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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 — November 16-17, 2009

Date: December 17, 2009

The attached report summarizes bylaw changes, policy changes and other actions the OPTN/UNOS Board of Directors approved at its November 2009 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 9 notices included on the 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 Staff	Transplant Program Directors	Transplant Social Workers	Transplant Surgeons	Page #
1 Inclusion of "Priority 1 pediatric lung candidates" as Urgent Status Candidates (Pediatric & Thoracic Organ Transplantation Committees)		X	X						X	X	X	X	X	X	X	X	4
2 Addition of the Actual Match-Run Classifications for Pediatric Heart Allocation (Pediatric & Thoracic Organ Transplantation Committees)	X			X	X	X	X	X	X	X	X	X	X	X	X	X	5
3 Proposal to Clarify, Reorganize and Update OPO Policy on Packaging and Labeling to Align with Current Practices (OPO Committee)	X	X	X	X	X	X		X	X	X	X	X		X		X	6
4 Policies to Improve the ABO Verification Process for Living Donors (Living Donor Committee)		X	X						X	X	X	X	X	X	X	X	8
5 Changes to Standardized MELD/PELD Exceptions and Regional Review Board (RRB) Guidelines (Liver and Intestinal Organ Transplantation Committee)									X	X	X	X		X		X	9
6 UNOS Bylaws Change to Reconcile Discrepancies in Patient Volume Requirements for Full and Conditional Program Approval when Qualifying Kidney, Liver, and Pancreas Primary Transplant Physicians (Membership and Professional Standards Committee)									X			X		X			11
7 Notification Requirements for OPOs, Transplant Hospitals, and Histocompatibility Labs When Faced with an Adverse Action Taken by Regulatory Agencies (Membership & Professional Standards Committee)	X				X	X		X	X			X		X		X	13
8 Proposal to Change the Bylaws to Clarify the Process for Reporting Changes in Key Personnel (Membership & Professional Standards Committee)									X			X		X		X	15

Overview of Policy Modifications/Board Actions and Affected Professionals

9 New Policy Added to Address Conflicts of Interest Associated with Having the Same Physician Declare Death and Perform Organ Procurement or Transplant Operation (Membership and Professional Standards Committee)	X	X	X		X	X			X			X		X	X	17
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Title of Policy Change: Inclusion of “Priority 1 pediatric lung candidates” as Urgent Status Candidates

Sponsoring Committees: Pediatric Transplantation, Thoracic Organ Transplantation

Policy Affected: Policy 3.2.1.8.1 (Waiting Time Modification for Urgent Status Candidates)

Action Required: Review Only

Effective Date: Upon Implementation in 2010

Professional Groups Affected by the Change:

Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Transplant Social Workers, Transplant Data Coordinators, Lab Directors, Lab Supervisors, Transplant Public Relations or Public Education Staff

Problem Statement	Changes	What You Need to Do
<p>The Board of Directors approved modifications for allocating pediatric donor lungs and a simple priority system for pediatric lung candidates in June 2008. In June 2009, the Executive Committee approved additional modifications that simplified implementation and aligned the policy with the original proposal’s intent.</p> <p>While preparing to implement these modifications, UNOS staff recognized that existing policy language did not allow for a timely adjustment of a Priority 1 pediatric lung candidate’s waiting time. Considering the urgent nature of these pediatric lung candidates, the process outlined in Policy 3.2.1.8 (Waiting Time Modification) would not sufficiently serve these candidates.</p>	<p>The Board approved including “Priority 1 pediatric lung candidates” as an urgent status in Policy 3.2.1.8.1. This will allow the Organ Center to appropriately adjust the waiting time of these patients after they receive the documentation noted in this policy.</p>	<p>Once UNOS has programmed and implemented the pediatric lung modifications, transplant centers must submit to the Organ Center the documentation described in Policy 3.2.1.8.1 if they want to adjust waiting time mistakes for Priority 1 pediatric lung candidates.</p>

Title of Policy Change: Addition of the Actual Match-Run Classifications for Pediatric Heart Allocation

Policy Affected: Policy 3.7.10.1 (Sequence of Pediatric Heart Allocation)

Sponsoring Committees: Pediatric Organ Transplantation, Thoracic Organ Transplantation

Action Required of the Reader: Review Only

Effective Date: Upon Implementation in 2010

Professional Groups Affected by the Change:

Organ Procurement Organization (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 Public Relations (PR) or Public Education staff, and Transplant PR or Public Education Staff

Problem Statement	Changes	What You Need to Do
<p>The combination of local and Zone A geographic classifications for pediatric heart allocation was not applied to candidates in the ABO-incompatible and <i>in utero</i> categories. The Committees intended for the broader sharing of pediatric hearts proposal passed by the Board in June 2008, and implemented in May 2009, to be applied to the entire match run.</p> <p>Further, it is difficult to completely understand the priorities for pediatric heart allocation. The reader must consider the general classifications outlined in Policy 3.7.10.1 along with elements described in Policy 3.7.8 (ABO Typing for Heart Allocation).</p>	<p>The Board approved replacing the general classifications for pediatric heart allocation with the exact classifications as they appear on pediatric heart match runs.</p>	<p>Transplant professionals should become familiar with the policy language.</p> <p>UNOS will notify procurement and transplant professionals of the policy implementation schedule for the combination of ABO-incompatible and <i>in utero</i> local and Zone A geographic classifications. These modifications do not alter any other classifications for the allocation of pediatric hearts. This effort will be incorporated in the programming of the pediatric ABO-incompatible heart changes.</p>

Title of Policy Change: Proposal to Clarify, Reorganize and Update OPO Policy on Packaging and Labeling to Align with Current Practices

Sponsoring Committee: OPO Committee

Policy Affected: Policy 5.0 (Standardized Packaging, Labeling and Transporting of Organs, Vessels and Tissue Typing Materials)

Action Required: Review; No Response Needed

Effective Date: January 17, 2010

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 Data Coordinators, Lab Directors, Lab Supervisors

Problem Statement	Changes	What You Need to Do
<p>Errors involving the packaging and labeling of organs have resulted in organ wastage. The OPO Committee rewrote and reorganized Policy 5.0 to clarify policy language and eliminate packaging and labeling errors. Additionally, the modifications make policy consistent with current practice.</p>	<p>Most of the policy changes were designed to reorganize the content and clarify the language; the intent of the language was not changed.</p> <p>Substantive changes to the policy include:</p> <ul style="list-style-type: none"> • The perfusion machine cassette must be labeled. • A rigid container is not required when transporting a heart. • Vessels require a rigid container if sent separately from an organ. • “UNOS Donor ID Number” was changed to “UNOS Donor ID.” • “Time out” is defined. • It is no longer required to report vessel disposition to the OPO; it must be reported only to UNOS. • Transplant center personnel may not leave the operating room without allowing the OPO to package and label the organ in accordance with 	<p>OPOs and transplant centers should review the policy and:</p> <ul style="list-style-type: none"> • determine if internal processes and protocols for packaging and labeling are consistent with the current policy; and, • determine if staff needs additional training on how to package and label organs, tissues, and tissue typing materials.

	<p>OPTN policy. The OPO must submit a report through the Patient Safety System when a transplant center does not comply.</p> <ul style="list-style-type: none">• Two unique identifiers are required for tissue typing materials.	
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Title of Policy Change: Policies to Improve the ABO Verification Process for Living Donors

Sponsoring Committee: Living Donor Committee

Policies Affected: Policy 12.3.1 (ABO Identification) and Policy 12.8.1.1 (Reporting Requirements)

Action Required: Review Only

Effective Date: January 17, 2010

Professional Groups Affected by the Change:

Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Transplant Social Workers, Transplant Data Coordinators, Lab Directors, Lab Supervisors, Independent Donor Advocates, Transplant Public Relations or Public Education Staff

Problem Statement	Changes	What You Need to Do
<p>The ABO verification process for deceased donors requires the OPO to send two ABO samples to two separate laboratories, or send two samples from separate blood draws to the same laboratory. Previously, no policy addressed the ABO verification process for living donors. Consequently, the ABO verification process for living donors was less stringent than the process required for deceased donors.</p>	<p>The Board approved adding a policy to address the ABO verification process for living donors.</p>	<p>Prior to donation, a transplant program must ABO type, and subtype if appropriate, each living donor on two separate occasions. The living donor transplant program must use the source documents from both ABO typings to enter the living donor's ABO on the Living Donor Feedback Form. Additionally, each living donor program must develop, implement, and comply with a procedure to verify that the living donor's ABO was correctly entered on the Living Donor Feedback Form. A transplant program must document that each ABO entry was performed according to the program's protocol. The program must maintain this documentation, and make it available to UNOS upon request.</p>

Title of Policy Change: Changes to Standardized MELD/PELD Exceptions and Regional Review Board (RRB) Guidelines

Sponsoring Committee: Liver and Intestinal Organ Transplantation Committee

Policy Affected: Policy 3.6.4.5 (Liver Candidates with Exceptional Cases)

Action Required: Review Only

Effective Date: Pending Programming and Notice to Members

Professional Groups Affected by the Change:

Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Transplant Data Coordinators

Problem Statement	Changes	What You Need to Do
<p>In June 2009, the Board approved standardized criteria and scores for the following:</p> <ul style="list-style-type: none"> • hepatopulmonary syndrome • cholangiocarcinoma • cystic fibrosis • familial amyloidosis • primary hyperoxaluria • portopulmonary hypertension <p>The Board did not approve the committee’s request for these cases to be automatically reviewed the by UNetSM MELD/PELD exception application. Therefore, some form of RRB review is necessary.</p> <p>The Board also modified the policy to state that, “Unless the applicable RRB has a pre-existing agreement regarding point assignment for these diagnoses, an initial MELD score of 22/ PELD score of 28 shall be assigned.”</p> <p>In November 2009, the Board approved changes to the policies and RRB guidelines to</p>	<p>The changes to policy :</p> <ul style="list-style-type: none"> • State that only those regional agreements that assign higher MELD scores than dictated by the policy would be accepted • Require regional agreements to be renewed each year • Clarify that extensions receive a 10 percent mortality increase every three months. <p>The committee modified Table 4 (criteria for cholangiocarcinoma (CCA)) for clarity.</p> <p>The committee modified the RRB Guidelines to allow the RRB chair to determine whether the case meets the criteria in policy. The chair will base his/her decision on the information submitted by the center. If the chair determines that the case does not meet criteria, then the case will be submitted to the RRB for a vote.</p>	<p>The Committee is developing data templates for each of the six diagnoses. Centers will use these templates when entering the required information in the MELD/PELD exception application.</p> <p>Liver transplant centers should be familiar with changes to the RRB Guidelines.</p>

accommodate the non-programming implementation of the policy. Several sections of the policy were also revised for clarity.		
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Title of Bylaw Change: UNOS Bylaws Change to Reconcile Discrepancies in Patient Volume Requirements for Full and Conditional Program Approval when Qualifying Kidney, Liver, and Pancreas Primary Transplant Physicians

Sponsoring Committee: Membership and Professional Standards Committee (MPSC)

Bylaws Affected: Appendix B, Attachment I, Section XIII (Transplant Programs), D, (1) Kidney Transplantation, (jj) Conditional Approval, (ii) and (v); Appendix B, Attachment I, Section XIII (Transplant Programs), D, (3) Liver Transplantation, (hh) Conditional Approval, (ii) and (v); and Appendix B, Attachment I, Section XIII (Transplant Programs), D, (5) Pancreas Transplantation, (ee) Conditional Approval, (ii) and (v).

Action Required: Review and Respond as Necessary

Effective Date: January 17, 2010

Professional Groups Affected by the Change:

Primary Transplant Physicians, Transplant Administrators, Transplant Program Directors

Problem Statement	Changes	What You Need to Do
<p>To gain conditional program approval, the MPSC would like transplant programs to meet at least 50 percent of the primary care volume requirements needed for full approval. Current bylaw language permits programs to propose and qualify primary physician candidates for conditional program approval without meeting 50 percent of the full requirement. The primary physician at the conditionally-approved program can then qualify that program for full approval status after one year at conditional approval without ever having met the same total patient volume requirements as the primary physician originally qualifying at a fully approved program. (See Table 1 below)</p>	<p>Table 1 below displays the changes the Board approved regarding the requirements needed by primary transplant physicians to qualify for conditional program approval, and the qualifications needed in order for conditionally approved programs to attain full approval.</p>	<p>If transplant programs want a primary transplant physician to qualify under the conditional-approval pathway, they need to document that the proposed physician has provided primary care for the number of transplant patients (see recently- approved bylaws and Table 1) for each respective organ when they submit their application. In addition, the transplant program will need to report to UNOS its progress towards caring for the total number of patients for each respective organ (see recently- approved bylaws Table 1) to attain full approval within 12 months of the conditional-approval date.</p>

Table 1- Board of Directors Approved Primary Care Patient Volume Requirements (Full and Conditional)

	Total Primary Care Patient Volume Requirement	Total Primary Care Patient Volume Requirement	Total Primary Care Patient Volume Requirement	Cumulative Primary Care Patient Volume Requirement after 1 year Conditional to Achieve Full Program Approval	Cumulative Primary Care Patient Volume Requirement after 1 year Conditional to Achieve Full Program Approval
	Full Approval	Conditional Approval	Conditional Approval	Full Approval	Full Approval
	Current	Current as of Nov '09	BOD Approved Nov '09	Current as of Nov '09	BOD Approved Nov '09
Kidney	45	15	23	30	45
Liver	50	15	25	30	50
Pancreas *	8	5	4	10	8

* applies to both (aa) training and (bb) acquired clinical experience qualification pathways

Title of Bylaw Change: Notification Requirements for OPOs, Transplant Hospitals, and Histocompatibility Labs When Faced with an Adverse Action Taken by Regulatory Agencies.

Sponsoring Committee: Membership & Professional Standards Committee (MPSC)

Bylaw Affected: Bylaws, Appendix B, Sections I, II, III: Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership

Action Required: Review Only

Effective Date: January 17, 2010

Professional Groups Affected by the Change:

OPO Executive Directors, Directors of Organ Procurement, OPO Medical Directors, Transplant Administrators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Lab Directors, Lab Supervisors

Problem Statement	Changes	What You Need to Do
<p>Current bylaws require members to notify UNOS of any threatened or real adverse action against them and must submit all materials relating to the issue, within five days. The Board of Directors approved existing bylaw language in June 2006, concurrent with public comment. At that time, and of particular interest now, the Centers for Medicare and Medicaid Services (CMS) had not yet finalized its process for approving transplant programs. The MPSC is aware that there are transplant programs that have not met CMS Conditions of Participation and that have applied for CMS approval, based on mitigating factors.</p> <p>The existing bylaws require members in this situation to notify UNOS, though few have done so. The MPSC, recognizing that the CMS-approval process may take several months and may require</p>	<p>The modifications include:</p> <ul style="list-style-type: none"> • Requiring members to notify UNOS of final adverse actions only (not threatened). • Requiring members to notify UNOS within 10 business days. • No longer requiring members to submit all materials relating to the issue. 	<p>OPOs, transplant programs, and histocompatibility labs faced with a final adverse action must notify the UNOS Membership department in writing within 10 days after they are notified of an adverse action. This written notification should include a copy of the original notice of deficiencies and the final determination letter.</p>

<p>multiple submissions of supporting documentation, recommended that UNOS modify the bylaws so that members are only required to notify UNOS about final adverse action(s).</p> <p>Though CMS is referenced, it should be noted that these requirements relate to any regulatory agency or its designee.</p>		
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Title of Bylaw Change: Proposal to Change the Bylaws to Clarify the Process for Reporting Changes in Key Personnel

Sponsoring Committee: Membership and Professional Standards Committee (MPSC)

Bylaw Affected: Appendix B, Section II, E (Key Personnel); and Bylaws, Appendix B, Attachment 1, Section III (Changes in Key Personnel)

Action Required: Review and Respond as Necessary

Effective Date: January 17, 2010

Professional Groups Affected by the Change:

Transplant Administrators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians

Problem Statement	Changes	What You Need to Do
<p>The staffs at member hospitals have had various misinterpretations of the bylaws addressing key personnel and changes in key personnel. The vague bylaw language has ultimately affected some transplant hospitals ability to comply. In response to this, the MPSC proposed changes for these sections.</p>	<p>The changes made to the bylaw language better articulate current practice without substantially adding to the requirements.</p> <p>Changes to the bylaws address these specific areas:</p> <ul style="list-style-type: none"> • Short term absences and reference to program coverage plans. • Reinstatement process for returning key personnel. • Reference to succession planning added. • Removed reference to 15-days to avoid confusion with vacation leave. • Sudden and unexpected changes in key personnel. • Requirement that hospitals submit written notification of a change within seven business days. • Defined implications if notice is not given within seven days. • Minimum number of days (30) a hospital has to 	<p>Transplant Hospitals should review and become familiar with the bylaw modifications.</p> <p>When a transplant hospital becomes aware of a key personnel change, it must notify UNOS in writing within seven business days. Notifications should include the nature of the change and the effective date. If a physician or surgeon has left or is no longer affiliated with the program, the transplant hospital needs to record the effective date as the last date the doctor is actively engaged in the program, not necessarily the date that accumulated leave time might end. The staff member responsible for the notice and the application should contact the UNOS Membership Coordinator to discuss the specific case and receive individualized assistance. The Membership Coordinator will provide the hospital with the appropriate application materials and due</p>

	<p>submit an application</p> <ul style="list-style-type: none"> • Defined implications if application is incomplete 	<p>dates.</p> <p>Transplant hospitals must submit a key personnel change application to UNOS at least 30 days before a change in key personnel (primary surgeon, primary physician) occurs.</p> <p>In addition, the transplant hospital is responsible for the development of a succession plan that addresses how it will handle planned and unplanned changes to key personnel in the future.</p>
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Notice of Policy Change: New Policy Added to Address Conflicts of Interest Associated with Having the Same Physician Declare Death and Perform Organ Procurement or Transplant Operation.

Sponsoring Committee: Membership and Professional Standards Committee (MPSC)

Policy Affected: Policy 3.4.1 (Avoidance of Conflicts of Interest)

Action Required: Review Only

Effective Date: December 17, 2009

Professional Groups Affected by the change:

OPO Executive Directors, Directors of Organ Procurement, OPO Procurement Coordinators, OPO Medical Directors, Transplant Administrators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians.

Current Issue/Policy	Change or Addition	What You Need to Do
<p>Policy 2.2.1 states that the host Organ Procurement Organization (OPO) is responsible for verifying that potential donor death has been pronounced according to applicable laws. There was no comparable policy for transplant hospitals that specifically prohibited a physician from declaring death and then later participating in procuring and transplanting those organs or tissues.</p>	<p>The new policy makes it clear that all physicians participating in the declaration of death of a potential donor are accountable for avoiding conflicts of interest with respect to removing or transplanting an organ from the decedent.</p>	<p>Transplant centers will need to review their current practices to ensure that they are in compliance. This new policy should not place an undue burden on transplant centers or OPOs since they should already be in compliance with their state laws that include similar language.</p>

Affected Policy Language:

Underlines and strikethroughs indicate language that has been added or removed.

- 3.2.1.8.1** **Waiting Time Modification for Urgent Status Candidates.** Adjustments will be permitted to the waiting time of Status 1 liver transplant candidates, ~~and~~ Status 1A heart transplant candidates, and Priority 1 pediatric lung candidates registered on the Waiting List if an error or miscommunication occurred in listing, modification, or accidental removal of the candidate, or in renewing the candidate's status. Supporting documentation must be submitted, including a written request from the physician/surgeon in charge of the candidate's care explaining the circumstance along with the appropriate status justification form and Wait Time Modification Form. Upon receipt of completed documentation, the requested modification will be made. Each case will be reported retrospectively to the appropriate regional review board for consideration.

To read the complete policy language visit www.unos.org or optn.transplant.hrsa.gov. From the UNOS website, select Resources from the main menu, and then select Policies. From the OPTN website, select Policy Management from the main menu, and then select Policies.

Affected Policy Language:

Underlines and strikethroughs indicate language that has been added or removed.

- 3.7.10.1 Sequence of Pediatric Heart Allocation.** Hearts recovered from 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. Local Status 1A Adult candidates~~
 - ~~3. Combined Local and Zone A Status 1B Pediatric candidates~~
 - ~~4. Local Status 1B Adult candidates~~
 - ~~5. Zone A Status 1A Adult candidates~~
 - ~~6. Zone A Status 1B Adult candidates~~
 - ~~7. Local Status 2 Pediatric candidates~~
 - ~~8. Local Status 2 Adult candidates~~
 - ~~9. Zone B Status 1A Pediatric candidates~~
 - ~~10. Zone B Status 1A Adult candidates~~
 - ~~11. Zone B Status 1B Pediatric candidates~~
 - ~~12. Zone B Status 1B Adult candidates~~
 - ~~13. Zone A Status 2 Pediatric candidates~~
 - ~~14. Zone A Status 2 Adult candidates~~
 - ~~15. Zone B Status 2 Pediatric candidates~~
 - ~~16. Zone B Status 2 Adult candidates~~
 - ~~17. Zone C Status 1A Pediatric candidates~~
 - ~~18. Zone C Status 1A Adult candidates~~
 - ~~19. Zone C Status 1B Pediatric candidates~~
 - ~~20. Zone C Status 1B Adult candidates~~
 - ~~21. Zone C Status 2 Pediatric candidates~~
 - ~~22. Zone C Status 2 Adult candidates~~
 - ~~23. Zone D Status 1A Pediatric candidates~~
 - ~~24. Zone D Status 1A Adult candidates~~
 - ~~25. Zone D Status 1B Pediatric candidates~~
 - ~~26. Zone D Status 1B Adult candidates~~
 - ~~27. Zone D Status 2 Pediatric candidates~~
 - ~~28. Zone D Status 2 Adult candidates~~
 - ~~29. Zone E Status 1A Pediatric candidates~~
 - ~~30. Zone E Status 1A Adult candidates~~
 - ~~31. Zone E Status 1B Pediatric candidates~~
 - ~~32. Zone E Status 1B Adult candidates~~
 - ~~33. Zone E Status 2 Pediatric candidates~~
 - ~~34. Zone E Status 2 Adult candidates~~
 1. Common OPO and Zone A Status 1A ABO Primary Ped Candidates for Pediatric Donor
 2. Common OPO and Zone A Status 1A ABO Secondary Ped Candidates for Pediatric Donor
 3. Common OPO Status 1A ABO Primary Candidates
 4. Common OPO Status 1A ABO Secondary Candidates
 5. Common OPO and Zone A Status 1B ABO Primary Ped Candidates for Pediatric Donor

6. Common OPO and Zone A Status 1B ABO Secondary Ped Candidates for Pediatric Donor
7. Common OPO Status 1B ABO Primary Candidates
8. Common OPO Status 1B ABO Secondary Candidates
9. Zone A Status 1A ABO Primary Candidates
10. Zone A Status 1A ABO Secondary Candidates
11. Zone A Status 1B ABO Primary Candidates
12. Zone A Status 1B ABO Secondary Candidates
13. Common OPO Status 2 ABO Primary Ped Candidates for Pediatric Donor
14. Common OPO Status 2 ABO Secondary Ped Candidates for Pediatric Donor
15. Common OPO Status 2 ABO Primary Candidates
16. Common OPO Status 2 ABO Secondary Candidates
17. Zone B Status 1A ABO Primary Ped Candidates for Pediatric Donor
18. Zone B Status 1A ABO Secondary Ped Candidates for Pediatric Donor
19. Zone B Status 1A ABO Primary Candidates
20. Zone B Status 1A ABO Secondary Candidates
21. Zone B Status 1B ABO Primary Ped Candidates for Pediatric Donor
22. Zone B Status 1B ABO Secondary Ped Candidates for Pediatric Donor
23. Zone B Status 1B ABO Primary Candidates
24. Zone B Status 1B ABO Secondary Candidates
25. Zone A Status 2 ABO Primary Ped Candidates for Pediatric Donor
26. Zone A Status 2 ABO Secondary Ped Candidates for Pediatric Donor
27. Zone A Status 2 ABO Primary Candidates
28. Zone A Status 2 ABO Secondary Candidates
29. Zone B Status 2 ABO Primary Ped Candidates for Pediatric Donor
30. Zone B Status 2 ABO Secondary Ped Candidates for Pediatric Donor
31. Zone B Status 2 ABO Primary Candidates
32. Zone B Status 2 ABO Secondary Candidates
33. Zone C Status 1A ABO Primary Ped Candidates for Pediatric Donor
34. Zone C Status 1A ABO Secondary Ped Candidates for Pediatric Donor
35. Zone C Status 1A ABO Primary Candidates
36. Zone C Status 1A ABO Secondary Candidates
37. Zone C Status 1B ABO Primary Ped Candidates for Pediatric Donor
38. Zone C Status 1B ABO Secondary Ped Candidates for Pediatric Donor
39. Zone C Status 1B ABO Primary Candidates
40. Zone C Status 1B ABO Secondary Candidates
41. Zone C Status 2 ABO Primary Ped Candidates for Pediatric Donor
42. Zone C Status 2 ABO Secondary Ped Candidates for Pediatric Donor
43. Zone C Status 2 ABO Primary Candidates
44. Zone C Status 2 ABO Secondary Candidates
45. Zone D Status 1A ABO Primary Ped Candidates for Pediatric Donor
46. Zone D Status 1A ABO Secondary Ped Candidates for Pediatric Donor
47. Zone D Status 1A ABO Primary Candidates
48. Zone D Status 1A ABO Secondary Candidates
49. Zone D Status 1B ABO Primary Ped Candidates for Pediatric Donor
50. Zone D Status 1B ABO Secondary Ped Candidates for Pediatric Donor
51. Zone D Status 1B ABO Primary Candidates

52. Zone D Status 1B ABO Secondary Candidates
53. Zone D Status 2 ABO Primary Ped Candidates for Pediatric Donor
54. Zone D Status 2 ABO Secondary Ped Candidates for Pediatric Donor
55. Zone D Status 2 ABO Primary Candidates
56. Zone D Status 2 ABO Secondary Candidates
57. Zone E Status 1A ABO Primary Ped Candidates for Pediatric Donor
58. Zone E Status 1A ABO Secondary Ped Candidates for Pediatric Donor
59. Zone E Status 1A ABO Primary Candidates
60. Zone E Status 1A ABO Secondary Candidates
61. Zone E Status 1B ABO Primary Ped Candidates for Pediatric Donor
62. Zone E Status 1B ABO Secondary Ped Candidates for Pediatric Donor
63. Zone E Status 1B ABO Primary Candidates
64. Zone E Status 1B ABO Secondary Candidates
65. Zone E Status 2 ABO Primary Ped Candidates for Pediatric Donor
66. Zone E Status 2 ABO Secondary Ped Candidates for Pediatric Donor
67. Zone E Status 2 ABO Primary Candidates
68. Zone E Status 2 ABO Secondary Candidates
69. Common OPO and Zone A Status 1A ABO Incompatible Ped Candidates for Pediatric Donor
70. Common OPO and Zone A Status 1B ABO Incompatible Ped Candidates for Pediatric Donor
71. Common OPO Status 2 ABO Incompatible Candidates
72. Zone B Status 1A ABO Incompatible Candidates
73. Zone B Status 1B ABO Incompatible Candidates
74. Zone C Status 1A ABO Incompatible Candidates
75. Zone C Status 1B ABO Incompatible Candidates
76. Zone D Status 1A ABO Incompatible Candidates
77. Zone D Status 1B ABO Incompatible Candidates
78. Zone E Status 1A ABO Incompatible Candidates
79. Zone E Status 1B ABO Incompatible Candidates
80. Common OPO and Zone A ABO Primary In Utero Candidates
81. Common OPO and Zone A ABO Secondary In Utero Candidates
82. Common OPO and Zone A ABO Incompatible In Utero Candidates
83. Zone B ABO Primary In Utero Candidates
84. Zone B ABO Secondary In Utero Candidates
85. Zone B ABO Incompatible In Utero Candidates
86. Zone C ABO Primary In Utero Candidates
87. Zone C ABO Secondary In Utero Candidates
88. Zone C ABO Incompatible In Utero Candidates
89. Zone D ABO Primary In Utero Candidates
90. Zone D ABO Secondary In Utero Candidates
91. Zone D ABO Incompatible In Utero Candidates
92. Zone E ABO Primary In Utero Candidates
93. Zone E ABO Secondary In Utero Candidates
94. Zone E ABO Incompatible In Utero Candidates

To read the complete policy language visit www.unos.org or optn.transplant.hrsa.gov. From the UNOS website, select Resources from the main menu, and then select Policies. From the OPTN website, select Policy Management from the main menu, and then select Policies.

Affected Policy Language:

The modifications to Policy 5.0 appear below. The entire policy was restructured and wording clarified. Because the changes would be difficult to read with continuous strikethroughs and underlines typically seen in these proposed policy documents, the Committee is presenting these policy changes differently. Most of the intent of the policy language has not changed; however, for your convenience:

- The approved, rewritten language is presented below.
- Any “substantive” content changes from the original policy language have been highlighted.
- Changes made in response to public comment are demonstrated by highlighting and strikethroughs (deletions) or a double underline (additions).
- Following the proposed new language, the existing policy language follows and is completely marked through with ~~strikethroughs~~.
- All references to Living Donors have been removed due to the creation of Policy 12.0 regarding living donation.

5.0 STANDARDIZED PACKAGING, LABELING AND TRANSPORTING OF ORGANS, VESSELS, AND TISSUE TYPING MATERIALS

The purpose of Policy 5.0 and its subsections is to:

- state requirements for packaging and labeling organs, tissue typing specimens, and vessels to prevent wastage (and/or to promote safe and efficient use);
- define terms and responsibilities related to packaging, labeling, and transporting organs, tissue typing specimens, and vessels; and
- state requirements for recovering, storing, and using vessels in solid organ recipients.

The responsibility for packaging and labeling deceased donor organs is assigned to the Host OPO. Transplant Center staff may not leave the operating room without allowing the OPO to package and label the organ in accordance with OPTN policy. The OPO must submit a report through the Patient Safety System when a Transplant Center fails to comply with this policy. The OPO will make all reasonable efforts to package and label the organ in a timely fashion. If an organ is repackaged by a transplant center for transport, the Transplant Center will package, label and ship the organ in accordance with this policy.

5.1 EXTERNAL PACKAGING SPECIFICATIONS

An external transport container is defined as a: disposable shipping box, cooler or mechanical preservation machine. The transplant center or OPO must use both internal and external transport containers to package a deceased ~~or living~~ donor organ that travels outside the recovery facility.

5.1.1 Disposable shipping box

- If organs, vessels and/or tissue typing materials are shipped commercially, a disposable shipping box must be used.
- The disposable shipping box must be labeled with the standardized label distributed by the OPTN contractor.
- Disposable boxes must not be reused.

- The outer box must be a **corrugated plastic** or corrugated cardboard that is coated with a water resistant substance ~~wax coated corrugated cardboard~~ with at least 200 pound burst strength.
- The inner container must be a 1.5 inches thick, insulated container OR have an equivalent “R” value.
- A closed **colored opaque plastic bag** must be placed between the outer container and the insulated container. Closed is defined as being secured in a manner to prevent leakage (i.e. watertight).
- A second closed plastic liner must also be placed inside the insulated container to encase the ice. Closed is defined as being secured in a manner to prevent leakage (i.e. water tight).

5.1.2 Cooler

- Coolers are permitted for non-commercial transporting of organs when the organ recovery team is transporting the **donor organ** with them from the donor hospital to the candidate transplant center.
- Coolers must be labeled with the standardized label provided by the OPTN contractor.
- Coolers may be reused if properly cleaned and sanitized.
- Before re-using a cooler, all labels from the previous donor organ must be removed.

5.1.3 Mechanical preservation machine

- Mechanical preservation machines are permitted for transporting an organ.
- **The cassette containing the organ must be labeled with the organ type (i.e. left kidney, right kidney), ABO, and UNOS ID.**
- The external surface of a mechanical preservation machine must be labeled with:
 - the standardized label provided by the OPTN contractor, or
 - an alternate label that contains all information **included on the OPTN contractor standardized label.**
- Before re-using a mechanical preservation machine that was used to transport an organ, all labels from the previous donor organ must be removed.

5.2 INTERNAL PACKAGING SPECIFICATIONS

All organs that have been packaged on the donor’s back table must be handled using universal precautions. The packaged organs from the donor’s surgical back table are to be placed directly into the wet iced shipping container. Proper insulation and temperature controlled packaging including adequate ice or refrigeration must be used to protect the organs during transport.

- Organs must be protected by a triple sterile barrier.
- Kidneys **and** pancreata **and hearts** must be placed in a rigid container, which, if sterile, can be one layer of the triple sterile barrier.
- **Hearts,** Livers, lungs, and intestines do not require a rigid container.
- **Vessels must be protected by a triple sterile barrier; if packaged separately from the organ, one barrier must be a rigid container.**

5.3 EXTERNAL LABELING REQUIREMENTS

When a disposable shipping box or cooler is used to transport a deceased donor organ, the Host OPO must use the standardized external label distributed by the OPTN contractor. When a mechanical preservation machine is used, the OPO or Transplant Center, as applicable, may use an alternative label if the label contains all of the required information.

The external transport container must be labeled with the: UNOS Donor I.D. Number, Donor ABO type, a description of the specific contents of the box, the sender's name and telephone number, and the Organ Center telephone number. The label must be securely affixed to the external transport container. The OPTN contractor distributes a standardized external label that includes this information.

5.4 INTERNAL LABELING REQUIREMENTS

5.4.1 Solid organ

The Host OPO is responsible for ensuring that the UNOS Donor I.D. number, donor ABO type, and a secure label identifying the specific contents (e.g., liver, right kidney, heart) are attached to the outer bag or rigid container housing the donor organ.

5.4.2 Tissue typing materials

Each separate specimen container of tissue typing material must have a secure label with two unique identifiers, one being the UNOS Donor I.D., and one of the following three: donor date of birth, donor initials or locally assigned unique ID, Number (donor ABO is not considered a unique identifier). Additionally each specimen should be labeled with Donor ABO, date and time the sample was procured and the type of tissue. In the preliminary evaluation of a donor, if the UNOS ID is not available, it is permissible to use a locally assigned unique ID and one other identifier for the transportation of initial screening specimens.

5.4.3 Vessels

If packaged separately from the organ, the vessels must be protected by a triple sterile barrier, one of which must be a rigid container, labeled with the: recovery date, ABO, all serology results, container contents, and the UNOS Donor ID Number. If the donor is in a "high risk"¹ group as defined by the Centers for Disease Control and Prevention (CDC), the label must indicate that the vessels are from a donor who meets the CDC criteria for high risk. The appropriate packaging of vessels should be completed in the donor operating room. The label should clearly state "for use in organ transplantation only."

5.5 DOCUMENTATION ACCOMPANYING THE ORGAN OR VESSEL

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>

5.5.1 Documentation accompanying the organ

- Complete donor documentation, as described in Policy 2.5.76.1, must be sent in the container with all transported organs.
- Donor documentation must be placed in a watertight container.
- Donor documentation may be placed in either:
 - a location specifically designed for documentation, or
 - between the outer and inner containers.
- Whenever a deceased donor organ is transported, the Host OPO or the Transplant Center, as applicable, must include in the donor documentation the source documentation.

5.5.2 Documentation accompanying the vessel

If the vessels are not shipped in the same package as the organ, the same documentation must be included with the vessels as is included with the organ.

5.6 VERIFICATION OF LABELING AND DOCUMENTATION INCLUDED WITH ORGANS OR VESSELS

5.6.1 Verification of labeling and documentation for deceased donor organs or vessels.

When a deceased donor organ or vessel(s) is procured, the Host OPO must ensure the accuracy of the donor's ABO on the container label and within the donor's documentation. Each OPO must establish and implement a procedure for verifying the accuracy of organ/vessel packaging labels by an individual other than the person initially performing the labeling and documentation requirements stated in policy 5.3, 5.4 and 5.5. The Host OPO must maintain documentation that such separate verification has taken place and make such documentation available for audit.

5.7 VERIFICATION OF INFORMATION UPON RECEIPT OF ORGAN

Upon receipt of a ~~living or~~ deceased donor organ and prior to implantation, the Transplant Center must determine that it has received the correct organ for the correct transplant candidate by verifying the recorded donor and recipient ABO, and UNOS Donor ID, as required by Policy 3.1.2. The Transplant Center must maintain documentation that this verification has taken place and make such documentation available for audit.

5.8 MATERIALS FOR TISSUE TYPING AND ABO CONFIRMATION

5.8.1 Policy for tissue typing specimen, medium, and shipping requirements

Each OPO must have a written policy established ~~and an agreement~~ with an OPTN member laboratory(s). The policy shall include specific descriptions of the type of specimen, and medium, in addition to the shipping requirements of same.

5.8.2 Blood for ABO Confirmation

A "red top" tube of blood, specifically for confirmation of ABO must be sent to the receiving OPO or transplant center with each deceased organ and tissue typing material. This tube must be labeled as described in Policy 5.4.2 with the exception that the blood type may not be indicated on the label, and placed within the insulated

container. The Host OPO is responsible for ensuring that the tube is appropriately labeled.

5.8.3 Typing material for each kidney and pancreas

In view of the frequent need for regional shipment of pancreas and kidney allografts, sufficient specimens for several crossmatches are required. However, minimal typing material to be obtained for EACH kidney and pancreas will include the following:

- 2 ACD (yellow top) tubes
- 3 to 5 lymph nodes
- One 2 X 4 cm. wedge of spleen in culture medium, if available

5.8.4 Typing material for all other organs

- The Host OPO will provide specimens for tissue typing if requested.

5.9 ~~LIVING OR DECEASED DONOR ORGANS THAT REMAIN IN THE SAME OPERATING ROOM SUITE AS THE INTENDED CANDIDATE(S)~~

5.9.1 When deceased donor organs are recovered and remain in the same operating room suite as the intended candidate(s), the Host OPO (if applicable) and Transplant Center must develop, implement, and comply with a procedure to ensure identification of the correct donor organ for the correct recipient. ~~The Transplant Center must document that the correct organ was identified for the correct candidate prior to transplant (refer to Policy 3.1.2).~~ A “time out” prior to leaving the donor operating room and an additional “time out” upon arrival in the candidate operating room are required. ~~These “time outs” are for tThe Transplant Center must to confirm and~~ document that the correct organ was identified for the correct candidate prior to transplant (refer to Policy 3.1.2).

5.10 VESSEL RECOVERY, TRANSPLANT, AND STORAGE

The intent of this policy is to permit:

- vessel recovery and immediate use in a solid organ transplant (for example either a current liver or pancreas transplant); and
- vessel recovery and storage for use in a subsequent solid organ transplant from a donor with a different UNOS Donor ID (for example, when the vessel(s) and the liver or pancreas allograft are being transplanted from different donors with different numbers).

5.10.1 Vessel recovery and transplant

- The consent forms used by the recovering OPO must include language that indicates that vessels will be used for transplant.
- The vessels cannot be used other than for the implantation or modification of a solid organ transplant.
- Vessels can be shared among transplant programs. If sharing occurs between transplant programs, the implanting program must submit to the OPTN a detailed explanation justifying the sharing. The justification will be reviewed

by the Membership and Professional Standards Committee (MPSC). The implanting transplant program must notify ~~the OPO and~~ the OPTN of subsequent disposition of the vessel(s).

- If the transplant center stores vessels and subsequently uses the vessels for the intended recipient or another transplant recipient, the ~~Host OPO and~~ the OPTN must be notified.
- If vascular conduits from donors with positive serology for hepatitis are subsequently used in other than the intended recipient, the implanting transplant center must provide a detailed explanation to the OPTN for the use of this conduit. The explanation will be reviewed by the MPSC.

5.10.2 Vessel storage

The Transplant Center must designate a person to monitor and maintain records, destroy, and notify the ~~Host recovering OPO and~~ OPTN of outcome and/or use of vessels. This designated person must maintain information on all donor vessels including monitoring and maintaining all records relating to the use and management of donor vessels (e.g. subsequent positive serology testing, monitor inventory of stored vascular conduits). This person must monitor the refrigerator, ensure records are up to date and available with the conduits, destroy the vessels when expired, and notify the ~~OPTN recovering OPO~~ of its use or disposal.

- The vessels must be stored in a Food and Drug Administration (FDA) approved preservation solution (ex. UW, Custodial HTK).
- The vessels must be stored in a **rigid, sterile** sealed container labeled with the recovery date, ABO, serology, container contents, and the **UNOS Donor ID Number** for tracking. The appropriate packaging of vessels should be completed in the donor operating room. Label should clearly state for use in organ transplantation only.
- The vessel(s) must be stored in a secured refrigerator **with a temperature monitor and maintained** within a range of 2 - 8 degrees Celsius.
- There must be daily monitoring of the vessel(s) with documented security and temperature checks by the transplant center.
- The vessel(s) can be stored up to a maximum of 14 days from the original recovery date.
- The transplant center must maintain a log of stored vessels.
- The transplant surgeon must have around the clock access to the donor information prior to using the donor vessel(s) in a recipient other than the intended recipient.

5.11 TRANSPORTATION RESPONSIBILITY

The purpose of this policy is to define the responsibility of transportation costs for deceased donor organs.

5.11.1 Renal organs

The Host OPO is responsible for transportation costs for deceased donor kidney(s) and associated tissue typing material **pursuant to CMS regulations**.

5.11.2 Non-renal organs

The member that accepted the organ is responsible for transportation costs for deceased donor non-renal organ(s) (to include kidney-pancreas and pancreas islet) and associated tissue typing material to its destination. If a donor organ is first accepted by one member and subsequently forwarded to another member, payment of transportation costs for forwarding the organ is the responsibility of the member that finally accepts the organ, **unless otherwise agreed upon by the parties involved.** If a non-renal organ has been accepted and transported, but cannot be used for transplantation, the member that finally accepted the organ is responsible for payment of transportation costs, **unless otherwise agreed upon by the parties involved.** The OPTN contractor will not incur transportation costs for non-renal organs or tissue typing material.

5.11.3 Tissue typing material

The Host OPO is responsible for payment of transportation costs for tissue typing material sent to crossmatch potential recipients of a deceased donor kidney. The member that requested the tissue typing material is responsible for the payment of transportation costs for the tissue typing material sent to crossmatch potential recipients for a non-renal organ.

~~5.0 STANDARDIZED PACKAGING AND TRANSPORTING OF ORGANS AND TISSUE TYPING MATERIALS~~

~~The following policies address standardized packaging of live and deceased donor organs and tissue typing materials to be transported for the purposes of organ transplantation. When a deceased donor organ is procured, the Host OPO shall be responsible for ensuring the accuracy of the donor's ABO on the container label and within the donor's documentation. Each OPO shall establish and implement a procedure for obtaining verification of donor ABO data by an individual other than the person initially performing the labeling and documentation requirements put forth in policy 5.2 and 5.3. The OPO shall maintain documentation that such separate verification has taken place and make such documentation available for audit.~~

~~Upon receipt of a live or deceased donor organ and prior to implantation, the Transplant Center shall be responsible for determining the accuracy and compatibility of the donor and recipient ABO and document this verification in compliance with Policy 3.1.2.~~

~~**5.1 — SPECIMEN COLLECTION AND STORAGE.** Each OPO shall have a written policy established with (a) laboratory(s) approved by the American Society for Histocompatibility and Immunogenetics (ASHI) or the OPTN. This policy should be determined by the specimen requirements of the typing laboratory and the quality assurance criteria of ASHI or the OPTN. The policy shall include specific descriptions of the type of specimen, and medium, in addition to the shipping requirements of same.~~

~~**5.2 — STANDARD LABELING SPECIFICATIONS.** The Host OPO or the Transplant Center, as applicable, shall be responsible for ensuring that the outermost surface of the~~

~~transport box containing organs and/or tissue typing specimen containers must have a completed standardized external organ container label (provided by the OPTN contractor). Any previous labels on the transport container must be removed prior to labeling the box so that only one label exists. The OPO shall label each specimen within the package in accordance with policy. The Host OPO is responsible for ensuring that each tissue or donor organ container that travels outside the recovery facility is labeled appropriately.~~

~~In the case of deceased or live donor organs that remain in the same operating room suite as the intended candidate(s), the Host OPO (if applicable) and Transplant Center must develop, implement, and comply with a procedure to ensure identification of the correct donor organ for the correct recipient. The Transplant Center must document that the correct organ was identified for the correct candidate prior to transplant. Some type of donor organ labeling and documentation must be present in the candidate chart. A “time out” prior to leaving the donor operating room and an additional “time out” upon arrival in the candidate operating room is recommended. Exception: In the case of a single donor organ/organ segment remaining in the same operating room suite as a single intended candidate for a simultaneous transplant, donor organ labeling and “time outs” are not necessary.~~

~~In the case of live donor organs that travel outside the recovery facility, the Transplant Center(s) involved shall be responsible for ensuring that packaging is consistent with the requirements of OPTN Policies 5.2.1 and 5.2.3, and that the outermost surface of the transport box containing the organ must have a completed OPTN/UNOS standardized external organ container label (provided by UNOS). The recovering Transplant Center shall label each specimen within the package in accordance with OPTN/UNOS policy. The recovering Transplant Center is responsible for ensuring that each container that travels outside the recovery facility is labeled appropriately.~~

~~**5.2.1** The Host OPO or the Transplant Center, as applicable is responsible for ensuring that the Donor I.D. number, donor ABO type, and a secure label identifying the specific contents (e.g., liver, right kidney, heart) are attached to the outer bag or rigid container housing the donor organ prior to transport.~~

~~**5.2.2** Each separate specimen container of tissue typing material must have a secure label with the Donor I.D. Number, donor ABO type, date and time the sample was procured and the type of tissue. The Host OPO or the Transplant Center, as applicable is responsible for labeling the materials appropriately.~~

~~**5.2.3** The Host OPO or the Transplant Center, as applicable is responsible for fixing to the transport container the standardized label completed with the Donor I.D. Number, Donor ABO type, a description of the specific contents of the box, the sender’s name and telephone number, and the Organ Center telephone number. A transport container is defined as a corrugated, wax coated disposable box, cooler, or mechanical preservation cassette or machine.~~

~~**5.3** **DOCUMENTATION.** ABO results must be provided by the Host OPO or the Transplant Center, as applicable in all circumstances during which a donor organ is transported. Properly packaged paperwork containing complete donor information, as described in~~

~~Policy 2.5.7.1, will be included with the organ transport container in all instances in which the organ is transported.~~

~~**5.4 PACKAGING.** In all circumstances during which donor organ is transported outside the recovery facility, the Host OPO or the Transplant Center, as applicable is responsible for packaging, labeling, and handling the organ in a manner which ensures arrival without compromise to the organ(s). Proper insulation and temperature controlled packaging including adequate ice or refrigeration shall be used to protect the organs during transport. All packaged organs, using disposable transport boxes, must have a red plastic bio hazard bag that is water tight secured to allow for safe handling by medical and non-medical personnel during transport. This red bag may be placed between the waxed cardboard box and the insulated material holding the wet ice and the organ.~~

~~All organs that have been packaged on the donor's back table must be handled using universal precautions. The packaged organs from the donor's surgical back table are to be placed directly into the wet iced shipping container.~~

~~**5.5 STANDARD ORGAN PACKAGE SPECIFICATIONS.** The re-use of disposable transport boxes is prohibited. If the deceased donor organ is to be commercially shipped, such as with a courier service, commercial airline or charter service, the deceased 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 deceased 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 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 must be placed between the outer container and the polystyrene insulated container to encase the ice.~~

~~**5.5.3** A closed plastic liner must also be placed inside the polystyrene container to encase the ice. Inside the insulated container, the organ must be protected by a triple sterile barrier and one rigid container which, if sterile, may be considered one of the triple barriers.~~

~~**5.5.3.1** The rigid container is not required for livers or lungs.~~

~~**5.5.4** The tissue typing specimen containers must be in a leak proof plastic bag and must not be imbedded in the ice.~~

~~**5.5.5** The deceased donor paperwork must be in a watertight container. It may be placed in a location specifically designed for the paperwork or inside the outer container, outside of the insulated container.~~

~~5.5.6~~ Accompanying each deceased organ and tissue typing material, a "red top" tube of blood, specifically for confirmation of ABO must be sent to the receiving OPO or transplant center. This tube must be labeled as described in Policy 5.2.2 and placed within the insulated container. The Host OPO is responsible for ensuring that the tube is appropriately labeled.

~~5.6~~ **TRANSPORTATION RESPONSIBILITY.** The Host OPO, as defined in Policy 2.1, is responsible for transportation of deceased donor kidney(s) and tissue typing material to the primary destination designated by the recipient member, (e.g., laboratory, transplant hospital, or OPO). In charter aircraft situations, before the Organ Center will arrange for this mode of transportation, the Host OPO must agree to use a charter aircraft, and it must be determined who will pay for the charter.

~~5.6.1~~ **Transportation Costs Incurred for Renal Organs.** Payment of transportation costs incurred by the OPTN contractor on behalf of a member for a donor kidney that is unconditionally accepted by a member and subsequently forwarded to another member is the responsibility of the member that forwarded the kidney. Payment of transportation costs incurred by the OPTN contractor on behalf of a member for a donor kidney that is conditionally accepted by a member and subsequently forwarded to another member is the responsibility of the Host OPO.

~~5.6.2~~ **Transportation Costs Incurred for Tissue Typing Material.** Payment of transportation costs incurred by the OPTN contractor on behalf of a member for tissue typing material sent to crossmatch backup recipients for a donor organ that is conditionally accepted by a member is the responsibility of the member which requested backup for the organ.

~~5.6.3~~ **Transportation Costs Incurred for Non-Renal Organs.** Payment of non-renal donor organ transportation costs incurred by the OPTN contractor on behalf of a member is the responsibility of the member that accepts the organ. Payment of transportation costs incurred by the OPTN contractor on behalf of a member for donor organs that have been accepted and transported, but cannot be utilized for transplantation, also is the responsibility of the member that accepted the organ. If a donor organ is first accepted by one member and subsequently forwarded to another member, payment of transportation costs incurred by UNOS on behalf of a member in forwarding the organ is the responsibility of the member that finally accepts the organ.

~~5.7~~ **VESSEL RECOVERY, STORAGE, and TRANSPLANT**

~~5.7.1~~ The practice of vessel recovery and immediate use in a solid organ transplant (for example either a current liver or pancreas transplant) should not be disrupted.

~~5.7.2~~ The sanction for vessel recovery and storage for use in a subsequent solid organ transplant from a different donor must be sustained: (for example, when the

~~vessels and the liver or pancreas allograft are being transplanted from different donors with different numbers). The vessels cannot be used other than for the implantation or modification of a solid organ transplant.~~

~~5.7.3 Vessels can be shared amongst transplant programs. If sharing occurs between transplant programs, the implanting program must write a detailed explanation justifying the sharing and that justification will be reviewed by the Membership and Professional Standards Committee (MPSC). It is the responsibility of the implanting transplant program to notify the OPO and the OPTN of subsequent disposition of the vessels.~~

~~5.7.4 If the vessels are stored and subsequently used for the intended recipient or another transplant recipient, the OPO and the OPTN must be notified.~~

~~5.7.5 The consent forms used by the recovering OPO must include language that indicates that vessels will be used for transplant.~~

~~5.7.6 If the vessels are being stored, the procedure of packaging, labeling, storage, the medium and temperature, the location, and the duration of storage must be addressed by the organ transplant community using the following standards.~~

~~5.7.6.1 The vessels must be stored in a Food and Drug Administration (FDA) approved preservation solution (ex. UW, Custodial HTK).~~

~~5.7.6.2. The vessels must be stored in a sealed container labeled with the recovery date, ABO, serology, container contents, and the Donor ID Number for tracking. The appropriate packaging of the vessel should be completed in the donor operating room. Label should clearly state for use in organ transplantation only.~~

~~5.7.6.3 The vessels must be stored in a secured refrigerator within a range of 2 to 8 °C.~~

~~5.7.6.4 The vessels can be stored up to a maximum of 14 days from the original recovery date.~~

~~5.7.6.5 The Transplant Center must designate a person to monitor and maintain records, destroy, and notify the OPO and OPTN of outcome and/or use of vessels. This designated person would maintain information on all donor vessels including monitoring and maintaining all records relating to the use and management of donor vessels (i.e. subsequent positive serology testing, monitor inventory of stored vascular conduits, monitor the refrigerator, ensure records are up to date and available with the conduits, destroy the vessel when expired, and notify the OPO of its use or disposal).~~

~~5.7.6.6~~ The transplant surgeon must be provided around the clock access to the donor information for his/her review prior to using the donor vessel in a recipient other than the intended recipient.

~~5.7.6.7~~ There must be daily monitoring of the vessels with documented security and temperature checks by the transplant center.

~~5.7.6.8~~ A log of stored vessels must be maintained by the transplant center at the point of storage.

~~5.7.7~~ If vascular conduits from donors with positive serology for hepatitis are subsequently used in other than the intended recipient, the implanting transplant center must provide a detailed explanation for the use of this conduit for review by the MPSC.

To read the complete policy language visit www.unos.org or optn.transplant.hrsa.gov. From the UNOS website, select Resources from the main menu, and then select Policies. From the OPTN website, select Policy Management from the main menu, and then select Policies.

Affected Policy Language:

Underlines indicate new and changed text.

12.3 Medical Evaluation of Living Donors**12.3.1 ABO Identification**

The member transplant hospital must ABO type, and subtype if appropriate, each living donor on two separate occasions prior to the donation. Two separate occasions are defined as two ABO samples taken at different times, and sent to the same or different laboratories.

12.8.1 Reporting Requirements

12.8.1.1 The living donor transplant program must use the source documents from both ABO typings to enter the living donor's ABO on the Living Donor Feedback Form. Additionally, each living donor program must develop, implement, and comply with a procedure to verify that the living donor's ABO was correctly entered on the Living Donor Feedback Form. A transplant program must document that each ABO entry was performed in adherence to the program's protocol. The program must maintain this documentation, and make it available to the OPTN Contractor, upon request.

To read the complete policy language visit www.unos.org or optn.transplant.hrsa.gov. From the UNOS website, select Resources from the main menu, and then select Policies. From the OPTN website, select Policy Management from the main menu, and then select Policies.

Affected Policy Language:

Underlines and strikethroughs indicate language that has been added or removed.

- 3.6.4.5 Liver Candidates with Exceptional Cases. Special cases require prospective review by the Regional Review Board. The center will request a specific MELD/PELD score and shall submit a supporting narrative. The Regional Review Board will accept or reject the center's requested MELD/PELD score based on guidelines developed by each RRB. Each RRB must set an acceptable time for Reviews to be completed, within twenty-one days after application; if approval is not given within twenty-one days, the candidate's transplant physician may list the candidate at the higher MELD or PELD score, subject to automatic referral 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. Exceptions to the MELD/PELD score must be reapplied every three months; otherwise the candidate's score will revert back to the candidate's current calculated MELD/PELD score. If the RRB does not recertify the MELD/PELD score exception, then the candidate will be assigned a MELD/PELD score based on current laboratory values. Centers may apply for a MELD/PELD score equivalent to a 10% increase in candidate mortality every 3 months as long as the candidate meets the original criteria. Extensions shall undergo prospective review by the RRB. A candidate's approved score will be maintained if the center enters the extension application more than 3 days prior to the due date and the RRB does not act prior to that date (i.e., the candidate will not be downgraded if the RRB does not act in a timely manner). If the extension application is subsequently denied then the candidate will be assigned the laboratory MELD score. Candidates meeting the criteria listed in 3.6.4.5.1 – 3.6.4.5.6 are eligible for additional MELD/PELD exception points, provided that the criteria are included in the clinical narrative. Unless the applicable RRB has a pre-existing agreement ~~regarding~~ for a higher point assignment for these diagnoses, an initial MELD score of 22/ PELD score of 28 shall be assigned. For candidates with Primary Hyperoxaluria meeting the criteria in 3.6.4.5.5, an initial MELD score of 28/ PELD score of 41 shall be assigned. These pre-existing agreements must be renewed on an annual basis.
- 3.6.4.5.1 Liver Candidates with Hepatopulmonary Syndrome (HPS). Candidates with a clinical evidence of portal hypertension, evidence of a shunt, and a PaO₂ < 60 mmHg on room air will be eligible for a MELD/PELD exception with a 10% mortality equivalent increase in points every three months if the candidate's PaO₂ stays below 60 mmHg. Candidates should have no significant clinical evidence of underlying primary pulmonary disease.
- 3.6.4.5.2 Liver Candidates with Cholangiocarcinoma. Candidates meeting the criteria listed in Table 4 will be will be eligible for a MELD/PELD exception with a 10% mortality equivalent increase every three months.
- 3.6.4.5.3 Liver Candidates with Cystic Fibrosis. Liver candidates with signs of reduced pulmonary function, defined as having an FEV₁ that falls below 40%, will be eligible for a MELD/PELD exception with a 10% mortality equivalent increase every three months.

- 3.6.4.5.4 Liver Candidates with Familial Amyloid Polyneuropathy (FAP). Candidates with a clear diagnosis, to include an echocardiogram showing the candidate has an ejection fraction > 40%, ambulatory status, and identification of TTR gene mutation (Val30Met vs. non-Val30Met) and a biopsy proven amyloid in the involved organ, will be eligible for a MELD/PELD exception with a 10% mortality equivalent increase every three months.
- 3.6.4.5.5 Liver Candidates with Primary Hyperoxaluria. Candidates with AGT deficiency proven by liver biopsy (sample analysis and/or genetic analysis), and listed for a combined liver-kidney transplant will be eligible for a MELD/PELD exception with a 10% mortality equivalent increase every three months. Candidates must have a GFR<= 25 ml/min for 6 weeks or more by MDRD6 or direct measurement (Iothalamate or iohexol).
- 3.6.4.5.6 Liver Candidates with Portopulmonary Syndrome. Candidates that meet the following criteria will be eligible for a MELD/PELD exception with a 10% mortality equivalent increase every three months if the mean pulmonary arterial pressure (MPAP) stays below 35 mmHg (confirmed by repeat heart catheterization).
- Diagnosis should include initial MPAP and pulmonary vascular resistance (PVR) levels, documentation of treatment, and post-treatment MPAP < 35 mmHg and PVR < 400 dynes/sec/cm⁻⁵.
 - Transpulmonary gradient should be required for initial diagnosis to correct for volume overload.

TABLE 4. Criteria for MELD Exception for Liver Transplant Candidates With Cholangiocarcinoma (CCA)

- Centers must submit a written protocol for patient care to the OPTN/UNOS Liver and Intestinal Organ Transplantation Committee before requesting a MELD score exception for a candidate with CCA. This protocol should include selection criteria, administration of neoadjuvant therapy before transplantation, and operative staging to exclude patients with regional hepatic lymph node metastases, intrahepatic metastases, and/or extrahepatic disease. The protocol should include data collection as deemed necessary by the OPTN/UNOS Liver and Intestinal Organ Transplantation Committee.
- Candidates must satisfy diagnostic criteria for hilar CCA: malignant-appearing stricture on cholangiography and one of the following: carbohydrate antigen 19-9 100 U/mL, or biopsy or cytology results demonstrating malignancy, ~~carbohydrate antigen 19-9 100 U/mL,~~ or aneuploidy. The tumor should be considered unresectable on the basis of technical considerations or underlying liver disease (e.g., primary sclerosing cholangitis).
- If cross-sectional imaging studies (CT scan, ultrasound, MRI) demonstrate a mass, the mass should be 3 cm or less.
- Intra- and extrahepatic metastases should be excluded by cross-sectional imaging studies of the chest and abdomen at the time of initial exception and every 3 months before score increases.
- Regional hepatic lymph node involvement and peritoneal metastases should be assessed by operative staging after completion of neoadjuvant therapy and before liver transplantation. Endoscopic ultrasound-guided aspiration of regional hepatic lymph nodes may be advisable to exclude patients with obvious metastases before neoadjuvant therapy is initiated.
- Transperitoneal aspiration or biopsy of the primary tumor (either by endoscopic ultrasound, operative, or percutaneous approaches) should be avoided because of the high risk of tumor seeding associated with these procedures.

Changes to the RRB Guidelines

B. Exceptional case requests for diagnoses included in 3.6.4.5.1 – 3.6.4.5.6

Exception applications for liver candidates with hepatopulmonary syndrome, cholangiocarcinoma, cystic fibrosis, familial amyloid polyneuropathy (FAP), primary hyperoxaluria, or portopulmonary syndrome, meeting the criteria specified in 3.6.4.5.1-3.6.4.5.6, will be submitted to the RRB chair. The chair will determine, based on the information contained in the clinical narrative, whether the case meets the criteria in policy and is eligible for the applicable higher MELD/PELD score (initial applications and extensions). If the chair determines that the case meets the criteria, UNOS RRB staff will mark the case as ‘approved.’ If the chair determines that the case does not meet criteria, then the case will be submitted to the RRB for a vote. If the case originates from the chair’s center, the alternate chair will decide on the case. If the alternate chair is unavailable, the case will be submitted to the RRB.

To read the complete policy language visit www.unos.org or optn.transplant.hrsa.gov. From the UNOS website, select Resources from the main menu, and then select Policies. From the OPTN website, select Policy Management from the main menu, and then select Policies.

Affected Bylaw Language:

Underlines and strikethroughs indicate language that has been added or removed.

APPENDIX B TO UNOS BYLAWS

Attachment I, XIII, Transplant Programs, D, (1), Kidney Transplantation

- (jj) In the case of a change in the primary kidney transplant physician at a UNOS approved kidney transplant program, if items (cc) iii or (ee) i-ii are not met, the replacement physician, a nephrologist can function as a kidney transplant physician for a maximum period of twelve months if the following conditions are met:
- (i) That the remaining parts of (cc) or (ee), as applicable, are met.
 - (ii) That the individual has been involved in the primary care of ~~15~~ 23 or more kidney transplant recipients, and has followed these patients for a minimum of 3 months from the time of their transplant. The application must be supported by a recipient log. Such a log should include at least the medical record and/or UNOS identification number of the recipient and date of transplant. Beginning January 1, 2007, this log should be signed by the program director, division chief, or department chair from program where the experience was gained.
 - (iii) That if the individual is qualifying as primary transplant physician by virtue of acquired clinical experience, this experience is equal to 12 months on an active kidney transplant service as the kidney transplant physician or under the direct supervision of a qualified kidney transplant physician and in conjunction with a kidney transplant surgeon at a UNOS approved kidney transplant center. This 12 month period of experience on the transplant service must be acquired over a maximum of 2 years.
 - (iv) That a consulting relationship with counterparts at another UNOS member transplant center approved for kidney transplantation has been established and documented.
 - (v) That activity reports are submitted to UNOS at two month intervals describing the transplant activity and results, physician recruitment efforts, and such other operating conditions as may be required by the Membership and Professional Standards Committee to demonstrate to the satisfaction of the Committee ongoing quality and efficient patient care. The reports must show that the individual is making sufficient progress to meet the objective of involvement in the primary care of at least ~~30~~ 45 kidney transplant recipients or that the program is making sufficient progress in recruiting and bringing to the program a transplant physician who meets this criterion as well as all other UNOS criteria for a qualified renal transplant physician by the date that is 12 months from the date of approval of the program under this section.
 - (vi) If the program is unable to demonstrate that it has an individual on site who can meet the requirements as described in sections (cc), (dd), (ee), (ff), (gg), (hh), or (ii) above at the end of 12 months, it shall inactivate. The requirements for program inactivation are described in Section II. The Membership and Professional Standards Committee may consider on a case by case basis, and grant a six month extension to a program that provides substantive evidence of progress towards completing the requirements but is unable to complete the requirements within one year.

Attachment I, XIII, Transplant Programs, D, (3), Liver Transplantation

- (hh) In the case of a change in the primary liver transplant physician at a UNOS approved transplant program, if items (aa) iii or (cc) i-ii are not met, the replacement physician, must be a gastroenterologist/hepatologist and can function as a liver transplant physician for a maximum period of twelve months if the following conditions are met:
 - (i) That the remaining parts of (aa) or (cc), as applicable, are met.
 - (ii) That the individual has been involved in the primary care of ~~45~~ 25 or more liver transplant recipients, and has followed these patients for a minimum of 3 months from the time of their transplant. The application must be supported by a recipient log. Such a log should include at least the medical record and/or UNOS identification number of the recipient and date of transplant. Beginning January 1, 2007, this log must be signed by the director and/or the primary transplant physician at the transplant program where the individual trained or gained this experience.
 - (iii) That if the individual is qualifying as primary transplant physician by virtue of acquired clinical experience, this experience must be a minimum of 12 months on an active liver transplant service as the qualified liver transplant physician or under the direct supervision of a qualified liver transplant physician and in conjunction with a liver transplant surgeon at a UNOS approved liver transplant center or an active foreign liver transplant program accepted as equivalent by the MPSC. This 12 month period of experience on the transplant service must be acquired over a maximum of 2 years.
 - (iv) That a consulting relationship with counterparts at another UNOS member transplant center approved for liver transplantation has been established and documented.
 - (v) That activity reports are submitted to UNOS at two month intervals describing the transplant activity and results, physician recruitment efforts, and such other operating conditions as may be required by the Membership and Professional Standards Committee to demonstrate to the satisfaction of the Committee ongoing quality and efficient patient care. The reports must show that the individual is making sufficient progress to meet the objective of involvement in the primary care of at least ~~30~~ 50 transplant recipients or that the program is making sufficient progress in recruiting and bringing to the program a transplant physician who meets this criterion as well as all other UNOS criteria for a qualified liver transplant physician by the date that is 12 months from the date of approval of the program under this section.

Attachment I, XIII, Transplant Programs, D, (5), Pancreas Transplantation

- (ee) In the case of a change in the primary transplant physician at a UNOS approved pancreas transplant program, if items (aa) iii or (cc) i-ii are not met, the replacement physician, a nephrologist/endocrinologist/diabetologist can function as a pancreas transplant physician for a maximum period of twelve months if the following conditions are met:
 - (i) That the remaining parts of (aa) or (cc), as applicable, are met.
 - (ii) That if the individual is qualifying as primary transplant physician by virtue of training, the individual has been involved in the primary care of ~~5~~ 4 or more pancreas

transplant recipients, and has followed these patients for a minimum of three months from the time of their transplant. The application must be supported by a recipient log. Such a log should include at least the medical record and/or UNOS identification number of the recipient and date of transplant. Beginning January 1, 2007 this log must be signed by the program director, division chief, or department chair from program where the experience was gained.

- (iii) That if the individual is qualifying as the primary pancreas transplant physician by virtue of acquired clinical experience, this experience is equal to 12 months on an active pancreas transplant service as the pancreas transplant physician or under the direct supervision of a qualified pancreas transplant physician and in conjunction with a pancreas transplant surgeon at a UNOS approved pancreas transplant center. Additionally, the individual will have been involved in the primary care of eight or more pancreas transplant recipients, and have followed these patients for a minimum of three months from the time of their transplant. This 12 month period of experience on the transplant service must be acquired over a maximum of 2 years. The application must be supported by a recipient log. Such a log should include at least the medical record and/or UNOS identification number of the recipient and date of transplant.
- (iv) That a consulting relationship with counterparts at another UNOS member transplant center approved for pancreas transplantation has been established and documented.
- (v) That activity reports are submitted to UNOS at two month intervals describing the transplant activity and results, physician recruitment efforts, and such other operating conditions as may be required by the Membership and Professional Standards Committee to demonstrate to the satisfaction of the Committee ongoing quality and efficient patient care. The reports must show that the individual is making sufficient progress to meet the objective of involvement in the primary care of at least ~~10~~ **8 (training)** or 15 **(experience)**, as applicable, transplant recipients or that the program is making sufficient progress in recruiting and bringing to the program a transplant physician who meets this criterion as well as all other UNOS criteria for a qualified pancreas transplant physician by the date that is 12 months from the date of approval of the program under this section.
- (vi) If the program is unable to demonstrate that it has an individual on site who can meet the requirements as described in sections (aa), (bb), (cc), or (dd), above at the end of 12 months, it shall inactivate. The requirements for program inactivation are described in section II. The Membership and Professional Standards Committee may consider, on a case by case basis, and grant a six month extension to a program that provides substantive evidence of progress towards completing the requirements but is unable to complete the requirements within one year.

To read the complete policy language visit www.unos.org or optn.transplant.hrsa.gov. From the UNOS website, select Resources from the main menu, and then select Policies. From the OPTN website, select Policy Management from the main menu, and then select Policies.

Affected Bylaw Language:

Underlines and strikethroughs indicate language that has been added or removed.

**APPENDIX B TO BYLAWS
OPTN**

Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership

I. Organ Procurement Organizations.

General. An organization designated as an organ procurement organization by the Secretary of the Department of Health and Human Services (HHS) under Section 1138(b) of the Social Security Act or an organization that meets all requirements for such designation other than OPTN membership (OPO) is eligible for membership in the OPTN.

OPOs shall abide by applicable provisions of the National Organ Transplant Act, as amended, 42 U.S.C. 273 *et seq.*; the requirements set forth in the OPTN Final Rule, 42 CFR Part 121; these Bylaws; and OPTN policies.

OPOs shall also submit to reviews (including on-site reviews) and requests for information as may be necessary to determine compliance with the OPTN Final Rule, 42 CFR Part 121; these Bylaws; and OPTN policies. Failure to conform with such requirements shall be cause for corrective action described in Appendix A of these Bylaws.

Each OPO shall fully inform the OPTN Contractor in writing within ~~five (5)~~ 10 business days, ~~to include copies of all related correspondence or reports, when any of the following events occur:~~

~~(1) an adverse action has been taken against it that leads to or threatens material change in the OPO's eligibility to procure organs or be reimbursed for organ procurement costs by Medicare or a state Medicaid program, including but not limited to any threatened or actual termination of Medicare designated status; and (2) any threatened or actual adverse action by a state or federal~~ the regulatory agency of its respective jurisdiction or it's the regulatory agency's designee that would impose a significant limitation upon the OPO's ability to procure organs.

[No further changes to this section]

II. Transplant Hospitals.

A. General. A hospital (i) that aspires to perform organ transplants, as evidenced by submission of an active application for designated transplant program status for at least one organ type, or in which organ transplantation is performed, and (ii) that participates in the Medicare or Medicaid programs (Transplant Hospital) is eligible for membership in the OPTN.

Transplant Hospitals shall abide by applicable provisions of the National Organ Transplant Act, as amended, 42 U.S.C. 273 *et seq.*; the requirements set forth in the OPTN Final Rule, 42 CFR Part 121; these Bylaws; and OPTN policies.

Transplant Hospitals shall also submit to reviews (including on-site reviews) and requests for information as may be necessary to determine compliance with the OPTN Final Rule, 42 CFR Part 121; these Bylaws; and OPTN policies.

~~For each of its organ-specific transplant programs, A Transplant Hospital shall fully inform the OPTN Contractor in writing within ~~five (5)~~ 10 business days, ~~to include copies of all related correspondence or reports~~, when an adverse action has been taken against or may impact related to any of its transplant programs has been taken any of the following events occur: (1) an adverse action that leads to or threatens material change in the status of the program's eligibility to perform or be reimbursed for organ transplants for Medicare or state Medicaid beneficiaries, in the status of the program's eligibility to perform or be reimbursed for organ transplants for Medicare or state Medicaid beneficiaries, including but not limited to initial approval of eligibility and any threatened or actual termination of eligibility; and (2) any threatened or actual adverse action by ~~a state or federal~~ the regulatory agency of its respective jurisdiction or its the regulatory agency's designee (e.g., the Joint Commission on Accreditation of Healthcare Organizations) which would impose a significant limitation upon the program's ability to serve transplant candidates or recipients.~~

[No further changes to this section]

III. Histocompatibility Laboratories.

General. An independent histocompatibility laboratory that serves at least one Transplant Hospital that is active in the field of human organ transplantation within its service area (Histocompatibility Laboratory) is eligible for membership in 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 Histocompatibility Laboratory that is separate and not under the direct or indirect control of the governing body of any of the Histocompatibility Laboratory's Transplant Hospitals or of the governing body of a commonly controlled group of the Histocompatibility Laboratory's Transplant Hospitals.

To attain membership in the OPTN, such a laboratory must conform to the Standards for Histocompatibility Testing set forth in Attachment II and applicable sub-attachments. The evaluation of each applicant laboratory will be performed in accordance with the OPTN Bylaws.

Additionally, Histocompatibility Laboratories shall abide by applicable provisions of the National Organ Transplant Act, as amended, 42 U.S.C. 273 *et seq.*; the requirements set forth in the OPTN Final Rule, 42 CFR Part 121; these Bylaws; and OPTN policies.

Histocompatibility Laboratories shall also submit to reviews (including on-site reviews) and requests for information as may be necessary to determine compliance with the OPTN Final Rule, 42 CFR Part 121; these Bylaws; and OPTN policies. Failure to conform with such requirements shall be cause for corrective action described in Appendix A of these Bylaws.

Each Histocompatibility Laboratory shall fully inform the OPTN Contractor in writing within ~~five (5)~~ 10 business days, ~~to include copies of all related correspondence or reports~~, when ~~any of the following events occur:~~

~~1) an adverse action has been taken against it that leads to or threatens material change in the laboratory's ability to perform histocompatibility testing or be reimbursed for the costs of such testing by Medicare or a state Medicaid program, including but not limited to any threatened or actual termination of Medicare participation; and~~

~~(2) any threatened or actual adverse action by ~~a state or federal~~ the regulatory agency of its respective jurisdiction or its the regulatory agency's designee that would impose a significant limitation upon the laboratory's ability to perform histocompatibility testing for the benefit of transplant candidates and recipients.~~

[No further changes to this section]

**APPENDIX B TO BYLAWS
UNITED NETWORK FOR ORGAN SHARING**

Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership

I. Organ Procurement Organizations.

General. An organization designated as an organ procurement organization by the Secretary of the Department of Health and Human Services (HHS) under Section 1138(b) of the Social Security Act or an organization that meets all requirements for such designation other than OPTN membership (OPO) is eligible for membership in the OPTN.

OPOs shall abide by applicable provisions of the National Organ Transplant Act, as amended, 42 U.S.C. 273 *et seq.*; the requirements set forth in the OPTN Final Rule, 42 CFR Part 121; these Bylaws; and OPTN policies.

OPOs shall also submit to reviews (including on-site reviews) and requests for information as may be necessary to determine compliance with the OPTN Final Rule, 42 CFR Part 121; these Bylaws; and OPTN policies. Failure to conform with such requirements shall be cause for corrective action described in Appendix A of these Bylaws.

Each OPO shall fully inform the OPTN Contractor in writing within ~~five (5)~~ 10 business days, ~~to include copies of all related correspondence or reports, when any of the following events occur: (1) an adverse action has been taken against it that leads to or threatens material change in the OPO's eligibility to procure organs or be reimbursed for organ procurement costs by Medicare or a state Medicaid program, including but not limited to any threatened or actual termination of Medicare designated status; and (2) any threatened or actual adverse action by a state or federal~~ the regulatory agency of its respective jurisdiction or the regulatory agency's designee that would impose a significant limitation upon the OPO's ability to procure organs.

[No further changes to this section]

II. Transplant Hospitals.

A. General. A hospital (i) that aspires to perform organ transplants, as evidenced by submission of an active application for designated transplant program status for at least one organ type, or in which organ transplantation is performed, and (ii) that participates in the Medicare or Medicaid programs (Transplant Hospital) is eligible for membership in the OPTN.

Transplant Hospitals shall abide by applicable provisions of the National Organ Transplant Act, as amended, 42 U.S.C. 273 *et seq.*; the requirements set forth in the OPTN Final Rule, 42 CFR Part 121; these Bylaws; and OPTN policies.

Transplant Hospitals shall also submit to reviews (including on-site reviews) and requests for information as may be necessary to determine compliance with the OPTN Final Rule, 42 CFR Part 121; these Bylaws; and OPTN policies. ~~For each of its organ-specific transplant programs, a~~

A Transplant Hospital shall fully inform the OPTN Contractor in writing within five (5) 10 business days, to include copies of all related correspondence or reports, when any of the following events occur: (1) an adverse action an adverse action has been taken against or may impact related to any of its transplant programs ~~has been taken~~ that leads to or threatens material change in the status of the program's eligibility to perform or be reimbursed for organ transplants for Medicare or state Medicaid beneficiaries, in the status of the program's eligibility to perform or be reimbursed for organ transplants for Medicare or state Medicaid beneficiaries, including but not

~~limited to initial approval of eligibility and any threatened or actual termination of eligibility; and (2) any threatened or actual adverse action by a state or federal~~ the regulatory agency of its respective jurisdiction or its the regulatory agency's designee (e.g., the Joint Commission on Accreditation of Healthcare Organizations) which would impose a significant limitation upon the program's ability to serve transplant candidates or recipients.

[No further changes to this section]

III. Histocompatibility Laboratories.

General. An independent histocompatibility laboratory that serves at least one Transplant Hospital that is active in the field of human organ transplantation within its service area (Histocompatibility Laboratory) is eligible for membership in 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 Histocompatibility Laboratory that is separate and not under the direct or indirect control of the governing body of any of the Histocompatibility Laboratory's Transplant Hospitals or of the governing body of a commonly controlled group of the Histocompatibility Laboratory's Transplant Hospitals.

To attain membership in the OPTN, such a laboratory must conform to the Standards for Histocompatibility Testing set forth in Attachment II and applicable sub-attachments. The evaluation of each applicant laboratory will be performed in accordance with the OPTN Bylaws.

Additionally, Histocompatibility Laboratories shall abide by applicable provisions of the National Organ Transplant Act, as amended, 42 U.S.C. 273 *et seq.*; the requirements set forth in the OPTN Final Rule, 42 CFR Part 121; these Bylaws; and OPTN policies.

Histocompatibility Laboratories shall also submit to reviews (including on-site reviews) and requests for information as may be necessary to determine compliance with the OPTN Final Rule, 42 CFR Part 121; these Bylaws; and OPTN policies. Failure to conform with such requirements shall be cause for corrective action described in Appendix A of these Bylaws.

Each Histocompatibility Laboratory shall fully inform the OPTN Contractor in writing within ~~five (5)~~ 10 business days, ~~to include copies of all related correspondence or reports,~~ when any of the following events occur: ~~1) an adverse action has been taken against it that leads to or threatens material change in the laboratory's ability to perform histocompatibility testing or be reimbursed for the costs of such testing by Medicare or a state Medicaid program, including but not limited to any threatened or actual termination of Medicare participation; and (2) any threatened or actual adverse action by a state or federal~~ the regulatory agency of its respective jurisdiction or its the regulatory agency's designee ~~that would impose a significant limitation upon the laboratory's ability to perform histocompatibility testing for the benefit of transplant candidates and recipients.~~

[No further changes to this section]

To read the complete policy language visit www.unos.org or optn.transplant.hrsa.gov. From the UNOS website, select Resources from the main menu, and then select Policies. From the OPTN website, select Policy Management from the main menu, and then select Policies.

Affected Bylaw Language:

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**APPENDIX B TO BYLAWS
OPTN**

Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership

I. No Changes

II. Transplant Hospitals.

A. – D. No Changes

- E. Key Personnel.** For each designated organ transplant program, the Transplant Hospital must identify a primary transplant surgeon and primary transplant physician and demonstrate that they meet the requirements set forth in the Bylaws, Appendix B, Attachment I. Where applicable these individuals must be the same individuals reported to the Center for Medicaid and Medicare Services (CMS) as serving in this capacity.

~~The Transplant Hospital must identify for any designated transplant program (as defined below) qualified as a transplant program by other than the requirements set forth in Attachment I and sub-attachments to Appendix B the primary surgeon and primary physician reported to the Center for Medicaid and Medicare Services (CMS) and demonstrate whether these individuals meet the requirements specified in this Appendix B, Attachment I, Section VI, and applicable sub-attachments.~~

~~When the Transplant Hospital learns that one or more of these individuals plan to leave, the OPTN Contractor must be notified immediately. At least 30 days (if possible) prior to the departure of the individual, the Transplant Hospital shall submit to the OPTN Contractor the name of the replacement physician or surgeon, Curriculum Vitae, and information documenting whether the individual meets the requirements specified in this Appendix B, Attachment I, Section VI, and applicable sub-attachments.~~

~~Failure to inform the OPTN Contractor of changes in primary physician and surgeon shall result in recommendation to the Board of Directors that the Board so notify the Secretary, and/or take appropriate action in accordance with Appendix A of these Bylaws, which action may include those defined as adverse under Section 3.01A.~~

[Note: The underlined text above is removed because it is not relevant to the new program approval process, which is the primary focus of this section of the bylaws.]

**ATTACHMENT I
TO APPENDIX B OF THE OPTN BYLAWS**

A transplant program that meets the following criteria shall be qualified as a designated transplant program to receive organs for transplantation:

I. Facilities and Resources No changes

- II. Reporting ~~Changes in~~ Key Personnel Changes:** Designated transplant programs must have key personnel -specifically a primary transplant surgeon and a primary transplant physician- who meet certain

minimum levels of commitment to and knowledge of organ procurement and transplantation as specified below. All programs should develop a succession plan that addresses changes in key personnel staffing.

~~When a designated transplant program is informed or learns that a key personnel change it must notify (such as the primary transplant surgeon or the primary transplant physician) upon whose participation the program's OPTN approval is based, plans to leave or is not substantively able to participate in the program for 15 or more consecutive days (such as military leave or temporary leave of absence), the OPTN Contractor must be notified immediately within 7 business days in writing, as described below in "Reporting Key Personnel Changes". The member must then follow the procedures for applications that are described in the Bylaws, Appendix A, Section 1.03A. Designated programs are also responsible for maintaining Program Coverage Plans as described below in Section VI. The Program Coverage Plan should address instances when key personnel are unavailable to perform their transplant duties for short periods of time.~~

Reporting Key Personnel Changes:

(A) The primary transplant surgeon and/or primary transplant physician departs from the program and/or is no longer involved with the program:

When the Transplant Hospital is informed that one or more of these individuals plan to leave or otherwise cease their active participation in the transplant program, the OPTN Contractor must be notified within 7 business days in writing. ("OPTN Contractor Notification Date")

~~No less than At least 30 days (if possible) prior to the end of the individual's active participation in the program departure of the key person, the Transplant Center Hospital is required to shall submit to the OPTN Contractor the name of the replacement key person, Curriculum Vitae, a complete Personnel Change Application, which and information demonstrating and documentsing compliance with OPTN criteria for a designated transplant program. Whether documents that the proposed new primary transplant surgeon or physician individual meets the requirements specified in this Appendix B, Attachment I, Section VI, and applicable sub-attachments.~~

If the Transplant Hospital receives less than 60 days advance notice of the key personnel change taking place, then the Transplant Hospital must submit a complete application (see paragraph above) to the OPTN Contractor within 30 days from the OPTN Contractor Notification Date.

If a program is unable to verify or propose through a complete Personnel Change Application that it has on site both a transplant surgeon and a transplant physician who meet the requirements for primary transplant surgeon and physician the Transplant Hospital must inactivate the program's membership, or relinquish or terminate its Designated Transplant Program Status as described in Appendix B, Section II, C of the Bylaws.

(B) The primary transplant surgeon and/or primary transplant physician remains involved in the program as an additional transplant surgeon or physician:

When the Transplant Hospital plans to change the individual designated as the primary transplant surgeon or primary transplant physician, the OPTN Contractor must be notified within 7 business days in writing.

No less than 30 days prior to the change in the individual's status, the Transplant Hospital is required to submit a complete Personnel Change Application to the OPTN Contractor. This Personnel Change Application documents that the individual meets the requirements specified in the Bylaws, Appendix B, Attachment I, Section VI, and applicable sub-attachments.

The transition to the new designated primary transplant surgeon or physician becomes effective after the application has been reviewed and approved by the Membership and Professional Standards Committee (MPSC) or an Ad hoc Subcommittee of the MPSC, as described below in the Processing Applications section of the bylaws.

C. The primary transplant surgeon and/or primary transplant physician will not be involved with the program on a temporary basis such as periods of military or medical leave:

(Temporary here is defined as greater than 30 days but less than 1 year.)

When the Transplant Hospital learns that one or more of these individuals must take a temporary leave of absence or otherwise temporarily cease their active participation in the transplant program, the OPTN Contractor must be notified within 7 business days in writing.

At least 30 days prior to the end of the individual's active participation in the program, the Transplant Hospital is required to submit to the OPTN Contractor a complete Personnel Change Application. This application documents compliance with OPTN criteria for a designated transplant program and indicates that the proposed new primary transplant surgeon or physician meets the requirements specified in the Bylaws, Appendix B, Attachment I, Section VI, and applicable sub-attachments.

If the Transplant Hospital receives less than 60 days notice of that the key personnel change will take place, the Transplant Hospital must submit a complete application (see paragraph above) to the OPTN Contractor within 30 days from the OPTN Contractor Notification Date.

If a program is unable to verify or propose through a complete Personnel Change Application that it has on site both a transplant surgeon and a transplant physician who meet the requirements for primary transplant surgeon and physician, the Transplant Hospital must inactivate the program's membership, or relinquish or terminate its Designated Transplant Program Status as described in Appendix B, Section II, C of the Bylaws.

D. Option for Reinstatement: If the previously named primary transplant surgeon or primary transplant physician returns to the same organ transplant program within 1 year of his/her departure date the individual can be considered for reinstatement as the primary transplant surgeon or physician if the Transplant Hospital submits a written reinstatement request to the OPTN Contractor. This written reinstatement request must include the following documentation:

- (1) A letter from the transplant program director, department chair, or chief of the division, attesting to the individual's current working knowledge; and
- (2) A letter from the individual confirming his/her commitment to the program and on site availability.
- (3) A current letter from the hospital credentialing committee verifying that the individual meets the requirements and is qualified and able to resume their previous role.

The Membership and Professional Standards Committee (MPSC) or an Ad hoc Subcommittee of the MPSC, as described below under Processing Applications, will review Requests for Reinstatement. In cases where reinstatement of an individual surgeon or physician may affect the program's status, the MPSC will recommend the appropriate new program status and any special conditions as indicated.

E. Failure to Provide Notification:

- (1) Failure to inform the OPTN Contractor of a change in primary transplant surgeon and/or primary transplant physician within the time frames specified above may result in the MPSC imposing a sanction on the member. A sanction may include a Notice of Uncontested Violation, Letter of Warning, or Letter of Reprimand, as described in detail in Appendix A of these Bylaws.
- (2) Failure to inform the OPTN Contractor of any changes in ~~key personnel~~ ~~may in~~ primary transplant surgeon and/or primary transplant physician or to submit the required Personnel Change Application shall result in ~~disciplinary action~~ a recommendation to the Board of Directors (Board) that the Board take appropriate action in accordance with Appendix A of these Bylaws. Potential adverse actions that the Board may choose to take are defined under Section 3.01A of the Bylaws. Additionally, the Board of Directors may notify the Secretary of HHS of the situation.

E. Processing Applications: For processing of applications to change key personnel, the Membership and Professional Standards Committee (MPSC) Chair is authorized to appoint an Ad hoc Subcommittee of at least two committee members, other than the MPSC chair, to review the credentials of the proposed new key personnel. The Subcommittee is empowered to provide, with the

concurrence of the MPSC Chair, interim approval effective until review by the full MPSC as its next meeting. Such interim approval shall not extend beyond the next meeting of the full MPSC and shall automatically expire if the full MPSC does not approve the interim action. Designated transplant programs are responsible for maintaining qualified key personnel for the program, without regard to the status of applications for change in key personnel.

**APPENDIX B TO BYLAWS, UNITED NETWORK FOR ORGAN SHARING
Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership**

APPENDIX B TO BYLAWS

UNITED NETWORK FOR ORGAN SHARING

II. Transplant Hospitals.

A-D No changes

- E. Key Personnel.** For each designated organ transplant program, the Transplant Hospital must identify a primary transplant surgeon and primary transplant physician and demonstrate that they meet the requirements set forth in the Bylaws, Appendix B, Attachment I. Where applicable these individuals must be the same individuals reported to the Center for Medicaid and Medicare Services (CMS) as serving in this capacity.

~~The Transplant Hospital must identify for any designated transplant program (as defined below) qualified as a transplant program by other than the requirements set forth in Attachment I and sub-attachments to Appendix B the primary surgeon and primary physician reported to the Center for Medicaid and Medicare Services (CMS) and demonstrate whether these individuals meet the requirements specified in this Appendix B, Attachment I, Section VI, and applicable sub-attachments.~~

~~When the Transplant Hospital learns that one or more of these individuals plan to leave, UNOS must be notified immediately. At least 30 days (if possible) prior to the departure of the individual, the Transplant Hospital shall submit to UNOS the name of the replacement physician or surgeon, Curriculum Vitae, and information documenting whether the individual meets the requirements specified in this Appendix B, Attachment I, Section VI, and applicable sub-attachments.~~

~~Failure to inform UNOS of changes in primary physician and surgeon shall result in recommendation to the Board of Directors that the Board take appropriate action in accordance with Appendix A of these Bylaws, which action may include those defined as adverse under Section 3.01A.~~

**ATTACHMENT I
TO APPENDIX B OF UNOS BYLAWS
Designated Transplant Program Criteria**

I.-II. No Changes

- III. Reporting ~~Changes in Key Personnel~~ Changes.** Designated transplant programs must have key personnel ~~– specifically a primary transplant surgeon and a primary transplant physician–~~ who meet certain minimum levels of commitment to and knowledge of organ procurement and transplantation as specified below. All programs should develop a succession plan that addresses changes in key personnel staffing.

When a designated transplant program is informed or learns that a key personnel change it must notify (such as the primary transplant surgeon or the primary transplant physician) upon whose participation the program's approval is based, plans to leave or is not substantively able to participate in the program for 15 or more consecutive days (such as military leave or temporary leave of absence). UNOS must be notified immediately within 7 business days in writing, as described below in "Reporting Key Personnel Changes. The member must also follow the procedures for applications that are described in the Bylaws, Appendix A, Section 1.03A. Designated programs are also responsible for maintaining Program Coverage Plans as described below in Section VI. The Program Coverage Plan should address instances when key personnel are unavailable to perform their transplant duties for short periods of time.

Reporting Key Personnel Changes:

- (1) The primary transplant surgeon and/or primary transplant physician is no longer involved with the program:

When the Transplant Hospital is informed that one or more of these individuals plans to leave, or otherwise cease their active participation in the transplant program, UNOS must be notified within 7 business days in writing. ("UNOS Notification Date")

No less than At least 30 days (if possible) prior to the end of the individual's active participation in the program departure of the key person, the program Transplant Hospital is required to shall submit to UNOS the name of the replacement key person, Curriculum Vitae, a complete Key Personnel Change Application, which and information demonstrating and documenting compliance with UNOS criteria for a designated transplant program that the proposed new primary surgeon or physician meets the requirements specified in the Bylaws, Appendix B, Attachment I and applicable subsections.

If the Transplant Hospital receives less than 60 days advance notice of the key personnel change taking place, then the Transplant Hospital must submit a complete application (see paragraph above) to UNOS within 30 days from the UNOS Notification Date.

If a program is unable to verify or propose through a complete Personnel Change Application that it has on site both a transplant surgeon and a transplant physician who meet the requirements for primary transplant surgeon and physician the Transplant Hospital must inactivate the program's membership, or relinquish or terminate its Designated Transplant Program Status as described in Appendix B, Section II, C of the Bylaws.

- (2) The primary transplant surgeon and/or primary transplant physician remains involved in the program as an additional transplant surgeon or physician:

When the Transplant Hospital plans to change the individual designated as the primary transplant surgeon or primary transplant physician, UNOS must be notified within 7 business days in writing. At least 30 days prior to the change in the individual's status, the Transplant Hospital shall submit a complete Personnel Change Application to UNOS, which documents that the individual meets the requirements specified in this Appendix B, Attachment I, Section VI, and applicable sub-attachments.

No less than 30 days prior to the change in the individual's status, the Transplant Hospital is required to submit a complete Personnel Change Application to UNOS. This Personnel Change Application documents that the individual meets the requirements specified in the Bylaws, Appendix B, Attachment I, Sections VII and XIII and applicable sub-attachments.

The transition to the new designated primary transplant surgeon or physician becomes effective after the application has been reviewed and approved by the Membership and Professional Standards Committee (MPSC) or an Ad hoc Subcommittee of the MPSC, as described below in the Processing Applications section of the Bylaws.

3. The primary transplant surgeon and/or primary transplant physician will not be involved with the program on a temporary basis such as periods of military or medical leave: (Temporary here is defined as greater than 30 days but less than 1 year.) When the Transplant Hospital learns that one or more of these individuals must take a temporary leave of absence or otherwise temporarily cease their active participation in the transplant program, UNOS must be notified within 7 business days in writing.

At least 30 days prior to the end of the individual's active participation in the program, the Transplant Hospital is required to submit to UNOS a complete Personnel Change Application. This application documents compliance with UNOS criteria for a designated transplant program and indicates that the proposed new primary transplant surgeon or physician meets the requirements specified in the Bylaws, Appendix B, Attachment I, Sections VII and XIII and applicable sub-attachments.

If the Transplant Hospital receives less than 60 days notice of that the key personnel change will take place, the Transplant Hospital must submit a complete application (see paragraph above) to UNOS within 30 days from the UNOS Notification Date.

If a program is unable to verify or propose through a complete Personnel Change Application that it has on site both a transplant surgeon and a transplant physician who meet the requirements for primary transplant surgeon and physician, the Transplant Hospital must inactivate the program's membership, or relinquish or terminate its Designated Transplant Program Status as described in the Bylaws, Appendix B, Section II, C.

4. Option for Reinstatement: If the previously named primary transplant surgeon or primary transplant physician returns to the same organ transplant program within 1 year of his/her departure date the individual can be considered for reinstatement as the primary transplant surgeon or physician if the Transplant Hospital submits a written reinstatement request to UNOS. This written reinstatement request must include the following documentation:
- (a) A letter from the transplant program director, department chair, or chief of the division, attesting to the individual's current working knowledge; and
 - (b) A letter from the individual confirming his/her commitment to the program and on site availability.
 - (c) A current letter from the hospital credentialing committee verifying that the individual meets the requirements and is qualified and able to resume their previous role.

The Membership and Professional Standards Committee (MPSC) or an Ad hoc Subcommittee of the MPSC, as described below under Processing Applications, will review Requests for Reinstatement. In cases where reinstatement of an individual surgeon or physician may affect the program's status, the MPSC will recommend the appropriate new program status and any special conditions as indicated.

5. Failure to Provide Notification:
- (a) Failure to inform UNOS of a change in primary transplant surgeon and/or primary transplant physician within the time frames specified above may result in the MPSC imposing a sanction on the member. A sanction may include a Notice of Uncontested Violation, Letter of Warning, or Letter of Reprimand, as described in detail in the Bylaws, Appendix A.
 - (b) Failure to inform the OPTN Contractor UNOS of any changes in key personnel may in primary transplant surgeon and/or primary transplant physician or to submit the required Personnel Change Application shall result in disciplinary action- a recommendation to the Board of Directors (Board) that the Board take appropriate action in accordance with Appendix A of the Bylaws. Potential adverse actions that the Board may choose to take are defined under Section 3.01A of the Bylaws. Additionally, the Board of Directors may notify the Secretary of HHS of the situation.

6. Processing Applications: For processing of applications to change key personnel, the Membership and Professional Standards Committee (MPSC) Chair is authorized to appoint an Ad hoc

Subcommittee of at least two committee members, other than the MPSC chair, to review the credentials of the proposed new key personnel. The Subcommittee is empowered to provide, with the concurrence of the MPSC Chair, interim approval effective until review by the full MPSC as its next meeting. Such interim approval shall not extend beyond the next meeting of the full MPSC and shall automatically expire if the full MPSC does not approve the interim action. Designated transplant programs are responsible for maintaining qualified key personnel for the program, without regard to the status of applications for change in key personnel.

To read the complete policy language visit www.unos.org or optn.transplant.hrsa.gov. From the UNOS website, select Resources from the main menu, and then select Policies. From the OPTN website, select Policy Management from the main menu, and then select Policies.

Affected Policy Language:

Underlines and strikethroughs indicate language that has been added or removed.

3.4 ORGAN PROCUREMENT, DISTRIBUTION AND ALTERNATIVE SYSTEMS FOR ORGAN DISTRIBUTION OR ALLOCATION. The following policies apply to organ procurement, distribution and alternative systems for organ distribution or allocation.

3.4.1 Avoidance of Conflicts of Interest. Neither the attending physician of the decedent at death nor the physician who determines the time of the decedent's death may participate in the operative procedure for removing or transplanting an organ from the decedent. For purposes of this section, "organ" is defined as set forth in the OPTN Final Rule (42 C.F.R Part 121.2), and "decedent" is defined as a deceased individual whose body is or may become the source of a donated organ.

[Following sections renumbered only]

3.4.12 Time Limit For Acceptance.....

3.4.23 Multiple Organ Retrieval.....

3.4.34 Department of Defense Directive.....

3.4.45 Multiple Organs Offer.

3.4.56 National Distribution of Organs.

3.4.67 Receiving and Responding to Organ Offers....

3.4.78 Application, Review, Dissolution and Modification Processes for Alternative Organ Distribution or Allocation Systems.....

3.4.7-18.1 Application

3.4.7-28.2 Data Submission Requirements

3.4.7-3-8.3 Dissolution of Alternative Assignment Systems

3.4.7-4-8.4 Modifications of Alternative Point Assignment Systems, Sharing

Arrangements and ALUs.

3.4.7-58.5 AAD Systems Approved Prior to March 15, 2005

3.4.89 Application, Review, Dissolution and Modification Processes for Variances.....

3.4.8-1-9.1 Application

3.4.8-2-9.2 Data Requirements.

3.4.8-3-9.3 Appeal to Secretary.

3.4.8-4-9.4 Termination of Member Participation in Variance.

3.4.8-5-9.5 Modification of Variance.

3.4.910 Development, Application, Review, Dissolution and Modification Processes for Committee-Sponsored Alternative Systems....

- ~~3.4.9.1~~ 10.1 Development and Application.
- ~~3.4.9.2~~ 10.2 Data Requirements.
- ~~3.4.9.3~~ 10.3 Termination of Member Participation in Committee-Sponsored Alternative System.
- ~~3.4.9.4~~ 10.4 Modification of Committee-Sponsored Alternative System.
- ~~3.4.9.5~~ 10.5 Committee-Sponsored Alternative Systems Approved Prior to March 15, 2005.

~~3.4.10.1~~ 11.1 Allocation of Organs During Regional/National Emergency Situations.....

- ~~3.4.10.1~~ 11.1 Regional/National Transportation Disruption.
- ~~3.4.10.2~~ 11.2 Regional/National Communications Disruption.
- ~~3.4.10.3~~ 11.3 Operational Disruption.

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