, if shorter than one hour, shall be communicated with the organ offer. The Organ Center will document each offer and each response. If the Host OPO chooses to share the zero antigen mismatch through UNetsm, the Host OPO must submit a completed Kidney Payback Accounting Sheet it must contact the Organ Center within 5 business days 24 hours of the organ(s) recovery, defined as cross clamping of the donor aorta, to report the sharing. A payback credit will not be assigned until: 1) the Organ Center receives the Kidney Payback Accounting Sheet documenting the zero antigen mismatch share; the Host OPO contacts the Organ Center and 2) the zero antigen mismatch share can be verified (i.e. cross clamp and final acceptance has been entered) in UNetsm. If the Host OPO does not report the sharing within 5 business days of the organ(s) recovery, the OPO will forfeit the payback credit.~~

NOTE: The amendments to Policy 3.5.3.5 (Time Limit) shall be effective pending distribution of appropriate notice and programming in UNetsm. (Approved at the September 2007 Board of Directors Meeting)

~~**3.8.1.67.1 Time Organ Offer Limit.** All pancreata to be shared as zero antigen mismatches, either alone or in combination with kidneys, must be offered to the appropriate recipient transplant centers through UNetsm or through the Organ Center within eight hours after organ procurement. The Organ Center will attempt to place the organ(s) for Offers must be made for the first 10 zero antigen mismatched candidates potential recipients² according to the national lists of candidates waiting for combined kidney/pancreas or isolated pancreas transplantation, as applicable. If there are less than 10 zero antigen mismatched potential recipients on the match list, offers must be made for all zero antigen mismatched potential recipients on the match list. for a period of four hours (starting from the time the Organ Center makes the first offer) after which time the Organ Center will notify ~~If these offers are turned down (either explicitly refused or the notification time or evaluation time is exceeded as defined in Policy 3.4.1), the Host OPO that it may:~~~~

- ~~allocate the organ(s) according to the standard geographic sequence of kidney allocation under Policy 3.5.6 and pancreas allocation under Policy 3.8.1, as applicable (first locally, then regionally, and then nationally); or~~
- allocate the organ(s) for the remaining zero antigen mismatched potential recipients.

~~The period of time allowed for acceptance of zero antigen mismatched pancreas offers made within the four hours permitted for placing these organs, but with less than an hour before the four hours will expire, shall equal the time remaining within the four-hour period for placement of zero mismatched donor pancreata. Time available for organ acceptance, if shorter than one hour, shall be communicated with the organ offer. In the event the Host OPO declines the opportunity to allocate the organ(s) locally, then the Organ Center shall continue to attempt to place the organ(s) for zero antigen mismatched candidates according to the national lists of waiting candidates. If the Host OPO continues to offer kidney/pancreas combinations for~~

² For the purposes of Policy 3.8.1.67.1, zero antigen mismatched potential recipients are zero antigen mismatched potential recipients who appear in the zero antigen mismatch classification on the match run.

zero antigen mismatched potential recipients beyond the 10th potential recipient, a kidney payback will be generated pursuant to Policy 3.5.5 (Payback Requirements). Acceptance of organs offered to declined by the Host OPO will not generate an obligation to pay back the kidney pursuant to Policy 3.5.4 (Payback Requirements) will be generated, even if accepted for a zero antigen mismatched candidate. The Organ Center will document each offer and each response. If the Host OPO chooses to share a zero antigen mismatched kidney/pancreas combination through UNetSM, the Host OPO must submit a completed Kidney Payback Accounting Sheet within 5 business days of the recovery of the organ(s), defined as cross clamp of the donor aorta, to report the share. A payback credit will not be assigned until: 1) the Organ Center receives the Kidney Payback Accounting Sheet documenting the zero antigen mismatch share; and 2) the zero antigen mismatch share can be verified (i.e. cross clamp and final acceptance has been entered) in UNetSM. No obligation to payback the pancreas will be generated. If the Host OPO does not report the sharing within 5 business days of the organ(s) recovery, the OPO will forfeit the payback credit.

NOTE 1: The amendments to Policy 3.8.1 (Pancreas Organ Allocation) shall be implemented pending appropriate notice and programming in UNetSM. (December 14, 2006 BOD Meeting)

~~7.6.1.2 Validation of Organ Center Offers of Organs Placed Through the Organ Center. Recipient specific refusal reasons for offers made recorded by the Organ Center (including offers of all mandatory kidney shares for zero mismatched recipients) will be recorded by the Organ Center staff to assure accuracy, and will be considered validated as recorded. The Organ Center staff will use the online procedure available in UNetSM for this purpose.~~

Committee Vote: 12 For; 0 Against; 0 Abstaining

2. Requested Language Clarification to Policy 5.5.2 – The UNOS Department of Evaluation and Quality requested that language in Policy 5.5.2 be modified for consistency regarding the type of plastic bag to be used in packaging organs. In a prior modification to Policy 5.4 the Committee proposed and the Board of Directors approved policy modifications that included defining “a plastic bag” as “a red plastic biohazard bag.” This language was not consistently applied within the entire policy. The Committee agreed that the requested clarifying language is necessary and does not change the initial policy intent. Therefore, the Committee recommends the following clarifying policy modifications for the Board of Directors consideration:

**** RESOLVED, that the proposed modification to Policy 5.5 (Standard Organ Package Specifications) as set forth below, is hereby approved effective pending distribution of notice to the Members.**

5.5 STANDARD ORGAN PACKAGE SPECIFICATIONS. The re-use of disposable transport boxes is prohibited. If the donor organ is to be commercially shipped, such as with a courier service, commercial airline or charter service, the donor organ must be packaged in a disposable transport box. Coolers are permitted for non-commercial transporting when the organ recovery team is taking the donor organ with them from the donor hospital to the candidate transplant center. The re-use of coolers is permitted. All labels for the previous donor organ must be removed

before re-using the cooler. The standard disposable package used by members must have the following properties:

5.5.1 A corrugated, wax coated outer container of 200 pound burst strength, or one of equal or greater strength and moisture resistance, must be used.

5.5.2 Inside the moisture resistant outer-container, 1-1/2" thick expanded polystyrene insulated container or its R-factor equivalent must be used. A closed red plastic bio-hazard bag liner must be placed between the outer container and the polystyrene insulated container to encase the ice.

Committee Vote: 13 For; 0 Against; 0 Abstaining