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IMPORTANT POLICY NOTICE

To: Transplant Professionals

From: Karl J. McCleary, Ph.D., M.P.H
UNOS Director of Policy, Membership and Regional Administration

RE: Summary of actions taken at the OPTN/UNOS Board of Directors Meeting—June 19-20, 2008

Date: July 18, 2008

The attached report summarizes bylaw changes, policy changes and other actions the OPTN/UNOS Board of Directors approved at its June 2008 meeting.

This format allows you to scan the outcome of committee actions and quickly determine what, if anything, is required by you. You can also access the modified policy language by clicking on the link below the summary table. If you are interested in reviewing policy changes from previous board meetings, go to www.unos.org and click on Newsroom and then select "view all Policy Notices." We have archived all policy notices from the March 2007 board meeting and forward.

Thank you for your careful review. If you have any questions about a particular notice within this document, please contact your regional administrator at (804) 782-4800.

Overview of Policy Modifications/Board Actions and Affected Professionals

Who should be aware of these actions? Please review the **17** notices included on the grid grid below and share with other colleagues as appropriate.

		Policy/Bylaw Change or Board Action *(Sponsoring Committee)*	Directors of Organ Procurement	Lab Directors	Lab Supervisors	OPO Data Coordinators	OPO Executive Directors	OPO Medical Directors	OPO PR/Public Education Staff	OPO Procurement Coordinators	Transplant Administrators	Transplant Coordinators	Transplant Data Coordinators	Transplant Physicians	Transplant PR/Public Education Sta	Transplant Program Directors	Transplant Social Workers	Transplant Surgeons	Page #
Link	1	Modifications to requirements for evaluating and screening potential organ donors for transmission of disease or medical conditions, including malignancies *(Disease Transmission Advisory Committee)*	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	5
Link	2	Modifications to requirements for transplant centers for communicating donor history and obtaining informed consent from the potential transplant recipient when a donor meets high risk of disease transmission (as defined by CDC guidelines). *(Executive Committee)*	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	6
Link	3	Modifications to create broader sharing of pediatric donor hearts *(Pediatric and Thoracic Organ Transplantation Committees)*	X			X	X	X	X	X	X	X	X	X	X	X	X	X	8
Link	4	Modifications to create broader sharing of pediatric donor lungs and a simple status based system of allocation for 0-11 year-old lung candidates (*Pediatric and Thoracic Organ Transplantation Committees)*	X			X	X	X	X	X	X	X	X	X	X	X	X	X	9
Link	5	Modifications to create broader sharing of pediatric donor livers and combined liver-intestines *(Pediatric and Liver and Intestinal Organ Transplantation Committees)*	X			X	X	X	X	X	X	X	X	X	X	X	X	X	10
Link	6	Modifications to allow continuous venovenous hemodialysis (CVVHD) as an acceptable form of dialysis for the purpose of calculating a liver candidate's MELD score *(Liver and Intestinal Organ Transplantation Committee)*									X	X	X	X	X	X	X	X	11

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Link	7	Clarification of Combined Liver-Intestine Allocation Policy *(Liver and Intestinal Organ Transplantation Committee)*	X			X	X	X	X	X	X	X	X	X	X	X	X	X	12
Link	8	Clarification to existing policies regarding access to the Match System (UNetSM) *(Executive Committee)*	X	X	X	X	X	X		X	X	X	X	X		X	X	X	13
Link	9	Modifications to requirements for mandatory sharing of zero antigen mismatch kidneys *(Kidney Transplantation Committee)*	X	X	X	X	X	X		X	X	X	X	X	X	X	X	X	14
Link	10	Modifications to policies detailing zero antigen mismatched kidney, pancreas and combined kidney-pancreas offers and time limits, and the validation of such offers placed through the Organ Center *(Operations Committee)*	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	15
Link	11	Modifications to allow an additional method for waiting time reinstatement for pancreas recipients *(Pancreas Transplantation Committee)*									X	X	X	X		X	X	X	17
Link	12	Guidance for the Development of Program-Specific Living Kidney Donor Medical Evaluation Protocols *(Living Donor Committee)*		X	X						X	X	X	X	X	X	X	X	18
Link	13	Modifications to bylaws to require that living donors be provided with contact information to report any grievances to the OPTN *(Living Donor Committee)*									X	X	X	X	X	X	X	X	19
Link	14	Modifications to the bylaws pertaining to conditional approval status for liver transplant programs that perform living donor transplants *(Membership and Professional Standards Committee)*									X			X		X		X	20

Overview of Policy Modifications/Board Actions and Affected Professionals

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Link	15	Modifications to the bylaws pertaining to the elector system for histocompatibility lab members and medical/scientific members *(Membership and Professional Standards Committee)*		X	X														21
Link	16	Modifications to the bylaws pertaining to restoration of membership privileges following an adverse action *(Membership and Professional Standards Committee)*		X	X		X	X			X					X			22
Link	17	Modifications to clarify standard organ packaging specifications *(Operations Committee)*	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	23

Notice of Policy Change: Modifications to requirements for evaluating and screening potential organ donors for transmission of disease or medical conditions, including malignancies *(Disease Transmission Advisory Committee)*

Action Required: Review Only

Effective Date: August 18, 2008

Professional Groups Affected by the change:
OPO Executive Directors, Directors of Organ Procurement, OPO Procurement Coordinators, OPO Data Coordinators, OPO Medical Directors, Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Transplant Social Workers, Transplant Data Coordinators, Lab Directors, Lab Supervisors, Transplant PR/Public Education Staff

Current Issue/Policy	Change or Addition	What You Need to Do
OPOs must use FDA-licensed screening tests to adequately and appropriately reduce the risk of of disease transmission through organ transplantation. For the purposes of organ donor testing, such screening tests historically have been considered preferable to diagnostic tests since the relatively high sensitivity levels in the screening test will likely detect if a donor has been previously infected by a specific disease. A number of vendors are discontinuing certain screening assays. Some serologic diagnostic tests are as sensitive as screening tests, and some labs are discontinuing the use of screening tests in favor of these serologic diagnostic tests. As a result, several OPOs have already had to accept this alternative testing.	We have revised policy to allow OPTN members to remain in compliance with policy while providing reasonable assurance that donors that are or have been infected with specific diseases will be identified prior to transplantation and potential disease transmission The policy now indicates that donors may be screened using **FDA-licensed, approved, or cleared serological tests** capable of determining whether the donor is or has been infected with a specific disease. We also need to modify Policy 2.2 in order to maintain consistency with requirements for screening versus diagnostic testing.	Continue screening potential organ donors for HIV according to Policies 2.2 and 4.1 as the HIV testing policy has not changed. (please note modifications to policy 4.1.1 in policy notice #2). You may use only FDA- approved screening tests. You can view donor screening testing kits approved by the FDA at: http://www.fda.gov/cber/tissue/prod.htm. Work with the labs you use for organ donor testing to identify which tests are capable of determining whether the donor is or has been infected with the diseases listed in Policy 2.2.8.1.

Click Here to View the Modified Policy Language

Notice of Policy Change: Modifications to Policy 4.1.1 (Communication of Donor History) *(Executive Committee*)

Action Required: Review Only

Effective Date: August 18, 2008

Professional Groups Affected by the change:
OPO Executive Directors, Directors of Organ Procurement, OPO Procurement Coordinators, OPO Data Coordinators, OPO Medical Directors, Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Transplant Social Workers, Transplant Data Coordinators, Lab Directors, Lab Supervisors, Transplant PR/Public Education Staff

Current Issue/Policy	Change or Addition	What You Need to Do
In December 2007, the Executive Committee approved policy language that required transplant centers to obtain informed consent from the potential transplant recipient when the donor meets high risk of disease transmission (as defined by CDC guidelines). The Executive Committee approved the policy prior to public comment to address potential patient safety issues.	The Executive Committee reviewed public comment feedback and approved modifications during its May 19, 2008 teleconference. Commenters suggested that the policy should include a reference to the CDC guidelines rather than incorporating excerpts into the policy, because if the CDC makes changes, then the policy will be out of date.	Host OPOs **must**: • obtain a history on each potential donor that helps them determine whether the potential donor is in a CDC – defined high riskgroupcommunicate this donor history information <u>to all institutions</u> receiving organs from the donor if the donor meets the criteria set forth in CDC for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissue and Organs (CDC Guidelines). When a transplant center receives information from the Host OPO that a donor meets any of the criteria set forth in the CDC Guidelines, it **must:** • inform the potential recipient <u>prior</u> to implantation • maintain documentation of the

		potential recipient's informed consent to receive an organ from the donor who meets any of the criteria. If the potential recipient is not able to provide informed consent, the legal next of kin, designated healthcare representative, or appropriate surrogate may provide consent.

Click Here to View the Modified Policy Language

To read the complete policy language visit www.unos.org or www.optn.org. From the UNOS Web site, select Resources from [1] To view the affected policy language, please turn to Exhibit 1. Veb site, select Policies from the main menu.

Notice of Policy Change: Modifications to Policies 3.7.5 (Allocation of Adolescent Donor Hearts to Pediatric Heart Candidates) and 3.7.10.1 (Sequence of Adolescent Donor Heart Allocation) *(Pediatric and Thoracic Organ Transplantation Committees)*

Action Required: Review Only

Effective Date: Pending Implementation (Estimated Second Quarter, 2009)

Professional Groups Affected by the change:
OPO Executive Directors, Directors of Organ Procurement, OPO Procurement Coordinators, OPO Data Coordinators, OPO Medical Directors, Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Transplant Social Workers, Transplant Data Coordinators, OPO PR/Public Education staff, Transplant PR/Public Education Staff

Current Issue/Policy	Change or Addition	What You Need to Do
Pediatric donor heart allocation is not specifically outlined in current OPTN policy. Although adolescent (11-17 year-old) donor hearts are allocated preferentially to pediatric candidates before adult candidates within each status and geographic zone, 0-10 year-old donor hearts are not. These small donor hearts are allocated using the same algorithm in place for adult donors.	This policy change will incorporate <u>all</u> pediatric donor hearts into the current adolescent algorithm and share all pediatric donor hearts more broadly to the sickest candidates. Additionally, pediatric candidates will be prioritized ahead of adults within each status and allocation zone for all pediatric donor hearts. For example: • Local and Zone A offers for Status 1A pediatric candidates will be **combined**. • Next, local adult Status 1A offers will be made. • **Combined** Local and Zone A offers for Status 1B pediatric candidates will follow.	Continue to follow the Match Run sequence for all organ offers. UNOS will issue a System Notice when we expect changes to be implemented in UNet^{sm}.

Click Here to View the Modified Policy Language

Notice of Policy Change: Modifications to Policies 3.7.6.2 (Candidates Age 0-11), 3.7.11 (Sequence of Adult Donor Lung Allocation) and 3.7.11.1 (Sequence of Pediatric Donor Lung Allocation) *(Pediatric and Thoracic Organ Transplantation Committees)*

Action Required: Review Only

Effective Date: Pending Implementation (Estimated Second Quarter, 2009)

Professional Groups Affected by the change:
OPO Executive Directors, Directors of Organ Procurement, OPO Procurement Coordinators, OPO Data Coordinators, OPO Medical Directors, Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Transplant Social Workers, Transplant Data Coordinators, OPO PR/Public Education staff, Transplant PR/Public Education Staff

Current Issue/Policy	Change or Addition	What You Need to Do
A lung allocation score, or LAS, is used to prioritize lung candidates who are 12 years of age or older. The lung allocation score accounts for medical urgency on the waiting list as well as survival after transplant. Candidates 12 and older are allocated lungs based on their LAS, blood type, and geographic location. Candidates who are less than 12 years of age currently receive priority for lung offers based on time spent on the waiting list, blood type, and geographic location.	In order to improve allocation to the sickest young pediatric candidates, the board approved two policy changes. The first creates a simple status system for pediatric candidates less than 12 years of age. Using objective medical characteristics, donor lungs are directed to the sickest of these pediatric candidates first. The second component improves access to organs for the sickest candidates by more broadly sharing 0-11 year-old donor lungs. Allocation offers will go first to **combined** local, Zone A and Zone B 0-11 year-old pediatric candidates by status, and then to **combined** local and Zone A adolescents before local offers are made to adults.	Once the change is implemented, you must enter clinical data on all candidates less than 12 years of age to justify their appropriate status. Programs may update this data any time a candidate's medical condition warrants a change, but programs <u>must</u> update every candidate's data at least once every six months after initial listing or implementation of this status system. We will notify transplant centers in advance of the date when they can begin entering this data in UNet^{sm} . Continue to follow the Match Run sequence for all organ offers. UNOS will issue a System Notice when we are ready to implement the changes in UNet^{sm}.

Click Here to View the Modified Policy Language

Notice of Policy Change: Modifications to Policies 3.6 (Allocation of Livers) and 3.11.4.2 (Combined Liver-Intestinal Organs from Donors 0-10 Years of Age) *(Pediatric and Liver and Intestinal Organ Transplantation Committees)*

Action Required: Review Only

Effective Date: Pending Implementation (Estimated Second Quarter, 2009)

Professional Groups Affected by the change:
OPO Executive Directors, Directors of Organ Procurement, OPO Procurement Coordinators, OPO Data Coordinators, OPO Medical Directors, Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Transplant Social Workers, Transplant Data Coordinators, OPO PR/Public Education staff, Transplant PR/Public Education Staff

Current Issue/Policy	Change or Addition	What You Need to Do
We currently allocate all livers based on the candidate's MELD (Model for End-Stage Liver Disease) or PELD (Pediatric End-Stage Liver Disease) score and geographic location.	This policy change will create a new allocation algorithm specifically for 0-10 year-old donor livers and combined liver-intestines. This change will allow us to more broadly share livers and combined liver intestines with the sickest pediatric candidates on a national level. OPOs will complete all **combined** Local and Regional offers followed by National offers to all 0-11 year-old Status 1A pediatric liver and combined liver-intestine candidates before making local adult Status 1A offers for 0-10 year-old donor livers and combined liver-intestines. The current allocation sequence for adolescent (11-17 year-old) donor livers has not changed.	Continue to follow the Match Run sequence for all organ offers. UNOS will issue a System Notice when we are ready to implement the changes in UNet℠.

Click Here to View the Modified Policy Language

To read the complete policy language visit www.unos.org or www.optn.org. From the UNOS Web site, select Resources from the main menu, and then select policies. From the OPTN Web site, select Policies from the main menu.

Notice of Policy Change: Modifications to Policy 3.6.4.1 (Adult Candidate Status) (*Liver and Intestinal Organ Transplantation Committee)*

Action Required: Review Only

Effective Date: Pending Programming (Estimated Fourth Quarter, 2008)

Professional Groups Affected by the change:
Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Transplant Social Workers, Transplant Data Coordinators, Transplant PR/Public Education Staff

Current Issue/Policy	Change or Addition	What You Need to Do
When determining a MELD score for dialysis candidates, the serum creatinine level is set to 4.0 mg/dl . A dialysis candidate in this case is someone who has had two or more dialysis treaments within the prior week. The Committee discussed whether the use of continuous veno-venous hemofiltration (CVVH) should be considered as a form of dialysis for the purposes of calculating MELD score.	The Committee determined that continuous venovenous hemodialysis (CVVHD) is an acceptable form of dialysis for the purpose of calculating a candidate's MELD score, and modified policy to specifically include this treatment in the definition.	Transplant programs must enter data on UNet^{SM} for the prognostic factors specified in Table 1 in Policy 3.6.4.1. When entering MELD data, transplant programs must specify whether or not a candidate had dialysis twice within a week prior to the lab test. This question will be modified to include the new policy language addressing CVVHD. These data must be based on the most recent clinical information (e.g., laboratory test results and diagnosis) and include the dates of the laboratory tests.

Click Here to View the Modified Policy Language

To read the complete policy language visit www.unos.org or www.optn.org. From the UNOS Web site, select Resources from the main menu, and then select policies. From the OPTN Web site, select Policies from the main menu.

Notice of Policy Change: Clarification of Combined Liver-Intestine Allocation Policy *(Liver and Intestinal Organ Transplantation Committee)*

Action Required: Review Only

Effective Date: August 18, 2008

Professional Groups Affected by the change:
OPO Executive Directors, Directors of Organ Procurement, OPO Procurement Coordinators, OPO Data Coordinators, OPO Medical Directors, Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Transplant Social Workers, Transplant Data Coordinators, OPO PR/Public Education staff, Transplant PR/Public Education Staff

Current Issue/Policy	Change or Addition	What You Need to Do
The current policies for the allocation of a combined liver-intestine graft do not provide OPOs with enough guidance. Current policy states that local OPOs may allocate the liver to a local, regional, or national intestine recipient based upon priority for receipt of the intestine using the intestine waiting list unless there is a Status 1A or 1B liver candidate locally, regionally, or nationally. This implies that the OPO must follow the liver match run *through* national 1B liver candidates, which includes local and regional MELD/PELD candidates. Also, this language only exists in the intestinal organ allocation policy (3.11) while the liver policy (3.6) only addressed the additional points given to combined liver-intestine candidates.	In order to more clearly guide OPOs, we modified Policy 3.11, Policy 3.6, and Policy 3.9. You can read the modified policy language by clicking the policy language link below.	This does not change current practice or the intent of the previous policy language. OPOs must make **all** offers sequentially on the liver allocation match run (including all MELD/PELD potential recipients) through national Status 1A and 1B candidates **before** making offers to combined liver-intestine potential recipients sequentially according to the intestine match run.

Click Here to View the Modified Policy Language

Notice of Policy Change: Clarification to existing policies regarding access to the Match System (UNet℠) *(Executive Committee)*

Action Required: Review Urgently; No Response Needed

Effective Date: September 19, 2008

Professional Groups Affected by the change:
OPO Executive Directors, Directors of Organ Procurement, OPO Procurement Coordinators, OPO Data Coordinators, OPO Medical Directors, Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Transplant Social Workers, Transplant Data Coordinators, Lab Directors, Lab Supervisors

Current Issue/Policy	Change or Addition	What You Need to Do
Since DonorNet® was implemented, UNOS has learned that organ placement for research purposes could occur more efficiently if research organizations, which are not Institutional Members, had access to DonorNet®. If an OPO gives other entities access to DonorNet®, there is no guarantee that these entities or other entities unknown to the OPO won't have access to confidential data within the current system. Access for Member transplant centers is handled differently.	UNOS/OPTN recognized the need for explicit requirements to protect the confidentiality and security of data when any Institutional Member gives a third party access to UNet℠. This policy modification clarifies that Institutional Members who give a third party access to UNet℠ must: • see that the third party agent adheres to all applicable policies and bylaws • have in place a data use agreement with the third party agent that thoroughly addresses issues of confidentiality and security.	Review your organization's relationships with third parties who require access to UNet℠. Verify that the third parties adhere to applicable policies and bylaws. Review and/or develop a data use agreement with the third parties to address the following data elements: • rights in data • access to patient-identified data • use of data • data confidentiality procedures • disposition of data upon completion of contracted taskprocedures to protect patient-identified data in the event of a breach, inadvertent or otherwise • remedies in the event of a violation of the data use agreement.

Click Here to View the Modified Policy Language

Notice of Policy Change: Modifications to requirements for mandatory sharing of zero antigen mismatch kidneys, Policy 3.5.3 (Mandatory Sharing of Zero Antigen Mismatched Kidneys) *(Kidney Transplantation Committee)*

Action Required: Review Only

Effective Date: Pending Implementation (Estimated Third Quarter, 2009)

Professional Groups Affected by the change:
OPO Executive Directors, Directors of Organ Procurement, OPO Procurement Coordinators, OPO Data Coordinators, OPO Medical Directors, Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Transplant Social Workers, Transplant Data Coordinators, Lab Directors, Lab Supervisors, Transplant PR/Public Education Staff

Current Issue/Policy	Change or Addition	What You Need to Do
Kidney allocation policy makes it mandatory for OPOs to share zero antigen mismatch kidneys, regardless of other donor or candidate characteristics. OPOs allocate the majority of these zero-antigen mismatch transplants to unsensitized adult candidates nationwide. This policy has resulted in disproportionate allocation of kidney grafts among racial/ethnic minority groups and barriers in access for simultaneous pancreas-kidney transplant candidates.	These modifications will remove adult candidates who have a PRA or CPRA $\leq$20% from the regional and national zero mismatch allocation categories.	Continue to follow the Match Run sequence for all organ offers. UNOS will issue a System Notice when we are ready to implement the changes in UNet^{sm}.

Click Here to View the Modified Policy Language

To read the complete policy language visit www.unos.org or www.optn.org. From the UNOS Web site, select Resources from the main menu, then select policies. From the OPTN Web site, select Policies from the main menu.

Notice of Policy Change: 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) *(Operations Committee)*

Action Required: Review Only

Effective Date: August 18, 2008

Professional Groups Affected by the change: OPO Executive Directors, Directors of Organ Procurement, OPO Procurement Coordinators, OPO Data Coordinators, OPO Medical Directors, Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Transplant Social Workers, Transplant Data Coordinators, Lab Directors, Lab Supervisors, OPO PR/Public Education staff, Transplant PR/Public Education staff

Current Issue/Policy	Change or Addition	What You Need to Do
Previous policy allowed only the Organ Center to make offers for zero antigen mismatched organs. Policy also dictated that the Organ Center must offer standard criteria donor kidneys for four hours and expanded criteria donor kidneys for two hours. OPOs have not always calculated time in the same way since they began making zero antigen mismatched offers, so there is the potential for candidates to be treated unequally. This change in process also made it challenging for UNOS staff to consistently monitor the time limits outlined in policy. Additionally, because of DonorNet® advances, time was no longer a practical way to measure organ offer limits. Using number of offers rather than number of hours solved all these problems. In September 2007, the Board approved changes to Policy 3.5.3.5- Organ Time Limit. The modification changed how OPOs must offer zero antigen mismatched kidneys. The	These policy modifications allow OPOs to make zero antigen mismatched organ offers for kidneys, pancreata,and kidney/pancreas combinations through UNet^{sm} instead of requiring OPOs to use the Organ Center to place all zero antigen mismatched organs. 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.	OPO and Transplant Center personnel need to review the policy modifications and familiarize themselves with the changes. The OPO may choose to allocate zero antigen mismatch kidneys, pancreata, and kidney/pancreas combinations through UNet^{sm} or may continue to use the Organ Center to make these offers. The approved policy requires an OPO or Organ Center to: • Offer standard criteria donor kidneys to the first 10 zero antigen potential recipients on the match run • Offer expanded criteria donor kidneys to the first 5 zero antigen potential recipients on the match run • Offer pancreata and kidney/pancreas combinations to the first 10 zero antigen mismatch potential recipients on the match

original policy required OPOs to offer kidneys for a certain number of *hours*; the modified policy required OPOs to make a certain number of *offers*. However, the policy for offering zero antigen mismatched pancreata and kidney/pancreas combinations was not changed at the same time.		run. These offers must be made within 8 hours of procurement for standard criteria donor kidneys, for pancreata, and for kidney/pancreas combinations, and within 4 hours of procurement for expanded criteria donor kidneys.

Click Here to View the Modified Policy Language

To read the complete policy language visit www.unos.org or www.optn.org. From the UNOS Web site, select Resources from the main menu, then select policies. From the OPTN Web site, select Policies from the main menu.

Notice of Policy Change: Proposal to Allow an Additional Method for Waiting Time Reinstatement for Pancreas Recipients (Modifications to Policy 3.8.8 (Waiting Time Reinstatement for Pancreas Recipients)) *(Pancreas Transplantation Committee)*

Action Required: Review Only

Effective Date: July 18, 2008

Professional Groups Affected by the Change:
Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Transplant Social Workers, Transplant Data Coordinators

Current Issue/Policy	Change or Addition	What You Need to Do
If pancreas graft failure occurs, the Organ Center cannot reinstate waiting time until they receive documentation of a pancreatectomy.	New policy language allows the Organ Center to reinstate waiting time prior to a pancreatectomy if the transplant center submits the following: • completed Pancreas Waiting Time Reinstatement Form • a statement of intent from the transplant center to perform a pancreatectomy • a statement that there is documented, radiographic evidence indicating that the transplanted pancreas has failed. Transplant centers must maintain this documentation and submit it upon request. This change allows waiting time to be reinstated so recipients can begin to receive offers for another pancreas while the recipient is being considered and prepared for an operative transplant pancreatectomy. This additional time may give recipients the option to undergo only one surgery rather than two (to remove a failed pancreas graft and immediately transplant another pancreas).	If a pancreas transplant fails within two weeks of the transplant and the center wishes to have its candidate's waiting time reinstated, it must submit a Pancreas Waiting Time Reinstatement form. This form should include a pancreatectomy operative report or a statement of intent to perform a pancreatectomy with a statement that there is radiographic evidence of graft failure. Once the Organ Center receives this documentation, it will reinstate the recipient's waiting time in UNet[sm]. You must maintain documentation of radiographic evidence indicating that the transplanted pancreas has failed and submit it to UNOS upon request.

Click Here to View the Modified Policy Language

Notice of Publication Guidance for the Development of Program-Specific Living Kidney Donor Medical Evaluation Protocols *(Living Donor Committee)*

Action Required: Review Only

Effective Date: June 20, 2008

Professional Groups Affected:
Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Transplant Social Workers, Transplant Data Coordinators, Lab Directors, Lab Supervisors, Transplant PR/Public Education staff

Current Issue/Policy	Change or Addition	What You Need to Do
There is wide variability in how transplant programs across the country evaluate potential living donors.	A resource is available to help transplant centers develop their program-specific protocols for the medical evaluation of living kidney donors. Living kidney donors may use this resource to assess their own medical evaluation at a transplant center.	Know that this resource has been developed, distributed, and is posted on OPTN/UNOS websites.

Click Here to View the Resource Document

To review this resource, visit www.unos.org or www.optn.org. From the UNOS Web site, select Resources and Living Donation.

Notice of Bylaw Change: Modifications to bylaws to require that living donors be provided with contact information to report any grievances to the OPTN (*Living Donor Committee)*

Bylaw Affected: Bylaws, Appendix B, Attachment I, Section XIII, D (2) and (4), Designated Transplant Program Criteria (Living Donor Committee).

Action Required: Review Urgently; No Response Needed

Effective Date: August 18, 2008

Professional Groups Affected by the change:
Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Transplant Social Workers, Transplant Data Coordinators, Transplant PR/Public Education Staff

Current Issue/Policy	Change or Addition	What You Need to Do
Transplant centers send written notification to transplant candidates that includes a telephone number for patients and others to report grievances to the OPTN. Potential or actual living donors do not receive this information.	During the consent process of a potential living donor, transplant centers must give the donor the telephone number that is available for reporting grievances to the OPTN.	Centers must modify their existing protocols to provide all living donors the telephone number for reporting grievances to the OPTN.

Click Here to View the Modified Bylaw Language

To read the complete bylaws language visit www.unos.org or www.optn.org. From the UNOS Web site, select Resources from the main menu, then select bylaws. From the OPTN Web site, select Policies from the main menu, then select bylaws.

Notice of Bylaw Change: Modifications to the bylaws pertaining to conditional approval status for liver transplant programs that perform living donor transplants *(Membership and Professional Standards Committee)*

Bylaw Affected: Attachment I, Appendix B, Section D, (4) *Liver Transplant Programs that Perform Living Donor Liver Transplants* of the OPTN/UNOS Bylaws

Action Required: Review Only

Effective Date: 6/20/2008, concurrent with public comment

Professional Groups Affected by the change: Transplant Administrators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians,

Current Issue/Policy	Change or Addition	What You Need to Do
The bylaws currently provide a conditional approval option for programs that do not have a second living donor liver surgeon who meets the criteria specified in the bylaws. However, the bylaws do not clearly indicate what happens when programs reach the end of the two-year conditional approval period (initial year plus a one-year extension) and still do not meet the requirements for full approval. The Committee agreed that it was important for the members to understand their options when facing this situation.	The bylaws amendment clarifies the options that are available to programs that reach the end of the conditional approval period yet still don't meet the requirements for full approval. When a term-limited approval status ends, a program is expected to fully meet the requirements, inactivate, or relinquish designated program status.	A transplant center that has conditional approval to perform living donor liver transplants should be aware of when its conditional approval term ends. Additionally, the center should continuously monitor its progress towards complying with the requirements for full approval by the end of the conditional term. We will continue to inform applicants that meet the conditional approval pathway of the need for meeting the full approval requirements by the end of the conditional period, and the options that are available to the center if it does not meet the requirements.

Click Here to View the Modified Bylaw Language

To read the complete bylaws language visit www.unos.org or www.optn.org. From the UNOS Web site, select Resources from the main menu, then select bylaws. From the OPTN Web site, select Policies from the main menu, then select bylaws.

Notice of Bylaw Change: Modifications to the elector system for histocompatibility lab members and medical/scientific members *(Membership and Professional Standards Committee)*

Bylaws Affected: OPTN and UNOS Bylaws, Article I, (Members); Article II (Board of Directors), Article VI (Officers).

Action Required: Review Only

Effective Date: June 20, 2008

Professional Groups Affected by the change: OPTN/UNOS Representatives at Independent Histocompatibility Laboratories, Lab Directors, Lab Supervisors, OPTN/UNOS Representatives at Medical/Scientific Organizations

Current Issue/Policy	Change or Addition	What You Need to Do
Medical/Scientific Members of OPTN and UNOS are represented by 24 separate national medical/scientific member electors even if the number of members in this category exceeds 24. Each medical/scientific member elector is entitled to one vote on OPTN/UNOS affairs that require a membership vote. Histocompatibility Laboratory Members as a class are represented by 33 separate histocompatibility laboratory member electors. Each histocompatibility laboratory member elector is entitled to one vote on OPTN/ UNOS affairs, and the histocompatibility laboratory members elect the electors.	A change in the bylaws eliminates the current elector system for voting privileges and responsibilities for Histocompatibility Laboratory Members and Medical/Scientific Organizations. It allows each histocompatibility laboratory and each medical/scientific member a single vote in OPTN/UNOS affairs and removes the need for separate national elections for these groups.	The OPTN/UNOS representatives for independent histocompatibility laboratories and medical/scientific organizations will now have voting privileges. No action is required by the member.

Click Here to View the Modified Bylaw Language

Notice of Bylaw Change: Modifications to bylaws pertaining to the restoration of membership privileges following an adverse action *(Membership and Professional Standards Committee)*

Bylaws Affected: Appendix A, Section 3.01A Paragraphs (1) and (3) and Section 5.05A, Addition of Section 5.07A.

Action Required: Review Only

Effective Date: June 20, 2008

Professional Groups Affected by the change: OPTN/UNOS Representatives, OPO Executive Directors, OPO Medical Directors, Transplant Administrators, Transplant Program Directors, Lab Directors, Lab Supervisors.

Current Issue/Policy	Change or Addition	What You Need to Do
The bylaws do not provide a clear mechanism or pathway to restore full membership privileges to a member that receives an adverse action such as "Member Not in Good Standing" or "Probation."	Changes further describe the circumstances under which the MPSC may consider restoring a member's full privileges. These changes also provide OPTN members with clear expectations of how much time must go by before they can request that their full membership privileges be restored. Changes include the following: • 5.05A – the content of this section was divided into four subsections with headers including 1) Request for Restoration of Membership Privileges, 2) Time Limits, 3) Additional Requirements, 4) Hearing. • 5.07A – Lesser Adverse Actions: Changes were made consistent with Section 5.05A as described above.	Any member who has received an adverse action should make a request for restoration of privileges after the time period outlined in the bylaw Otherwise, no action is required.

Click Here to View the Modified Bylaw Language

Notice of Policy Change: Modifications to clarify standard organ packaging specifications *(Operations Committee)*

Action Required: Review Only

Effective Date: August 18, 2008

Professional Groups Affected by the change: OPO Executive Directors, Directors of Organ Procurement, OPO Procurement Coordinators, OPO Data Coordinators, OPO Medical Directors, Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Transplant Social Workers, Transplant Data Coordinators, Lab Directors, Lab Supervisors, OPO PR/Public Education staff, Transplant PR/Public Education staff

Current Issue/Policy	Change or Addition	What You Need to Do
Current policy requires that a "closed plastic liner" be placed between the outer container used to transport an organ and the inner polystyrene insulated container. This bag is meant to encase the ice used to cool a donor organ during transport and prevent any leakage.	This policy modification clarifies that the "plastic liner" mentioned throughout the policy refers to "a red biohazard bag." The language was not consistent throughout the policy, and therefore, the modification to Policy 5.5.2 was necessary.	OPO and transplant center personnel must place a red biohazard bag between the outer container and the inner polystyrene container used to transport an organ.

Click Here to View the Modified Policy Language

To read the complete policy language visit www.unos.org or www.optn.org. From the UNOS Web site, select Resources from the main menu, then select policies. From the OPTN Web site, select Policies from the main menu.

Exhibit 1

Modifications to requirements for evaluating and screening potential organ donors for transmission of disease or medical conditions, including malignancies *(Disease Transmission Advisory Committee)*

Affected Policy Language:

Proposed language is underlined while language to be removed is ~~stricken through~~.

4.6 SCREENING POTENTIAL ORGAN DONORS FOR TRANSMISSION OF DISEASES OR MEDICAL CONDITIONS, INCLUDING MALIGNANCIES. All potential donors are to be screened for transmissible diseases or medical conditions, including malignancies, through the collection of medical/social history information. Medical conditions that should be screened for by history include the presence of malignancies, treated and untreated, or any other known condition that may be transmitted by the donor organ that may reasonably impact the candidate or recipient. In addition, donors shall be tested for recognized transmissible diseases, as defined in policy 2.2.8.1, ~~using screening tests licensed by the FDA for testing these specific diseases.~~ using FDA-licensed, approved, or cleared serological tests capable of determining whether the donor is or has been infected with these specific diseases. If additional testing is performed, the results of these tests must be communicated immediately to all recipient institutions. The OPO is responsible for timely follow-up of donor screening tests. Documentation of any suspected or confirmed transmissible disease or medical condition identified prior to or following procurement must be communicated by the Host OPO to all potential recipient centers and the OPTN according to Policy 4.7.

2.2 EVALUATION OF POTENTIAL DONORS. The Host OPO is responsible for performing the following activities and communicating this information to the OPO or transplant center for every donor:

2.2.1 Verifying that death has been pronounced according to applicable laws.
2.2.2 Performing pertinent tests including:
- ABO typing;
- FDA licensed Anti-HIV I, II.

In addition, the Host OPO shall perform the following evaluations and provide this information to the OPO or transplant center, documenting in the donor record circumstances when such information is not available.

2.2.3 Determining whether there are conditions which may influence donor acceptance.
2.2.4 Obtaining the donor's history.
2.2.5 Reviewing the donor's medical chart.
2.2.6 Performing a physical examination of the donor.
2.2.7 Obtaining the donor's vital signs.
2.2.8 Performing pertinent tests including:

2.2.8.1 For all potential donors:

- CBC;
- Electrolytes;
- Hepatitis ~~screen~~serological testing; including HBsAg, HBcAb, and Anti-HCV;
- VDRL or RPR;
- Anti-HTLV I/II;
- Anti-CMV;
- EBV ~~antibody screening~~serological testing;
- Blood and urine cultures if the donor is hospitalized 72 hours or longer;
- Urinalysis within 24 hours of cross clamp; and
- Chest x-ray.

In all cases, the transplant center will make the clinical decision whether to accept or reject the organ based on the available data or the need for additional information.

Exhibit 2

Modifications to Policy 4.1.1 (Communication of Donor History) *(Executive Committee)*

Affected Policy Language:

For your convenience in reviewing, new language is underlined and language that is to be removed is ~~stricken through~~. Changes to language resulting from public comment feedback appear with a double underline and/or a double ~~strikethrough~~.

4.0 ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS), HUMAN PITUITARY DERIVED GROWTH HORMONE (HPDGH), AND REPORTING OF POTENTIAL RECIPIENT DISEASES OR MEDICAL CONDITIONS, INCLUDING MALIGNANCIES, OF DONOR ORIGIN

4.1 SCREENING POTENTIAL ORGAN DONORS FOR HIV. All potential donors are to be tested by use of a screening test licensed by the U.S. Food and Drug Administration (FDA) for Human Immune Deficiency Virus (HIV). If the potential donor's pre-transfusion test for HIV is negative and blood for subsequent transfusions has been tested and found to be negative for HIV, retesting the potential donor for HIV is not necessary. If no pre-transfusion sample of the potential donor's blood is available, the Host OPO (as defined in Policy 2.1) must provide, to the recipient transplant center the screening test results and a complete history of all transfusions received by the donor during the ten (10) day period immediately prior to removal of the organ. Organs from donors with a positive screening test are not suitable for transplantation unless subsequent confirmation testing indicates that the original tests' results were falsely positive for HIV. If additional tests related to HIV are performed, the results of all tests must be communicated immediately to the Organ Center and all institutions receiving organs from the donor. Exceptions for cases in which the testing cannot be completed prior to transplant are provided in paragraph 4.1.3 below.

4.1.1 Communication of Donor History. The Host OPO will obtain a history on each potential donor in an attempt to determine whether the potential donor is in a "high risk" group, as defined by the Centers for Disease Control and Prevention (CDC). If the donor meets the criteria ~~below~~ set forth in CDC for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissue and Organs (CDC Guidelines),[1] the Host OPO must communicate this information regarding donor history to all institutions receiving organs from the donor.

~~Behavior/History Criteria~~

~~i) Men who have had sex with another man in the preceding 5 years.~~

[1] Rogers MF, Simonds RJ, Lawton KE, et al. Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissue and Organs. CDC MMWR Recommendations and Reports. 1994; May 20/ 43(RR-8):1-17.
http://www.cdc.gov/mmwr/preview/mmwrhtml/00031670.htm

~~ii) Persons who report nonmedical intravenous, intramuscular, or subcutaneous injection of drugs in the preceding 5 years.~~

~~iii) Persons with hemophilia or related clotting disorders who have received human derived clotting factor concentrates.~~

~~iv) Men and women who have engaged in sex in exchange for money or drugs in the preceding 5 years.~~

~~v) Persons who have had sex in the preceding 12 months with any person described in terms i-iv above or with a person known or suspected to have HIV infection.~~

~~vi) Persons who have been exposed in the preceding 12 months to known or suspected HIV-infected blood through percutaneous inoculation or through contact with an open wound, nonintact skin, or mucous membrane.~~

~~vii) Inmates of correctional systems (This exclusion is to address issues such as difficulties with informed consent and increased prevalence of HIV in this population).~~

~~Pediatric Donor Criteria~~

~~viii) Children meeting any of the criteria listed above for adults.~~

~~ix) Children born to mothers with HIV infection or mothers who meet the behavioral or laboratory criteria for adult donors (regardless of their HIV status) unless they are greater than 18 months of age, have not been breast fed within the last 12 months and the child's antibody tests, physical examination, and review of medical records do not indicate evidence of HIV infection.~~

~~x) Children less than or equal to 18 months of age who are born to mothers with or at risk for HIV infection or who have been breast fed within the past 12 months.~~

~~Laboratory and Other Medical Criteria~~

~~xi) Persons who cannot be tested for HIV infection because of refusal, inadequate blood samples (e.g., hemodilution that could result in false negative tests), or another other reasons.~~

~~xii) Persons with a repeatedly reactive screening assay for HIV-1 or HIV-2 antibody regardless of the results of supplemental assays.~~

~~xiii) Persons whose history, physical examination, or medical records reveal other evidence of HIV infection or high risk behavior, such as a diagnosis of AIDS, unexplained weight loss, night sweats, blue or purple spots on the skin or mucous membranes typical of Kaposi's sarcoma, unexplained lymphadenopathy lasting greater than 1 month, unexplained temperature greater than 100.5 F (38.6 C) for greater than10 days, unexplained persistent cough and shortness of breath, opportunistic infections, unexplained persistent diarrhea, male to male sexual contact, sexually transmitted diseases, or needle tracks or other signs of parenteral drug abuse.~~

If the transplant center receives information from the Host OPO that the donor meets any of the ~~above~~ criteria set forth in the CDC Guidelines, the transplant center must inform the potential recipient prior to implantation. The transplant center shall maintain documentation of the potential recipient's informed consent to receive an organ from the donor who meets any of the ~~above~~ those criteria. In the event that the

potential recipient is not able to provide informed consent, the legal next of kin, designated healthcare representative, or appropriate surrogate may provide consent on this matter.

Exhibit 3

Modifications to Policies 3.7.5 (Allocation of Adolescent Donor Hearts to Pediatric Heart Candidates) and 3.7.10.1 (Sequence of Adolescent Donor Heart Allocation) *(Pediatric and Thoracic Organ Transplantation Committees)*

Affected Policy Language:

The modifications to current policy appear below. For your convenience in reviewing, new language is underlined and language that is to be removed is ~~stricken through~~. Changes to language resulting from public comment feedback appear with a double underline and/or a ~~double strikethrough~~.

3.7.5 Allocation of ~~Adolescent~~ Pediatric Donor Hearts to Pediatric Heart Candidates. Within each heart status, a heart retrieved from a~~n~~ ~~adolescent~~ pediatric organ donor shall be allocated to a pediatric heart candidate (i.e., less than 18 years old at the time of listing) before the heart is allocated to an adult candidate. For the purpose of Policy 3.7, a~~n~~ ~~adolescent~~ pediatric organ donor is defined as an individual who is ~~11 years of age or older, but less than 18~~ ~~0-17~~ less than 18 years of age.

3.7.10.1 Sequence of ~~Adolescent~~ Pediatric Heart Allocation. ~~Donor~~ ~~h~~Hearts recovered from ~~adolescent~~ pediatric donors shall be allocated in the following sequence in accordance with Policies 3.7.3, 3.7.4, 3.7.5, 3.7.7, 3.7.8, and 3.7.9:

1. Combined Local **and** Zone A Status 1A Pediatric candidates

~~2. Zone A Status 1A Pediatric candidates~~

~~3.~~2. Local Status 1A Adult candidates

~~4.~~3. Combined Local **and** Zone A Status 1B Pediatric candidates

~~5. Zone A Status 1B Pediatric candidates~~

~~6.~~4. Local Status 1B Adult candidates

~~7.~~5. Zone A Status 1A Adult candidates

~~8.~~6. Zone A Status 1B Adult candidates

~~9.~~7. Local Status 2 Pediatric candidates

~~10.~~8. Local Status 2 Adult candidates

~~11.~~9. Zone B Status 1A Pediatric candidates

~~12.~~10. Zone B Status 1A Adult candidates

~~13.~~11. Zone B Status 1B Pediatric candidates

~~14.~~12. Zone B Status 1B Adult candidates

~~15.~~ 13. Zone A Status 2 Pediatric candidates

~~16.~~14. Zone A Status 2 Adult candidates

~~17.~~15. Zone B Status 2 Pediatric candidates

~~18.~~16. Zone B Status 2 Adult candidates

~~19.~~17. Zone C Status 1A Pediatric candidates

~~20.~~18. Zone C Status 1A Adult candidates

~~21.~~19. Zone C Status 1B Pediatric candidates

~~22.~~20. Zone C Status 1B Adult candidates

~~23.~~21. Zone C Status 2 Pediatric candidates

~~24.~~22. Zone C Status 2 Adult candidates

~~25.~~23. Zone D Status 1A Pediatric candidates

~~26.~~24. Zone D Status 1A Adult candidates

~~27.~~25. Zone D Status 1B Pediatric candidates

~~28.~~26. Zone D Status 1B Adult candidates

~~29.~~27. Zone D Status 2 Pediatric candidates

~~30.~~28. Zone D Status 2 Adult candidates

~~31.~~29. Zone E Status 1A Pediatric candidates

~~32.~~30. Zone E Status 1A Adult candidates

~~33.~~31. Zone E Status 1B Pediatric candidates

~~34.~~32. Zone E Status 1B Adult candidates

~~35.~~33. Zone E Status 2 Pediatric candidates

~~36.~~34. Zone E Status 2 Adult candidates

Exhibit 3

To read the complete policy language visit www.unos.org or www.optn.org. From the UNOS Web site, select Resources from the main menu, then select policies. From the OPTN Web site, select Policies from the main menu.

Exhibit 4

Modifications to Policies 3.7.6.2 (Candidates Age 0-11), 3.7.11 (Sequence of Adult Donor Lung Allocation) and 3.7.11.1 (Sequence of Pediatric Donor Lung Allocation) *(Pediatric and Thoracic Organ Transplantation Committees)*

Affected Policy Language:

The modifications to current policy appear below. For your convenience in reviewing, new language is underlined and language that is to be removed is ~~stricken through~~. Changes to language resulting from public comment feedback appear with a double underline and/or a double ~~strikethrough~~.

3.7.6.2 **Candidates Age 0 - 11**. Candidates 0 – 11 years old are assigned priority for lung offers ~~based upon waiting time.~~ according to the status categories defined below. (See Policy 3.7.6.1 for lung allocation to candidates 12 years of age and older.) Within each status, candidates will be ranked by ABO according to Policy 3.7.8.2 and then by waiting time. Status 1 candidates will be ranked in descending order according to the length of time waiting at that status. For Status 2 candidates, total active waiting time (defined for this purpose as beginning when the candidate was added to the waiting list and ending when the lung match run was generated) will be used to rank candidates on the match run.

Clinical data used to justify a candidate's status may be updated at any time a program believes a candidate's medical condition warrants such modifications. Programs must update every candidate variable, except those candidate variables that are obtained only by heart catherization, for Status 1 candidates, at least once every six months after initial listing on the lung waiting list. If at any time, more than six months have elapsed since the last six month "anniversary" date of the candidate's initial listing without an update, then the candidate's status will automatically revert to Status 2.

If multiple candidates have accrued the same amount of time waiting as Status 1, these candidates' total active waiting time will be used to determine priority on the match run for receiving lung offers. The total waiting time is the amount of time spent waiting as a Status 1 *and* Status 2.

Status 1: candidates with one or more of the following criteria:

- **Respiratory failure, defined as:**
  - Requiring continuous ~~Full-time~~ mechanical ventilation;

or,

- o Requiring supplemental oxygen delivered by any means to achieve FiO_2 greater than 50% ~~necessary~~ in order to maintain oxygen saturation levels greater than 90%;

or,

- o Having an arterial or capillary PCO_2 greater than 50 mmHg, or a venous PCO_2 greater than 56mmHg.

- **~~Refractory~~ Pulmonary hypertension, defined as:**
  - o ~~Medical treatment failure (any~~ Exhibiting any of the following, in spite of medical therapy: suprasystemic PA pressure on cardiac catheterization or by echocardiogram estimate, cardiac index less than 2 L/min/M^2, recurrent syncope, or hemoptysis~~) while on 2 or more drugs for pulmonary hypertension~~

    Examples of accepted medical therapy for pulmonary hypertension will be listed in UNet^{SM}. Transplant centers must indicate which of these medical therapies the candidate has received. If the candidate has not received any of the listed therapies, the transplant center must submit an exception request to the Lung Review Board for prospective consideration.

    or,

  - o ~~Candidates with~~ Having pulmonary vein stenosis involving 3 or more vessels.

- **Exceptional cases by prospective submission to the Lung Review Board**

Status 2: ~~all c~~Candidates who do not meet the criteria for Status 1 ~~will~~ must be listed as Status 2.

3.7.9.3 Waiting Time Accrual for Lung Candidates Less than 12 Years of Age.

Candidates listed as a Status 1 or Status 2 will accrue waiting time within each status. When waiting time is used for thoracic organ allocation, a candidate will receive a preference over other candidates who have accumulated less waiting time within the same status category (see Policy 3.7.9). However, a candidate's waiting time accrued while listed as Status 2 will not be used in prioritizing the

candidate for lung allocation if the candidate is upgraded to Status 1.

If multiple candidates have accrued the same amount of time waiting as Status 1, these candidates' total active waiting time will be used to determine priority on the match run for receiving lung offers. The total accrued waiting time is the amount of time spent waiting as a Status 1 *and* Status 2.

3.7.11 **Sequence of Adult Donor Lung Allocation.** Candidates age 12 and older awaiting a lung transplant whether it is a single lung transplant or a double lung transplant will be grouped together for adult (18 years old and older) donor lung allocation. If one lung is allocated to a candidate needing a single lung transplant, the other lung will be then allocated to another candidate waiting for a single lung transplant.

Lungs from adult donors will first be offered to candidates age 12 and older, and then to candidates 0 – 11 years old. Lungs from adult donors will be allocated locally first, then to candidates in Zone A, then to candidates in Zone B, then to candidates in Zone C, then to candidates in Zone D and finally to candidates in Zone E. In each of those six geographic areas, candidates will be grouped so that candidates who have an ABO blood type that is identical to that of the donor are ranked according to applicable allocation priority; the lungs will be allocated in descending order to candidates in that ABO identical type. If the lungs are not allocated to candidates in that ABO identical type, they will be allocated in descending order according to applicable allocation priority to the remaining candidates in that geographic area who have a blood type that is compatible (but not identical) with that of the donor.

In summary, the allocation sequence for adult donor lungs is as follows:

~~i.~~ 1. ~~First locally to~~ Local ABO identical candidates age 12 and older according to Lung Allocation Score in descending order;
~~ii.~~ 2. ~~Next, locally to~~ Local ABO compatible candidates age 12 and older according to Lung Allocation Score in descending order;
~~iii.~~ 3. ~~Next, locally to~~ Local ABO identical Status 1 candidates 0 – 11 years old according to length of waiting time;
~~iv.~~ 4. ~~Next, locally to~~ Local ABO compatible Status 1 candidates 0 – 11 years old according to length of waiting time;
~~v.~~ 5. Local ABO identical Status 2 candidates 0 – 11 years old according to length of waiting time;
~~vi.~~ 6. Local ABO compatible Status 2 candidates 0 – 11 years old according to length of waiting time;
~~vii.~~ 7. ~~Next, to~~ ABO identical candidates age 12 and older in Zone A according to Lung Allocation Score in descending order;
~~viii.~~ 8. ~~Next, to~~ ABO compatible candidates age 12 and older in Zone A according to Lung Allocation Score in descending order;
~~ix.~~ 9. ~~Next, to~~ ABO identical Status 1 candidates 0 – 11 years old in Zone A according to length of waiting time;

~~x.~~10. ~~Next, to~~ ABO compatible Status 1 candidates 0 – 11 years old in Zone A according to length of waiting time;

~~xi.~~11. ABO identical Status 2 candidates 0 – 11 years old in Zone A according to length of waiting time;

~~xii.~~12. ABO compatible Status 2 candidates 0 – 11 years old in Zone A according to length of waiting time;

~~xiii.~~13. ~~Next, to~~ ABO identical candidates age 12 and older in Zone B according to Lung Allocation Score in descending order;

~~xiv.~~14. ~~Next, to~~ ABO compatible candidates age 12 and older in Zone B according to Lung Allocation Score in descending order;

~~xv.~~15. ~~Next, to~~ ABO identical Status 1 candidates 0 – 11 years old in Zone B according to length of waiting time;

~~xvi.~~16. ~~Next, to~~ ABO compatible Status 1 candidates 0 – 11 years old in Zone B according to length of waiting time;

~~xvii.~~17. ABO identical Status 2 candidates 0 – 11 years old in Zone B according to length of waiting time;

~~xviii.~~18. ABO compatible Status 2 candidates 0 – 11 years old in Zone B according to length of waiting time;

~~xix.~~19. ~~Next, to~~ ABO identical candidates age 12 and older in Zone C according to Lung Allocation Score in descending order;

~~xx.~~20. ~~Next, to~~ ABO compatible candidates age 12 and older in Zone C according to Lung Allocation Score in descending order;

~~xxi.~~21. ~~Next, to~~ ABO identical Status 1 candidates 0 – 11 years old in Zone C according to length of waiting time;

~~xxii.~~22. ~~Next, to~~ ABO compatible Status 1 candidates 0 – 11 years old in Zone C according to length of waiting time;

~~xxiii.~~23. ABO identical Status 2 candidates 0 – 11 years old in Zone C according to length of waiting time;

~~xxiv.~~24. ABO compatible Status 2 candidates 0 – 11 years old in Zone C according to length of waiting time;

~~xxv.~~25. ~~Next, to~~ ABO identical candidates age 12 and older in Zone D according to Lung Allocation Score in descending order;

~~xxvi.~~26. ~~Next, to~~ ABO compatible candidates age 12 and older in Zone D according to Lung Allocation Score in descending order;

~~xxvii.~~27. ~~Next, to~~ ABO identical Status 1 candidates 0 – 11 years old in Zone D according to length of waiting time;

~~xxviii.~~28. ~~Next, to~~ ABO compatible Status 1 candidates 0 – 11 years old in Zone D according to length of waiting time~~.;~~

~~xxix.~~29. ABO identical Status 2 candidates 0 – 11 years old in Zone D according to length of waiting time;

~~xxx.~~30. ABO compatible Status 2 candidates 0 – 11 years old in Zone D according to length of waiting time;

~~xxxi.~~31. ~~Next, to~~ ABO identical candidates age 12 and older in Zone E according to Lung Allocation Score in descending order;

~~xxxii.~~32. ~~Next, to~~ ABO compatible candidates age 12 and older in Zone E according to Lung Allocation Score in descending order;

~~xxxiii.~~33. ~~Next, to~~ ABO identical Status 1 candidates 0 – 11 years old in Zone E according to length of waiting time; and

~~xxxiv.~~34. ~~Next, to~~ ABO compatible Status 1 candidates 0 – 11 years old in Zone E according to length of waiting time.

~~xxxv.~~35. ABO identical Status 2 candidates 0 – 11 years old in Zone E according to length of waiting time;

~~xxxvi.~~36. ABO compatible Status 2 candidates 0 – 11 years old in Zone E according to length of waiting time;

3.7.11.1 **Sequence of Pediatric Donor Lung Allocation.** Candidates 0 – 11 years old awaiting a single or double lung transplant will be grouped together for allocation purposes. If one lung is allocated to a candidate waiting for a single lung transplant, the other lung will be then allocated to another candidate waiting for a single lung transplant

Candidates 12 – 17 years old awaiting a single or double lung transplant will be grouped together for pediatric (0 – 17 years old) donor lung allocation. If one lung is allocated to a candidate waiting for a single lung transplant, the other lung will be then allocated to another candidate waiting for a single lung transplant.

Lungs from donors 0 – 11 years old will first be offered to candidates age 0 – 11; then to candidates age 12 – 17; then to candidates 18 years and older. ~~Lungs will be allocated locally first, then to candidates in Zone A, then to candidates in Zone B, then to candidates in Zone C, then to candidates in Zone D, and finally to candidates in Zone E. In each of those six geographic areas, c~~Candidates will be grouped so that ~~candidates~~ those who have an ABO blood type that is identical to that of the donor are ranked according to applicable allocation priority; the lungs will be allocated in descending order to candidates in that ABO identical type. If the lungs are not allocated to candidates in that ABO identical type, they will be allocated in descending order according to applicable allocation priority to the remaining candidates in that geographic area who have a blood type that is compatible (but not identical) with that of the donor.

- Offers for 0-11 year-olds will first be made to **combined** local, Zone A and Zone B candidates by status and waiting time. After adolescent and adult offers are completed through Zone B, offers will continue to these younger candidates in Zones C, D and E prior to adolescents and adults within in each zone.

- Offers for 12-17 year-olds will first be made to **combined** local and Zone A candidates according to lung allocation score in descending order after the completion of 0-11 year-old offers through Zone B. Once adult Zone A offers are completed, offers will continue to adolescent candidates in Zones B, C, D and E after the younger 0-11 candidates and before the adult candidates within each zone.

- Offers to adult candidates (18 years and older) will be made after the completion of 0-11 year old offers through Zone B and adolescent offers through Zone A. After local and Zone A adult offers are completed, offers will continue in Zones B, C, D and E after the completion of all pediatric offers within each zone.

In summary, the allocation sequence for lungs from donors 0-11 years old is as follows:

~~i. First locally to ABO identical candidates 0 – 11 years old according to length of time waiting;~~

~~ii. Next, locally to ABO compatible candidates 0 – 11 years old according to length of time waiting;~~

1. Combined local, Zone A and Zone B ABO identical Status 1 candidates 0-11 years old according to length of waiting time;

2. Combined local, Zone A and Zone B ABO compatible Status 1 candidates 0-11 years old according to length of waiting time;

3. Combined local, Zone A and Zone B ABO identical Status 2 candidates 0-11 years old according to length of waiting time;

4. Combined local, Zone A and Zone B ABO compatible Status 2 candidates 0-11 years old according to length of waiting time;

5. Combined local and Zone A ABO identical candidates 12 – 17 years old according to Lung Allocation Score in descending order;

6. Combined Local and Zone A ABO compatible candidates 12 – 17 years old according to Lung Allocation Score in descending order;

~~iii. Next, locally to ABO identical candidates 12 – 17 years old according to Lung Allocation Score in descending order;~~

~~vii. Next, locally to ABO compatible candidates 12 – 17 years old according to Lung Allocation Score in descending order;~~

~~viii.~~ 7. ~~Next, locally to~~ Local ABO identical candidates 18 years old and older according to Lung Allocation Score in descending order;

~~ix.~~ 8. ~~Next, locally to~~ Local ABO compatible candidates 18 years old and older according to Lung Allocation Score in descending order;

~~vii. Next, to ABO identical candidates 0 – 11 years old in Zone A according to length of time waiting;~~

~~viii. Next, to ABO compatible candidates 0 – 11 years old in Zone A according to length of time waiting;~~

~~ix. Next, to ABO identical candidates 12 – 17 years old in Zone A according to Lung Allocation Score in descending order;~~

~~x. Next, to ABO compatible candidates 12 – 17 years old in Zone A according to Lung Allocation Score in descending order;~~

~~x.~~9. ~~Next, to~~ ABO identical candidates 18 years old and older in Zone A according to Lung Allocation Score in descending order;

~~xi.~~10. ~~Next, to~~ ABO compatible candidates 18 years old and older in Zone A according to Lung Allocation Score in descending order;

~~xiii. Next, to ABO identical candidates 0 – 11 years old in Zone B according to length of time waiting;~~

~~xiv. Next, to ABO compatible candidates 0 – 11 years old in Zone B according to length of time waiting;~~

~~xii.~~11. ~~Next, to~~ ABO identical candidates 12 – 17 years old in Zone B according to Lung Allocation Score in descending order;

~~xiii.~~12. ~~Next, to~~ ABO compatible candidates 12 – 17 years old in Zone B according to Lung Allocation Score in descending order;

~~xiv.~~13. ~~Next, to~~ ABO identical candidates 18 years old and older in Zone B according to Lung Allocation Score in descending order;

~~xv.~~14. ~~Next, to~~ ABO compatible candidates 18 years old and older in Zone B according to Lung Allocation Score in descending order;

~~xvi.~~15. ~~Next, to~~ ABO identical Status 1 candidates 0 – 11 years old in Zone C according to length of time waiting;

~~xvii.~~16. ~~Next, to~~ ABO compatible Status 1 candidates 0 – 11 years old in Zone C according to length of time waiting;

~~xviii.~~ 17. ABO identical Status 2 candidates 0-11 years old in Zone C according to length of waiting time;

18. ABO compatible Status 2 candidates 0-11 years old in Zone C according to length of waiting time;

~~xx.~~19. ~~Next, to~~ ABO identical candidates 12 – 17 years old in Zone C according to Lung Allocation Score in descending order;

~~xxi.~~20. ~~Next, to~~ ABO compatible candidates 12 – 17 years old in Zone C according to Lung Allocation Score in descending order;

~~xxii.~~21. ~~Next, to~~ ABO identical candidates 18 years old and older old in Zone C according to Lung Allocation Score in descending order;

~~xxiii.~~22. ~~Next, to~~ ABO compatible candidates 18 years old and older in Zone C according to Lung Allocation Score in descending order;

~~xxiv.~~23. ~~Next, to~~ ABO identical Status 1 candidates 0 – 11 years old in Zone D according to length of time waiting;

~~xxvi.~~24. ~~Next, to~~ ABO compatible Status 1 candidates 0 – 11 years old in Zone D according to length of time waiting;

25. ABO identical Status 2 candidates 0-11 years old in Zone D according to length of waiting time;

26. ABO compatible Status 2 candidates 0-11 years old in Zone D according to length of waiting time;

~~xxvii.~~27. ~~Next, to~~ ABO identical candidates 12 – 17 years old in Zone D according to Lung Allocation Score in descending order;

~~xxviii.~~28. ~~Next, to~~ ABO compatible candidates 12 – 17 years old in Zone D according to Lung Allocation Score in descending order;

~~xxix.~~29. ~~Next, to~~ ABO identical candidates 18 years old and older in Zone D according to Lung Allocation Score in descending order; and

~~xxx.~~30. ~~Next, to~~ ABO compatible candidates 18 years old and older in Zone D according to Lung Allocation Score in descending order.

~~xxxi.~~31. ~~Next, to~~ ABO identical Status 1 candidates 0 – 11 years old in Zone E according to length of time waiting;

~~xxxii.~~32. ~~Next, to~~ ABO compatible Status 1 candidates 0 – 11 years old in Zone E according to length of time waiting;

33. ABO identical Status 2 candidates 0-11 years old in Zone E according to length of waiting time;

34. ABO compatible Status 2 candidates 0-11 years old in Zone E according to length of waiting time;

~~xxxv.~~35. ~~Next, to~~ ABO identical candidates 12 – 17 years old in Zone E according to Lung Allocation Score in descending order;

~~xxxvi.~~36. ~~Next, to~~ ABO compatible candidates 12 – 17 years old in Zone E according to Lung Allocation Score in descending order;

~~xxxvii.~~ 37. ~~Next, to~~ ABO identical candidates 18 years old and older in Zone E according to Lung Allocation Score in descending order; and

~~xxxviii.~~38. ~~Next, to~~ ABO compatible candidates 18 years old and older in Zone E according to Lung Allocation Score in descending order.

Lungs from donors 12 – 17 years old will first be offered to candidate-s age 12 – 17 years old; then to candidates age 0 – 11; then to candidates 18 years and older. Lungs will be allocated locally first, then to candidates in Zone A, then to candidates in Zone B, then to candidates in Zone C, then to candidates in Zone D and finally to candidates in Zone E.. In each of those six geographic areas, candidates will be grouped so that candidates who have an ABO blood type that is identical to that of the compatible (but not identical) with that of the donor.

In summary, the allocation sequence for lungs from donors 12 – 17 years old is as follows:

~~i.~~1. ~~First locally to~~ Local ABO identical candidates 12 – 17 years old according to Lung Allocation Score in descending order;

~~ii.~~2. ~~Next, locally to~~ Local ABO compatible candidates 12 – 17 years old according to Lung Allocation Score in descending order;

~~iii.~~3. ~~Next, locally to~~ Local ABO identical Status 1 candidates 0 – 11 years old according to length of time waiting;

~~iii.~~4. Local ABO compatible Status 1candidates 0 – 11 years old according to length of time waiting;

5. Local ABO identical Status 2 candidates 0 – 11 years old according to length of time waiting;

6. Local ABO compatible Status 2 candidates 0 – 11 years old according to length of time waiting;

~~vi.~~7. ~~Next, locally to~~ Local ABO identical candidates 18 years old and older according to Lung Allocation Score in descending order;

~~vii.~~8. ~~Next, locally to~~ Local ABO compatible candidates 18 years old and older according to Lung Allocation Score in descending order;

~~viii.~~9. ~~Next, to~~ ABO identical candidates 12 – 17 years old in Zone A according to Lung Allocation Score in descending order;

~~vix.~~10. ~~Next, to~~ ABO compatible candidates 12 – 17 years old in Zone A according to Lung Allocation Score in descending order;

~~x.~~11. ~~Next, to~~ ABO identical Status 1candidates 0 – 11 years old in Zone A according to length of time waiting;

~~xi.~~12. ~~Next, to~~ ABO compatible Status 1candidates 0 – 11 years old in Zone A according to length of time waiting;

~~xii.~~13. ABO identical Status 2 candidates 0 – 11 years old in Zone A according to length of time waiting;

14. ABO compatible Status 2 candidates 0 – 11 years old in Zone A according to length of time waiting;

~~xiv.~~15. ~~Next, to~~ ABO identical candidates 18 years old and older in Zone A according to Lung Allocation Score in descending order;

~~xv.~~16. ~~Next, to~~ ABO compatible candidates 18 years old and older in Zone A according to Lung Allocation Score in descending order;

~~xvi.~~17. ~~Next, to~~ ABO identical candidates 12 – 17 years old in zone B according to Lung Allocation Score in descending order;

~~xvii.~~18. ~~Next, to~~ ABO compatible candidates 12 – 17 years old in zone B according to Lung Allocation Score in descending order;

~~xviii.~~19. ~~Next, to~~ ABO identical Status 1candidates 0 – 11 years old in Zone B according to length of time waiting;

~~xix.~~20. ~~Next, to~~ ABO compatible Status 1candidates 0 – 11 years old in Zone B according to length of time waiting;

21. ABO identical Status 2 candidates 0 – 11 years old in Zone B according to length of time waiting;

22. ABO compatible Status 2 candidates 0 – 11 years old in Zone B according to length of time waiting;

~~xxii.~~23. ~~Next, to~~ ABO identical candidates 18 years old and older in Zone B according to Lung Allocation Score in descending order;

~~xxiii.~~24. ~~Next, to~~ ABO compatible candidates 18 years old and older in Zone B according to Lung Allocation Score in descending order;

~~xxiv.~~25. ~~Next, to~~ ABO identical candidates 12 – 17 years old in zone C according to Lung Allocation Score in descending order;

~~xxv.~~26. ~~Next, to~~ ABO compatible candidates 12 – 17 years old in zone C according to Lung Allocation Score in descending order;

~~xxvi.~~27. ~~Next, to~~ ABO identical Status 1 candidates 0 – 11 years old in Zone C according to length of time waiting;

~~xxvii.~~28. ~~Next, to~~ ABO compatible Status 1 candidates 0 – 11 years old in Zone C according to length of time waiting;

29. ABO identical Status 2 candidates 0 – 11 years old in Zone C according to length of time waiting;

30. ABO compatible Status 2 candidates 0 – 11 years old in Zone C according to length of time waiting;

~~xxx.~~31.~~Next, to~~ ABO identical candidates 18 years old and older old in Zone C according to Lung Allocation Score in descending order;

~~xxxi.~~32. ~~Next, to~~ ABO compatible candidates 18 years old and older in Zone C according to Lung Allocation Score in descending order;

~~xxxii.~~33. ~~Next, to~~ ABO identical candidates 12 – 17 years old in zone D according to Lung Allocation Score in descending order;

~~xxxiii.~~34. ~~Next, to~~ ABO compatible candidates 12 – 17 years old in zone D according to Lung Allocation Score in descending order;

~~xxxiv.~~35. ~~Next, to~~ ABO identical Status 1candidates 0 – 11 years old in Zone D according to length of time waiting;

~~xxxv.~~36. ~~Next, to~~ ABO compatible Status 1 candidates 0 – 11 years old in Zone D according to length of time waiting;

37. ABO identical Status 2 candidates 0 – 11 years old in Zone D according to length of time waiting;

38. ABO compatible Status 2 candidates 0 – 11 years old in Zone D according to length of time waiting;

~~xxxviii.~~39. ~~Next, to~~ ABO identical candidates 18 years old and older in Zone D according to Lung Allocation Score in descending order; and

~~xxxix.~~40. ~~Next, to~~ ABO compatible candidates 18 years old and older in Zone D according to Lung Allocation Score in descending order.

~~xxxx.~~41. ~~Next, to~~ ABO identical candidates 12 – 17 years old in Zone E according to Lung Allocation Score in descending order;

~~xxxxi.~~42. ~~Next, to~~ ABO compatible candidates 12 – 17 years old in Zone E according to Lung Allocation Score in descending order;

~~xxxxii.~~43. ~~Next, to~~ ABO identical Status 1 candidates 0 – 11 years old in Zone E according to length of time waiting;

~~xxxxiii.~~44. ~~Next, to~~ ABO compatible Status 1 candidates 0 – 11 years old in Zone E according to length of time waiting;

45. ABO identical Status 2 candidates 0 – 11 years old in Zone E according to length of time waiting;

46. ABO compatible Status 2 candidates 0 – 11 years old in Zone E according to length of time waiting;

~~xxxxvi.~~47. ~~Next, to~~ ABO identical candidates 18 years old and older in Zone E according to Lung Allocation Score in descending order; and

~~xxxxvii.~~48. ~~Next, to~~ ABO compatible candidates 18 years old and older in Zone E according to Lung Allocation Score in descending order.

To read the complete policy language visit www.unos.org or www.optn.org. From the UNOS Web site, select Resources from the main menu, then select policies. From the OPTN Web site, select Policies from the main menu.

Exhibit 5

Modifications to Policies 3.6 (Allocation of Livers) and 3.11.4.2 (Combined Liver-Intestinal Organs from Donors 0-10 Years of Age) *(Pediatric and Liver and Intestinal Organ Transplantation Committees)*

Affected Policy Language:

The modifications to current policy appear below. For your convenience in reviewing, new language is underlined and language that is to be removed is ~~stricken through~~.

3.6 ALLOCATION OF LIVERS

[…]

0-10 year-old Pediatric Donor Liver Allocation Algorithm

Combined Local and Regional

1. Pediatric Status 1A candidates (age 0-17) in descending point order

National

2. Pediatric Status 1A (age 0-11) in descending point order

~~**Regional**~~

~~2. Pediatric Status 1A candidates (age 0-17) in descending point order~~

Local

3. Adult Status 1A candidates in descending point order

Regional

4. Adult Status 1A candidates in descending point order

Combined Local and Regional

5. Pediatric Status 1B candidates (age 0-17) in descending point order

Regional

~~6. Pediatric Status 1B candidates (age 0-17) in descending point order~~

~~7.~~6. Pediatric Candidates age 0-11 in descending order of mortality risk scores (probability of candidate death)

Local

~~8.~~7. Pediatric candidates age 12-17 with MELD scores of 15 or greater, in descending order of mortality risk scores (probability of candidate death)

~~9.~~8. Adult candidates with MELD scores of 15 or greater, in descending order of mortality risk scores (probability of candidate death)

Regional

~~10.~~9. Pediatric candidates age 12-17 with MELD scores of 15 or greater, in descending order of mortality risk scores (probability of candidate death)

~~11.~~10. Adult candidates with MELD scores of 15 or greater, in descending order of mortality risk scores (probability of candidate death)

Local

~~12.~~11. All other pediatric candidates age 12-17 in descending order of mortality risk scores (probability of candidate death)

~~13.~~12. All other adult candidates in descending order of mortality risk scores (probability of candidate death)

Regional

~~14.~~13. All other pediatric candidates age 12-17 in descending order of mortality risk scores (probability of candidate death)

~~15.~~14. All other adult candidates in descending order of mortality risk scores (probability of candidate death)

National

~~16.~~15. Pediatric Status 1A (age 12-17) candidates in descending point order

~~17.~~16. Adult Status 1A candidates in descending point order

~~18.~~17. Pediatric Status 1B candidates in descending point order

~~19.~~18. All other pediatric candidates age 0-11 in descending order of mortality risk scores (probability of candidate death)

~~20.~~19. All remaining pediatric candidates in descending order of mortality risk scores (probability of candidate death)

~~21.~~20. All remaining adult candidates in descending order of mortality risk scores (probability of candidate death)

11-17 year-old Pediatric Donor Liver Allocation Algorithm

*(Please note, **no changes** are proposed to current pediatric allocation algorithm for adolescent donors. This simply creates language to direct allocation if approval is received that will subdivide pediatric donors into categories for young children and adolescent categories.)*

Local

Exhibit 5

1. Pediatric Status 1A candidates (age 0-17) in descending point order

Regional

2. Pediatric Status 1A candidates (age 0-17) in descending point order

Local

3. Adult Status 1A candidates in descending point order

Regional

4. Adult Status 1A candidates in descending point order

Local

5. Pediatric Status 1B candidates (age 0-17) in descending point order

Regional

6. Pediatric Status 1B candidates (age 0-17) in descending point order
7. Pediatric Candidates age 0-11 in descending order of mortality risk scores (probability of candidate death)

Local

8. Pediatric candidates age 12-17 with MELD scores of 15 or greater, in descending order of mortality risk scores (probability of candidate death)
9. Adult candidates with MELD scores of 15 or greater, in descending order of mortality risk scores (probability of candidate death)

Regional

10. Pediatric candidates age 12-17 with MELD scores of 15 or greater, in descending order of mortality risk scores (probability of candidate death)
11. Adult candidates with MELD scores of 15 or greater, in descending order of mortality risk scores (probability of candidate death)

Local

12. All other pediatric candidates age 12-17 in descending order of mortality risk scores (probability of candidate death)
13. All other adult candidates in descending order of mortality risk score (probability of candidate death)

Regional

14. All other pediatric candidates age 12-17 in descending order of mortality risk scores (probability of candidate death)

15. All other adult candidates in descending order of mortality risk scores (probability of candidate death)

National

16. Pediatric Status 1A candidates in descending point order

17. Adult Status 1A candidates in descending point order
18. Pediatric Status 1B candidates in descending point order

19. All other pediatric candidates age 0-11 in descending order of mortality risk scores (probability of candidate death)

20. All remaining pediatric candidates in descending order of mortality risk scores (probability of candidate death)

21. All remaining adult candidates in descending order of mortality risk scores (probability of candidate death)

3.11.4.2 **Combined Liver-Intestinal Organs from Donors 0-10 Years of Age.** For donors 0-10 years of age, offers will be made using the liver match run with candidates prioritized as follows:

- ~~Pediatric Liver Status 1A or 1B~~
- ~~Regional Liver Candidates with a PELD > 20~~
- ~~National Intestine Candidates with a PELD score~~

Combined Local and Regional

1. Pediatric Status 1A Liver and Liver-Intestine Candidates (age 0-17) in descending point order

National

2. Pediatric Status 1A Liver and Liver-Intestine candidates (age 0-11) in descending point order
3. Pediatric Status 1A Liver-Intestine candidates (age 12-17) in descending point order

Local

4. Adult Status 1A Liver and Liver-Intestine candidates in descending point order

Regional

5. Adult Status 1A Liver and Liver-Intestine candidates in descending point order

Combined Local and Regional

6. Pediatric Status 1B Liver and Liver-Intestine candidates (age 0-17) in descending point order
7. Pediatric Liver and Liver-Intestine candidates (age 0-11) by PELD greater than 20

National

8. Pediatric Status 1B Liver-Intestine candidates (age 0-17) in descending point order
9. Pediatric Liver-Intestine candidates (age 0-11) by PELD greater than 20

Combined Local and Regional

10. Pediatric Liver and Liver-Intestine candidates (age 0-11) by PELD less than or equal to 20

Local

11. Pediatric Liver and Liver-Intestine candidates (age 12-17) by MELD greater than or equal to 15
12. Adult Liver and Liver-Intestine candidates by MELD greater than or equal to 15

Regional

13. Pediatric Liver and Liver-Intestine candidates (age 12-17) by MELD greater than or equal to 15
14. Adult Liver and Liver-Intestine candidates by MELD greater than or equal to 15

Local

15. Other Pediatric Liver and Liver-Intestine candidates (12-17) by MELD
16. Other Adult Liver and Liver-Intestine candidates by MELD

Regional

17. Other Pediatric Liver and Liver-Intestine candidates (12-17) by MELD
18. Other Adult Liver and Liver-Intestine candidates by MELD

National

19. Pediatric Status 1A Liver candidates (age 12-17) in descending point order
20. Adult Status 1A Liver and Liver-Intestine candidates in descending point order
21. Pediatric Status 1B Liver candidates (age 0-17) in descending point order
22. Other Pediatric Liver and Liver-Intestine candidates (0-11) by PELD
23. Remaining Pediatric Liver and Liver-Intestine candidates (0-17) by MELD/PELD
24. Remaining Adult Liver and Liver-Intestine candidates by MELD

Exhibit 6

Modifications to Policy 3.6.4.1 (Adult Candidate Status) (Liver and Intestinal Organ Transplantation Committee)

Affected Policy Language:

For your convenience in reviewing, new language is underlined and language that is to be removed is ~~stricken through~~.

3.6.4.1 Adult Candidate Status. Medical urgency is assigned to an adult liver transplant candidate (greater than or equal to 18 years of age) based on either the criteria defined below for Status 1A, or the candidate's mortality risk score as determined by the prognostic factors specified in Table 1 and calculated in accordance with the MELD Scoring System. A candidate who does not have a MELD score that, in the judgment of the candidate's transplant physician, appropriately reflects the candidate's medical urgency, may nevertheless be assigned a higher MELD score upon application by his/her transplant physician(s) and justification to the applicable Regional Review Board that the candidate is considered, by consensus medical judgment, using accepted medical criteria, to have an urgency and potential for benefit comparable to that of other candidates having the higher MELD score. The justification must include a rationale for incorporating the exceptional case as part of MELD calculation. A report of the decision of the Regional Review Board and the basis for it shall be forwarded to for review by the Liver and Intestinal Organ Transplantation and Membership and Professional Standards Committees to determine consistency in application among and within Regions and continued appropriateness of the MELD criteria.

Status	Definition
7	A candidate listed as Status 7 is temporarily inactive. Candidates who are considered to be temporarily unsuitable transplant candidates are listed as Status 7, temporarily inactive.
1A	A candidate greater than or equal to 18 years of age listed as Status 1A has fulminant liver failure with a life expectancy without a liver transplant of less than 7 days. For the purpose of Policy 3.6, fulminant liver failure shall be defined as described in (i)-(iv). Centers that list candidates not meeting these criteria for Status 1A will have the case retrospectively reviewed by the Regional Review Board (RRB). Cases not resolved at the

regional level will[1] be referred to the Liver and Intestinal Organ Transplantation Committee for review; this review by the Liver and Intestinal Organ Transplantation Committee may result in further referral of the matter to the Membership and Professional Standards Committee for appropriate action in accordance with Appendix A of the Bylaws. Candidates meeting the criteria in (i)-(iv) will be listed in Status 1A without RRB review.

(i) fulminant hepatic failure defined as the onset of hepatic encephalopathy within 8 weeks of the first symptoms of liver disease. The absence of pre-existing liver disease is critical to the diagnosis. One of three criteria below must be met to list an adult candidate, who must be in the ICU, with fulminant liver failure: (1) ventilator dependence (2) requiring dialysis or continuous veno-venous hemofiltration (CVVH) or continuous veno-venous hemodialysis (CVVD) or (3) INR > 2.0, or

(ii) primary non-function of a transplanted liver within 7 days of implantation; as defined by (a) or (b):

(a) AST ≥ 3,000 and one or both of the following:

- an INR ≥ 2.5
- Acidosis, defined as having an arterial pH ≤ 7.30 or venous pH of 7.25 and/or Lactate ≥ 4 mMol/L

(b) Anhepatic candidate, or

(iii) hepatic artery thrombosis in a transplanted liver within 7 days of implantation, with evidence of severe liver injury as defined in (ii(a)) and (ii(b)) above; Candidates with HAT in a transplanted liver within 14 days of implantation not meeting the above criteria will be listed at a MELD of 40; or

[1] ***NOTE: This modification to Policy 3.6.4.1 (Adult Candidate Status) shall be effective pending distribution of appropriate notice and programming in UNet^{SM}. (Approved Dec. 2006)***

(iv) acute decompensated Wilson's disease.

For (ii) and (iii), all labs must be from the same blood draw within 24 hours to 7 days following the transplant. For (ii)(a), there is no AST requirement for recipients of segmental grafts from deceased or living donors.

Candidates who are listed as a Status 1A automatically revert back to their most recent MELD Score after 7 days unless these candidates are relisted as Status 1A by an attending physician. Candidates must be listed with MELD laboratory values in accordance with Policy 3.6.4.1.1 (Adult Candidate Recertification and Reassessment Schedule) at the time of listing. A completed Liver Status 1A Justification Form must be submitted on UNet^{SM} for a candidate's original listing as a Status 1A and each relisting as a Status 1A. If a completed Liver Status 1A Justification Form is not entered into UNet^{SM} when a candidate is registered as a Status 1A, the candidate shall be reassigned to their most recent MELD score. A relisting request to continue a Status 1A listing for the same candidate waiting on that specific transplant beyond 14 days accumulated time will result in a review of all local Status 1A liver candidate listings.

All other adult liver transplant candidates on the Waiting List shall be assigned a mortality risk score calculated in accordance with the MELD scoring system. For each liver candidate registration, the listing transplant center shall enter data on UNet^{SM} for the prognostic factors specified in Table 1. These data must be based on the most recent clinical information (e.g., laboratory test results and diagnosis) and include the dates of the laboratory tests.

Table 1

Model for End-Stage Liver Disease (MELD) Scoring System

Prognostic Factor	Regression Coefficient	Std. Error	*P*
Serum creatinine (Log_e value)	**0.957**	**0.142**	**<0.01**
Serum bilirubin (Log_e value)	**0.378**	**0.117**	**<0.01**
INR (Log_e value)	**1.120**	**0.331**	**<0.01**

* The maximum serum creatinine considered within the MELD score equation will be 4.0mg/dl (i.e., for candidates with a serum creatinine of greater than 4.0 mg/dl, the serum creatinine level will be set to 4.0 mg/dl). For candidates on dialysis, defined as having 2 or more dialysis treatments within the prior

week, or candidates who have received 24 hours of CVVHD within the prior week, the serum creatinine level will automatically be set to 4.0 mg/dl.

Using these prognostic factors and regression coefficients, the UNet^{SM} shall assign a MELD score for each candidate based on the following calculation:

MELD Score = 0.957 x Log_e(creatinine mg/dL) + 0. 378 x Log_e(bilirubin mg/dL) + 1.120 x Log_e (INR) + 0.643

Laboratory values less than 1.0 will be set to 1.0 for the purposes of the MELD score calculation.

As an example, for a hypothetical candidate with cirrhosis caused by hepatitis C virus who has a serum creatinine concentration of 1.9 mg/dL, a serum bilirubin concentration of 4.2 mg/dL and an INR value of 1.2, the risk score would be calculated as follows:

MELD Score= (0.957 x Log_e1.9) + (0.378 x Log_e4.2) + (1.120 x Log_e1.2) + 0.643= 2.0039

The MELD score for each liver transplant candidate derived from this calculation shall be rounded to the tenth decimal place and then multiplied by 10. The hypothetical candidate in the example described above, therefore, would be assigned a risk score of 20. The MELD score will be limited to a total of 40 points maximum.

(No further changes to policy text)

Exhibit 7

Clarification of Combined Liver-Intestine Allocation Policy (Liver and Intestinal Organ Transplantation Committee)

Affected Policy Language:

For your convenience in reviewing, new language is underlined and language that is to be removed is ~~stricken through~~.

3.11.4 Combined Intestine-Liver ~~Organ Candidates~~Allocation. For ~~candidates awaiting a~~ combined intestine-liver allocation ~~transplant~~, the liver ~~may be allocated by the local OPO to a local, regional, or national intestine recipient based upon priority for receipt of the intestine using the intestine Waiting List unless there is a Status 1A or 1B liver candidate locally, regionally, or nationally.~~ must first be offered:

- according to the liver match run
- sequentially to **each** potential liver recipient (including all MELD/PELD potential recipients) through national Status 1A and 1B offers.

The liver may then be offered to combined liver-intestine potential recipients sequentially according to the intestine match run.

3.6.4.7 Combined Liver-Intestine Candidates. Candidates awaiting a combined liver-intestine transplant who are registered and active on both waiting lists will automatically receive an additional increase in their MELD/PELD score equivalent to a 10% risk of 3-month mortality. Candidates age 0-17 will receive a 23 point increase in their calculated MELD/PELD score instead of the 10% increase. The center must verify that an intestinal transplant is required and took place.

3.6.4.8 Combined Liver-Intestine Allocation. For combined liver-intestine allocation, the liver must first be offered:

- according to the liver match run
- sequentially to **each** potential liver recipient (including all MELD/PELD potential recipients) through national Status 1A and 1B offers.

The liver may then be offered to combined liver-intestine potential recipients sequentially according to the intestine match run.

3.9.3 Organ Allocation to Multiple Organ Transplant Candidates. Candidates for a multiple organ transplant where one of the required organs is a heart, lung or liver shall be registered on the individual Waiting list for each organ. When the candidate is eligible to receive a heart, lung or liver pursuant to Policies 3.6 (ALLOCATION OF LIVERS) and 3.7 (ALLOCATION OF THORACIC ORGANS) or an approved variance to these policies, the second required organ shall be allocated to the multiple organ candidate from the same donor if the donor is located with the same local organ distribution unit where the multiple organ candidate is registered. If the multiple organ candidate is on a waiting list outside the local organ distribution unit where the donor is located, voluntary sharing of the second organ is recommended. When the second organ is shared, the same organ of an identical blood type shall be paid back to the Host OPO from the next acceptable donor procured by the recipient OPO, unless the second organ is a kidney in which case the organ shall be paid back pursuant to Policy 3.5.4 (Payback Requirements). This policy shall not apply to the allocation of heart-lung combinations. Heart-lung combinations shall be allocated in accordance with Policy 3.7.7 (Allocation of Thoracic Organs to Heart-Lung Candidates) and all other applicable provisions of Policy 3.7, or an approved variance to these policies. For candidates awaiting a combined liver-intestine transplant, ~~the liver may be allocated using the intestine list unless there is a Status 1 Liver candidate in the Region~~ please refer to Policy 3.11.4 or Policy 3.6.4.8.

Clarification to existing policies regarding access to the Match System (UNet^{SM}) *(Executive Committee)*

Affected Policy Language:

For your convenience in reviewing, new language is underlined and language that is to be removed is ~~stricken through~~.

~~**3.2.1.2 Prohibition of Access by Non-Members**. Only Members will be permitted to have access to the "Match System", which matches donors with waiting potential recipients for the purpose of organ allocation. Members shall neither allow non-members access to the Match System nor use the Match System on behalf of non-members.~~

3.2.1.2 Permissible Access to UNet^{sm}. The purpose of this policy is to protect confidential and/or sensitive information in UNet^{sm}. UNet^{sm} is the web-based electronic utility used by the OPTN Contractor to conduct the business of the OPTN. UNet^{sm} is comprised of the Match System, all computer software, applications, and security architecture utilized by the OPTN Contractor to fulfill the responsibilities of the OPTN. Institutional Members are permitted access to the Match System. Institutional Members may not allow non-members access to the Match System nor use the Match System on behalf of non members unless all of the following criteria are met:

i) the non member is a third party assisting the Institutional Member with: facilitating transplants, placing organs for purposes other than transplantation, or reporting data to the OPTN; and

ii) the member institution has in place a data use agreement (DUA) with the third party that thoroughly addresses issues of confidentiality and security. At a minimum, the DUA must include the following elements:

a. rights in data;
b. access to patient-identified data;
c. use of data;
d. data confidentiality procedures;
e. disposition of data upon completion of contracted task;
f. procedures to protect patient-identified data in the event of a breach, inadvertent or otherwise; and
g. remedies in the event of a violation of the data use agreement.

The member institution must maintain a copy of this DUA and provide it to the OPTN contractor upon request.

To read the complete policy language visit www.unos.org or www.optn.org. From the UNOS Web site, select Resources from the main menu, then select policies. From the OPTN Web site, select Policies from the main menu.

Exhibit 9

Modifications to requirements for mandatory sharing of zero antigen mismatch kidneys, Policy 3.5.3 (Mandatory Sharing of Zero Antigen Mismatched Kidneys) *(Kidney Transplantation Committee)*

Affected Policy Language:

The modifications to policy 3.5.3 (Mandatory Sharing of Zero Antigen Mismatched Kidneys) appear below. For your convenience in reviewing, new language is underlined and language that is to be removed is ~~stricken through~~. Due to the underlining, it may appear that the sensitization level introduced is CPRA greater than or equal to 20%. Please be aware that the value is actually **CPRA greater than 20%**.

3.5.3 **Mandatory Sharing of Zero Antigen Mismatched Kidneys.** The following policies apply to allocation of any deceased expanded criteria or standard donor kidney for which there is ~~a candidate~~ a pediatric candidate or a sensitized adult candidate (CPRA>20%) on the Waiting List with a zero antigen mismatch:

3.5.3.1 Definition. A zero antigen mismatch is defined as occurring when a candidate on the Waiting List has an ABO blood type that is compatible with that of the donor and the candidate and donor both have all six of the same HLA-A, B, and DR antigens. A zero antigen mismatch is also defined as a match occurring when there is phenotypic identity between the donor and recipient with regard to HLA, A, B, and DR antigens when at least one antigen is identified at each locus. Phenotypic identity means that the donor and candidate each has the same antigens identified at each pair of A, B, and DR HLA loci. Candidates with only one antigen identified at an HLA locus (A, B, or DR) are presumed "homozygous" at that locus (i.e. homologous chromosomes are presumed to code for identical antigens at that locus). For example, a donor or candidate typed as A2, A- (blank) would be considered A2, A2. A zero antigen mismatch would also include cases where both antigens are identified at a locus in the candidate but the donor is typed as being homozygous for one of the candidate's antigens at that locus. For example, there would be a zero antigen mismatch if the recipient were typed as A1, A31, B8, B14, DR3, DR4 and the donor were typed as A1.A- (blank), B8, B14. DR3, DR-(blank). If the donor is homozygous at any A, B, or DR locus, the match can be said to be a zero antigen mismatch, as long as none of the identified A, B, or DR donor antigens are different from those of the recipient.

3.5.3.2 Computer Entry. Information regarding each and every deceased kidney donor must be entered into UNet^{SM} prior to kidney allocation, to

determine whether there is a zero antigen mismatch between the donor and any candidate on the Waiting List. Pre-procurement tissue typing is expected consistent with Policy 2.7 (Expedited Organ Procurement and Placement) in allocating expanded criteria donor kidneys. In the absence of pre-procurement tissue typing, allocation of expanded criteria donor kidneys shall proceed pursuant to Policy 3.5.12 according to candidate waiting time. If pre-procurement tissue typing is not initiated, the Host OPO shall provide a written explanation of the reasons to the OPTN contractor.

3.5.3.3 Sharing. With the exception of deceased kidneys procured for simultaneous kidney and non-renal organ transplantation as described in Policy 3.5.3.4, and deceased kidneys procured from Donation after Cardiac Death donors[1] if there is ~~any candidate~~ a pediatric candidate or a sensitized adult candidate (CPRA>20%) on the Waiting List for whom there is a zero antigen mismatch with a standard donor, the kidney(s) from that donor shall be offered to the appropriate OPTN Member for the candidate with the zero antigen mismatch subject to time limitations for such organ offers set forth in Policy 3.5.3.5. With the exception of deceased kidneys procured for simultaneous kidney and non-renal organ transplantation as described in Policy 3.5.3.4, and deceased kidneys procured from Donation after Cardiac Death donors[1], if there is ~~any candidate~~ a pediatric candidate or a sensitized adult candidate (CPRA>20%) on the Waiting List who has agreed to receive expanded criteria donor kidneys for whom there is a zero antigen mismatch with an expanded criteria donor, the kidney(s) from that donor shall be offered to the appropriate OPTN Member for the candidate with the zero antigen mismatch who has agreed to be transplanted with expanded criteria donor kidneys subject to time limitations for such organ offers set forth in Policy 3.5.3.5. If both donor kidneys are transplantable, the recipient center that was offered the kidney for a candidate with a zero antigen mismatch does not have the implicit right to choose between the two kidneys.

The final decision as to which of the two kidneys is to be shared rests with the Host OPO. In lieu of the four additional points for a candidate with a PRA of 80% or higher and a preliminary negative crossmatch (Policy 3.5.11.3) four additional points will be added to all candidates for whom there is a zero antigen mismatch with a standard donor and whose PRA is 80% or higher regardless of preliminary crossmatch results. For kidneys procured from Donation after Cardiac Death donors, if there is any candidate on the Waiting List for whom there is a zero antigen mismatch with the donor, the kidney(s) from that donor shall be offered to the appropriate OPTN Member for the candidate listed locally with the

zero antigen mismatch, by blood group identical and then compatible; then to all other local candidates in point sequence according to Policy 3.5.11 (The Point System for Kidney Allocation) or 3.5.12 (The Point System for Expanded Criteria Donor Kidney Allocation) depending upon whether the donor is standard or defined by expanded criteria; then to regional and then national pediatric or sensitized adult candidates (CPRA>20%) in point sequence according to Policy 3.5.11 (The Point System for Kidney Allocation) or 3.5.12 (The Point System for Expanded Criteria Donor Kidney Allocation) depending upon whether the donor is standard or defined by expanded criteria. When multiple zero antigen mismatches are found for a single donor, the allocation will be in the following sequence:

[1]For purposes of Policy 3.5 (Allocation of Deceased Kidneys), Donation after Cardiac Death donors shall be defined as follows: (1) A controlled Donation after Cardiac Death donor is a donor whose life support will be withdrawn and whose family has given written consent for organ donation in the controlled environment of the operating room; (2) An uncontrolled Donation after Cardiac Death donor is a candidate who expires in the emergency room or elsewhere in the hospital before consent for organ donation is obtained and catheters are placed in the femoral vessels and peritoneum to cool organs until consent can be obtained. Also, an uncontrolled Donation after Cardiac Death donor is a candidate who is consented for organ donation but suffers a cardiac arrest requiring CPR during procurement of the organs.

3.5.3.3.1 First to identical blood type zero antigen mismatched candidates in descending point sequence in the case of standard donor kidneys, and by waiting time in the case of expanded criteria donor kidneys, as follows:

i local candidates; then to

ii 80% or higher PRA candidates on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5; then to

iii 80% or higher PRA candidates on the regional waiting list; then to

iv 80% or higher PRA candidates on the national waiting list; then to

v less than 80% PRA candidates who are less than 18 years old on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5; then to

vi less than 80% PRA candidates who are less than 18 years old on the regional waiting list; then to

vii less than 80% PRA candidates who are less than 18 years old on the national waiting list; then to

viii 21%-79% PRA candidates on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5; then to

ix 21%-79% PRA candidates on the regional waiting list; then to

x 21%-79% PRA candidates on the national waiting list; ~~then to~~

xi ~~less than or equal to 20% PRA candidates on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5, except for candidates on the list of OPOs that owe ten or more short-term payback obligations and/or do not meet applicable thresholds for reducing long-term debt (please see Policy 3.5.5.2 (Kidney Payback Debt Limit) for definitions of "short-term" and "long-term" debt); then to~~

~~xii less than or equal to 20% PRA candidates on the regional waiting list, except for candidates on the list of OPOs that owe ten or more short-term payback obligations and/or do not meet applicable thresholds for reducing long-term debt (please see Policy 3.5.5.2 (Kidney Payback Debt Limit) for definitions of "short-term" and "long-term" debt); then to~~

~~xiii less than or equal to 20% PRA candidates on the national waiting list, except for candidates on the list of OPOs that owe ten or more short-term payback obligations and/or do not meet applicable thresholds for reducing long-term debt (please see Policy 3.5.5.2 (Kidney Payback Debt Limit) for definitions of "short-term" and "long-term" debt); then to~~

3.5.3.3.2 Next (1) in the case of blood type O donor kidneys, to blood type B zero antigen mismatched candidates, first, in descending point sequence in the case of standard donor kidneys, and by waiting time in the case of expanded criteria donor kidneys, as set forth in (i)-(xiv) below, and, then, to blood type A and AB zero antigen mismatched candidates, also in descending point sequence in the case of standard donor kidneys, and by waiting time in the case of expanded criteria donor kidneys, as set forth in (i)-(xiv) below, and (2) in the case of blood type A, B, and AB donor kidneys, to ~~all~~ all pediatric and sensitized adult candidates (CPRA > 20%) who are ~~compatible blood type~~ blood type compatible zero antigen mismatched candidates in descending point sequence in the case of standard donor kidneys, and by waiting time in the case of expanded criteria donor kidneys, as set forth in (i)-(xiv) below:

i local candidates; then to

ii 80% or higher PRA candidates on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5; then to

iii 80% or higher PRA candidates on the regional waiting list; then to

iv 80% or higher PRA candidates on the national waiting list; then to

v less than 80% PRA candidates who are less than 18 years old on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5; then to

vi less than 80% PRA candidates who are less than 18 years old on the regional waiting list; then to

vii less than 80% PRA candidates who are less than 18 years old on the national waiting list; then to

viii 21%-79% PRA candidates on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5; then to

ix 21%-79% PRA candidates on the regional waiting list; then to

x 21%-79% PRA candidates on the national waiting list; then to

xi ~~less than or equal to 20% PRA candidates on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5, except for candidates on the list of OPOs that owe ten or more short-term payback obligations and/or do not meet applicable thresholds for reducing long-term debt (please see Policy 3.5.5.2 (Kidney Payback Debt Limit) for definitions of "short-term" and "long-term" debt); then to~~

~~xii less than or equal to 20% PRA candidates on the regional waiting list, except for candidates on the list of OPOs that owe ten or more short-term payback obligations and/or do not meet applicable thresholds for reducing long-term debt (please see Policy 3.5.5.2 (Kidney Payback Debt Limit) for definitions of "short-term" and "long-term" debt); then to~~

~~xiii less than or equal to 20% PRA candidates on the national waiting list, except for candidates on the list of OPOs that owe ten or more short-term payback obligations and/or do not meet applicable thresholds for reducing long-term debt (please see Policy 3.5.5.2 (Kidney Payback Debt Limit) for definitions of "short-term" and "long-term" debt); then to~~

~~xiv less than or equal to 20% PRA candidates on the list of OPOs that owe ten or more short-term payback obligations and/or do not meet applicable thresholds for reducing long-term debt (please see Policy 3.5.5.2 (Kidney Payback Debt Limit) for definitions of "short-term" and "long-term" debt), ranked by OPO in inverse order of the highest number of payback obligations owed by the OPO if more than one OPO is in this category.~~

Exhibit 9

To read the complete policy language visit www.unos.org or www.optn.org. From the UNOS Web site, select Resources from the main menu, then select policies. From the OPTN Web site, select Policies from the main menu.

Exhibit 10

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) (Operations Committee)

Affected Policy Language:

The modifications to Policy 3.5.3.3 (Organ Offer Limit), Policy 3.8.1.7.1 (Time Limit), and Policy 7.6.1.2 (Validation of Offers of Organs Placed through the Organ Center) appear below. For your convenience in reviewing, the new policy language is the existing language with new language double underlined and language that is to be removed with ~~double strikethroughs~~. Language with a single underline or a ~~single strikethrough~~ was changed by the Board of Directors at a previous Board meeting but has not been implemented yet.

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 UNet[sm] 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 recipients[1] ~~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~~ must either:

- 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

[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.

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, 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 UNet^{sm}, 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 UNet^{sm}. 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 UNet^{sm}. (Approved at the September 2007 Board of Directors Meeting)

3.8.1.~~6~~7.1 ~~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 UNet[sm] 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 recipients[2] 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~~ must either:

- 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 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 UNet[sm], 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 UNet[sm]. 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.

[2] For the purposes of Policy 3.8.1.~~6~~7.1, zero antigen mismatched potential recipients are zero antigen mismatched potential recipients who appear in the zero antigen mismatch classification on the match run.

NOTE 1: The amendments to Policy 3.8.1 (Pancreas Organ Allocation) shall be implemented pending appropriate notice and programming in UNet℠. (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 UNet℠ for this purpose.

Proposal to Allow an Additional Method for Waiting Time Reinstatement for Pancreas Recipients
(Pancreas Transplantation Committee)

Affected Policy Language:

For your convenience in reviewing, new language is underlined and language that is to be removed is ~~stricken through~~.

3.8.~~7~~8 Waiting Time Reinstatement for Pancreas Recipients. In those instances where there is immediate and permanent non-function of a transplanted deceased or living donor pancreas, the candidate may be reinstated to the waiting list and retain the previously accumulated waiting time without interruption for that transplant only. For purposes of this policy, immediate and permanent non-function shall be defined as pancreas graft failure ~~resulting in~~ requiring the removal of the organ within the first two weeks of transplant. Waiting time will be reinstated upon receipt by the Organ Center of ~~a completed Pancreas Waiting Time Reinstatement Form and documentation, including but not limited to, the candidate operative report~~

- A completed Pancreas Waiting Time Reinstatement Form, and
- A pancreatectomy operative report

OR

- A completed Pancreas Waiting Time Reinstatement Form, and
- A statement of intent from the transplant center to perform a pancreatectomy, and
- A statement that there is documented, radiographic evidence indicating that the transplanted pancreas has failed. This documentation must be maintained and submitted upon request.

~~The OPTN contractor will notify the OPO serving the recipient transplant center of the relisting and forward a copy of the relisting form to that OPO.~~

The Organ Center will send a notice of waiting time reinstatement to the transplant center involved.

To read the complete policy language visit www.unos.org or www.optn.org. From the UNOS Web site, select Resources from the main menu, then select policies. From the OPTN Web site, select Policies from the main menu.

OPTN The Organ Procurement and Transplantation Network

UNOS DONATE LIFE
UNITED NETWORK FOR ORGAN SHARING

Guidance for the Development of Program-Specific Living Kidney Donor Medical Evaluation Protocols

Summary and Goals

On June 16, 2006, HRSA published a notice in the Federal Register in which the Secretary of HHS directed the OPTN to develop policies regarding living organ donors and organ donor recipients. The notice stipulated that noncompliance with such policies will subject OPTN members to the same consequences as noncompliance with OPTN policies regarding deceased donor transplantation. In response, the Board of Directors adopted changes to the Bylaws requiring transplant programs that perform living donor transplants to develop and follow written protocols that address all phases of the living donation process, including the evaluation, pre-operative, operative, and post-operative care, as well as the submission of data.[1]

To assist members, the Living Donor Committee developed a non-exhaustive set of elements to serve as a resource that could be used by transplant programs in developing their own program specific living kidney donor medical evaluation protocols, as required by the Bylaws. Since this resource is not considered OPTN or UNOS policy, it does not carry the monitoring or enforcement implications of policy. It is not an official guideline for clinical practice, and it is not intended to be clinically prescriptive or to define a standard of care. This resource will not be used to determine member compliance with policies or Bylaws; rather it is a resource being provided to the members for examples and amplification of the elements mentioned in the Bylaws. It is intended for members' voluntary use.

Both new and existing living donor transplant programs can use this guidance when developing medical evaluation protocols for their potential living donors. A parallel document will be developed for use by potential donors and the public.

I. Pre-evaluation Guidance

While it must be recognized that each potential donor is unique, and no single evaluation protocol is applicable to all living donors, the potential living donor should be informed about all phases of the transplant center's evaluation protocol. The donor evaluation includes psychosocial and medical components. These evaluations should help determine if an individual is a suitable donor. The psychosocial evaluation should determine the presence of psychosocial problems that might complicate donation (e.g., lack of social support to aid in their post operative recovery). The medical evaluation

may uncover conditions that could significantly increase the risk of donation to the potential donor. The evaluation should also screen for diseases that the donor could

transmit to the potential recipient, particularly in the presence of immunosuppression. Lastly, this evaluation should define the anatomy of the potential organ so the surgical team can assess the anatomical suitability of the organ and properly plan the surgery.

To the extent possible, the potential donor and the intended recipient should be made aware of the alternatives to living donor transplantation prior to beginning the donor evaluation. Both the potential donor and intended recipient should be informed of the donor and recipient outcomes of living donor transplantation nationally and at the particular institution.

It is important to inform the potential donor that he/she can stop the evaluation or donation process at any time. If a potential donor chooses to not proceed with the evaluation or donation process, the center may state that the donor did not meet the program's criteria for donation to help avoid difficult social situations.

Donor Risk

Living kidney donation involves risk.

Most of the risks and complications associated with the donor nephrectomy procedure occur in the peri-operative period, are relatively well known, and can include:

- Risks associated with anesthesia;
- Surgical complications such as pain, infection, blood loss, blood clots; and
- Death - the risk of dying from living donor surgery is 0.04%.

Further study comparing the risk of ESRD in the general public to that in living kidney donors is needed. Since there has been no national systematic long-term data collection on the risks associated with living organ donation, the risk of renal dysfunction for the living kidney donor is not well known. However, recent OPTN data do reveal:

- The risk of end stage kidney disease, and the need for dialysis or to receive a kidney transplant is between 0.10 to 0.52%;

- This risk may be higher if the prospective donor is African American;

- Between January, 1996 and February, 2008, there were 172 kidney waiting list candidates identified to be previous living kidney donors. The median time from donation to listing was 19 years.

The concern about the long-term risk of donation has to be balanced against the benefit of transplantation for the recipient.

It is clear that those patients who remain on dialysis have an increased risk of death as compared to patients who are transplanted. Furthermore, there is strong evidence that the longer a transplant candidate remains on dialysis, the greater the risk of graft loss and mortality after transplantation.

The potential donor and the medical team should discuss these risks and whether the risk of nephrectomy to the living donor is warranted in comparison to the benefit the recipient receives from transplantation.

Risks of Donor Evaluation

Risk's is associated with medical screening may include:

- Contrast materials used in abdominal imaging may cause mild to severe allergic reaction;
- Both risks and benefits may result from medical testing. The evaluation may lead to the early discovery of infections or malignancies unknown to the potential donor;
- Positive test results for some infections must be reported by law to health agencies;
- HLA testing could reveal the true identity of family relationships, and create issues that the donor or other family members may not wish exposed; and
- Testing may bring unexpected decisions for the donor and medical team as well as the need for additional testing and treatments that may be the financial responsibility of the donor or donor's insurance.

Physician knowledge and experience are important components in this process. The involved professionals' medical judgment will always need to direct the course of the evaluation. The health care team should be judicious in the choice of screening tests and circumspect in the interpretation of the positive findings.

Decision Regarding Donation

The final decision regarding whether the donor can donate an organ is based upon:

- the medical test results;
- the donor's psychosocial evaluation;
- the relationship of the donor to the prospective recipient and;

- assessment of risk based upon current medical knowledge.

The donor should make the decision to donate in concurrence with the independent donor advocate and the medical team.

If a decision to donate is made, the recipient should be consulted to determine if transplantation should proceed. Under these circumstances, both the donor and recipient should be informed of the risks of both procedures given the specifics of the donor and recipient circumstances (e.g. severity of recipient illness, donor anatomy, etc).

Prospective living donors may be willing to undergo varying degrees of personal risk to provide an organ needed by a transplant candidate, and this difference needs to be taken into consideration.

Transplant candidates may be willing to undergo varying degrees of communicable disease and organ quality risk from acceptance of the prospective living donor's gift of his or her organ.

II. Evaluation Guidance

This document presents a list of tests and procedures that may be necessary to assess the medical and psychosocial suitability of the donor.

To date, there have been no randomized controlled trials to determine the testing required for the evaluation of a living kidney donors. The process described here is representative of general medical practice for the assessment of living donors at existing practices at US transplant programs.

This list should be viewed as suggestive and opinions will vary. The list will require modification over time as improved screening tests become available. At all times, the transplant program should assess the risk of the screening procedures versus the benefit of the information derived.

Psychosocial Evaluation

As required by the Bylaws, this evaluation be performed by a psychiatrist, psychologist or social worker with experience in transplantation. The psychosocial evaluation should:

- Review psychosocial issues that might complicate the living donor's recovery and identify potential risks for poor psychosocial outcome;

- Attempt to identify factors that warrant educational or therapeutic intervention prior to donation and provide the necessary referrals for further psychological or psychiatric evaluation if current or prior psychiatric disorders are suspected;

- Determine if the potential donor understands the short- and long-term medical risks associated with living donation as currently understood with the information available;

- Allow the transplant program to explore the reason(s) for volunteering to donate to determine that the decision is free of coercion;

- Determine if the potential donor is able to make an informed decision and has the ability to cope with the major surgery and related stress. This includes a realistic plan for donation and recovery, with social, emotional and financial support available as needed;

- Review the financial circumstances of the potential donor (employment, insurance coverage, etc) and determine if the potential donor understands the possible financial implications of living donation and the availability of financial resources where applicable;

- Inform the donor that he/she may experience problems in obtaining future disability and health insurance following donation; and

- Inform the donor that health information obtained during their evaluation will be subject to the same regulations as regular medical records and may not be additionally protected.

To protect the potential donor, the most sensitive questions should be asked at the end of the psychosocial evaluation, which prevents recording responses to very sensitive questions in the medical record of inappropriate candidates.

DONOR MEDICAL EVALUATION

The OPTN/UNOS Bylaws state that a thorough medical evaluation be performed by a physician or surgeon experienced in living donation. The goal of the medical evaluation is to:

- Assess the immunologic compatibility of the donor to the recipient;
- Assess the general health and surgical risk of the donor including screening for conditions that may predict complications from having one kidney in the future;
- Determine if there are diseases present that may be transmitted from donor to recipient; and
- Assess the anatomy of the kidneys.

The OPT/UNOS Living Donor Committee, in consultation with experts, will at the appropriate time, review and update the guidance in this document.

Components of the Medical Evaluation

1. **General History:**

- Evaluate for significant medical conditions such as hypertension, diabetes, lung disease, heart disease, gastrointestinal disease, autoimmune disease, neurologic disease, genitourinary disease, history of cancer, history of infections, hematologic disorders, and bleeding/clotting disorders
- Smoking, alcohol and drug use/abuse, including intravenous drug use/abuse and other high risk behavior
- Active and past medications (nephrotoxic, chronic use of pain medications and NSAIDS, other)
- Allergies
- Family history (coronary artery disease, cancer, other)

  - Kidney Specific Personal History:
    - Kidney disease, proteinuria
    - Kidney injury
    - Diabetes
    - Chronic infection
    - Nephrolithiasis
    - Recurrent urinary tract infections
    - Gout or other arthritis
    - Gestational diabetes
  - Kidney Specific Family History:
    - Kidney disease
    - Diabetes
    - Hypertension
    - Reflux

2. **Social History:**

Although a full psychosocial evaluation will be carried out, an evaluation should be part of the medical evaluation to include special emphasis on:

- Employment, health insurance status, living arrangements, social stability
- Psychiatric illness, depression, suicide attempts

3. **Physical Exam:**

- Height, weight, BMI
- Examination of all major organ systems

4. **Kidney-specific:**

- Blood pressure (Measure after sitting for 5 minutes, take twice at the same visit, and obtain 2 different assessments of blood pressure on different days). It may however be preferable to perform a 24-hour blood pressure monitor as cohort studies show improved accuracy for determining the correct blood pressure category with 24-hour monitoring
- Vascular evaluation (abdominal, femoral, carotid bruits, etc)
- Microscopic evaluation

5. **General Laboratory Tests**:

- CBC with platelet count
- Prothrombin Time/Partial Thromboelastin Time
- Comprehensive panel (electrolytes, transaminase levels, albumin, calcium, phosphorus, alkaline phosphatase, bilirubin)
- HCG quantitative pregnancy test for women < 55 years old
- Age and gender appropriate cancer screening tests. The transplant program may choose to follow the screening recommendations from the American Cancer Society.
- Chest X-Ray
- Electrocardiogram (ECG)
- Evaluation for coronary artery disease, as suggested by the American College of Physicians
- Pulmonary function tests for smokers, as suggested by the American College of Anesthesiology and American Lung Association

6. **Kidney-specific Tests:**

- Urinalysis; microscopy as indicated
- Urine culture if clinically indicated
- Measurement of protein excretion
- Measurement of glomerular filtration rate by 24 hour urine collection or equivalent testing
- Screening for Polycystic Kidney Disease as indicated by family history. If the prospective donor is over age 30, this is usually accomplished with an ultrasound. In those under age 30, genetic testing remains the gold standard.
- Uric acid
- GTT in relatives of diabetics as indicated

7. **Immunological testing:**

- ABO blood group typing
- Human Leukocyte Antigen (HLA) typing
- Cross match

8. **Metabolic Focused Testing:**

- Fasting blood glucose
- Fasting cholesterol levels (Cholesterol, Triglycerides, HDL Cholesterol, and LDL Cholesterol) with Fasting Lipid Profile if cholesterol/triglycerides are elevated.
- Uric acid (High uric acid levels are associated with the metabolic syndrome and independently with reduced kidney function)
- If the risk of diabetes is higher than the general population by presence of a first degree relative with diabetes or the presence of metabolic syndrome characteristics, but the prospective donor does not meet the definition of diabetes, they should be counseled that he or she are at an increased risk to develop diabetes and perhaps kidney disease

The goal of these tests is to determine the number of elements of the metabolic syndrome present: Donor may be at increased risk of kidney disease if ≥ 3 risk actors (central obesity, high blood pressure BP >130/85, fasting blood glucose ≥ 100mg/dl, triglyceride levels > 150mg/dl, HDL < 40 for a man and <50mg/dl for a woman).

9. <u>Anatomic Assessment:</u>

This assessment is used to determine which kidney is most anatomically suitable for transplantation (typically dependent upon the number of arteries going to the kidneys) and whether the kidneys are of equal size or have masses, cysts, or stones. The donor should preferably keep the kidney with the fewest issues. Based on these findings, the surgeon will determine 1) the suitability of the organ, and 2) any additional risks associated with anatomical variants. The radiologic imaging may reveal serendipitous findings that will need to be investigated. These finding may be related, or unrelated to the organ of interest.

- The test of choice will depend upon the local radiological expertise and surgical preference, but may include CT angiogram, MR angiogram or angiogram, used singly or in combination.

10. <u>Screening for transmissible diseases:</u>

This screening is used to identify the risk of passing an infection or disease to a recipient. This screening may also identify a condition that may require donor treatment or may increase the risk of donation. Infectious disease testing typically includes testing for the following:

- CMV (Cytomegalovirus)
- EBV (Epstein Barr Virus) – VCA or EBNA antibody test may be performed if the recipient is EBV seronegative
- HIV 1,2 (Human Immunodeficiency Virus)
- HTLV I (Human T-cell Lymphotropic Virus) antibody testing
- HBsAg (Hepatitis B surface antigen)
- HBcAB (Hepatitis B core antibody)

- HBSAB (Hepatitis B surface antibody)
- HCV (Hepatitis C Virus)
- RPR (Rapid Plasma Reagin Test for syphilis)
- Tuberculosis
  Other diseases may be tested for depending on program preference and donor risk profile:
  - Strongyloides for donors from endemic areas
  - Trypanosoma cruzi for donors from endemic areas
  - West Nile for endemic areas
  - Toxoplasmosis: Transmission is low if recipients are treated with trimethoprim-sulfamethoxazole

11. <u>Cancer screening</u>:

The screening tests follow the practices advised by the American Cancer Society. Screenings to be performed depending upon gender, age, or family history include:

- Cervical Cancer
- Breast Cancer
- Prostate Cancer
- Colon Cancer
- Skin Cancer

Lung cancer screening is not currently recommended by the American Cancer Society, but could be considered in the older patient with a strong smoking history.

POSSIBLE EXCLUSION CRITERIA

A variety of criteria may make an individual unsuitable for living donation. Some of these may include:

- Age < 18 years, or mentally incapable to make an informed decision,
- Uncontrollable hypertension, history of hypertension with evidence of end stage organ damage, history of hypertension in a Caucasian younger than age 50 or greater than age 50 on more than one anti-hypertensive medication, or hypertension in a non-Caucasian. High blood pressure is associated with a more significant effect on progression of kidney disease in the non-Caucasian population, or in patients taking more than one anti-hypertensive medication.
- Diabetes
- Significant history of thrombosis or embolism
- Bleeding disorders
- Uncontrollable psychiatric illness
- Morbid obesity
- Clinically significant Coronary and/or Peripheral Vascular Artery Disease

- Symptomatic Valvular Disease
- Chronic lung disease with impairment of oxygenation or ventilation
- Recent malignancy, or cancers with long times to recurrence (e.g., breast cancer)
- History of melanoma
- History of metastatic cancer
- Bilateral or recurrent nephrolithiasis
- Significant urologic abnormalities of donor kidney
- Creatinine clearance < 80 ml/min/1.73m^2, or projected GFR with removal of one kidney at 80 years old of < 40 cc/min/1.73m^2 (based upon Thiel in Living Donor Kidney Transplantation, editors Gaston and Wadstrom, 2005)
- Proteinuria (protein in the urine) > 300 mg/24 hours, excluding postural proteinuria
- Human Immunodeficiency Virus infection
- Hepatitis C Virus infection
- Active Hepatitis B Virus infection

OPTN/UNOS LIVING DONOR FOLLOW-UP

The organ recipient's transplant center is required to submit to OPTN/UNOS information on the status of each living donor for a minimum of two years. Any information received is used determine if living donors experience short term health complications and how living donation may impact quality of life. Follow up information submitted by transplant centers is the only method currently available to obtain information on living donors.

MEDICAL EVALUATION AFTER LIVING DONATION

Following kidney donation, donors should remain informed about their health and have the basic evaluations performed as listed below:

- Blood pressure
- Height, weight and waist circumference
- An age appropriate physical exam

Laboratory studies may include:

- Urinalysis
- Urine albumin:creatinine ratio
- Serum creatinine
- Fasting blood glucose
- Lipid profile

All living kidney donors are encouraged to maintain lifestyle choices that will protect their overall health and in particular kidney health. Like all adults, kidney donors should be advised to establish a health evaluation schedule as recommended by the American

College of Physicians. These evaluations may be the financial responsibility of the donor.

[1] Bylaws, Appendix B, Attachment I, Section XIII, D (2) and (4), Designated Transplant Program Criteria

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Exhibit 13

Modifications to bylaws to require that living donors be provided with contact information to report any grievances through the OPTN (*Living Donor Committee)*

Affected Bylaw Language:

The modifications to the Bylaw appear below. For your convenience in reviewing, new language is underlined.

XIII. Transplant Programs.

A.-D. 2) b. (iii). [No Change]

(iv) Informed Consent: Kidney transplant programs that perform living donor kidney transplants must develop, and once developed, must comply with written protocols for the Informed Consent for the Donor Evaluation Process and for the Donor Nephrectomy, which include, at a minimum, the following elements:

(1) discussion of the potential risks of the procedure including the medical, psychological, and financial risks associated with being a living donor;

(2) assurance that all communication between the potential donor and the transplant center will remain confidential;

(3) discussion of the potential donor's right to opt out at any time during the donation process;

(4) discussion that the medical evaluation or donation may impact the potential donor's ability to obtain health, life, and disability insurance; and

(5) disclosure by the transplant center that it is required, at a minimum, to submit Living Donor Follow-up forms addressing the health information on each living donor at 6 months, one-year, and two-years post donation. The protocol must include a plan to collect the information about each donor.

(6) the telephone number that is available for living donors to report concerns of grievances through the OPTN

[No further changes]

(3) Liver Transplantation – [No changes]

(4) Live Donor Liver Transplant Programs that Perform Living Donor Liver Transplants.

a.-b. (iii) [No changes]

(iv) Informed Consent: Liver transplant programs that perform living donor liver transplants must develop, and once developed, must comply with written protocols for the Informed Consent for the Donor Evaluation Process and for the Donor Hepatectomy, which include, at a minimum, the following elements:

(1) discussion of the potential risks of the procedure including the medical, psychological, and financial risks associated with being a living donor;

(2) assurance that all communication between the potential donor and the transplant center will remain confidential;

(3) discussion of the potential donor's right to opt out at any time during the donation process;

(4) discussion that the medical evaluation or donation may impact the potential donor's ability to obtain health, life, and disability insurance; and

(5) disclosure by the transplant center that it is required, at a minimum, to submit Living Donor Follow-up forms addressing the health information on of each living donor at 6 months, one-year, and two-years post donation. The protocol must include a plan to collect the information about each donor.

(6) the telephone number that is available for living donors to report concerns of grievances through the OPTN

[No further changes]

Modifications to the bylaws pertaining to conditional approval status for liver transplant programs that perform living donor transplants *(Membership and Professional Standards Committee)*

Affected Bylaw Language:

For your convenience in reviewing, new language is underlined and language that is to be removed is ~~stricken through~~.

Proposed Modification to OPTN/UNOS Bylaws, Appendix B, Attachment 1, Section XIII, D (4)

(4) Liver Transplant Programs that Perform Living Donor Liver Transplants.

a. No Changes

b. No Changes

c. Conditional Approval Status: If the transplant center does not have on site a second surgeon who can meet the requirement for having performed 7 live donor liver procedures within the prior 5-year period, but who has completed the requirement for obtaining experience in 20 major hepatic resection surgeries (as described above), as well as all of the other requirements to be designated as a primary liver transplant surgeon, the program may be eligible for Conditional Approval Status. The transplant program can be granted one year to fully comply with applicable membership criteria with a possible one year extension. This option shall be available to new programs as well as previously approved programs that experience a change in key personnel. During this period of conditional approval, both of the designated surgeons must be present at the donor's operative procedure.

The program shall comply with such interim operating policies and procedures as shall be required by the Membership and Professional Standards Committee (MPSC).

This may include the submission of reports describing the surgeon's progress towards meeting the requirements and such other operating conditions as may be required by the MPSC to demonstrate ongoing quality and efficient patient care. The center must provide a report prior to the conclusion of the first year of conditional approval, which must document that that the surgeon has met or is making sufficient progress to meet the objective of performing 7 live donor liver procedures or that the program is making sufficient progress in recruiting and bringing to the program a transplant surgeon who meets this criterion as well as all other criteria for a qualified live donor liver surgeon. Should the surgeon meet the requirements prior to the end of the period of conditional approval, the program may submit a progress report and request review by the MPSC.

The transplant program must comply with all applicable policies and procedures and must demonstrate continuing progress toward full compliance with Criteria for Institutional Membership.

The program's approval status shall be made available to the public.

If the program is unable to demonstrate that it has two designated surgeons on site who can fully meet the primary living donor liver surgeon requirements [as described above] at the end of the 2-year conditional approval period, it must stop performing living donor liver transplants by either

(i) inactivating the living donor part of the program for a period up to 12 months, or

(ii) relinquishing the designated transplant program status for the living donor part of the liver transplant program until it can meet the requirements for full approval.

The requirements for making changes in program status are described in Section II, C.

Exhibit 15

Modifications to the elector system for histocompatibility lab members and medical/scientific members *(Membership and Professional Standards Committee)*

Affected Bylaw Language:

For your convenience in reviewing, new language is underlined and language that is to be removed is ~~stricken through~~. Double underline and/or ~~double strikeouts~~ are changes recommended by the MPSC or Board of Directors after considering public comment feedback.

ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK (OPTN)

BYLAWS

ARTICLE I

MEMBERS

1.1 **Membership Categories**. No Changes

1.2 **Institutional Members**. No Change.

1.3 **Medical/Scientific Members.** No Changes.

1.4 **Public Organization Members.** No Changes

1.5 **Business Members**. No changes

1.6 **Individual Members**. No Changes

1.7 **Application Process and Requirements/Appeal Protocol.** No Changes

1.8 **Terms**. No Changes.

1.9 **Voting Privileges and Responsibilities**. There shall be six classes of voting Members: (i) Transplant Hospital Members, (ii) OPO Members, (iii) Histocompatibility Laboratory Members, (iv) Medical/Scientific Members, (v) Public Organization Members, and (vi) Individual Members. OPTN Members designated "OPTN Members Not in Good Standing" shall not have voting or other OPTN Member privileges until such designation has been removed; provided, however, that all OPTN Members, including Members designated "OPTN Members Not in Good Standing" shall be obligated to comply with OPTN Member responsibilities. Business Members shall not be entitled to voting privileges in OPTN affairs.

a. **Transplant Hospital Members.** Each Transplant Hospital Member shall be entitled to one vote on OPTN affairs requiring a vote of the Membership; provided, however, that a Transplant Hospital must have received approval as a designated transplant program for at least one organ before it is entitled to vote on affairs of the OPTN.

b. **OPO Members.** Each OPO Member shall be entitled to one vote on OPTN affairs requiring a vote of the Membership; provided, however, that an OPO must be independent of the Transplant Hospital(s) it serves, which may include a single Transplant Hospital, before it is entitled to vote on affairs of the OPTN. For purposes of the OPTN Charter and Bylaws, independence from Transplant Hospital(s) served shall be defined by demonstration of a distinct governing body for the OPO that is separate and not under the direct or indirect control of the governing body of any of the OPO's Transplant Hospitals or of the governing body of a commonly controlled group of the OPO's Transplant Hospitals.

c. **Histocompatibility Laboratory Members.** ~~Histocompatibility Laboratories, as a class, shall be represented by 33 separate Histocompatibility Laboratory Member Electors.~~ Each Histocompatibility Laboratory Member ~~Elector~~ shall be entitled to one vote on OPTN affairs requiring a vote of the Membership. ~~Histocompatibility Laboratory Member Electors shall be elected by and from among the Histocompatibility Laboratory Members as follows:~~

~~(i) Histocompatibility Laboratory Members residing within each of the 11 Regions (as defined in Article 2.4 of these Bylaws) shall elect two Histocompatibility Laboratory Member Electors from their respective region. If there are no Histocompatibility Laboratory Members residing within a Region, then the number of national Histocompatibility Laboratory Member Electors described in (ii) below shall be increased by two for every such Region without Histocompatibility Laboratory Members.~~

~~(ii) All Histocompatibility Laboratory Members, collectively, shall elect eleven national Histocompatibility Laboratory Member Electors or, if there are no Histocompatibility Laboratory Members residing in one or more regions, as many national Histocompatibility Laboratory Member Electors as necessary so that there are no more than and no fewer than 33 Histocompatibility Laboratory Member Electors.~~

~~(iii) Any person serving as or designated by the named OPTN Representative for a Histocompatibility Laboratory Member may serve as a Histocompatibility Laboratory Member Elector upon nomination for and election to this office. OPTN Representatives for Histocompatibility Laboratory Members may submit their own names as candidates for Histocompatibility Laboratory Member Elector, representing Histocompatibility Laboratory Members at the regional or national level. For the number of Histocompatibility Laboratory Member Electors to be elected regionally or nationally, those receiving the highest number of votes among eligible candidates shall be elected.~~

~~(iv) The term of a Histocompatibility Laboratory Member Elector shall be two years. Histocompatibility Laboratory Member Electors may serve successive terms.~~

~~(v) Nominations and elections for Histocompatibility Laboratory Member Elector shall be conducted through the Internet using the OPTN web site, www.optn.org, and/or the United States mail.~~

~~The number of Histocompatibility Laboratory Member Electors shall be re-evaluated from time to time by the Board of Directors and increased or decreased as necessary to reflect between approximately 9% and 11% of the then current total number of Institutional Members.~~

~~Notwithstanding the foregoing, in the event the total number of Histocompatibility Laboratory Members at any time at which a vote of the OPTN membership is to take place is equal to or fewer than the then current number of Histocompatibility Laboratory Member Electors, the process for voting through Member Electors described above shall be suspended and each such Histocompatibility Laboratory Member shall be entitled to one vote on any OPTN matter requiring a vote of the Membership.~~

d. Medical/Scientific Members. ~~Medical/Scientific Members that provide services and/or are involved in activities on an interregional or national basis, as a class, shall be represented by 24 separate national Medical/Scientific Member Electors.~~ Each Medical/Scientific Member ~~Elector~~ shall be entitled to one vote on OPTN affairs requiring a vote of the Membership. ~~Medical/Scientific Member Electors shall be elected by and from among the Medical/Scientific Members as follows:~~

~~(i) All Medical/Scientific Members, collectively, shall elect the 24 national Medical/Scientific Member Electors.~~

~~(ii) Any person serving as or designated by the named OPTN Representative for a Medical/Scientific Member may serve as a Medical/Scientific Member Elector upon nomination for and election to this office. OPTN Representatives for Medical/Scientific Members may submit their own names as candidates for Medical/Scientific Member Elector, representing Medical/Scientific Members at the national level. For the number of Medical/Scientific Member Electors to be elected nationally, those receiving the highest number of votes among eligible candidates shall be elected.~~

~~(iii) The term of a Medical/Scientific member Elector shall be two years or the remaining OPTN Membership term of the Medical/Scientific member with whom the Medical/Scientific Member Elector is affiliated, whichever is shorter. Medical/Scientific Member Electors may serve successive terms.~~

~~(iv) Nominations and elections for Medical/Scientific Member Elector shall be conducted through the Internet using the OPTN web site, www.optn.org, and/or the United States mail.~~

~~The number of Medical/Scientific Member Electors shall be re-evaluated from time to time by the Board of Directors and increased or decreased as necessary to reflect between approximately 6% and 8% of the then current total number of Institutional members.~~

~~Medical/Scientific Members must provide services and/or be involved in activities on an interregional or national basis to participate in the election of Medical/Scientific Member Electors.~~

~~Notwithstanding the foregoing, in the event the total number of Medical/Scientific Members in good standing at any time at which a vote of the OPTN membership is to take place is equal to or fewer than the then current number of Medical/Scientific Member Electors, the process for~~

~~voting through Member Electors described above shall be suspended and each such Medical/Scientific Member shall be entitled to one vote on any OPTN matter requiring a vote of the Membership.~~

e. **Public Organization Members.** No Changes.

f. **Individual Members.** Individual Members, as a class, shall be represented by 12 separate Individual Member Electors. Each Individual Member Elector shall be entitled to one vote on OPTN affairs requiring a vote of the Membership. Individual Member Electors shall be elected by and from among the Individual Members as follows:

(i) Individual Members residing within each of the 11 Regions (as defined in Article 2.4 of these Bylaws) shall elect one Individual Member Elector from their respective region. If there are no Individual Members residing within a Region, then the number of national Individual Member Electors described in (ii) below shall be increased by one for every such Region without Individual Members.

(ii) All Individual Members, collectively, shall elect a twelfth national Individual Member Elector or, if there are no Individual Members residing in one or more regions, as many national Individual Member Electors as necessary so that there are no more than and no fewer than 12 Individual Member Electors.

(iii) With the exception of employees currently employed by or independent contractors currently working with OPOs, Transplant Hospitals, or Histocompatibility Laboratories, any Individual Member may serve as an Individual Member Elector upon nomination for and election to this office. Individual Members may submit their own names as candidates for Individual Member Elector, representing Individual Members at the regional or national level. For the number of Individual Member Electors to be elected nationally, those receiving the highest number of votes among eligible candidates shall be elected.

(iv) The term of an Individual Member Elector shall be two years or the remaining OPTN Membership term of the Individual Member elected to the office of Individual Member Elector, whichever is shorter. Individual Member Electors may serve successive terms.

(v) Nominations and elections for Individual Member Elector shall be conducted through the Internet using the OPTN web site, www.optn.org, and/or the United States mail.

The number of Individual Member Electors shall be re-evaluated from time to time by the Board of Directors and increased or decreased as necessary to reflect between approximately 3% and 5% of the then current total number of Institutional Members.

Notwithstanding the foregoing, in the event the total number of Individual Members at any time at which a vote of the OPTN membership is to take place is equal to or fewer than the then current number of Individual Member Electors, the process for voting through Member Electors described above shall be suspended and each such Individual Member shall be entitled to one vote on any OPTN matter requiring a vote of the Membership.

Affairs of the OPTN involving a vote of the Membership include, for example, election of the Board of Directors (see Article II of these Bylaws), election of the Principal Officers (see Article VI of these Bylaws), and amendment of these Bylaws (see Article X of these Bylaws).

Cumulative voting on affairs of the OPTN is not allowed.

Upon being elected to Membership in the OPTN, each Institutional Member, Medical/Scientific Member and Public Organization Member shall indicate its acceptance by appointing a representative with authority to vote and act for the Member in all affairs of the OPTN and an alternate representative who shall have such authority if the representative is unable to vote or act. Additionally, each Institutional Member, Medical/Scientific Member and Public Organization Member shall notify the Executive Director in writing of the name and address of its representative, to whom all notices may be sent, and of its alternate representative. Upon being elected to Membership in the OPTN, each Business Member shall indicate its acceptance by designating in writing the name of a representative and address to which notices may be sent. Upon his or her election, each Individual Member shall notify the Executive Director in writing of his or her name and address to which notices may be sent.

A majority of the Transplant Hospital Members, OPO Members, Histocompatibility Laboratory Members ~~Electors~~, Medical/Scientific Members ~~Electors~~, Public Organization Member Electors, and Individual Member Electors, eligible to vote represented in person or by proxy, shall constitute a quorum for the transaction of business at any meeting. A vote of a majority of those present and eligible to vote shall be sufficient to transact any business that might come before the meeting, except where a greater or lesser vote is provided for in the Bylaws.

1.10 Member Obligations. No Changes

1.11 Removal of Non-Qualifying Members. No Changes

1.12 Meetings. The annual meeting of the Members to elect a Board of Directors pursuant to Article 2.1 of these Bylaws, to elect Principal Officers pursuant to Section 6.1 of these Bylaws and to address such other matters as may be appropriate shall be held in February or March of each calendar year and may be held in conjunction with the annual meeting of the Board of Directors. Special meetings of the Members may be called at any time by the President, Executive Director, or a majority of the Board of Directors, or by written application of a majority of the Transplant Hospital Members, OPO Members, Histocompatibility Laboratory Members ~~Electors~~, Public Organization Member Electors, Medical/Scientific Members ~~Electors~~, and Individual Member Electors stating the time, place, and purpose of the meeting. Members attending meetings shall do so at no cost to the OPTN. Meetings of the OPTN membership typically shall be open to the public; however, discussions involving confidential matters including, OPTN member admission, credentialing, monitoring, or disciplinary matters and matters involving individuals' privacy where disclosure would constitute a clearly unwarranted invasion of personal privacy, shall be reserved for closed sessions as appropriate and consistent with the OPTN Contract. Representatives from the Federal government serving on the Board of Directors, or their designees, shall not be precluded from attending such closed sessions of OPTN meetings.

Written notice of any regular or special meeting of the Members shall state the date, time, and place of the meeting and the purpose for which the meeting is called, and shall be mailed to each Member not fewer than 25 or more than 60 days before the date of the meeting. Giving notice of a meeting of Members to a Member or Member Elector who is not eligible to vote does not imply that the Member or Member Elector may vote.

A written waiver of notice signed at any time by a Member or Member Elector shall be the equivalent of any notice required herein. A Member or Member Elector who attends a meeting shall be deemed to have had timely and proper notice of the meeting unless the Member or Member Elector attends for the express purpose of objecting that the meeting is not lawfully called or convened.

1.13 Registration Fees. No changes

1.14 Expenses Incurred on Behalf of Members. No Changes.

1.15 Affiliated Organizations. No Changes.

ARTICLE II

BOARD OF DIRECTORS

2.1 Authority. The OPTN Board of Directors governs the OPTN and is responsible for developing policies and criteria within the mission of the OPTN.

2.2 Election/Terms. Members of the OPTN Board of Directors shall be elected by majority vote of Transplant Hospital Members, OPO Members, Histocompatibility Laboratory Members ~~Electors~~, Public Organization Member Electors, Medical/Scientific Members ~~Electors~~, and Individual Member Electors represented in person or by proxy at each annual meeting of the Members at which a quorum is present. Directors may also be elected at any special meeting of the Members if the Board of Directors is being expanded. Directors shall serve for a term of two years, with exceptions as noted below, which shall begin immediately following the conclusion of the last regular meeting of the Board of Directors prior to July 1 of each calendar year. Members of the Board who are transplant candidates, transplant recipients, organ donors, or family members, or representatives of voluntary health organizations or the general public shall serve for a term of three years. Board members who also hold positions as Officers serve one year terms, with the exception of the Treasurer and Secretary who shall have staggered terms with one another and shall serve two year terms and the Vice President of Patient & Donor Affairs who shall serve for a term of two years. Each voting Transplant Hospital Member, OPO Member, Histocompatibility Laboratory Member ~~Elector~~, Public Organization Member Elector, Medical/Scientific Member ~~Elector~~, and Individual Member Elector is entitled to one vote for each Director position to be elected. There shall be no cumulative voting.

2.3 Number. [No changes].

2.4 **Regions.** There shall be eleven (11) geographic regions in the United States. The current composition of these regions is set forth in Article IX. Changes to this composition shall require approval of the Board of Directors. The Board shall maintain procedures for the election of one "Councillor" and one "Associate Councillor" from each region by vote of the Transplant Hospital Members, OPO Members, Histocompatibility Laboratory Members~~ Electors~~, Public Organization Member Electors, and Individual Member Electors for the Region and individuals who both reside in the region and have voting privileges at regional meetings as set forth in this section. The Councillor will serve as the representative of these Members and individuals. The Associate Councillor shall represent the region on the Membership and Professional Standards Committee and act in place of the Councillor during his absence or disability. Unless otherwise directed by the Board of Directors or the President, regional elections shall be completed on or before December 31 of each year and shall be held in accordance with one of the following protocols selected by the incumbent Councillor after consultation with or vote of his region's Transplant Hospital Members, OPO Members, Histocompatibility Laboratory Members~~ Electors~~, Public Organization Member Electors, and Individual Member Electors and individuals residing in the region who have voting privileges at Regional meetings as set forth in this section:

a. There shall be a single slate of nominees for Councillor submitted by Transplant Hospital Members, OPO Members, Histocompatibility Laboratory Members~~ Electors~~, the Public Organization Member Elector, the Individual Member Elector, or individuals with voting privileges at regional meetings. The person who receives the second highest number of votes in the election shall be the Associate Councillor; or

b. There shall be a slate of nominees for Councillor and a separate slate for the Associate Councillor, chosen in either case from nominations submitted by Transplant Hospital Members, OPO Members, Histocompatibility Laboratory Members~~ Electors~~, the Public Organization Member Elector, the Individual Member Elector, or persons with voting privileges at regional meetings; or

c. There shall be a separate slate for Councillor and another slate for Associate Councillor/Councillor-Elect. After one such election, there shall be a slate for a new Associate Councillor/Councillor-Elect, with the incumbent in that position becoming the Councillor automatically. In each case, the slate shall be composed of nominations submitted by Transplant Hospital Members, OPO Members, Histocompatibility Laboratory Members~~ Electors~~, the Public Organization Member Elector, the Individual Member Elector, or persons with voting privileges at regional meetings.

The Councillor and Associate Councillor of each region shall be elected for the same term, which shall be either one year or two years, beginning in each case on the date of the annual meeting of the Members following his or her election. The Councillors or Associate Councillors shall not succeed themselves in office. The Councillor from each region shall be responsible, along with the President and the Executive Director, for organizing and coordinating regional activities to carry out purposes of the OPTN. The Nominating Committee in preparing its slate of nominees for election as Director at each annual meeting of Members, shall include as a Director nominee each Councillor who has been elected by the region's Transplant Hospital Members, OPO Members, Histocompatibility Laboratory Members~~ Electors~~, the Public Organization Member

Elector, the Individual Member Elector, and persons residing in the regions who have voting privileges at regional meetings to serve for a term that includes the year following the upcoming annual meeting of Members, with the goal of assuring to the greatest extent possible that at least one representative of each region will serve on the Board of Directors at all times. A Councillor may be removed from office with or without cause by majority vote of all the region's Transplant Hospital Members, OPO Members, Histocompatibility Laboratory Members ~~Electors~~, the Public Organization Member Elector, the Individual Member Elector, and persons residing in the region who have voting privileges at regional meetings, as evidenced by signed ballots presented to the President or the Board of Directors.

Each Transplant Hospital Member, OPO Member, Regional Histocompatibility Laboratory Member ~~Elector~~, the Regional Public Organization Member Elector, and the Regional Individual Member Elector (other than an Institutional Member or Public Organization Member from a category that is not named in the Charter as amended or restated) who resides in a region shall have one vote on any matter before the region for a vote, including the election of Councillor and Associate Councillor. Any person currently serving on an OPTN standing committee who is a representative of the general public (including, for example, patients and their families, donors, donor families, and individuals drawn from the fields of law, theology, ethics, health care financing, the social and behavioral sciences, and labor and management unrelated to the field of health care) and who is not employed by or on the medical staff of an Institutional Member, Medical/Scientific Member or Public Organization Member also may vote on all regional business. Additionally, one or more representatives of Medical/Scientific Members with principal offices located in a Region may vote on regional business, as determined by and pursuant to such protocols as developed by the respective Regions.

2.5 Meetings. No Changes.

2.6 Notice of Meetings. No Changes.

2.7 Quorum. No Changes.

2.8 Committees. No Changes.

2.9 Conflicts of Interest. No Changes.

2.10 Removal from Office. A Director may be removed from office with or without cause, but only by the Transplant Hospital Members, OPO Members, Histocompatibility Laboratory Members ~~Electors~~, Public Organization Member Electors, Medical/Scientific Members ~~Electors~~, and Individual Member Electors at a meeting called and noticed expressly for the purpose of voting to remove him/her.

2.11 Relationship of OPTN Board and OPTN Contractor's Board. No Changes.

Exhibit 15

ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK (OPTN)

BYLAWS

These Bylaws govern the structure and operation of the Organ Procurement and Transplantation Network (OPTN). By accepting membership in the OPTN, each Member agrees to comply with all applicable provisions of the National Organ Transplant Act, as amended, 42 U.S.C. 273 *et seq*.; OPTN Final Rule, 42 CFR Part 121; these Bylaws; and OPTN policies as in effect from time to time. The OPTN will conduct ongoing and periodic reviews and evaluations of each Member OPO and Transplant Hospital for compliance with the OPTN Final Rule and OPTN policies. All OPTN Members are subject to review and evaluation for compliance with OPTN policies. All such compliance monitoring is performed using processes and protocols developed by the OPTN Contractor in accordance with the contract with the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA), to operate the OPTN (OPTN Contract).

ARTICLE VI

OFFICERS

6.1 Officers. The Principal Officers of the OPTN shall be a President, Vice President, Vice President of Patient and Donor Affairs, Treasurer, and Secretary. They shall be elected by the Transplant Hospital Members, OPO Members, Histocompatibility Laboratory Members ~~Electors~~, Public Organization Member Electors, Medical/Scientific Members ~~Electors~~, and Individual Member Electors at the annual meeting of Members and shall assume the duties of their respective positions immediately following the conclusion of the last regular meeting of the Board of Directors prior to July 1 of each calendar year. The Assistant Officers shall be one or more Assistant Treasurers and one or more Assistant Secretaries, who shall be elected from time to time by the Board of Directors upon nomination by the President. The Principal Officers shall serve for a term of one year, except for the Secretary and Treasurer, who shall have staggered terms with one another and shall serve for a term of two years, and except for the Vice President of Patient and Donor Affairs who shall serve for a term of two years. No person may hold more than one position at the same time, except that the Treasurer shall also serve as an Assistant Secretary. All Principal Officers shall serve without compensation.

[No Further changes to this section]

Exhibit 15

UNOS Bylaws

ARTICLE I

MEMBERS

1.1 [No changes]

1.2 **Institutional Members** [No changes]

1.3 **Medical/Scientific Members.** [No changes]

1.4 **Public Organization Members.** [No changes]

1.5 **Business Members**. [No changes]

1.6 **Individual Members**. . [No changes]

1.7 **Application Process and Requirements/Appeal Protocol.** [No changes].

1.8 **Terms.** [No changes].

1.9 **Voting Privileges and Responsibilities.** There shall be six classes of voting Members: (i) Transplant Hospital Members, (ii) OPO Members, (iii) Histocompatibility Laboratory Members, (iv) Medical/Scientific Members, (v) Public Organization Members, and (vi) Individual Members. Members designated "Members Not in Good Standing" shall not have voting or other Member privileges until such designation has been removed; provided, however, that all UNOS Members, including Members designated "Members Not in Good Standing" shall be obligated to comply with Member responsibilities. Business Members shall not be entitled to voting privileges in UNOS corporate affairs. All voting members of the Organ Procurement and Transplantation Network (OPTN) shall be entitled to voting privileges in UNOS Board of Directors and Officer elections.

a. Transplant Hospital Members. [No changes]

b. OPO Members. [No changes]

c. Histocompatibility Laboratory Members. ~~Histocompatibility Laboratories, as a class, shall be represented by 33 separate Histocompatibility Laboratory Member Electors.~~ Each Histocompatibility Laboratory Member ~~Elector~~ shall be entitled to one vote on UNOS affairs requiring a vote of the Membership. ~~Histocompatibility Laboratory Member Electors shall be elected by and from among the Histocompatibility Laboratory Members as follows:~~

~~(i) Histocompatibility Laboratory Members residing within each of the 11 Regions (as defined in Article 2.4 of these Bylaws) shall elect two Histocompatibility Laboratory Member Electors from their respective region. If there are no~~

~~Histocompatibility Laboratory Members residing within a Region, then the number of national Histocompatibility Laboratory Member Electors described in (ii) below shall be increased by two for every such Region without Histocompatibility Laboratory Members.~~

~~(ii) All Histocompatibility Laboratory Members, collectively, shall elect eleven national Histocompatibility Laboratory Member Electors or, if there are no Histocompatibility Laboratory Members residing in one or more regions, as many national Histocompatibility Laboratory Member Electors as necessary so that there are no more than and no fewer than 33 Histocompatibility Laboratory Member Electors.~~

~~(iii) Any person serving as or designated by the named UNOS Representative for a Histocompatibility Laboratory Member may serve as a Histocompatibility Laboratory Member Elector upon nomination for and election to this office. UNOS Representatives for Histocompatibility Laboratory Members may submit their own names as candidates for Histocompatibility Laboratory Member Elector, representing Histocompatibility Laboratory Members at the regional or national level. For the number of Histocompatibility Laboratory Member Electors to be elected regionally or nationally, those receiving the highest number of votes among eligible candidates shall be elected.~~

~~(iv) The term of a Histocompatibility Laboratory Member Elector shall be two years. Histocompatibility Laboratory Member Electors may serve successive terms.~~

~~(v) Nominations and elections for Histocompatibility Laboratory Member Elector shall be conducted through the Internet using the UNOS web site, www.unos.org, and/or the United States mail.~~

~~The number of Histocompatibility Laboratory Member Electors shall be re-evaluated from time to time by the Board of Directors and increased or decreased as necessary to reflect between approximately 9% and 11% of the then current total number of Institutional Members.~~

~~Notwithstanding the foregoing, in the event the total number of Histocompatibility Laboratory Members at any time at which a vote of the UNOS membership is to take place is equal to or fewer than the then current number of Histocompatibility Laboratory Member Electors, the process for voting through Member Electors described above shall be suspended and each such Histocompatibility Laboratory Member shall be entitled to one vote on any UNOS matter requiring a vote of the Membership.~~

d. **Medical/Scientific Members.** ~~Medical/Scientific Members that provide services and/or are involved in activities on an interregional or national basis, as a class, shall be represented by 24 separate national Medical/Scientific Member Electors.~~ Each Medical/Scientific Member ~~Elector~~ shall be entitled to one vote on UNOS affairs requiring a vote of the Membership. ~~Medical/Scientific Member Electors shall be elected by and from among the Medical/Scientific Members as follows:~~

~~(i) All Medical/Scientific Members, collectively, shall elect the 24 national~~

~~Medical/Scientific Member Electors.~~

~~(ii) Any person serving as or designated by the named UNOS Representative for a Medical/Scientific Member may serve as a Medical/Scientific Member Elector upon nomination for and election to this office. UNOS Representatives for Medical/Scientific Members may submit their own names as candidates for Medical/Scientific Member Elector, representing Medical/Scientific Members at the national level. For the number of Medical/Scientific Member Electors to be elected nationally, those receiving the highest number of votes among eligible candidates shall be elected.~~

~~(iii) The term of a Medical/Scientific member Elector shall be two years or the remaining UNOS Membership term of the Medical/Scientific member with whom the Medical/Scientific Member Elector is affiliated, whichever is shorter. Medical/Scientific Member Electors may serve successive terms.~~

~~(iv) Nominations and elections for Medical/Scientific Member Elector shall be conducted through the Internet using the UNOS web site, www.unos.org, and/or the United States mail.~~

~~The number of Medical/Scientific Member Electors shall be re-evaluated from time to time by the Board of Directors and increased or decreased as necessary to reflect between approximately 6% and 8% of the then current total number of Institutional members.~~

~~Medical/Scientific Members must provide services and/or be involved in activities on an interregional or national basis to participate in the election of Medical/Scientific Member Electors.~~

~~Notwithstanding the foregoing, in the event the total number of Medical/Scientific Members in good standing at any time at which a vote of the UNOS membership is to take place is equal to or fewer than the then current number of Medical/Scientific Member Electors, the process for voting through Member Electors described above shall be suspended and each such Medical/Scientific Member shall be entitled to one vote on any UNOS matter requiring a vote of the Membership.~~

e. Public Organization Members. [No changes]

f. **Individual Members.** Individual Members, as a class, shall be represented by 12 separate Individual Member Electors. Each Individual Member Elector shall be entitled to one vote on UNOS affairs requiring a vote of the Membership. Individual Member Electors shall be elected by and from among the Individual Members as follows:

(i) Individual Members residing within each of the 11 Regions (as defined in Article 2.4 of these Bylaws) shall elect one Individual Member Elector from their respective region. If there are no Individual Members residing within a Region, then the number of national Individual Member Electors described in (ii) below shall be increased by one for every such Region without Individual Members.

(ii) All Individual Members, collectively, shall elect a twelfth national Individual Member Elector or, if there are no Individual Members residing in one or more regions, as many national Individual Member Electors as necessary so that there are no more than and no fewer than 12 Individual Member Electors.

(iii) With the exception of employees currently employed by or independent contractors currently working with OPOs, Transplant Hospitals, or Histocompatibility Laboratories, any Individual Member may serve as an Individual Member Elector upon nomination for and election to this office. Individual Members may submit their own names as candidates for Individual Member Elector, representing Individual Members at the regional or national level. For the number of Individual Member Electors to be elected nationally, those receiving the highest number of votes among eligible candidates shall be elected.

(iv) The term of an Individual Member Elector shall be two years or the remaining UNOS Membership term of the Individual Member elected to the office of Individual Member Elector, whichever is shorter. Individual Member Electors may serve successive terms.

(v) Nominations and elections for Individual Member Elector shall be conducted through the Internet using the UNOS web site, www.unos.org, and/or the United States mail.

The number of Individual Member Electors shall be re-evaluated from time to time by the Board of Directors and increased or decreased as necessary to reflect between approximately 3% and 5% of the then current total number of Institutional Members.

Notwithstanding the foregoing, in the event the total number of Individual Members at any time at which a vote of the UNOS membership is to take place is equal to or fewer than the then current number of Individual Member Electors, the process for voting through Member Electors described above shall be suspended and each such Individual Member shall be entitled to one vote on any UNOS matter requiring a vote of the Membership.

Affairs of the UNOS involving a vote of the Membership include, for example, election of the Board of Directors (see Article II of these Bylaws), election of the Principal Officers (see Article VI of these Bylaws), and amendment of these Bylaws (see Article X of these Bylaws).

Cumulative voting on affairs of the UNOS is not allowed.

Upon being elected to Membership in the UNOS, each Institutional Member, Medical/Scientific Member and Public Organization Member shall indicate its acceptance by appointing a representative with authority to vote and act for the Member in all affairs of the UNOS and an alternate representative who shall have such authority if the representative is unable to vote or act. Additionally, each Institutional Member, Medical/Scientific Member and Public Organization Member shall notify the Executive Director in writing of the name and address of its representative, to whom all notices may be sent, and of its alternate representative. Upon

being elected to Membership in UNOS, each Business Member shall indicate its acceptance by designating in writing the name of a representative and address to which notices may be sent. Upon his or her election, each Individual Member shall notify the Executive Director in writing of his or her name and address to which notices may be sent.

A majority of the Transplant Hospital Members, OPO Members, Histocompatibility Laboratory Members ~~Electors~~, Medical/Scientific Members ~~Electors~~, Public Organization Member Electors, and Individual Member Electors, eligible to vote represented in person or by proxy, shall constitute a quorum for the transaction of business at any meeting. A vote of a majority of those present and eligible to vote shall be sufficient to transact any business that might come before the meeting, except where a greater or lesser vote is provided for in the Bylaws.

1.10 **Member Obligations**. [No changes]

1.11 **Removal of Non-Qualifying Members**. [No changes]

1.12 **Meetings**. The annual meeting of the Members to elect a Board of Directors pursuant to Article 2.1 of these Bylaws, to elect Principal Officers pursuant to Section 6.1 of these Bylaws and to address such other matters as may be appropriate shall be held in February or March of each calendar year and may be held in conjunction with the annual meeting of the Board of Directors. Special meetings of the Members may be called at any time by the President, Executive Director, or a majority of the Board of Directors, or by written application of a majority of the Transplant Hospital Members, OPO Members, Histocompatibility Laboratory Members ~~Electors~~, Public Organization Member Electors, Medical/Scientific Members ~~Electors~~, and Individual Member Electors stating the time, place, and purpose of the meeting. Members attending meetings shall do so at no cost to UNOS. Meetings of the UNOS membership typically shall be open to the public; however, discussions involving confidential matters including, UNOS member admission, credentialing, monitoring, or disciplinary matters and matters involving individuals' privacy where disclosure would constitute a clearly unwarranted invasion of personal privacy, shall be reserved for closed sessions as appropriate and consistent with the OPTN Contract.

Written notice of any regular or special meeting of the Members shall state the date, time, and place of the meeting and the purpose for which the meeting is called, and shall be mailed to each Member not fewer than 25 or more than 60 days before the date of the meeting. Giving notice of a meeting of Members to a Member or Member Elector who is not eligible to vote does not imply that the Member or Member Elector may vote.

A written waiver of notice signed at any time by a Member or Member Elector shall be the equivalent of any notice required herein. A Member or Member Elector who attends a meeting shall be deemed to have had timely and proper notice of the meeting unless the Member or Member Elector attends for the express purpose of objecting that the meeting is not lawfully called or convened.

[No further changes to this section]

Exhibit 15

ARTICLE II

BOARD OF DIRECTORS

2.1 Authority. [No changes].

2.2 Election/Terms. Members of the Board of Directors shall be elected by majority vote of Transplant Hospital Members, OPO Members, Histocompatibility Laboratory Members ~~Electors~~, Public Organization Member Electors, Medical/Scientific Members ~~Electors~~, and Individual Member Electors represented in person or by proxy at each annual meeting of the Members at which a quorum is present. Directors may also be elected at any special meeting of the Members if the Board of Directors is being expanded. Directors shall serve for a term of two years, with the exceptions noted below, which shall begin immediately following the conclusion of the last regular meeting of the Board of Directors prior to July 1 of each calendar year. Members of the Board who are transplant candidates, transplant recipients, organ donors, or family members, or representatives of voluntary health organizations or the general public shall serve for a term of three years. Board members who also hold positions as Officers serve one year terms, with the exception of the Treasurer and Secretary who shall have staggered terms with one another and shall serve two year terms and the Vice President of Patient & Donor Affairs, who shall serve for a term of two years. Each voting Transplant Hospital Member, OPO Member, Histocompatibility Laboratory Member ~~Elector~~, Public Organization Member Elector, Medical/Scientific Member ~~Elector~~, and Individual Member Elector is entitled to one vote for as many persons as there are Directors to be elected. There shall be no cumulative voting.

2.3 Number. [No changes]

2.4 Regions. There shall be eleven (11) geographic regions in the United States. The current composition of these regions is set forth in Article IX. Changes to this composition shall require approval of the Board of Directors. The Board shall maintain procedures for the election of one "Councillor" and one "Associate Councillor" from each region by vote of the Transplant Hospital Members, OPO Members, Histocompatibility Laboratory Members ~~Electors~~, Public Organization Member Electors, and Individual Member Electors for the Region and individuals who both reside in the region and have voting privileges at Regional meetings as set forth in this section. The Councillor will serve as the representative of these Members and individuals. The Associate Councillor shall represent the region on the Membership and Professional Standards Committee and act in place of the Councillor during his or her absence or disability. Unless otherwise directed by the Board of Directors or the President, regional elections shall be completed on or before December 31 of each year and shall be held in accordance with one of the following protocols selected by the incumbent Councillor after consultation with or vote of his region's Transplant Hospital Members, OPO Members, Histocompatibility Laboratory Members ~~Electors~~, Public Organization Member Electors, and Individual Member Electors and individuals residing in the region who have voting privileges at Regional meetings as set forth in this section:

a. There shall be a single slate of nominees for Councillor submitted by Transplant Hospital Members, OPO Members, Histocompatibility Laboratory Members ~~Electors~~, the Public Organization Member Elector, or individuals with voting privileges at Regional meetings. The person who receives the second highest number of votes in the election shall be the Associate Councillor; or

b. There shall be a slate of nominees for Councillor and a separate slate for the Associate Councillor, chosen in either case from nominations submitted by Transplant Hospital Members, OPO Members, Histocompatibility Laboratory Members ~~Electors~~, the Public Organization Member Elector, the Individual Member Elector, or persons with voting privileges at Regional meetings; or

c. There shall be a separate slate for Councillor and another slate for Associate Councillor/Councillor-Elect. After one such election, there shall be a slate for a new Associate Councillor/Councillor-Elect, with the incumbent in that position becoming the Councillor automatically. In each case, the slate shall be composed of nominations submitted by Transplant Hospital Members, OPO Members, Histocompatibility Laboratory Members ~~Electors~~, the Public Organization Member Elector, the Individual Member Elector, or persons with voting privileges at Regional meetings.

The Councillor and Associate Councillor of each region shall be elected for the same term, which shall be either one year or two years, beginning in each case on the date of the annual meeting of the Members following his or her election. The Councillors or Associate Councillors shall not succeed themselves in office. The Councillor from each region shall be responsible, along with the President and the Executive Director, for organizing and coordinating regional activities to carry out the purposes of the Corporation. The Nominating Committee in preparing its slate of nominees for election as Director at each annual meeting of Members, shall include as a Director nominee each Councillor who has been elected by the region's Transplant Hospital Members, OPO Members, Histocompatibility Laboratory Members ~~Electors~~, the Public Organization Member Elector, the Individual Member Elector, and persons residing in the region who have voting privileges at regional meetings to serve for a term that includes the year following the upcoming annual meeting of Members, with the goal of assuring to the greatest extent possible that at least one representative of each region will serve on the Board of Directors at all times. A Councillor may be removed from office with or without cause by majority vote of all the region's Transplant Hospital Members, OPO Members, Histocompatibility Laboratory Members ~~Electors~~, the Public Organization Member Elector, the Individual Member Elector, and persons residing in the region who have voting privileges at Regional meetings, as evidenced by signed ballots presented to the President or the Board of Directors.

Each Transplant Hospital Member, OPO Member, Regional Histocompatibility Laboratory Member ~~Elector~~, the Regional Public Organization Member Elector, and the Regional Individual Member Elector (other than an Institutional Member or Public Organization Member from a category that is not named in the Articles of Incorporation as amended or restated) who resides in a region shall have one vote on any matter before the region for a vote, including the election of Councillor and Associate Councillor. Any person currently serving on a UNOS standing committee who is a representative of the general public (including, for example, patients and their families, donors, donor families, and individuals drawn from the fields of law, theology, ethics, health care financing, the social and behavioral sciences, and labor and management unrelated to the field of health care) and who is not employed by or on the medical staff of an Institutional Member, Medical/Scientific Member or Public Organization Member also may vote on all regional business. Additionally, one or more representatives of Medical/Scientific Members with principal offices located in a Region may vote on regional business, as determined by and pursuant to such protocols as developed by the respective Regions.

2.5 Meetings. [No changes].

2.6 Notice of Meetings. [No changes].

2.7 Quorum. [No changes].

2.8 Committees. [No changes].

2.9 Conflicts of Interest. [No changes].

2.10 Removal from Office. A Director may be removed from office with or without cause, but only by the Transplant Hospital Members, OPO Members, Histocompatibility Laboratory Members ~~Electors~~, Public Organization Member Electors, Medical/Scientific Members ~~Electors~~, and Individual Member Electors at a meeting called and noticed expressly for the purpose of voting to remove him/her.

2.11 Relationship of UNOS Board of Directors and OPTN Board of Directors. [No changes].

ARTICLE VI

OFFICERS

6.1 Officers. The principal Officers of the Corporation shall be a President, Vice President, Vice President of Patient and Donor Affairs, Treasurer, and Secretary. Such principal Officers shall be elected by the Transplant Hospital Members, OPO Members, Histocompatibility Laboratory Members ~~Electors~~, Public Organization Member Electors, Medical/Scientific Members ~~Electors~~, and Individual Member Electors at the annual meeting of Members and shall assume the duties of their respective offices immediately following the conclusion of the last regular meeting of the Board of Directors prior to July 1 of each calendar year. The assistant Officers shall be one or more Assistant Treasurers and one or more Assistant Secretaries, who shall be elected from time to time by the Board of Directors upon nomination by the President. The Principal Officers shall serve for a term of one year, except for the Treasurer and Secretary, who shall have staggered terms with one another and shall serve for a term of two years and except for the Vice President of Patient and Donor Affairs who shall serve for a term of two years. No person may hold more than one office at the same time, except that the Treasurer shall also serve as an Assistant Secretary. Election as President shall constitute appointments as Chairman of the Board of Directors. All principal Officers shall serve without compensation.

[No further changes to this section]

To read the complete bylaws language visit www.unos.org or www.optn.org. From the UNOS Web site, select Resources from the main menu, then select bylaws. From the OPTN Web site, select Policies from the main menu, then select bylaws.

Exhibit 16

Modifications to bylaws pertaining to the restoration of membership privileges following an adverse action *(Membership and Professional Standards Committee)*

Affected Bylaw Language:

For your convenience in reviewing, new language is underlined and language that is to be removed is ~~stricken through~~. Double underline and/or ~~double strikeouts~~ are changes recommended by the MPSC or Board of Directors after considering public comment feedback.

APPENDIX A TO UNOS BYLAWS
Interviews and Hearings

3.01A Definition of "Adverse"

(1) **Recommendations or Actions**: Subject to Section 3.01A (4) below, the following recommendations or actions shall, if deemed adverse pursuant to Section 3.01A (2) below, entitle the applicant or member affected thereby to a hearing:

(a) Rejection of initial membership or rejection of designation as a transplant program;

(b) Probation;

(c) Initial declaration of "Member Not in Good Standing" and subsequent determinations by the Board of Directors or Executive Committee not to restore the Member to unrestricted membership status;

(d) Suspension of membership privileges either directly or after a period of probation;

(e) Termination of membership, either directly or after a period of probation or suspension; and

(f) Any other action specified in Section 121.10(c) of the OPTN Final Rule, 42 CFR § 121.10(c) including, by way of example and not limitation, removal of designation as a transplant program.

(2) **When Deemed Adverse:** A recommendation or action listed in Section 3.01A (1) above shall be deemed adverse only when it has been:

(a) Recommended by the MPSC or, in the case of: (i) rejection of initial membership, (ii) rejection of designation as a transplant program, or (iii) findings with respect to Category I potential violations, recommended by a Subcommittee of the MPSC; or

(b) Taken by the Board of Directors or the Executive Committee contrary to a favorable recommendation by the MPSC or subcommittee of the MPSC under circumstances where no right to a hearing existed; or

(c) Taken by the Board of Directors or the Executive Committee on its own initiative without benefit of a prior recommendation by the MPSC.

(3) **Interviews:** Except in the case of Category I potential violations, when the MPSC or MPSC-PCSC is considering making an adverse recommendation concerning an applicant or a Member or issuing a letter of reprimand, or when an organ-specific committee refers a matter to the MPSC/MPSC-PCSC with a recommendation that the MPSC consider such an action under Section 2.05A above, the applicant or Member shall be entitled to an interview before the MPSC or the MPSC-PCSC. The interview shall not constitute a hearing, shall be preliminary in nature, and shall not be conducted according to the procedural rules provided with respect to hearings. The applicant or Member shall be informed of the general nature of the circumstances and may present information relevant thereto. A summary record of such interview shall promptly be made by the MPSC and a copy promptly provided to the applicant or Member who was granted the interview.

Notwithstanding the foregoing, upon determination by the Board of Directors based on available evidence that an alleged violation of UNOS requirements poses a substantial and imminent threat to the quality of patient care, the Board may take appropriate action even if the Member has not had the opportunity for an interview and/or other procedural rights described below.

Members shall not be entitled to an interview in the case of Category I potential violations; or if action is being considered pursuant to 5.05A or 5.07A of these Bylaws.

(a) An applicant or Member shall have the right to one hearing proceeding, and subsequent appellate review unless the Board of Directors conducts the hearing, with respect to any application for membership, application for designation as a transplant program, and request for corrective action to enforce membership requirements in which an adverse recommendation or action is taken. The hearing may be requested upon the first to occur of the adverse recommendations or actions listed in section 3.01A(1) above or, if waived at such time by the applicant's or member's failure to request a hearing within the time and in the manner specified in section 3.02A below, upon any subsequent adverse recommendation or action arising out of the same application for membership, application for designation as a transplant program, or request for corrective action to enforce membership requirements.

(b) **Category I Potential Violations.** In the case of a determination of time sensitive threat to patient health or public safety in connection with Category I potential violations, the hearing and any subsequent appellate review will commence together with or follow rather than precede the Executive Committee's or the Board's decision regarding and action upon the MPSC subcommittee's recommendation, as set forth below:

(i) The MPSC subcommittee recommendation will be referred immediately to the Executive Committee. At the same time, notice will be given to the Member by registered or certified mail, return receipt requested, as well as facsimile transmission. Where the finding continues to be a Category I potential violation with time sensitive threat to patient health or public safety, the MPSC subcommittee action shall include a recommendation for designation of the Member to be Member Not in Good Standing and that the offending transplant program or institution voluntarily inactivate, and, failing acceptance of this recommendation to voluntarily inactivate with immediate action to so inactivate (including notice to and assistance for patients pursuant to UNOS requirements);

(ii) Following receipt of the MPSC subcommittee recommendation, the Executive Committee shall determine whether it or the Board of Directors shall consider the matter and the Executive Committee or the Board, as the case may be, shall consider the same and affirm, modify, or reverse the recommendation or action in the matter. A concise statement of the result and the reasons therefore, and all documentation considered, shall be transmitted to the Executive Director;

(iii) The Executive Director, or his/her designee, shall promptly send a copy of the result to the Member by registered or certified mail, return receipt requested (as well as facsimile transmission) if the decision continues to be adverse to the Member. A copy of the result also shall be forwarded to the MPSC or to the Board of Directors, as determined by the Executive Committee, in the event the Member exercises its rights to a hearing under Section 3.02A of the Bylaws. The Member may request that a copy of the supporting documentation be furnished at the Member's expense;

(iv) Notice of a decision by the Executive Committee or Board that the Member has been placed on probation or declared Not in Good Standing shall be circulated to all Members; and

(v) In the event the Member exercises its right to a hearing, the process described in Section 3.02A will be initiated or continued, as applicable, consistent with the timing of delivery and receipt of notices. The hearing will be before the MPSC, the Board or the Executive Committee as determined by the Executive Committee.

Notwithstanding the foregoing, upon determination by the Board of Directors based on available evidence that an alleged violation of UNOS requirements poses a substantial and imminent threat to the quality of patient care, the Board may take other appropriate action using other appropriate process even if the steps noted above for a Category I proceeding have not been completed or the Member otherwise has not had the opportunity for a hearing and/or subsequent appellate review.

Members will not be entitled to a Hearing in the case that action is being considered pursuant to 5.05A or 5.07A of these Bylaws, except as provided in those sections.

3.02 A - no changes

3.03 A - no changes

4.01A – no changes

Effect of Board Actions

5.01A – no changes

5.02A – no changes

5.03A – no changes

5.04A [RESERVED]

5.05A Restoration of Unrestricted Membership

Upon presentation of evidence to the satisfaction of the MPSC that a probationary Member, Member declared Not in or a suspended Member has fully complied with UNOS Good Standing, requirements, including completion of actions prescribed as a result of the imposition of sanctions, the MPSC shall recommend that the Board of Directors restore unrestricted membership privileges, in the case of a Member placed on probation or declared Not in Good Standing, or recommend restoration of unrestricted membership privileges, in the case of suspension of the Member's membership privileges.

1) **Request for Restoration of Membership Privileges**. A Member may request restoration of membership privileges after demonstration of substantial compliance with the corrective action plan. The Member must demonstrate to the satisfaction of the MPSC that:

   (i) the Member is in substantial compliance with OPTN requirements;
   (ii) the Member has fully implemented any corrective action plan or action plan previously required by the MPSC; and
   (iii) the Member has demonstrated that the underlying cause for the adverse action has been corrected, or eliminated.

   For the purposes of this section, "substantial compliance" means that there are no pending compliance issues that might lead to a Category I violation, and that the type of violation that resulted in the adverse action is not likely to occur again.

There is no presumption in favor of granting requests for restoration of unrestricted membership, in that time passed does not demonstrate compliance or remedy. The burden is on the Member at all times to demonstrate that restoration of membership privileges is appropriate.

2) **Time Limits**. The burden is on the member to demonstrate that restoration of membership privileges is appropriate. However, the MPSC will only consider requests during its regularly scheduled meetings. The Member may not request restoration of membership privileges until on or after:

   a) twelve months after the approval of a corrective action plan, or
   b) twelve months after the approval of an action plan subsequent to the Board of Director's or Secretary's adverse action.

   In the event that the MPSC denies the Member's request for restoration of membership privileges, the Member may renew its request six months from the date of the MPSC denial of its prior request.

3) **Additional Requirements.** In its discretion, the MPSC may require an unannounced site survey and/or peer conducted site visit prior to consideration of the request.

4) **Hearing.** If the MPSC denies the Member's request for restoration of privileges under this section, then the Member shall be entitled to a Hearing with the MPSC at the next regularly scheduled meeting of the MPSC after the Member submits such request and at the Member's expense consistent with these bylaws. ~~regarding restoration of unrestricted membership only if the MPSC denies the request by the Member and the Member alleges that the MPSC acted arbitrarily and capriciously.~~

5.06A Restoration of Privileges after Violation of Mandatory Policies under Section 121.10(c) of the OPTN Final Rule

Upon presentation of evidence to the satisfaction of the MPSC that a Member ~~penalized~~ sanctioned for violation of a mandatory policy under Section 121.10(c) of the OPTN Final Rule, 42 CFR § 121.10(c), has fully complied with requirements for the restoration of membership privileges, including completion of actions prescribed as a result of the imposition of sanctions, the MPSC shall recommend to the Board of Directors that the ~~penalty~~ sanction be removed.

5.07A – Lesser Adverse Actions

If a Member requests restoration of unrestricted membership pursuant to Section 5.05A of Appendix A to the Bylaws, or the declaration of a lesser adverse action than is currently imposed on the member, the MPSC may recommend to the Board of Directors the lesser adverse actions of "Probation" or, if the existing status is Probation, a trial

reinstatement period. The recommendation may be considered if the Member has demonstrated to the MPSC's satisfaction that it is:

i) in substantial compliance with OPTN requirements;
ii) the underlying cause for the adverse action is substantially corrected; and
iii) the corrective action plan or action plan are in the process of being implemented.

For the purposes of this section, "substantial compliance" means that there are no pending compliance issues that might lead to a Category I violation, and that the type of violation that resulted in the adverse action is not likely to occur again.

There is no timeline for consideration of requests for a modification of adverse actions, in that time passed does not demonstrate substantial compliance or correction. There is no presumption in favor of a recommendation for a lesser adverse action ~~granting requests for unrestricted membership~~, in that time passed does not demonstrate compliance or remedy. The burden is on the Member at all times to demonstrate that a lesser adverse action ~~restoration of membership privileges~~ is appropriate. However, the MPSC ~~may~~ will only consider requests during its regularly scheduled meetings. ~~Beginning:~~ The Member may not request a lesser adverse action ~~restoration of membership privileges~~ under this section until on or after:

a) Twelve months after the approval of a corrective action plan, or
b) Twelve months after the approval of an action plan subsequent to the Board of Director's or Secretary's adverse action.

In its discretion, the MPSC may require an unannounced site survey and/or peer conducted site visit prior to consideration of the request.

The consideration of lesser adverse actions pursuant to this section shall not entitle the Member to an Interview or Hearing under these bylaws. If the MPSC denies the request by the member and the member alleges that the MPSC acted arbitrarily and capriciously ~~I~~the Member shall be entitled to a Hearing with the MPSC at the next regularly schedued meeting of the MPSC and at the Member's expense consistent with these bylaws, regarding the recommendation for the action of "Probation" or trial reinstatement ~~only if the MPSC denies the request by the Member and the Member alleges that the MPSC acted arbitrarily and capriciously~~. In the event that the MPSC denies the Member's request for ~~restoration of membership privileges~~ a lesser adverse action under this section, the Member may renew its request six months from the date of the MPSC denial of its prior request.

No further changes to Appendix A

To read the complete bylaws language visit www.unos.org or www.optn.org. From the UNOS Web site, select Resources from the main menu, then select bylaws. From the OPTN Web site, select Policies from the main menu, then select bylaws.

Modifications to clarify standard organ packaging specifications *(Operations Committee)*

Affected Policy Language:

The modifications to policy 5.5 (Standard Organ Package Specifications) appear below. For your convenience in reviewing, new language is underlined and language that is to be removed is ~~stricken through~~.

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.

To read the complete policy language visit www.unos.org or www.optn.org. From the UNOS Web site, select Resources from the main menu, then select policies. From the OPTN Web site, select Policies from the main menu.