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## **IMPORTANT POLICY NOTICE**

**To:** Transplant Professionals

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

**RE:** Summary of actions taken at the OPTN/UNOS Board of Directors  
Meeting—June 22-23, 2009

**Date:** July 23, 2009

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The attached report summarizes bylaw changes, policy changes and other actions the OPTN/UNOS Board of Directors approved at its June 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](http://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.

You will notice that the effective dates for many of the approved policies are listed as “pending programming” or “pending implementation”. Given the current schedule of work for programming policy changes, some of these policies may not be implemented until late in 2010. UNOS will circulate a UNet<sup>SM</sup> system notice prior to the implementation of each policy to notify you of the impending change.

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 **10** 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 Staf	Transplant Program Directors	Transplant Social Workers	Transplant Surgeons	Page #
1 Proposal to Allow the Kidney Paired Donation Pilot Program to be Monitored by the Membership and Professional Standards Committee (Kidney Transplantation Committee)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	4
2 Modifications to the Allocation of Lungs to Pediatric Candidates and from Donors Less than 12 Years of Age (Pediatric Transplantation and Thoracic Organ Transplantation Committees)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	5
3 Change in OPTN Patient Registration Fee and UNOS Computer Registration Fee (Finance Committee)	X	X		X	X	X		X	X	X				X			6
4 Standardized MELD/PELD Exception Criteria and Scores (Liver and Intestinal Organ Transplantation Committee)		X	X						X	X	X	X	X	X	X	X	7
5 Requirement for a Conference Call Prior to Using the MELD/PELD Exception "Override" Option (Liver and Intestinal Organ Transplantation Committee)		X	X				X		X	X	X	X	X	X	X	X	9
6 Regional Distribution of Livers to Status 1A/1B Candidates (Liver and Intestinal Organ Transplantation Committee)	X			X	X	X	X	X	X	X	X	X	X	X	X	X	10
7 Clarification that the largest tumor dimension must be reported on HCC Exception Applications (Liver and Intestinal Organ Transplantation Committee)		X	X						X	X	X	X		X	X	X	11
8 Relocation of Existing Living Donation Policies into a New, Separate Policy Section (12.0) Specific to Living Donation (Living Donor Committee)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	12
9 Add Factors "Current Bilirubin" and "Change in Bilirubin" to the Lung Allocation Score (LAS) (Thoracic Organ Transplantation Committee)									X	X	X	X	X	X	X	X	13

## Overview of Policy Modifications/Board Actions and Affected Professionals

10	Change to Effective Date of Modifications to the OPTN/UNOS Bylaws to Better Define Functional Inactivity, Voluntary Inactive Membership Transplant Program Status, Relinquishment of Designated Transplant Program Status, and Termination of Designated Transplant Program Status as Approved by the Board of Directors in November 2008 (Membership and Professional Standards Committee)									X	X	X	X	X	X	X	X	14
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**Title of Bylaw Change:** Proposal to Allow the Kidney Paired Donation Pilot Program to be Monitored by the Membership and Professional Standards Committee

**Sponsoring Committee:** Kidney Transplantation

**Bylaw Affected:** Appendix B, Attachment 1, Section XIII, D(2)c (Kidney Paired Donation)

**Action Required:** Review Only

**Effective Date:** August 24, 2009

**Professional Groups Affected by the Change:**

OPO Executive Directors, Directors of Organ Procurement, OPO Procurement Coordinators, OPO Data Coordinators, OPO Medical Directors, Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Transplant Social Workers, Transplant Data Coordinators, Lab Directors, Lab Supervisors, OPO Public Relations or Public Education staff, Transplant Public Relations or Public Education Staff

Problem Statement	Changes	What You Need to Do
<p>In June 2008, the Board of Directors approved a proposal for a Kidney Paired Donation (KPD) Pilot Program, administered by the OPTN, to match incompatible candidate/donor pairs at a national level. The proposal stated that Operational Guidelines would contain the rules that govern the program and that policy or bylaw language would <i>not</i> be written during the pilot phase. The monitoring and evaluation plan stated that the Membership and Professional Standards Committee (MPSC) would monitor the program using its standard processes.</p> <p>The MPSC evaluates members based on their compliance with policies and bylaws, so a policy or bylaw was needed to explicitly allow the MPSC to monitor the KPD Pilot Program.</p>	<p>This change to the OPTN and UNOS bylaws explicitly allows the MPSC to monitor the Kidney Paired Donation Pilot Program through its existing due process and confidential medical peer review functions.*</p> <p>*Note: The Executive Committee approved this bylaw change on May 27, 2009.</p>	<p>Member institutions that choose to participate in the Kidney Paired Donation Pilot Program must follow the rules of the program in addition to all other relevant policies and bylaws.</p>

**Title of Policy Change:** Modifications to the Allocation of Lungs to Pediatric Candidates and from Donors Less than 12 Years of Age

**Sponsoring Committees:** Pediatric Transplantation and Thoracic Organ Transplantation

**Policies Affected:** 3.7.6.2 (Candidates Age 0-11), 3.7.9 (Time Waiting for Thoracic Organ Candidates), 3.7.9.3 (Waiting Time Accrual for Lung Candidates Less than 12 Years of Age), 3.7.11 (Sequence of Adult Donor Lung Allocation), and 3.7.11.1 (Sequence of Pediatric Donor Lung Allocation)

**Action Required:** Review Only

**Effective Date:** Pending UNet<sup>SM</sup> Programming

**Professional Groups Affected by the Change:**

OPO Executive Directors, Directors of Organ Procurement, OPO Procurement Coordinators, OPO Data Coordinators, OPO Medical Directors, Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Transplant Social Workers, Transplant Data Coordinators, Lab Directors, Lab Supervisors, OPO Public Relations or Public Education staff, Transplant Public Relations or Public Education Staff

Problem Statement	Changes	What You Need to Do
<p>The current lung allocation system may not be allowing quicker access to donated lungs for the more medically urgent lung candidates who are younger than 12 years old. To improve allocation to these sicker pediatric candidates, the BOD approved modifications to the policies referenced above at its June 2008 meeting. (<a href="#">See the July 18, 2008 Policy Notice.</a>) During policy implementation, UNOS staff identified concerns with programming the policy as written. UNOS staff then proposed altering some details of the policy while keeping the policy’s intent. The modifications are meant to shorten the timeline for implementation, lower programming cost, minimize risk introduced to the UNet<sup>SM</sup> system, and clarify some of the policy’s expectations.</p>	<p>The follow policy modifications were approved:</p> <ul style="list-style-type: none"> <li>• Use the term “priority” instead of “status” to avoid confusion with the term “status” used for heart candidates;</li> <li>• Use only the most-recent amount of time spent as Priority 1 for breaking ties;</li> <li>• Clarify that the total amount of time the candidate has been on the Waitlist<sup>SM</sup> includes inactive time;</li> <li>• Provide an example to clarify “anniversary date”; and,</li> <li>• Remove “recurrent” from the Priority 1 pulmonary hypertension syncope criterion. *</li> </ul> <p>*Note- The Executive Committee approved these policy changes on June 22, 2009.</p>	<p>OPO and transplant professionals should become familiar with the revised policy language.</p> <p>Through a UNet<sup>SM</sup> System Notice, UNOS will alert OPOs and transplant centers of the implementation date and when programming is complete.</p>

**Title of Board Action:** Change in OPTN Patient Registration Fee and UNOS Computer Registration Fee

**Sponsoring Committee:** Finance

**Policy Affected:** Policy 11.0

**Action Required:** Review Only

**Effective Date:** October 1, 2009

**Professional Groups Affected by the Change:**

OPO Executive Directors, Directors of Organ Procurement, OPO Procurement Coordinators, OPO Data Coordinators, OPO Medical Directors, Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Lab Directors

<b>Problem Statement</b>	<b>Changes</b>	<b>What You Need to Do</b>
Provide funding for OPTN and UNOS operations in FY 2010 (October 1, 2009 – September 30, 2010). In addition to regular operating expenses, further funding is required for core computer programming to operate the OPTN.	<p>The OPTN Board of Directors approved an increase in the OPTN patient registration fee from \$547 to \$557, subject to final approval by HRSA.</p> <p>Separately, the UNOS Board of Directors approved an increase in the UNOS computer registration fee from \$75 to \$84 to fund operations. It also approved an additional \$30 increase to provide funding to upgrade computer systems. Including the two increases approved by the UNOS Board of Directors, the total UNOS Computer Registration fee will be \$114 as of October 1, 2009.</p>	Notify program finance departments of impending change.

**Title of Policy Change:** Standardized MELD/PELD Exception Criteria and Scores

**Sponsoring Committee:** Liver and Intestinal Organ Transplantation

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

**Action Required:** Review and Respond as Necessary

**Effective Date:** Pending Notification of the Membership; the Liver Committee is developing guidance for centers and Regional Review Boards (RRBs) to use in order to comply with the policy language approved by the Board of Directors.

**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

<b>Problem Statement</b>	<b>Changes</b>	<b>What You Need to Do</b>
<p>Currently there are no specific listing criteria in Policy 3.6.4.5 (Liver Candidates with Exceptional Cases) for candidates with hepatopulmonary syndrome, cholangiocarcinoma, cystic fibrosis, familial amyloidosis, primary hyperoxaluria, and portopulmonary hypertension. Those diagnoses make up 20% of non-HCC MELD/PELD exception requests. There is a great deal of variation across the county on the scores assigned for the diagnoses. This policy provides consistent criteria and exception score assignments for liver transplant candidates with the diagnoses.</p>	<p>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 Regional Review Board (RRB) has a pre-existing agreement regarding point assignment for these diagnoses, an initial MELD score of 22, or 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, or PELD score of 41, shall be assigned.</p>	<p>Physicians submitting MELD/PELD exception applications for candidates with these diagnoses must ensure that the criteria listed in the policy are included in the clinical narrative.</p> <p>Regions with pre-existing agreements regarding point assignment for the diagnoses should provide this information to their transplant programs and RRB representatives.</p> <p>Centers listing candidates with cholangiocarcinoma must submit a written protocol for patient care to the OPTN/UNOS Liver and Intestinal Organ Transplantation Committee before requesting a MELD score exception.</p> <p><i>The RRBs will still vote on each case submitted, in adherence to the criteria listed in the policy. That system is different from the system in the original proposal,</i></p>

		<i>which recommended an automated approach. The provision was reconsidered due to the costs associated with programming into UNet<sup>SM</sup>.</i>
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**Title of Policy Change:** Requirement for a Conference Call Prior to Using the MELD/PELD Exception “Override” Option

**Sponsoring Committee:** Liver and Intestinal Organ Transplantation

**Policies Affected:** Policies 3.6.4.3 (Pediatric Liver Transplant Candidates with Metabolic Diseases), 3.6.4.4 (Liver Transplant Candidates with Hepatocellular Carcinoma (HCC)), and 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 Social Workers, Transplant Data Coordinators, Lab Directors, Lab Supervisors, OPO Public Relations or Public Education staff, Transplant Public Relations or Public Education Staff

<b>Problem Statement</b>	<b>Changes</b>	<b>What You Need to Do</b>
Policy 3.6.4.5 states that “[e]ach 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 patient’s transplant physician may list the patient at the higher MELD or PELD score, subject to automatic referral to the Liver and Intestinal Organ Transplantation and Membership and Professional Standards Committees.” The feature in UNet <sup>SM</sup> allowing that option had been removed but now will be reinstated.	Physicians will be able to list a candidate at a MELD/PELD score after the request has been denied by the RRB. The candidate’s physician must hold a conference call with the RRB prior to exercising that option, thus exhausting the appeals process. The case then will be automatically referred to the Liver and Intestinal Organ Transplantation and Membership and Professional Standards Committees.	Physicians should understand that the option to list a patient at a higher score is available after fulfilling the requirement for a conference call and that the case will be referred to the Liver and Intestinal Organ Transplantation and Membership and Professional Standards Committees.

**Title of Policy Change:** Regional Distribution of Livers to Status 1A/1B Candidates

**Sponsoring Committee:** Liver and Intestinal Organ Transplantation

**Policy Affected:** Policy 3.6 (Allocation of Livers)

**Action Required:** Review Only

**Effective Date:** Pending Implementation

**Professional Groups Affected by the Change:** OPO Executive Directors, Directors of Organ Procurement, OPO Procurement Coordinators, OPO Data Coordinators, OPO Medical Directors, Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Transplant Social Workers, Transplant Data Coordinators, OPO Public Relations or Public Education staff, Transplant Public Relations or Public Education Staff

<b>Problem Statement</b>	<b>Changes</b>	<b>What You Need to Do</b>
This policy change is intended to reduce waiting list mortality for the most urgent candidates awaiting a liver transplant by increasing access to donor organs.	Donor livers will be offered first to <u>combined local and regional</u> Status 1A potential transplant recipients and then to <u>combined local and regional</u> Status 1B potential transplant recipients prior to being offered to candidates listed with a MELD/PELD score. This change means that local Status 1A/1B candidates will no longer receive priority over candidates listed within the same region.	Centers should be aware that the adult liver allocation algorithm will first prioritize all Status 1A potential transplant recipients within the region in which the donor liver is procured, then prioritize all Status 1B potential transplant recipient within the region in which the donor liver is procured.

**Title of Policy Change:** Clarification that the Largest Tumor Dimension Must be Reported on HCC Exception Applications

**Sponsoring Committee:** Liver and Intestinal Organ Transplantation

**Policy Affected:** 3.6.4.4 (Liver Transplant Candidates with Hepatocellular Carcinoma (HCC))

**Action Required:** Review Only

**Effective Date:** August 24, 2009

**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

<b>Problem Statement</b>	<b>Changes</b>	<b>What You Need to Do</b>
The UNet <sup>SM</sup> application for HCC exceptions requests a one-dimensional measurement for each tumor reported; policy currently does not specify, however, that the <i>largest</i> dimension of a tumor be reported.	This policy change clarifies that the largest dimension must be reported for each tumor entered into the HCC exception application.	Physicians submitting an HCC exception application must report the largest dimension of each tumor listed in the application. For example, if a tumor is 3.0cm by 5.2cm, the tumor must be listed as 5.2cm.

**Title of Policy Change:** Relocation of Existing Living Donation Policies into a New, Separate Policy Section (12.0) Specific to Living Donation

**Sponsoring Committee:** Living Donor

**Policy Affected:** 12.0 (Living Donation)

**Action Required:** Review Only

**Effective Date:** August 24, 2009

**Professional Groups Affected by the Change:**

OPO Executive Directors, Directors of Organ Procurement, OPO Procurement Coordinators, OPO Data Coordinators, OPO Medical Directors, Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Transplant Social Workers, Transplant Data Coordinators, Lab Directors, Lab Supervisors, OPO Public Relations or Public Education Staff, Transplant Public Relations or Public Education Staff

Problem Statement	Changes	What You Need to Do
<p>Currently, policies specifically addressing living donation are interspersed throughout existing OPTN/UNOS policies. The majority of those existing policies, however, address the procurement, allocation, and distribution of organs from <i>deceased</i> donors. Providing a separate policy section specific to <i>living</i> donor transplantation should reduce confusion over which policies apply to living donors.</p>	<p>Policies related to living donation have been consolidated into Policy 12.0 (Living Donation). The intent of the existing living donor policies were <i>not</i> changed when they were moved to the newly created section.</p> <p>Language added to Policy 12.0 includes an introduction to explain the living donation process and the policy’s purpose. Policy language modifications were mostly stylistic — removing all references to deceased donors, using the term “living donor” instead of “live donor,” and removing all references to the “Host OPO” since OPOs are seldom involved in living donation.</p>	<p>Transplant professionals should become familiar with Policy 12.0 (Living Donation), which is the new location for all living donation policies.</p>

**Title of Policy Change:** Add Factors “Current Bilirubin” and “Change in Bilirubin” to the Lung Allocation Score (LAS)

**Sponsoring Committee:** Thoracic Organ Transplantation

**Policy Affected:** 3.7.6.1 (Candidates Age 12 and Older)

**Action Required:** Review Only

**Effective Date:** Upon Implementation

**Professional Groups Affected by the Change:**

Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Transplant Social Workers, Transplant Public Education Staff, and Transplant Data Coordinators

Problem Statement	Changes	What You Need to Do
<p>There continue to be waiting list deaths among lung transplant candidates who are 12 years of age or older. Further, the death rate in the diagnosis Group B<sup>1</sup> population appears to have increased slightly. This lung transplant waitlist mortality rate prompted an effort to enhance the ability of the LAS to better predict waitlist urgency and reduce deaths on the waiting list for lung transplant candidates.</p>	<p>This policy adds the following two factors to the LAS to better predict a lung transplant candidate’s waiting list urgency:</p> <ol style="list-style-type: none"> <li>1) Current bilirubin that is at least 1.0 mg/dL for all diagnosis groups; and</li> <li>2) A change (increase) in bilirubin of at least 50% for a candidate in diagnosis Group B only when: <ul style="list-style-type: none"> <li>• the increase occurs during a six-month period, and</li> <li>• the higher bilirubin value is at least 1.0 mg/dL.</li> </ul> </li> </ol>	<p>Transplant professionals should become familiar with the bilirubin policy language.</p> <p>The OPTN Contractor will implement Policy 3.7.6.1.c (Bilirubin in the Lung Allocation Score) once the Executive Committee determines an appropriate implementation plan, which may include an administrative solution – i.e., in lieu of programming bilirubin in the LAS in UNet<sup>SM</sup>. The OPTN Contractor will notify transplant professionals of this final implementation plan and related educational efforts.</p>

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<sup>1</sup> Diagnoses currently included in Group B: congenital malformation; crest - pulmonary hypertension; eisenmenger's syn: atrial septal defect; eisenmenger's syn: multi congenital anomalies; eisenmenger's syn: other specify; eisenmenger's syn: pda; eisenmenger's syn: vsd; portopulmonary hypertension; primary pulmonary hypertension; pulmonary telengectasia - pulmonary hypertension; pulmonary thromboembolic disease; pulmonary vascular disease; pulmonary veno-occlusive disease; pulmonic stenosis; right hypoplastic lung; scleroderma - pulmonary hypertension; secondary pulmonary hypertension; and, thromboembolic pulmonary hypertension.

**Notice of Change:** Change to Effective Date of Modifications to the OPTN/UNOS Bylaws to Better Define Functional Inactivity, Voluntary Inactive Membership Transplant Program Status, Relinquishment of Designated Transplant Program Status, and Termination of Designated Transplant Program Status as Approved by the Board of Directors in November 2008

**Sponsoring Committee:** Membership and Professional Standards Committee (MPSC)

**Bylaw Affected:** Appendix B, Section II, C (Inactive Membership Status)

**Action Required:** Review Only

**Effective Date:** August 1, 2009

**Professional Groups Affected by the Change:**

Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Transplant Social Workers, Transplant Data Coordinators, Transplant PR/Public Education Staff

Problem Statement	Changes	What You Need to Do
<p>Current bylaws do not include waiting list inactivation in the definition of functional inactivity, nor do the bylaws clearly delineate patient notification responsibilities in the event a transplant program waiting list is inactivated.</p> <p>Member hospitals may elect to voluntarily inactivate or relinquish designated program status for a given transplant program if there is an extended period of transplant inactivity. The bylaws currently do not outline the process for program inactivation or relinquishment, and neither do the bylaws currently provide timelines for patient notification and transfer.</p>	<p>The bylaw changes clarify definitions of functional inactivity and notify hospitals of MPSC review of waiting list inactivation as part of its performance review processes. The bylaw changes also define responsibilities for notifying patients of waiting list inactivation.</p> <p>Changes in Sections 2 and 3 describe the requirements for members that elect to inactivate or relinquish designated status for a transplant program, the process for candidate transfers, and the requirements for notifying patients.</p> <p>Other modifications allow for candidates on the waiting list of an inactivated or withdrawn transplant program to continue accruing waiting time while the inactivating program works to transfer the candidate.</p>	<p>Effective August 1, 2009, transplant programs are expected to comply with these requirements and respond to MPSC inquiries regarding periods of functional inactivity. Once these changes have been programmed, reports will be available within UNet<sup>SM</sup> for transplant programs to monitor periods of waiting list inactivation. These reports will allow member hospitals to provide advance notice to candidates and conduct prospective analysis of inactive waiting list periods.</p> <p>UNOS sent this notice in December 2008 after the Board of Directors approved the changes. You are being notified now because the effective date has changed. There are no changes to the approved language.</p>

<b>Problem Statement</b>	<b>Changes</b>	<b>What You Need to Do</b>
	<p>Finally, the modifications remove duplicative language from Attachment I to Appendix B to the bylaws.</p>	<p>Members intending to inactivate or withdraw from OPTN membership should use these bylaws for guidance in notifying, transferring, and removing listed transplant candidates.</p> <p>Hospitals that have candidates remaining on the waiting list after a program is closed must remove these candidates from the waitlist within one year of the program closure date.</p>

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

**Affected Bylaw Language:**

Appendix B, Attachment 1, Section XIII, D(2)c (Kidney Paired Donation Pilot Program)  
Attachment 1 to Appendix B of the Bylaws  
Designated Transplant Program Criteria

XIII. Transplant Programs

A.-C. *No changes*

D.

(1) *No changes*

(2) **Kidney Transplant Programs that Perform Living Donor Kidney Transplants:**

a.-b. *No changes*

c. Kidney Paired Donation- Members that choose to participate in any OPTN kidney paired donation must agree to abide by the kidney paired donation program rules. Potential violations may be forwarded by the Kidney Transplantation Committee to the Membership and Professional Standards Committee for review.

This language will be mirrored in the OPTN bylaws.

To read the complete policy language visit [www.unos.org](http://www.unos.org) or [optn.transplant.hrsa.gov](http://optn.transplant.hrsa.gov). From the UNOS Web site, select Resources from the main menu, and then select Policies. From the OPTN Web site, select Policy Management, and then select Policies.

## Affected Policy Language:

**3.7.6.2 Candidates Age 0 - 11.** ~~Candidates 0 – 11 years old are assigned priority for lung offers based upon waiting time, according to the status categories UNet<sup>SM</sup> ranks candidates who are 0 – 11 years old for lung offers according to the priorities defined below. Within each status priority, UNet<sup>SM</sup> will rank candidates ~~will be ranked~~ by ABO (according to Policy 3.7.8.2) and then by waiting time, in descending order. For Priority ~~Status 1~~, UNet<sup>SM</sup> will only consider the most current period of time a candidate has spent as Priority 1, i.e., UNet<sup>SM</sup> will not tally the time waiting during multiple Priority 1 periods. ~~candidates will be ranked in descending order according to the length of time waiting at that status.~~ For Priority ~~Status 2~~ candidates, and if there is ever a tie among Priority 1 candidates, UNet<sup>SM</sup> will use these candidates' total waiting time to determine the order for receiving lung offers. Total waiting time includes time spent waiting as Priority 1, Priority 2, and inactive. ~~total active waiting time (defined for this purpose as beginning when the candidate was added to the waiting list and ending when the lung match run was generated) will be used to rank candidates on the match run.~~~~

~~A program may update clinical data used to justify a candidate's status priority may be updated at any time a program it believes a candidate's medical condition warrants such modifications. For a candidate listed as Priority 1, a program must update every candidate variable each qualifying criterion, except those candidate variables that which is are obtained only by heart catheterization, for Status 1 candidates, at least once every in each six months period following the candidate's registration after initial listing on the waiting list Waitlist<sup>SM</sup>. If at any time, more than six months have elapsed since the last six month "anniversary" date of the candidate's initial listing without an update, without data updates after the candidate's last six-month "anniversary" of his or her Waitlist<sup>SM</sup> registration, then the candidate's status Priority 1 will automatically revert to Status Priority 2. UNet<sup>SM</sup> will assess the currency of lung variables for each candidate on every six-month "anniversary" date. (For example, if a candidate is first registered on the Waitlist<sup>SM</sup> on January 1, 2011, and the most recent six-month "anniversary" is January 1, 2012, then UNet<sup>SM</sup> will consider any variables collected on or after July 1, 2011 as current until June 30, 2012. UNet<sup>SM</sup> will reassess the currency of the lung variables on July 1, 2012, and then any variables with test dates that are on or after January 1, 2012 would be considered current.)~~

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

**Status Priority 1:** Candidates with one or more of the following criteria:

- **Respiratory failure, defined as:**
  - Requiring continuous mechanical ventilation; *or*,
  - Requiring supplemental oxygen delivered by any means to achieve FiO<sub>2</sub> greater than 50% in order to maintain oxygen saturation levels greater than 90%;
  - or,*
  - Having an arterial or capillary PCO<sub>2</sub> greater than 50 mmHg, or a venous PCO<sub>2</sub> greater than 56mmHg.

- **Pulmonary hypertension, defined as:**
  - Having pulmonary vein stenosis involving 3 or more vessels; **or**
  - Exhibiting any of the following, in spite of medical therapy: suprasystemic PA pressure on cardiac catheterization or by echocardiogram estimate, cardiac index less than 2 L/min/M<sup>2</sup>, ~~recurrent~~ syncope, or hemoptysis

Examples of accepted medical therapy for pulmonary hypertension will be listed in UNet<sup>SM</sup>. Transplant centers must indicate which of these medical therapies the candidate has received. If the candidate has not received any of the listed therapies, the transplant center must submit an exception request to the Lung Review Board ~~for prospective consideration~~ as described below.

~~**or;**~~

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

- ~~Exceptional cases by prospective submission to~~ **An exception case approved by the Lung Review Board:**
  - In its review of exception requests, the Lung Review Board will follow the prospective review process described in Policy 3.7.6.4 (Lung Candidates with Exceptional Cases).

**Status 2:** Candidates who do not meet the criteria for ~~Status~~ Priority 1 must be listed ~~Status~~ as Priority 2.

**3.7.9 Time Waiting for Thoracic Organ Candidates.** Calculation of the time a candidate has been waiting for a thoracic organ transplant begins with the date and time the candidate is first registered as active on the Waiting List. Waiting time will not be accrued by candidates awaiting a thoracic organ transplant while they are registered on the Waiting List as inactive, except as specified in Policy 3.7.9.3 (Waiting Time Accrual for Lung Candidates Less than 12 Years of Age). When time waiting is used for thoracic organ allocation, a candidate will receive a preference over other candidates who have accumulated less waiting time within the same status/priority category. Where applicable, waiting time accrued by a candidate for a single thoracic organ transplant (heart or single lung) while waiting on the Waiting List also may be accrued for a second thoracic organ, when it is determined that the candidate requires a multiple thoracic organ (heart-lung or double lung) transplant. In addition, where applicable, waiting time accrued by a candidate for a multiple thoracic organ transplant while waiting on the Waiting List may be transferred to the Waiting List for a single thoracic organ transplant.

**3.7.9.3 Waiting Time Accrual for Lung Candidates Less than 12 Years of Age.** ~~Candidates listed as a Status Priority 1 or Status Priority 2 will accrue waiting time within each status priority. When waiting time is used for thoracic organ allocation, a Priority 1 and Priority 2 candidates will receive a preference over other candidates within a match run classification who have accumulated less waiting time within the same status category (see Policy 3.7.9). However, a candidate's waiting time accrued while listed as Status 2 will not be used in prioritizing the candidate for lung allocation if the candidate is upgraded to~~

Status 1. For Priority 1 candidates, UNet<sup>SM</sup> will only consider the most recent time spent as Priority 1, i.e., UNet<sup>SM</sup> will not tally the time waiting during multiple Priority 1 periods.

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

For Priority 2 candidates, and if there is ever a tie among Priority 1 candidates, UNet<sup>SM</sup> will use total waiting time. Total waiting time includes time spent waiting as Priority 1, Priority 2, and inactive.

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

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

- ~~i.~~ 1. First locally to Local ABO identical candidates age 12 and older according to Lung Allocation Score in descending order;
- ~~ii.~~ 2. Next, locally to Local ABO compatible candidates age 12 and older according to Lung Allocation Score in descending order;
- ~~iii.~~ 3. Next, locally to Local ABO identical ~~Status~~ Priority 1 candidates 0 – 11 years old according to length of waiting time;
- ~~iv.~~ 4. Next, locally to Local ABO compatible ~~Status~~ Priority 1 candidates 0 – 11 years old according to length of waiting time;
- ~~v.~~ 5. Local ABO identical ~~Status~~ Priority 2 candidates 0 – 11 years old according to length of waiting time;
- ~~vi.~~ 6. Local ABO compatible ~~Status~~ Priority 2 candidates 0 – 11 years old according to length of waiting time;
- ~~vii.~~ 7. Next, to ABO identical candidates age 12 and older in Zone A according to Lung Allocation Score in descending order;
- ~~viii.~~ 8. Next, to ABO compatible candidates age 12 and older in Zone A according to Lung Allocation Score in descending order;
- ~~ix.~~ 9. Next, to ABO identical ~~Status~~ Priority 1 candidates 0 – 11 years old in Zone A according to length of waiting time;
- ~~x.~~ 10. Next, to ABO compatible ~~Status~~ Priority 1 candidates 0 – 11 years old in Zone A according to length of waiting time;
- ~~xi.~~ 11. ABO identical ~~Status~~ Priority 2 candidates 0 – 11 years old in Zone A according to length of waiting time;
- ~~xii.~~ 12. ABO compatible ~~Status~~ Priority 2 candidates 0 – 11 years old in Zone A according to length of waiting time;

- ~~xxiii.13. Next, to ABO identical candidates age 12 and older in Zone B according to Lung Allocation Score in descending order;~~
- ~~xxiv.14. Next, to ABO compatible candidates age 12 and older in Zone B according to Lung Allocation Score in descending order;~~
- ~~xxv.15. Next, to ABO identical Status Priority 1 candidates 0 – 11 years old in Zone B according to length of waiting time;~~
- ~~xxvi.16. Next, to ABO compatible Status Priority 1 candidates 0 – 11 years old in Zone B according to length of waiting time;~~
- ~~xxvii.17. ABO identical Status Priority 2 candidates 0 – 11 years old in Zone B according to length of waiting time;~~
- ~~xxviii.18. ABO compatible Status Priority 2 candidates 0 – 11 years old in Zone B according to length of waiting time;~~
- ~~xxix.19. Next, to ABO identical candidates age 12 and older in Zone C according to Lung Allocation Score in descending order;~~
- ~~xxx.20. Next, to ABO compatible candidates age 12 and older in Zone C according to Lung Allocation Score in descending order;~~
- ~~xxxi.21. Next, to ABO identical Status Priority 1 candidates 0 – 11 years old in Zone C according to length of waiting time;~~
- ~~xxxii.22. Next, to ABO compatible Status Priority 1 candidates 0 – 11 years old in Zone C according to length of waiting time;~~
- ~~xxxiii.23. ABO identical Status Priority 2 candidates 0 – 11 years old in Zone C according to length of waiting time;~~
- ~~xxxiv.24. ABO compatible Status Priority 2 candidates 0 – 11 years old in Zone C according to length of waiting time;~~
- ~~xxxv.25. Next, to ABO identical candidates age 12 and older in Zone D according to Lung Allocation Score in descending order;~~
- ~~xxxvi.26. Next, to ABO compatible candidates age 12 and older in Zone D according to Lung Allocation Score in descending order;~~
- ~~xxxvii.27. Next, to ABO identical Status Priority 1 candidates 0 – 11 years old in Zone D according to length of waiting time;~~
- ~~xxxviii.28. Next, to ABO compatible Status Priority 1 candidates 0 – 11 years old in Zone D according to length of waiting time;~~
- ~~xxxix.29. ABO identical Status Priority 2 candidates 0 – 11 years old in Zone D according to length of waiting time;~~
- ~~xxxx.30. ABO compatible Status Priority 2 candidates 0 – 11 years old in Zone D according to length of waiting time;~~
- ~~xxxxi.31. Next, to ABO identical candidates age 12 and older in Zone E according to Lung Allocation Score in descending order;~~
- ~~xxxii.32. Next, to ABO compatible candidates age 12 and older in Zone E according to Lung Allocation Score in descending order;~~
- ~~xxxiii.33. Next, to ABO identical Status Priority 1 candidates 0 – 11 years old in Zone E according to length of waiting time; and~~
- ~~xxxiv.34. Next, to ABO compatible Status Priority 1 candidates 0 – 11 years old in Zone E according to length of waiting time.~~
- ~~xxxv.35. ABO identical Status Priority 2 candidates 0 – 11 years old in Zone E according to length of waiting time;~~
- ~~xxxvi.36. ABO compatible Status Priority 2 candidates 0 – 11 years old in Zone E according to length of waiting time;~~

### 3.7.11.1

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

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

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

- Offers for 0-11 year-olds will first be made to **combined** local, Zone A and Zone B candidates by ~~status~~ priority and waiting time. After adolescent and adult offers are completed through Zone B, offers will continue to these younger candidates in Zones C, D, and E prior to adolescents and adults within in each zone.
- Offers for 12-17 year-olds will first be made to **combined** local and Zone A candidates according to lung allocation score in descending order after the completion of 0-11 year-old offers through Zone B. Once adult Zone A offers are completed, offers will continue to adolescent candidates in Zones B, C, D, and E after the younger 0-11 candidates and before the adult candidates within each zone.
- Offers to adult candidates (18 years and older) will be made after the completion of 0-11 year old offers through Zone B and adolescent offers through Zone A. After local and Zone A adult offers are completed, offers will continue in Zones B, C, D, and E after the completion of all pediatric offers within each zone.

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

- i. ~~First locally to ABO identical candidates 0 – 11 years old according to length of time waiting;~~
- ii. ~~Next, locally to ABO compatible candidates 0 – 11 years old according to length of time waiting;~~
1. Combined local, Zone A and Zone B ABO identical ~~Status~~ Priority 1 candidates 0-11 years old according to length of waiting time;
2. Combined local, Zone A and Zone B ABO compatible ~~Status~~ Priority 1 candidates 0-11 years old according to length of waiting time;
3. Combined local, Zone A and Zone B ABO identical ~~Status~~ Priority 2 candidates 0-11 years old according to length of waiting time;
4. Combined local, Zone A and Zone B ABO compatible ~~Status~~ Priority 2 candidates 0-11 years old according to length of waiting time;
5. Combined local and Zone A ABO identical candidates 12 – 17 years old according to Lung Allocation Score in descending order;
6. Combined Local and Zone A ABO compatible candidates 12 – 17 years

- old according to Lung Allocation Score in descending order;
- ~~iii.~~ Next, locally to ~~ABO identical candidates 12 – 17 years old according to Lung Allocation Score in descending order;~~
  - ~~vii.~~ Next, locally to ~~ABO compatible candidates 12 – 17 years old according to Lung Allocation Score in descending order;~~
  - ~~viii.~~ 7. Next, locally to Local ~~ABO identical candidates 18 years old and older according to Lung Allocation Score in descending order;~~
  - ~~ix.~~ 8. Next, locally to Local ~~ABO compatible candidates 18 years old and older according to Lung Allocation Score in descending order;~~
  - ~~vii.~~ Next, to ~~ABO identical candidates 0 – 11 years old in Zone A according to length of time waiting;~~
  - ~~viii.~~ Next, to ~~ABO compatible candidates 0 – 11 years old in Zone A according to length of time waiting;~~
  - ~~ix.~~ Next, to ~~ABO identical candidates 12 – 17 years old in Zone A according to Lung Allocation Score in descending order;~~
  - ~~x.~~ Next, to ~~ABO compatible candidates 12 – 17 years old in Zone A according to Lung Allocation Score in descending order;~~
  - ~~x.~~ 9. Next, to ~~ABO identical candidates 18 years old and older in Zone A according to Lung Allocation Score in descending order;~~
  - ~~xi.~~ 10. Next, to ~~ABO compatible candidates 18 years old and older in Zone A according to Lung Allocation Score in descending order;~~
  - ~~xiii.~~ Next, to ~~ABO identical candidates 0 – 11 years old in Zone B according to length of time waiting;~~
  - ~~xiv.~~ Next, to ~~ABO compatible candidates 0 – 11 years old in Zone B according to length of time waiting;~~
  - ~~xii.~~ 11. Next, to ~~ABO identical candidates 12 – 17 years old in Zone B according to Lung Allocation Score in descending order;~~
  - ~~xiii.~~ 12. Next, to ~~ABO compatible candidates 12 – 17 years old in Zone B according to Lung Allocation Score in descending order;~~
  - ~~xiv.~~ 13. Next, to ~~ABO identical candidates 18 years old and older in Zone B according to Lung Allocation Score in descending order;~~
  - ~~xv.~~ 14. Next, to ~~ABO compatible candidates 18 years old and older in Zone B according to Lung Allocation Score in descending order;~~
  - ~~xvi.~~ 15. Next, to ~~ABO identical Status Priority 1 candidates 0 – 11 years old in Zone C according to length of time waiting;~~
  - ~~xvii.~~ 16. Next, to ~~ABO compatible Status Priority 1 candidates 0 – 11 years old in Zone C according to length of time waiting;~~
  - ~~xviii.~~ 17. ABO identical Status Priority 2 candidates 0-11 years old in Zone C according to length of waiting time;
  - 18. ABO compatible Status Priority 2 candidates 0-11 years old in Zone C according to length of waiting time;
  - ~~xx.~~ 19. Next, to ~~ABO identical candidates 12 – 17 years old in Zone C according to Lung Allocation Score in descending order;~~
  - ~~xxi.~~ 20. Next, to ~~ABO compatible candidates 12 – 17 years old in Zone C according to Lung Allocation Score in descending order;~~
  - ~~xxii.~~ 21. Next, to ~~ABO identical candidates 18 years old and older old in Zone C according to Lung Allocation Score in descending order;~~
  - ~~xxiii.~~ 22. Next, to ~~ABO compatible candidates 18 years old and older in Zone C according to Lung Allocation Score in descending order;~~
  - ~~xxiv.~~ 23. Next, to ~~ABO identical Status Priority 1 candidates 0 – 11 years old in Zone D according to length of time waiting;~~
  - ~~xxvi.~~ 24. Next, to ~~ABO compatible Status Priority 1 candidates 0 – 11 years old in Zone D according to length of time waiting;~~
  - 25. ABO identical Status Priority 2 candidates 0-11 years old in Zone D according to length of waiting time;

26. ABO compatible ~~Status~~ Priority 2 candidates 0-11 years old in Zone D according to length of waiting time;
- ~~xxvii.~~27. Next, to ABO identical candidates 12 – 17 years old in Zone D according to Lung Allocation Score in descending order;
- ~~xxviii.~~28. Next, to ABO compatible candidates 12 – 17 years old in Zone D according to Lung Allocation Score in descending order;
- ~~xxix.~~29. Next, to ABO identical candidates 18 years old and older in Zone D according to Lung Allocation Score in descending order; and
- ~~xxx.~~30. Next, to ABO compatible candidates 18 years old and older in Zone D according to Lung Allocation Score in descending order.
- ~~xxxi.~~31. Next, to ABO identical ~~Status~~ Priority 1 candidates 0 – 11 years old in Zone E according to length of time waiting;
- ~~xxxii.~~32. Next, to ABO compatible ~~Status~~ Priority 1 candidates 0 – 11 years old in Zone E according to length of time waiting;
33. ABO identical ~~Status~~ Priority 2 candidates 0-11 years old in Zone E according to length of waiting time;
34. ABO compatible ~~Status~~ Priority 2 candidates 0-11 years old in Zone E according to length of waiting time;
- ~~xxxv.~~35. Next, to ABO identical candidates 12 – 17 years old in Zone E according to Lung Allocation Score in descending order;
- ~~xxxvi.~~36. Next, to ABO compatible candidates 12 – 17 years old in Zone E according to Lung Allocation Score in descending order;
- ~~xxxvii.~~37. Next, to ABO identical candidates 18 years old and older in Zone E according to Lung Allocation Score in descending order; and
- ~~xxxviii.~~38. Next, to ABO compatible candidates 18 years old and older in Zone E according to Lung Allocation Score in descending order.

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

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

- ~~i.~~1. First locally to Local ABO identical candidates 12 – 17 years old according to Lung Allocation Score in descending order;
- ~~ii.~~2. Next, locally to Local ABO compatible candidates 12 – 17 years old according to Lung Allocation Score in descending order;
- ~~iii.~~3. Next, locally to Local ABO identical ~~Status~~ Priority 1 candidates 0 – 11 years old according to length of time waiting;
- ~~iii.~~4. Local ABO compatible ~~Status~~ Priority 1 candidates 0 – 11 years old according to length of time waiting;
5. Local ABO identical ~~Status~~ Priority 2 candidates 0 – 11 years old according to length of time waiting;
6. Local ABO compatible ~~Status~~ Priority 2 candidates 0 – 11 years old according to length of time waiting;

- ~~vi.~~7. ~~Next, locally to Local~~ Local ABO identical candidates 18 years old and older according to Lung Allocation Score in descending order;
- ~~vii.~~8. ~~Next, locally to Local~~ Local ABO compatible candidates 18 years old and older according to Lung Allocation Score in descending order;
- ~~viii.~~9. ~~Next, to~~ ABO identical candidates 12 – 17 years old in Zone A according to Lung Allocation Score in descending order;
- ~~vix.~~10. ~~Next, to~~ ABO compatible candidates 12 – 17 years old in Zone A according to Lung Allocation Score in descending order;
- ~~x.~~11. ~~Next, to~~ ABO identical ~~Status~~ Priority 1 candidates 0 – 11 years old in Zone A according to length of time waiting;
- ~~xi.~~12. ~~Next, to~~ ABO compatible ~~Status~~ Priority 1 candidates 0 – 11 years old in Zone A according to length of time waiting;
- ~~xii.~~13. ABO identical ~~Status~~ Priority 2 candidates 0 – 11 years old in Zone A according to length of time waiting;
14. ABO compatible ~~Status~~ Priority 2 candidates 0 – 11 years old in Zone A according to length of time waiting;
- ~~xiv.~~15. ~~Next, to~~ ABO identical candidates 18 years old and older in Zone A according to Lung Allocation Score in descending order;
- ~~xv.~~16. ~~Next, to~~ ABO compatible candidates 18 years old and older in Zone A according to Lung Allocation Score in descending order;
- ~~xvi.~~17. ~~Next, to~~ ABO identical candidates 12 – 17 years old in zone B according to Lung Allocation Score in descending order;
- ~~xvii.~~18. ~~Next, to~~ ABO compatible candidates 12 – 17 years old in zone B according to Lung Allocation Score in descending order;
- ~~xviii.~~19. ~~Next, to~~ ABO identical ~~Status~~ Priority 1 candidates 0 – 11 years old in Zone B according to length of time waiting;
- ~~xix.~~20. ~~Next, to~~ ABO compatible ~~Status~~ Priority 1 candidates 0 – 11 years old in Zone B according to length of time waiting;
21. ABO identical ~~Status~~ Priority 2 candidates 0 – 11 years old in Zone B according to length of time waiting;
22. ABO compatible ~~Status~~ Priority 2 candidates 0 – 11 years old in Zone B according to length of time waiting;
- ~~xxii.~~23. ~~Next, to~~ ABO identical candidates 18 years old and older in Zone B according to Lung Allocation Score in descending order;
- ~~xxiii.~~24. ~~Next, to~~ ABO compatible candidates 18 years old and older in Zone B according to Lung Allocation Score in descending order;
- ~~xxiv.~~25. ~~Next, to~~ ABO identical candidates 12 – 17 years old in zone C according to Lung Allocation Score in descending order;
- ~~xxv.~~26. ~~Next, to~~ ABO compatible candidates 12 – 17 years old in zone C according to Lung Allocation Score in descending order;
- ~~xxvi.~~27. ~~Next, to~~ ABO identical ~~Status~~ Priority 1 candidates 0 – 11 years old in Zone C according to length of time waiting;
- ~~xxvii.~~28. ~~Next, to~~ ABO compatible ~~Status~~ Priority 1 candidates 0 – 11 years old in Zone C according to length of time waiting;
29. ABO identical ~~Status~~ Priority 2 candidates 0 – 11 years old in Zone C according to length of time waiting;
30. ABO compatible ~~Status~~ Priority 2 candidates 0 – 11 years old in Zone C according to length of time waiting;
- ~~xxx.~~31. ~~Next, to~~ ABO identical candidates 18 years old and older old in Zone C according to Lung Allocation Score in descending order;
- ~~xxxi.~~32. ~~Next, to~~ ABO compatible candidates 18 years old and older in Zone C according to Lung Allocation Score in descending order;
- ~~xxxii.~~33. ~~Next, to~~ ABO identical candidates 12 – 17 years old in zone D according to Lung Allocation Score in descending order;
- ~~xxxiii.~~34. ~~Next, to~~ ABO compatible candidates 12 – 17 years old in zone D according to Lung Allocation Score in descending order;

- ~~xxxiv.~~35. ~~Next, to~~ ABO identical ~~Status~~ Status Priority 1 candidates 0 – 11 years old in Zone D according to length of time waiting;
- ~~xxxv.~~36. ~~Next, to~~ ABO compatible ~~Status~~ Status Priority 1 candidates 0 – 11 years old in Zone D according to length of time waiting;
37. ABO identical ~~Status~~ Status Priority 2 candidates 0 – 11 years old in Zone D according to length of time waiting;
38. ABO compatible ~~Status~~ Status Priority 2 candidates 0 – 11 years old in Zone D according to length of time waiting;
- ~~xxxviii.~~39. ~~Next, to~~ ABO identical candidates 18 years old and older in Zone D according to Lung Allocation Score in descending order; and
- ~~xxxix.~~40. ~~Next, to~~ ABO compatible candidates 18 years old and older in Zone D according to Lung Allocation Score in descending order.
- ~~xxxx.~~41. ~~Next, to~~ ABO identical candidates 12 – 17 years old in Zone E according to Lung Allocation Score in descending order;
- ~~xxxxi.~~42. ~~Next, to~~ ABO compatible candidates 12 – 17 years old in Zone E according to Lung Allocation Score in descending order;
- ~~xxxvii.~~43. ~~Next, to~~ ABO identical ~~Status~~ Status Priority 1 candidates 0 – 11 years old in Zone E according to length of time waiting;
- ~~xxxviii.~~44. ~~Next, to~~ ABO compatible ~~Status~~ Status Priority 1 candidates 0 – 11 years old in Zone E according to length of time waiting;
45. ABO identical ~~Status~~ Status Priority 2 candidates 0 – 11 years old in Zone E according to length of time waiting;
46. ABO compatible ~~Status~~ Status Priority 2 candidates 0 – 11 years old in Zone E according to length of time waiting;
- ~~xxxv.~~47. ~~Next, to~~ ABO identical candidates 18 years old and older in Zone E according to Lung Allocation Score in descending order; and
- ~~xxxvii.~~48. ~~Next, to~~ ABO compatible candidates 18 years old and older in Zone E according to Lung Allocation Score in descending order.

To read the complete policy language visit [www.unos.org](http://www.unos.org) or [optn.transplant.hrsa.gov](http://optn.transplant.hrsa.gov). From the UNOS Web site, select Resources from the main menu, and then select Policies. From the OPTN Web site, select Policy Management, and then select Policies.

**Affected Policy Language:**

**11.0 REGISTRATION FEE**

The Registration Fee, as provided in Article I, Section 1.13 of the Bylaws for the listing of candidates as required by Policy 3.2.1 for listing a potential recipient in UNet<sup>SM</sup>, shall consist of two separate fees. These fees shall be the OPTN Patient Registration Fee ~~\$547~~ \$557 and the UNOS Computer Registration Fee ~~\$75~~ \$114.

***NOTE: The amendments to UNOS Policy 11.0 (Registration Fee) shall be effective October 1, 2009.***

To read the complete policy language visit [www.unos.org](http://www.unos.org) or [optn.transplant.hrsa.gov](http://optn.transplant.hrsa.gov). From the UNOS Web site, select Resources from the main menu, and then select Policies. From the OPTN Web site, select Policy Management, and then select Policies.

**Affected Policy Language:**

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 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 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.

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 PaO<sub>2</sub> < 60 mmHg on room air will be eligible for a MELD/PELD exception listed at a MELD score of 22 without RRB review with a 10% increase in points every three months if the candidate's PaO<sub>2</sub> stays below 60 mmHg. ~~referred to the RRB for consideration of a MELD score that would provide them a reasonable probability of being transplanted within 3 months.~~ Candidates should have no significant clinical evidence of underlying primary pulmonary disease.

~~3.6.4.5.2 Liver Candidates with Familial Amyloidosis or Primary Oxaluria. Candidate with familial amyloidosis or primary oxaluria may be referred to the RRB for consideration of a MELD score that would allow them to be transplanted within 3 months.~~

3.6.4.5.2 Liver Candidates with Cholangiocarcinoma. Candidates meeting the criteria listed in Table 4 will be eligible for a MELD/PELD exception listed at a MELD score of 22 without RRB review with a 10% 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 FEV<sub>1</sub> that falls below 40%, will be eligible for a MELD/PELD exception listed at a MELD score of 22/PELD score of 32 without RRB review with a 10% 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/or a biopsy proven amyloid in the involved organ, will be eligible for a MELD/PELD exception will be listed at a MELD score of 22/PELD score of 32 without RRB review with a 10% 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 will be listed at a MELD score of 28/PELD score of 41 without RRB review with a 10% 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 will be listed at a MELD score of 22 points with a 10% 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<sup>-5</sup>.
  - 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 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.
- 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.

To read the complete policy language visit [www.unos.org](http://www.unos.org) or [optn.transplant.hrsa.gov](http://optn.transplant.hrsa.gov). From the UNOS Web site, select Resources from the main menu, and then select Policies. From the OPTN Web site, select Policy Management, and then select Policies.

**Affected Policy Language:**

**3.6.4.3 Pediatric Liver Transplant Candidates with Metabolic Diseases.** A pediatric liver transplant candidate with a urea cycle disorder or organic acidemia shall be assigned a PELD (less than 12 years old) or MELD (12-17 years old) score of 30. If the candidate does not receive a transplant within 30 days of being listed with a MELD/PELD of 30, then the candidate may be listed as a Status 1B. Candidates meeting these criteria will be listed in as a MELD/PELD of 30 and subsequent Status 1B without RRB review. Hospitalization is not a requirement for listing in Status 1B for these candidates. Candidates with other metabolic diseases may apply to the Regional Review Board for an appropriate PELD (less than 12 years old) or MELD (12-17 years old) score. Decisions by the Regional Review Boards in these cases shall be guided by standards developed jointly by the Liver/Intestinal Organ Transplantation and Pediatric Transplantation Committees. In such cases the requested score must receive prospective approval by the applicable RRB within twenty-one days after application; if approval is not given and the physician wishes to pursue the listing, then the physician and the RRB must meet by conference call to review the case; ~~if approval is not given within~~ twenty-one days, the candidate's transplant physician may list the candidate at the higher PELD or MELD 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.

<< No further changes to 3.6.4.3 >>

**3.6.4.4 Liver Transplant Candidates with Hepatocellular Carcinoma (HCC).**

<< No changes until the following text >>

If the initial request is denied by the RRB, the center may appeal via a conference call with the RRB but the candidate will not receive the additional MELD/PELD priority until the case is approved by the RRB. Cases where the appropriate RRB has found the listing center to be out of compliance with Policy 3.6.4.4 will be referred to the Liver and Intestinal Organ Transplantation Committee for review and possible action. Cases not resolved within 21 days will be referred to the Liver and Intestinal Organ Transplantation Committee for review; this review by the Liver and Intestinal Organ Transplantation Committee may result in further referral of the matter to the Membership and Professional Standards Committee for appropriate action in accordance with Appendix A of the Bylaws.

<< No further changes to 3.6.4.4 >>

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 and the physician wishes to pursue the listing, then the physician and the RRB must meet by conference call to review the case; ~~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.

**<< No further changes to 3.6.4.5 >>**

To read the complete policy language visit [www.unos.org](http://www.unos.org) or [optn.transplant.hrsa.gov](http://optn.transplant.hrsa.gov). From the UNOS Web site, select Resources from the main menu, and then select Policies. From the OPTN Web site, select Policy Management, and then select Policies.

**Affected Policy Language:**

**3.6 ALLOCATION OF LIVERS.**

<< No changes to introductory paragraph>>

At each level of distribution, adult livers (i.e., greater than or equal to 18 years old) will be allocated in the following sequence (adult donor liver allocation algorithm):

**Adult Donor Liver Allocation Algorithm**

**Combined Local and Regional**

1. Status 1A candidates in descending point order

**~~Regional~~**

- ~~2. Status 1A candidates in descending point~~

**Combined Local and Regional**

- ~~2.~~ 3. Status 1B candidates in descending order.

**~~Regional~~**

- ~~4. Status 1B candidates in descending point order~~

<< No further changes to Policy 3.6 >>

To read the complete policy language visit [www.unos.org](http://www.unos.org) or [optn.transplant.hrsa.gov](http://optn.transplant.hrsa.gov). From the UNOS Web site, select Resources from the main menu, and then select Policies. From the OPTN Web site, select Policy Management, and then select Policies.

**Affected Policy Language:**

**3.6.4.4 Liver Transplant Candidates with Hepatocellular Carcinoma (HCC).** Candidates with Stage II HCC in accordance with the modified Tumor-Node-Metastasis (TNM) Staging Classification set forth in Table 3 that meet all of the medical criteria specified in (i) and (ii) may receive extra priority on the Waiting List as specified below. A candidate with an HCC tumor that is greater than or equal to 2 cm and less than 5cm or no more than 3 lesions, the largest being less than 3 cm in size (Stage T2 tumors as described in Table 3) may be registered at a MELD/PELD score equivalent to a 15% probability of candidate death within 3 months. The largest dimension of each tumor must be reported (i.e., 3.2cm x 5.1cm must be reported as 5.1cm).

To read the complete policy language visit [www.unos.org](http://www.unos.org) or [optn.transplant.hrsa.gov](http://optn.transplant.hrsa.gov). From the UNOS Web site, select Resources from the main menu, and then select Policies. From the OPTN Web site, select Policy Management, and then select Policies.

**Affected Policy Language:****12.0 Living Donation**

The following policies apply to the entire continuum of organ donation from living donors. The process of living donation begins at the time that an individual considers donating an organ, continues through the evaluation of the donor, placement of the organ (whether directed or nondirected), recovery of the organ, and post-donation care and follow-up of the donor.

The following policies, apply to member institutions involved in living donation. These policies do not supplant medical judgment or decision-making by transplant professionals or potential or realized living donors.

**12.1 Definitions**

*Reserved*

**12.2 Informed Consent of Living Donors**

*Reserved*

**12.3 Medical Evaluation of Living Donors**

*Reserved*

**12.4 Independent Donor Advocates**

*Reserved*

**12.5 Placement of Living Donor Organs****12.5.1 Kidney Placement.**

~~3.5.17~~ **12.5.1.1 Prospective Crossmatching.** A prospective crossmatch is mandatory for all ~~candidates~~ potential living donor recipients. ~~except where clinical circumstances support its omission. The transplant program and its histocompatibility laboratory must have a joint written policy that states when the prospective crossmatch may be omitted.~~ Guidelines for policy development, including assigning risk and timing of crossmatch testing, are set out in Appendix D to Policy 3.

**12.5.2 Liver Placement.**

*Reserved*

**12.5.3 Thoracic Placement.**

*Reserved*

**12.5.4 Pancreas Placement.**

Reserved

### **12.5.5 Intestinal Placement.**

Reserved

~~3.3.7~~ **12.6 Center Acceptance and Transplant of Organs from Living Donors. Acceptance of Living Donor Organs.** Transplant Centers that perform living donor transplants must only accept and transplant living donor organs recovered at OPTN member transplant hospitals. )

~~5.0~~ **12.7 STANDARDIZED PACKAGING AND TRANSPORTING OF ORGANS AND TISSUE TYPING MATERIALS Responsibility for Transport of Living Donor Organs.** The following policies address standardized packaging of ~~live and deceased~~ living donor organs and tissue typing materials to be transported for the purposes of organ transplantation. When an ~~an deceased donor~~ organ from a living donor is procured, the ~~Host OPO~~ Transplant Center shall be responsible for ensuring the accuracy of the donor's ABO on the container label and within the donor's documentation. ~~Each OPO~~ The Transplant Center 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~~ Transplant Center shall maintain documentation that such separate verification has taken place and make such documentation available for audit.

Upon receipt of an ~~live or deceased donor~~ organ from a living donor 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.

~~5.2~~ **12.7.1 Standard Labeling Specifications.** The ~~Host OPO or the~~ Transplant Center 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~~ transplant center shall label each specimen within the package in accordance with policy. The ~~Host OPO~~ transplant center 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 from living donors that who 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 from living donors 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 OPTN Contractor). 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~~ **12.7.2** The ~~Host OPO or the~~ Transplant Center, ~~as applicable~~ is responsible for ensuring that the Donor I.D., Donor ABO type, and a secure label identifying the specific contents (e.g., liver segment, right kidney, ~~heart~~) are attached to the outer bag or rigid container housing the donor organ prior to transport.

~~5.2.2~~ **12.7.3** Each separate specimen container of tissue typing material must have a secure label with the Donor I.D., 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~~ **12.7.4** 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., 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~~ **12.7.5 Packaging.** 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~~ **12.7.6 Packaging.** In all circumstances during which a 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.

## **12.8 Reporting Requirements.**

~~7.5.1~~ **12.8.1** Information pertaining to deceased donor feedback must be submitted to the OPTN within five working days of the procurement date. All living donors must be registered with the OPTN Contractor via the living donor feedback form prior to surgery.

~~7.1.5~~ **12.8.2** The follow-up period for living donors will be a minimum of two years.

~~7.3.2~~ **12.8.3** Living Donor Registration Forms (LDR) must be submitted to the OPTN within 60 days of the form generation date. Recipient transplant centers must complete the LDR form when the donor is discharged from the hospital or by six weeks following the transplant date, whichever is first. The recipient transplant center must submit LDF forms for each living donor at six months, one year and two years from the date of donation.

**12.8.4 Submission of Living Donor Death and Organ Failure Data.** Transplant programs must report all instances of living donor deaths and failure of the living donor's native organ function within 72 hours after the program becomes aware of the living donor death or failure of the living donors' native organ function. Live donors' native organ failure is defined as listing for transplant for liver donors, and as transplant, listing for transplant or the need for dialysis in renal donors. Transplant centers must report these incidents through the UNet<sup>SM</sup> Patient Safety System for a period of two years from the date of the donation. The MPSC will review and report all adverse events to the Board.

## **12.9 Long-term Care or Support of Living Donors.**

### **12.9.1 Follow-up**

*Reserved*

### **12.9.2 Insurance.**

*Reserved*

~~3.5.11.6~~ **12.9.3 Donation Status. Priority on the Waitlist.** A candidate will be assigned 4 points if he or she has donated for transplantation within the United States his or her vital organ or a segment of a vital organ (i.e., kidney, liver segment, lung segment, partial pancreas, small bowel segment). To be assigned 4 points for donation status under Policy 3.5.11.6, the candidate's physician must provide the name of the recipient of the donated organ or organ segment, the recipient's transplant facility and the date of transplant of the donated organ or organ segment, in addition to all other candidate information required to be submitted under policy. Additionally, at the local level of organ distribution only, candidates assigned 4 points for donation status shall be given first priority for kidneys that are not shared mandatorily for 0 HLA mismatching, or for renal/non-renal organ allocation irrespective of the number of points assigned to the candidate relative to other candidates. When multiple transplant candidates assigned 4 points for donation status are eligible for organ offers under this policy, organs shall be allocated for these candidates according to length of time waiting.

**3.5.5.2\_12.9.4 Exception for Prior Living Donor Organs.** Kidneys procured from standard criteria deceased donors shall be allocated locally first for prior living organ donors as defined in Policy 3.5.11.6 (Donation Status) before they are offered in satisfaction of kidney payback obligations.

To read the complete policy language visit [www.unos.org](http://www.unos.org) or [optn.transplant.hrsa.gov](http://optn.transplant.hrsa.gov). From the UNOS Web site, select Resources from the main menu, and then select Policies. From the OPTN Web site, select Policy Management, and then select Policies.

**Affected Policy Language:**

**3.7.6.1 Candidates Age 12 and Older.** Candidates age 12 and older are assigned priority for lung offers based upon Lung Allocation Score, which is calculated using the following measures: (i) waitlist urgency measure (expected number of days lived without a transplant during an additional year on the waitlist), (ii) post-transplant survival measure (expected number of days lived during the first year post-transplant), and (iii) transplant benefit measure (post-transplant survival measure minus waitlist urgency measure). Waitlist urgency measure and post-transplant survival measure (used in the calculation of transplant benefit measure) are developed using Cox proportional hazards models. Factors determined to be important predictors of waitlist mortality and post-transplant survival are listed below in Tables 1 and 2. It is expected that these factors will change over time as new data are available and added to the models. The Thoracic Organ Transplantation Committee will review these data in regular intervals of approximately six months and will propose changes to Tables 1 and 2 as appropriate.

**Table 1**  
**Factors Used to Predict Risk of Death on the Lung Transplant Waitlist**

1. Forced vital capacity (FVC)
2. Pulmonary artery (PA) systolic pressure (Groups A, C, and D – see 3.7.6.1.a)
3. O<sub>2</sub> required at rest (Groups A, C, and D – see 3.7.6.1.a)
4. Age
5. Body mass index (BMI)
6. Diabetes
7. Functional status
8. Six-minute walk distance
9. Continuous mechanical ventilation
10. Diagnosis
11. PCO<sub>2</sub> (see 3.7.6.1.b)
12. Bilirubin (current bilirubin – all gGroups; change in bilirubin – Group B; see 3.7.6.1.c)

[No further changes are proposed to this section of Policy 3.7.6.1.]

a. Lung Disease Diagnosis Groups

[No changes are proposed to this section of Policy 3.7.6.1.]

b. PCO<sub>2</sub> in the Lung Allocation Score

[No changes are proposed to this section of Policy 3.7.6.1.]

c. Bilirubin in the Lung Allocation Score

UNet<sup>SM</sup> will use two measures of total bilirubin in a candidate's lung allocation score calculation: current bilirubin (for all candidates), and change in bilirubin (for Group B only). There are two types of bilirubin change calculations: "threshold change" and "threshold change maintenance." This section of Policy 3.7.6.1 explains how UNet<sup>SM</sup> uses bilirubin in the lung allocation score.

(i) Definition of Current Bilirubin

Current bilirubin is the total bilirubin value with the most recent test date and time entered in UNet<sup>SM</sup>. UNet<sup>SM</sup> will include in the lung allocation score calculation a current bilirubin value that is at least 1.0 mg/dL.

(ii) Expiration of Current Bilirubin Value

UNet<sup>SM</sup> will evaluate a current bilirubin value as expired according to Policy 3.7.6.3.2.

(iii) Use of Normal Clinical Value for Current Bilirubin

The normal clinical value of current bilirubin is 0.7 mg/dL. UNet<sup>SM</sup> will substitute this normal clinical value in the lung allocation score calculation when the value of current bilirubin is less than 0.7 mg/dL, missing, or expired.

(iv) Bilirubin Values Used in the Change Calculations (Group B Only)

There are two types of bilirubin change calculations: threshold change and threshold change maintenance.

The threshold change calculation evaluates whether the bilirubin change is 50% or higher. In this calculation, UNet<sup>SM</sup> will use highest and lowest values of bilirubin. The test date of the lowest value must be earlier than the test date of the highest value. The highest value must be at least 1.0 mg/dL. Test dates of these highest and lowest values cannot be more than 6 months apart. If necessary, UNet<sup>SM</sup> will use an expired lowest value, but not an expired highest value. If a value is less than 0.7 mg/dL, UNet<sup>SM</sup> will substitute the normal clinical value of 0.7 mg/dL before calculating change. The equation for threshold change is  $[(\text{highest bilirubin} - \text{lowest bilirubin})/\text{lowest bilirubin}]$ .

The threshold change maintenance calculation occurs *after* the candidate receives the impact from threshold change in the lung allocation score. This maintenance calculation determines the candidate's eligibility for retaining the impact from threshold change in the lung allocation score. To maintain the impact from threshold change in the lung allocation score, the current bilirubin value must be at least 50% higher than the lowest value used in the threshold change calculation. The equation for threshold change maintenance is  $[(\text{current bilirubin} - \text{lowest bilirubin})/\text{lowest bilirubin}]$ .

UNet<sup>SM</sup> will perform the threshold change maintenance calculation either when the current bilirubin value expires (Policy 3.7.6.3.2) or a new current bilirubin value is entered. For this calculation, the lowest and highest values that were used in the threshold change calculation can be expired. The current bilirubin value can be the highest one that was used in the threshold change calculation. If a current bilirubin value expires, the candidate's lung allocation score will lose the impact from threshold change. The reason for this loss is that when a current bilirubin value expires, UNet<sup>SM</sup> will substitute that expired value with the normal clinical value of 0.7 mg/dL. This normal value, therefore, cannot be 50% higher than the lowest value in the threshold change calculation.

If a center enters a new current bilirubin value for a candidate who has lost the impact from threshold change, UNet<sup>SM</sup> will perform the threshold change maintenance calculation. If the new current bilirubin value is at least 50% higher than the lowest value used in the threshold change calculation, UNet<sup>SM</sup> will *reapply* the impact from threshold change to the candidate's lung allocation score.

(v) *Impact of Bilirubin Threshold Change in the Lung Allocation Score (Group B only)*

A change in bilirubin that is 50% or higher, or threshold change, will impact a candidate's lung allocation score. The candidate will not lose the lung allocation score impact from threshold change provided that the current bilirubin is at least 50% higher than the lowest value used in the threshold change calculation.

To read the complete policy language visit [www.unos.org](http://www.unos.org) or [optn.transplant.hrsa.gov](http://optn.transplant.hrsa.gov). From the UNOS Web site, select Resources from the main menu, and then select Policies. From the OPTN Web site, select Policy Management, and then select Policies.

**Affected Bylaws Language:**

*OPTN Version:*

**APPENDIX B TO BYLAWS**

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

**I. Organ Procurement Organizations.** [No Change]

**II. Transplant Hospitals.**

**A. General.** [No Change]

**B. Survival Rates.** [No Change]

**C. Inactive Membership Status. Functional Inactivity, Voluntary Inactive Membership Inactive Transplant Program Status, Relinquishment of Designated Transplant Program Status and Termination of Designated Transplant Program Status.** ~~A Member Transplant Hospital that fails to remain functionally active with respect to any designated transplant program (as defined below) may voluntarily stop transplantation at that transplant program for a period of up to twelve months by notice to the Executive Director, or may relinquish designated transplant program status for the program. This voluntary action to stop transplantation may be extended beyond twelve months upon request to the MPSC and demonstration to the MPSC’s satisfaction of the benefit of such extension, together with a plan and timeline for re-starting transplantation at the program which shall include assurance that all OPTN membership criteria will be met at the time of re-starting transplantation. The MPSC may also require, in its discretion, that the Member participate in a discussion regarding a performance review. The discussion may be with the MPSC, a subcommittee or work group, as the MPSC may direct. The discussion referenced above will be conducted according to the principles of confidential medical peer review, as described in Section 2.07A of Appendix A to the OPTN Bylaws. The discussion is not an adverse action or an element of due process. A Member who participates in a discussion with the MPSC is entitled to receive a summary of the discussion.~~

For the purposes of these bylaws, a candidate is defined as an individual who has been added to the waiting list. A potential candidate is defined as an individual who is under evaluation for transplant by the transplant program. Each reference to a candidate includes potential candidates if and as applicable.

1. **Functional Inactivity.** Transplant programs must remain functionally active. Transplant program functional activity will be reviewed periodically by the Membership and Professional Standards Committee (MPSC).

For purposes of these Bylaws, ~~“functionally inactive-Functional Inactivity”~~ means is defined as any or all of the items below:

- (+) (a) The inability to serve patients, potential candidates, candidates, and or recipients, as a group, for a sustained and significant time period, where a period of 15 days or more consecutively is presumed to be sustained and significant, or ;

- (2) ~~No transplant performed for a period of time defined as:~~
- (b) failure to perform a transplant during the following stated periods of time:
- i. ~~No transplant performed in three months~~ In the case of kidney, liver, and heart transplant programs, within three consecutive months;
  - ii. ~~No transplant performed in six months~~ In the case of pancreas and lung programs, and within six consecutive months;
  - iii. ~~No transplant performed in one year~~ In the case of transplant programs located in stand-alone pediatric transplant hospitals, within twelve consecutive months.
- (c) waiting list inactivation of 15 or more consecutive days and/or 28 cumulative days or more over any 365 consecutive day period.
- (d) given their experimental and evolving nature, functional inactivity thresholds and waiting list notification requirements regarding functional inactivity have not been established for pancreatic islet and intestinal transplant programs.

~~with no explanation deemed satisfactory by the MPSC that the program remains qualified pursuant to the criteria defined in this Appendix B to provide transplant services.~~

Any programs identified to be functionally inactive shall be provided the opportunity to explain its inactivity through reports requested by the MPSC.

A transplant program must provide written notice to candidates when the transplant program:

- Inactivates its waiting list or is unable to perform transplants for 15 consecutive days or more;
- Inactivates its waiting list or is unable to perform transplants for 28 cumulative days or more over any 365 consecutive day period;

The MPSC may also require, at its discretion, that the Member participate in an informal discussion regarding a performance review. The informal discussion may be with the MPSC, a subcommittee or work group, as the MPSC may direct.

The discussion referenced above will be conducted according to the principles of confidential medical peer review, as described in Section 2.07A of Appendix A to the ~~OPTN~~ Bylaws. The discussion is not an adverse action or an element of due process. A Member who participates in an informal discussion with the MPSC is entitled to receive a summary of the discussion.

A functionally inactive transplant program should voluntarily inactivate for a period of up to twelve months by providing written notice to the Executive Director. If the transplant program expects to be inactive for more than twelve months, the Member should relinquish designated transplant program status for the program in accordance with these bylaws.

The MPSC may recommend that a program inactivate or relinquish its designated transplant program status due to the program's functional inactivity. If the program fails

to inactivate or relinquish its designated transplant status upon the MPSC's recommendation to do so, the MPSC may recommend the Board of Directors take appropriate action in accordance with Appendix A of these Bylaws. Potential adverse actions are defined under Section 3.01A of the bylaws. Additionally, the Board of Directors may notify the Secretary of HHS of the situation.

~~If the Member fails to take either action voluntarily, the Membership and Professional Standards Committee may recommend that the Board of Directors take appropriate action in accordance with Appendix A of these Bylaws in all other cases, which action may include those defined as adverse under Section 3.01A. Program inactivation or relinquishment of designated transplant program status involves (i) prompt suspension of transplantation, (ii) notice to patients of the need to inactivate, removal of these patients from the program's waiting list, or if the patient desires transfer of the patient to the list of another Member Transplant Hospital, and (iii) assistance for patients in identifying the designated transplant programs to which they can transfer. Upon submission and review of information establishing that the Member has again become active in human organ transplantation and that all other criteria for membership are met, the Membership and Professional Standards Committee shall recommend to the Board of Directors that the Member be designated as an active member.~~

~~To assure equity in waiting times, and facilitate smooth transfer of patients from the waiting list of a program that is inactivated or relinquishes designated transplant status, patients on the waiting list of a designated transplant program at the time of inactivation or relinquishment of designated status may retain existing waiting time and continue to accrue waiting time appropriate to their status on the waiting list at the time of inactivation or relinquishment of designated status of their program for a maximum of 90 days following that program's inactivation or relinquishment of designated status. This total acquired waiting time may be, with agreement of the accepting center, transferred to the patient's credit when s(he) is listed with a new program.~~

~~It is expected that all Transplant Hospitals will duly inform their patients on the waiting list if there will be an extended period of time when a designated transplant program will be unable to perform transplants. Programs that are not able to serve patients, as a group, for a period of 15 consecutive days or more are further expected to notify UNOS and their patients as described above.~~

2. **Inactive Transplant Program Status-Voluntary.** ~~For the purposes of these bylaws, inactive transplant program status is defined as:~~

- an inactive transplant program waiting list status in UNet<sup>SM</sup> (short-term inactivation), or
- an inactive transplant program waiting list status in UNet<sup>SM</sup> and an inactive membership status (long-term inactivation).

A Member may voluntarily inactivate a transplant program, on a short-term or long-term basis, for reasons including but not limited to:

- inability to meet functional activity requirements;
- temporarily lacking required physician and/or surgeon coverage;
- substantial change in operations that require temporary cessation of transplantation.

- a. Short-Term Inactivation.** Short-term inactivation means that a transplant program may be inactive for up to 14 consecutive days. A Member may voluntarily inactivate a transplant program for a period not to exceed 14 days by changing the program's waiting list status in UNet<sup>SM</sup>.
- i. Notice to the OPTN Contractor.** When a Member intends to voluntarily inactivate a transplant program on a short-term basis, the Member is not required to notify the OPTN contractor.
- ii. Notice to Patients.** In accordance with Attachment I to Appendix B, Section VII each transplant program\* must provide potential candidates, candidates, and recipients with a written summary of its Program Coverage Plan at the time of listing or when there are any substantial changes in program or personnel.
- b. Long-Term Inactivation.** Long-term inactivation means inactivation of a transplant program for 15 or more days consecutively. Members should voluntarily inactivate programs that are not able to serve potential candidates, candidates, or recipients, for a period of 15 or more days consecutively. Voluntary inactivation may extend for a period of up to 12 months.
- i. Notice to the OPTN Contractor.** When a Member intends to voluntarily inactivate a transplant program for 15 or more days consecutively, it must provide written notice, including the reason(s) for inactivation, to the OPTN Executive Director upon deciding to inactivate the transplant program
- ii. Notice to the Patients.** When a Member intends to inactivates a transplant program for 15 or more days consecutively, it must provide:
- a) written notice to the transplant program's potential candidates, candidates, recipients, and living donors currently being followed by the transplant program. Written notice should be mailed at least 30 days prior to the anticipated inactivation date by certified mail/return receipt requested. Written notice must be mailed no later than seven days following inactivation and include:
- 1) the reason(s) for inactivating the transplant program;
  - 2) notice that while still on the waiting list of the inactive program the candidate cannot receive an organ offer through this member program;
  - 3) options for potential candidates, candidates, recipients, and living donors to transfer to an alternative designated transplant program with the phone number of the administrative office of the inactivating program to help with potential candidate, candidate, recipient, and living donor transfers.
- The Member must provide a representative copy of the patient notice to the OPTN contractor along with a list of potential candidates, candidates, recipients, and living donors who received the notice.
- In the event of a natural disaster that adversely affects a transplant program, the patient notification requirements shall be applied reasonably and flexibly.

**iii. Transition Plan.** When the Member inactivates a transplant program for 15 or more days consecutively, it must:

- a) promptly suspend organ implantation for that transplant program;
- b) assist potential candidates and candidates in identifying designated transplant programs to which they can transfer;
- c) provide a list to the OPTN contractor of all of the transplant program's candidates at the time of inactivation and update it throughout this process;
- d) indicate on the list provided the decision of each potential candidate and each candidate to transfer, with the following additional information:
  - i) if a candidate or potential candidate chooses not to transfer to an alternative transplant program, provide the reason and indicate whether the candidate has been completely informed of the implications of this decision;  
or
  - ii) if a candidate or potential candidate chooses to transfer, indicate the transplant program to which the candidate is transferring. Periodic updates will be required as to the status of each candidate's transfer progress until the candidate is evaluated by the accepting program and an official decision is made regarding the candidate's listing status.
- e) expedite removal of all candidates from the inactive transplant program's waiting list, or, if the candidate requests, transfer the candidate to another OPTN Member transplant hospital;
- f) initiate transfer of all active candidates or potential candidates hospitalized at the inactive transplant program to an accepting transplant hospital within seven days of inactivation of the transplant program. The inactive transplant program must complete the transfer process within 14 days unless transfer would be unsafe or discharge is anticipated within that time; or circumstances outside of the program's control exist that prevent transfer within 14 days. The program must document and submit to the OPTN contractor all efforts for transfer of its hospitalized candidates or potential candidates if it is unable to meet the time periods within this section.
- g) provide a priority list of the most urgent candidates or potential candidates at the inactive transplant program with an individualized plan of transfer, potential alternative transplant programs, and a timeline for transferring these candidates according to the following priorities:
  - i) for liver candidates, all Status 1A and 1B candidates must be transferred within seven days of program inactivation, followed by all active candidates in descending MELD/PELD score order, with all candidates whose MELD/PELD score exceeds 25 to be

- transferred within 30 days, followed by all inactive candidates;
- ii) for lung candidates, active candidates should be transferred according to descending Lung Allocation Scores followed by inactive candidates;
  - iii) for kidney candidates, those whose PRA(measured or calculated) is over 80% should be transferred first, followed by all other active candidates in order of waiting time, then transfer of all inactive candidates;
  - iv) for heart candidates, all Status 1A and 1B must be transferred within seven days of inactivation;
  - v) for multi-visceral organ transplant candidates, transfer must be completed within 30 days of inactivation; and
  - vi) notwithstanding these guidelines, all active candidates who choose to transfer should be transferred within 60 days of inactivation.
  - vii) The program must document and submit to the OPTN contractor all efforts for transfer of its candidates if it is unable to meet the time periods within this section.
- h) document all efforts to transfer candidates to an alternative designated transplant program including all contacts made to facilitate the transfer of candidates; and
- i) remove every transplant candidate from the inactive transplant program's waiting list within 12 months of the program's inactivation date in the cases when a program does not intend to reactivate.

Transplant programs that inactivate for 15 or more days consecutively may still have the ability to provide care to transplant candidates, recipients and living donors. Should the transplant program continue to provide follow-up care to transplant recipients and living donors, the program must continue to submit OPTN follow-up forms via UNet<sup>SM</sup>. Alternatively, transplant recipients may transfer care to another institution.

**Extension of Voluntary Inactive Program Status beyond Twelve Months.** A Member transplant hospital may request an extension of voluntary inactive program status beyond twelve months by making a request to the MPSC. The request must demonstrate to the MPSC's satisfaction the benefit of such an extension, and be accompanied by a comprehensive plan with a timeline for re-starting transplantation at the program. This demonstration must include assurance that all membership criteria will be met at the time of re-starting transplantation.

**Reactivation after Voluntary Long Term Inactivation.** A Member transplant hospital may reactivate its program after long term voluntary inactivation by submitting application materials deemed appropriate by the MPSC that establishes that the program has again become active in organ transplantation and that all criteria for membership are met. The Membership and Professional Standards Committee shall recommend to the Board of Directors that the Board so notify the Secretary of HHS.

**3. Relinquishment or Termination of Designated Transplant Program Status**  
Relinquishment of Designated Transplant Program Status means that a Member may voluntarily give up its designated transplant program status upon written notice to the OPTN. Members that relinquish designated transplant program status are voluntarily closing the transplant program.

Termination of Designated Transplant Program Status means that a Member's designated program status is terminated by the Secretary of the Department of Health and Human Services ("Secretary"). In the case of noncompliance with policies covered by Section 1138 of the Social Security Act, the MPSC may recommend that the Board of Directors and/or the Executive Committee request approval from the Secretary to terminate a Member's designated transplant program status in accordance with Appendix A Section 2.06A of these Bylaws. The Board of Directors and/or the Executive Committee may, on its own accord, request such approval from the Secretary.

Once a Member relinquishes a designated transplant program status or it is terminated by the Secretary of HHS, that transplant program may no longer perform organ transplants. The Member must facilitate the transfer of the subject transplant program's candidates to another transplant program.

**a. Notice to the OPTN Contractor.** A Member transplant hospital must provide written notice to the OPTN contractor within 30 days of the intent to relinquish its designated transplant program status and the reasons therefor upon deciding to relinquish designated transplant program status.

**b. Notice to the Patients.** When a Member transplant hospital intends to relinquish its designated transplant program status, or its designated transplant program status is terminated, it must provide:

- i)** written notice to the transplant program's potential candidates, candidates, recipients, and living donors currently being followed by the transplant program. Written notice should be mailed at least 30 days prior to the anticipated date of relinquishment or termination by certified mail/return receipt requested. Written notice must be mailed no later than seven days following relinquishment/termination and include:
  1. the reason(s) for loss of designated transplant program status;
  2. notice that while still on the waiting list of the inactive program the candidate cannot receive an organ offer through this member program;
  3. options for potential candidates, candidates, recipients, and living donors to transfer to an alternative designated transplant program with the phone number of the administrative office of the inactivating program to help with potential candidate, candidate, and recipient transfers; and

The Member transplant hospital must provide a representative copy of the patient notice to the OPTN contractor along with a list of potential candidate, candidate, and recipient names who received the notice.

- c. Transition Plan.** When a Member transplant hospital relinquishes a transplant program's designated program status or its designated program status is terminated, it must:
- i. promptly suspend organ implantation for the transplant program;
  - ii. assist potential candidates and candidates in identifying designated transplant programs to which they can transfer;
  - iii. provide a list to the OPTN contractor of all of the transplant program's candidates on the waiting list at the time of relinquishment or termination and update it throughout this process;
  - iv. indicate on the list provided the decision of each potential candidate and each candidate to transfer, with the following additional information:
    1. if a candidate or potential candidate chooses not to transfer to an alternative transplant program, provide the reason and indicate whether the candidate has been completely informed of the implications of this decision; or
    2. if a candidate or potential candidate chooses to transfer, indicate the transplant program to which the candidate is transferring. Periodic updates will be required as to the status of each candidate's transfer progress until the candidate is evaluated by the accepting program and an official decision is made regarding the candidate's listing status.
  - v. expedite removal of all candidates from the transplant program's waiting list, or, if the patient requests, transfer the candidate to another OPTN Member transplant hospital;
  - vi. initiate transfer of all active candidates hospitalized at the transplant program to an accepting transplant hospital within seven days of relinquishment of the transplant program. The transplant program must complete the transfer process within 14 days unless transfer would be unsafe or discharge is anticipated within that time; or circumstances outside of the program's control exist that prevent transfer within 14 days. The program must document and submit to the OPTN contractor all efforts to transfer its hospitalized candidates if it is unable to meet the time periods within this section.
  - vii. provide a priority list of the most urgent candidates listed at the transplant program with an individualized plan of transfer, potential alternative transplant programs, and a timeline for transferring these candidates according to the following priorities:
    1. for liver candidates, all Status 1A and 1B candidates must be transferred within seven days of relinquishment, followed by all active candidates in descending MELD/PELD score order, with all candidates whose MELD/PELD score exceeds 25 to be transferred within 30 days, followed by all inactive candidates;
    2. for lung candidates, active candidates should be transferred according to descending Lung Allocation Scores with highest scores first, followed by inactive candidates;
    3. for kidney candidates, those whose PRA (measured or calculated) is over 80% should be transferred first, followed by all other active candidates in order of waiting time, then transfer of all inactive candidates;
    4. for heart candidates, all Status 1A and 1B must be transferred within seven days of relinquishment;

5. for multi-visceral organ transplant candidates, transfer must be completed within 30 days of relinquishment; and
6. notwithstanding these guidelines, all active candidates should be transferred within 60 days of relinquishment; and;
7. The program must document and submit to the OPTN contractor all efforts for transfer of its candidates if it is unable to meet the time periods within this section.
- viii. document all efforts to transfer candidates to an alternative designated transplant program including all contacts made to facilitate the transfer of candidates; and
- ix. remove every transplant candidate from the transplant program's waiting list within 12 months of the program's relinquishment date.

A Member that relinquishes or terminates a designated transplant program may still have the ability to temporarily provide care to transplant candidates and provide follow-up care to transplant recipients and living donors. Should the transplant program continue to provide follow-up care to transplant recipients and living donors, the program must continue to submit OPTN follow up forms via UNet<sup>sm</sup>. Alternatively, transplant recipients may transfer care to another institution.

4. **Waiting Time on Waiting List.** To assure equity in waiting times, and facilitate smooth transfer of candidates from the waiting list of affected programs (i.e. programs that voluntarily inactivate, relinquish or lose designated transplant program status), candidates on the waiting list in such instances may retain existing waiting time and continue to accrue waiting time appropriate to their status on the waiting list at the time of the programs' inactivation, relinquishment, or loss of designated status. This total acquired waiting time will be transferred to the candidate's credit when s(he) is listed with a new program.

~~If the candidate remains on the waitlist of an inactivated program past the maximum 90 days stated above then a Waiting Time Modification per OPTN/UNOS Policy 3.2.1.8 Waiting Time Modification will be required.~~

5. **Laboratory Tests.** The inactivated program remains responsible for evaluating its candidates. This includes, but is not limited to performing laboratory tests and evaluations required to maintain the candidate's appropriate status on the waiting list until the time of transfer.

### III. **Histocompatibility Laboratories.** [No Change]

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

[No change] 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 change]

**II. ~~Inactive Program Status.~~** ~~Designated transplant programs qualified in accordance with these Attachment I criteria that fail to remain functionally active shall voluntarily stop transplantation at that transplant program for a period of up to twelve months by notice to the Executive Director, or may relinquish designated transplant program status for the program. This voluntary action to stop transplantation may be extended beyond twelve months upon request to the MPSC and demonstration to the MPSC's satisfaction of the benefit of such extension, together with a plan and timeline for re-starting transplantation at the program which shall include assurance that all OPTN membership criteria will be met at the time of re-starting transplantation. For purposes of these Bylaws, "functionally inactive" is defined as:~~

- ~~(1) — The inability to serve patients, as a group, for a sustained and significant time period, where a period of 15 days or more is presumed to be sustained and significant, or~~
- ~~(2) — No transplant performed for a period of time defined as:
 
  - ~~(a) — No transplant performed in three months in the case of kidney, liver, and heart transplant programs,~~
  - ~~(b) — No transplant performed in six months in the case of pancreas and lung programs, and~~
  - ~~(c) — No transplant performed in one year in the case of transplant programs located in stand-alone pediatric transplant hospitals, with no explanation deemed satisfactory by the MPSC that the program remains qualified pursuant to the criteria defined in this Appendix B to provide transplant services.~~~~

~~If the program fails to take either action voluntarily, the Membership and Professional Standards Committee may recommend that the Board of Directors take appropriate action in accordance with Appendix A of these Bylaws, which action may include those defined as adverse under Section 3.01A. Program inactivation or relinquishment of designated transplant program status involves (i) prompt suspension of transplantation, (ii) notice to patients (with a copy to the organization under contract with HHS to operate the OPTN (OPTN Contractor)) of the need to inactivate, removal of these patients from the program's waiting list, or — if the patient desires — transfer of the patient to the list of another OPTN Member Transplant Hospital, and (iii) assistance for patients in identifying the designated transplant programs to which they can transfer. Upon submission and review of information establishing that the Member has again become active in human organ transplantation and that all other criteria for OPTN membership are met, the Membership and Professional Standards Committee shall recommend to the Board of Directors that the Board so notify the Secretary of HHS.~~

~~To assure equity in waiting times, and facilitate smooth transfer of patients from the waiting list of a program that is inactivated or relinquishes designated transplant status, patients on the waiting list of a designated transplant program at the time of inactivation or relinquishment of designated status may retain existing waiting time and continue to accrue waiting time~~

~~appropriate to their status on the waiting list at the time of inactivation or relinquishment of designated status of their program for a maximum of 90 days following that program's inactivation or relinquishment of designated status. This total acquired waiting time may be, with agreement of the accepting center, transferred to the patient's credit when s(he) is listed with a new program.~~

~~It is expected that all designated transplant programs will duly inform their patients on the waiting list if there will be an extended period of time when the program will be unable to perform transplants. Programs that are not able to serve patients, as a group, for a period of 15 consecutive days or more are further expected to notify the OPTN Contractor and their patients as described above.~~

- III. Reporting Changes in Key Personnel.** [No change]
- IIIV. Investigation of Personnel.** [No change]
- IV. OPO Affiliation.** [No change]
- VI. Histocompatibility Laboratory Affiliation.** [No change]
- VII. Transplant Surgeon and Physician.** [No change]

UNOS Version:

## APPENDIX B TO BYLAWS

### UNITED NETWORK FOR ORGAN SHARING

#### II. Transplant Hospitals.

A. **General.** [No Change]

B. **Survival Rates.** [No Change]

C. ~~**Inactive Membership Status. Functional Inactivity, Inactive Transplant Program Status, Relinquishment of Designated Transplant Program Status and Termination of Designated Transplant Program Status.**~~ A Member Transplant Hospital that fails to remain functionally active with respect to any designated transplant program (as defined below) may voluntarily stop transplantation at that transplant program for a period of up to twelve months by notice to the Executive Director, or may relinquish designated transplant program status for the program. This voluntary action to stop transplantation may be extended beyond twelve months upon request to the MPSC and demonstration to the MPSC's satisfaction of the benefit of such extension, together with a plan and timeline for re-starting transplantation at the program which shall include assurance that all OPTN membership criteria will be met at the time of re-starting transplantation. The MPSC may also require, in its discretion, that the Member participate in a discussion regarding a performance review. The discussion may be with the MPSC, a subcommittee or work group, as the MPSC may direct. The discussion referenced above will be conducted according to the principles of confidential medical peer review, as described in Section 2.07A of Appendix A to the UNOS Bylaws. The discussion is not an adverse action or an element of due process. A Member who participates in a discussion with the MPSC is entitled to receive a summary of the discussion.

For purposes of these bylaws, a candidate is defined as an individual who has been added to the waiting list. A potential candidate is defined as an individual who is under evaluation for transplant by the transplant program. Each reference to a candidate includes potential candidates if and as applicable.

1. **Functional Inactivity.** Transplant programs must remain functionally active. Transplant program functional activity will be reviewed periodically by the Membership and Professional Standards Committee (MPSC).

For purposes of these Bylaws, "~~functionally inactive~~ Functional Inactivity" is defined as any or all of the items below:

- (1) ~~(a) The inability to serve patients potential candidates, candidates, or recipients, as a group, for a sustained and significant time period, where a period of 15 days or more consecutively; is presumed to be sustained and significant, or~~
- (2) ~~No transplant performed for a period of time defined as:~~
  - (b) failure to perform a transplant during the following stated periods of time:

- (i) ~~No transplant performed in three months~~ In the case of kidney, liver, and heart transplant programs, within three consecutive months;
- (ii) ~~No transplant performed in six months~~ In the case of pancreas and lung programs, and within six consecutive months;
- (iii) ~~No transplant performed in one year~~ In the case of transplant programs located in stand-alone pediatric transplant hospitals, within twelve consecutive months.

(c) waiting list inactivation of 15 or more consecutive days and/or 28 cumulative days or more over any 365 consecutive day period.

(d) given their experimental and evolving nature, functional inactivity thresholds and waiting list notification requirements regarding functional inactivity have not been established for pancreatic islet and intestinal transplant programs.

~~with no explanation deemed satisfactory by the MPSC that the program remains qualified pursuant to the criteria defined in this Appendix B to provide transplant services.~~

Any programs identified to be functionally inactive, shall be provided the opportunity to explain its inactivity through reports requested by the MPSC.

A transplant program must provide written notice to candidates when the transplant program:

- Inactivates its waiting list or is unable to perform transplants for 15 consecutive days or more;
- Inactivates its waiting list or is unable to perform transplants for 28 cumulative days or more over any 365 consecutive day period.

The MPSC may also require, at its discretion, that the Member participate in an informal discussion regarding a performance review. The informal discussion may be with the MPSC, a subcommittee or work group, as the MPSC may direct.

The discussion referenced above will be conducted according to the principles of confidential medical peer review, as described in Section 2.07A of Appendix A to the Bylaws. The discussion is not an adverse action or an element of due process. A Member who participates in an informal discussion with the MPSC is entitled to receive a summary of the discussion.

A functionally inactive transplant program should voluntarily inactivate for a period of up to twelve months by providing written notice to the Executive Director. If the transplant program expects to be inactive for more than twelve months, the Member should-relinquish designated transplant program status for the program in accordance with these bylaws.

The MPSC may recommend that a program inactivate or relinquish its designated transplant program status due to the program's functional inactivity. If the program fails to inactivate or relinquish its designated transplant status upon the MPSC's recommendation to do so, the MPSC may recommend the Board of Directors take appropriate action in accordance with Appendix A of these Bylaws. Potential adverse

actions are defined under Section 3.01A of the bylaws. Additionally, the Board of Directors may notify the Secretary of HHS of the situation.

~~If the Member fails to take either action voluntarily, the Membership and Professional Standards Committee may recommend that the Board of Directors take appropriate action in accordance with Appendix A of these Bylaws in all other cases, which action may include those defined as adverse under Section 3.01A. Program inactivation or relinquishment of designated transplant program status involves (i) prompt suspension of transplantation, (ii) notice to patients of the need to inactivate, removal of these patients from the program's waiting list, or—if the patient desires—transfer of the patient to the list of another Member Transplant Hospital, and (iii) assistance for patients in identifying the designated transplant programs to which they can transfer. Upon submission and review of information establishing that the Member has again become active in human organ transplantation and that all other criteria for membership are met, the Membership and Professional Standards Committee shall recommend to the Board of Directors that the Member be designated as an active member.~~

~~To assure equity in waiting times, and facilitate smooth transfer of patients from the waiting list of a program that is inactivated or relinquishes designated transplant status, patients on the waiting list of a designated transplant program at the time of inactivation or relinquishment of designated status may retain existing waiting time and continue to accrue waiting time appropriate to their status on the waiting list at the time of inactivation or relinquishment of designated status of their program for a maximum of 90 days following that program's inactivation or relinquishment of designated status. This total acquired waiting time may be, with agreement of the accepting center, transferred to the patient's credit when s(he) is listed with a new program.~~

~~It is expected that all Transplant Hospitals will duly inform their patients on the waiting list if there will be an extended period of time when a designated transplant program will be unable to perform transplants. Programs that are not able to serve patients, as a group, for a period of 15 consecutive days or more are further expected to notify UNOS and their patients as described above.~~

**2. Inactive Transplant Program Status.** For the purposes of these bylaws, inactive transplant program status is defined as:

- an inactive transplant program waiting list status in UNet<sup>SM</sup> (short-term inactivation), or
- an inactive transplant program waiting list status in UNet<sup>SM</sup> and an inactive membership status (long-term inactivation).

A Member may voluntarily inactivate a transplant program, on a short-term or long-term basis, for reasons including but not limited to:

- inability to meet functional activity requirements;
- temporarily lacking required physician and/or surgeon coverage;
- substantial change in operations that require temporary cessation of transplantation.

**a. Short-Term Inactivation.** Short-term inactivation means that a transplant program may be inactive for up to 14 consecutive days. A Member may

voluntarily inactivate a transplant program for a period not to exceed 14 days by changing the program's waiting list status in UNet<sup>SM</sup>.

- i. Notice to UNOS. When a Member intends to voluntarily inactivate a transplant program on a short-term basis, the Member is not required to notify UNOS.
- ii. Notice to Patients. In accordance with Attachment I to Appendix B, Section VII transplant program must provide potential candidates, candidates, and recipients with a written summary of its Program Coverage Plan at the time of listing or when there are any substantial changes in program or personnel.

**b.** **Long-Term Inactivation.** **Long-term inactivation means inactivation of a transplant program for 15 or more days consecutively. Members should voluntarily inactivate programs that are not able to serve potential candidates, candidates, or recipients for a period of 15 or more days. Voluntary inactivation may extend for a period of up to 12 months.**

**i.** **Notice to UNOS.** When a Member intends to voluntarily inactivate a transplant program for 15 or more days consecutively, it must provide written notice, including the reason(s) for inactivation, to the UNOS Executive Director upon deciding to inactivate the transplant program.

- ii.** **Notice to the Patients.** When a Member intends to inactivate a transplant program for 15 or more days consecutively, it must provide:
- a) written notice to the transplant program's potential candidates, candidates, recipients, and living donors currently being followed by the transplant program. Written notice should be mailed at least 30 days prior to the anticipated inactivation date by certified mail/return receipt requested. Written notice must be mailed no later than seven days following inactivation and include:
    - 1) the reason(s) for inactivating the transplant program;
    - 2) notice that while still on the waiting list of the inactive program the candidate cannot receive an organ offer through this member program;
    - 3) options for potential candidates, candidates, recipients, and living donors to transfer to an alternative designated transplant program with the phone number of the administrative office of the inactivating program to help with potential candidate, candidate, recipient, and living donor transfers.

The Member must provide a representative copy of the patient notice to UNOS along with a list of potential candidates, candidates, recipients, and living donors who received the notice.

In the event of a natural disaster that adversely affects a transplant program, the patient notification requirements shall be applied reasonably and flexibly.

- iii.** **Transition Plan.** When the Member inactivates a transplant program for 15 or more days consecutively, it must:
- a) promptly suspend organ implantation for that transplant program;

- b) assist potential candidates and candidates in identifying designated transplant programs to which they can transfer;
- c) provide a list to UNOS of all of the transplant program's candidates at the time of inactivation and update it throughout this process;
- d) indicate on the list provided the decision of each potential candidate and each candidate to transfer, with the following additional information:
  - i) if a candidate or potential candidate chooses not to transfer to an alternative transplant program, provide the reason and indicate whether the candidate has been completely informed of the implications of this decision; or
  - ii) if a candidate or potential candidate chooses to transfer, indicate the transplant program to which the candidate is transferring. Periodic updates will be required as to the status of each candidate's transfer progress until the candidate is evaluated by the accepting program and an official decision is made regarding the candidate's listing status.
- e) expedite removal of all candidates from the inactive transplant program's waiting list, or, if the candidate requests, transfer the candidate to another UNOS Member transplant hospital;
- f) initiate transfer of all active candidates or potential candidates hospitalized at the inactive transplant program to an accepting transplant hospital within seven days of inactivation of the transplant program. The inactive transplant program must complete the transfer process within 14 days unless transfer would be unsafe or discharge is anticipated within that time; or circumstances outside of the program's control exist that prevent transfer within 14 days. The program must document and submit to UNOS all efforts for transfer of its hospitalized candidates or potential candidates if it is unable to meet the time periods within this section.
- g) provide a priority list of the most urgent candidates or potential candidates at the inactive transplant program with an individualized plan of transfer, potential alternative transplant programs, and a timeline for transferring these candidates according to the following priorities:
  - i) for liver candidates, all Status 1A and 1B candidates must be transferred within seven days of program inactivation, followed by all active candidates in descending MELD/PELD score order, with all candidates whose MELD/PELD score exceeds 25 to be transferred within 30 days, followed by all inactive candidates;
  - ii) for lung candidates, active candidates should be transferred according to descending Lung Allocation Scores followed by inactive candidates;
  - iii) for kidney candidates, those whose PRA(measured or calculated) is over 80% should be transferred first, followed by all other active candidates in order of waiting time, then transfer of all inactive candidates;
  - iv) for heart candidates, all Status 1A and 1B must be transferred within seven days of inactivation;
  - v) for multi-visceral organ transplant candidates, transfer must be completed within 30 days of inactivation; and
  - vi) notwithstanding these guidelines, all active candidates who choose to transfer should be transferred within 60 days of inactivation.

- vii) The program must document and submit to UNOS all efforts for transfer of its candidates if it is unable to meet the time periods within this section.
- h) document all efforts to transfer candidates to an alternative designated transplant program including all contacts made to facilitate the transfer of candidates; and
- i) remove every transplant candidate from the inactive transplant program's waiting list within 12 months of the program's inactivation date in the cases when a program does not intend to reactivate.

Transplant programs that inactivate for 15 or more days consecutively may still have the ability to provide care to transplant candidates, recipients and living donors. Should the transplant program continue to provide follow-up care to transplant recipients and living donors, the program must continue to submit follow-up forms via UNet<sup>SM</sup>. Alternatively, transplant recipients may transfer care to another institution.

**Extension of Voluntary Inactive Program Status beyond Twelve Months.** A Member transplant hospital may request an extension of voluntary inactive program status beyond twelve months by making a request to the MPSC. The request must demonstrate to the MPSC's satisfaction the benefit of such an extension, and be accompanied by a comprehensive plan with a timeline for re-starting transplantation at the program. This demonstration must include assurance that all membership criteria will be met at the time of re-starting transplantation.

**Reactivation after Voluntary Long Term Inactivation.** A Member transplant hospital may reactivate its program after long term voluntary inactivation by submitting application materials deemed appropriate by the MPSC that establishes that the program has again become active in organ transplantation and that all criteria for membership are met. The Membership and Professional Standards Committee shall recommend to the Board of Directors that the Board so notify the Secretary of HHS.

**3. Relinquishment or Termination of Designated Transplant Program Status.** Relinquishment of Designated Transplant Program Status means that a Member may voluntarily give up its designated transplant program status upon written notice to UNOS. Members that relinquish designated transplant program status are voluntarily closing the transplant program.

Termination of Designated Transplant Program Status means that a Member's designated program status is terminated by the Secretary of the Department of Health and Human Services ("Secretary"). In the case of noncompliance with policies covered by Section 1138 of the Social Security Act, the MPSC may recommend that the Board of Directors and/or the Executive Committee request approval from the Secretary to terminate a Member's designated transplant program status in accordance with Appendix A Section 2.06A of these Bylaws. The Board of Directors and/or the Executive Committee may, on its own accord, request such approval from the Secretary.

Once a Member relinquishes a designated transplant program status or it is terminated by the Secretary of HHS, that transplant program may no longer perform organ transplants. The Member must facilitate the transfer of the subject transplant program's candidates to another transplant program.

**a. Notice to UNOS.** A Member transplant hospital must provide written notice to UNOS within 30 days of the intent to relinquish its designated transplant program status and the reasons therefor upon deciding to relinquish designated transplant program status.

**b. Notice to the Patients.** When a Member transplant hospital intends to relinquish its designated transplant program status, or its designated transplant program status is terminated, it must provide:

- i) written notice to the transplant program's potential candidates, candidates, recipients, and living donors currently being followed by the transplant program. Written notice should be mailed at least 30 days prior to the anticipated date of relinquishment or termination by certified mail/return receipt requested. Written notice must be mailed no later than seven days following relinquishment/termination and include:
  - 1. the reason(s) for loss of designated transplant program status;
  - 2. notice that while still on the waiting list of the inactive program the candidate cannot receive an organ offer through this member program;
  - 3. options for potential candidates, candidates, recipients, and living donors to transfer to an alternative designated transplant program with the phone number of the administrative office of the inactivating program to help with potential candidate, candidate, and recipient transfers; and

The Member transplant hospital must provide a representative copy of the patient notice to UNOS along with a list of potential candidate, candidate, and recipient names who received the notice.

**c. Transition Plan.** When a Member transplant hospital relinquishes a transplant program's designated program status or its designated program status is terminated, it must:

- i. promptly suspend organ implantation for the transplant program;
- ii. assist potential candidates and candidates in identifying designated transplant programs to which they can transfer;
- iii. provide a list to UNOS of all of the transplant program's candidates on the waiting list at the time of relinquishment or termination and update it throughout this process;
- iv. Indicate on the list provided the decision of each potential candidate and each candidate to transfer, with the following additional information:
  - 1. if a candidate or potential candidate chooses not to transfer to an alternative transplant program, provide the reason and indicate whether the candidate has been completely informed of the implications of this decision; or
  - 2. if a candidate or potential candidate chooses to transfer, indicate the transplant program to which the candidate is transferring. Periodic updates will be required as to the status of each candidate's transfer progress until the candidate is evaluated by the accepting program and an official decision is made regarding the candidate's listing status.

- v. expedite removal of all candidates from the transplant program's waiting list, or, if the patient requests, transfer the candidate to another UNOS Member transplant hospital;
- vi. initiate transfer of all active candidates hospitalized at the transplant program to an accepting transplant hospital within seven days of relinquishment of the transplant program. The transplant program must complete the transfer process within 14 days unless transfer would be unsafe or discharge is anticipated within that time; or circumstances outside of the program's control exist that prevent transfer within 14 days. The program must document and submit to UNOS all efforts to transfer its hospitalized candidates if it is unable to meet the time periods within this section.
- vii. provide a priority list of the most urgent candidates listed at the transplant program with an individualized plan of transfer, potential alternative transplant programs, and a timeline for transferring these candidates according to the following priorities:
  - 1. for liver candidates, all Status 1A and 1B candidates must be transferred within seven days of relinquishment, followed by all active candidates in descending MELD/PELD score order, with all candidates whose MELD/PELD score exceeds 25 to be transferred within 30 days, followed by all inactive candidates;
  - 2. for lung candidates, active candidates should be transferred according to descending Lung Allocation Scores with highest scores first, followed by inactive candidates;
  - 3. for kidney candidates, those whose PRA (measured or calculated) is over 80% should be transferred first, followed by all other active candidates in order of waiting time, then transfer of all inactive candidates;
  - 4. for heart candidates, all Status 1A and 1B must be transferred within seven days of relinquishment;
  - 5. for multi-visceral organ transplant candidates, transfer must be completed within 30 days of relinquishment; and
  - 6. notwithstanding these guidelines, all active candidates should be transferred within 60 days of relinquishment; and;
  - 7. The program must document and submit to UNOS all efforts for transfer of its candidates if it is unable to meet the time periods within this section.
- viii. document all efforts to transfer candidates to an alternative designated transplant program including all contacts made to facilitate the transfer of candidates; and
- ix. remove every transplant candidate from the transplant program's waiting list within 12 months of the program's relinquishment date.

A Member that relinquishes or terminates a designated transplant program may still have the ability to temporarily provide care to transplant candidates and provide follow-up care to transplant recipients and living donors. Should the transplant program continue to provide follow-up care to transplant recipients and living donors, the program must continue to submit follow up forms via UNet<sup>sm</sup>. Alternatively, transplant recipients may transfer care to another institution.

- 4. Waiting time on waiting list.** To assure equity in waiting times, and facilitate smooth transfer of candidates from the waiting list of affected programs (i.e.

programs that voluntarily inactivate, relinquish or lose designated transplant program status), candidates on the waiting list in such instances may retain existing waiting time and continue to accrue waiting time appropriate to their status on the waiting list at the time of the programs' inactivation, relinquishment, or loss of designated status. This total acquired waiting time will be transferred to the candidate's credit when s(he) is listed with a new program.

~~If the candidate remains on the waitlist of an inactivated program past the maximum 90 days stated above then a Waiting Time Modification per OPTN/UNOS Policy 3.2.1.8 Waiting Time Modification will be required.~~

- 5. Laboratory Tests.** The inactivated program remains responsible for evaluating its candidates. This includes, but is not limited to performing laboratory tests and evaluations required to maintain the candidate's appropriate status on the waiting list until the time of transfer.

### III. Histocompatibility Laboratories. [No Change]

## ATTACHMENT I TO APPENDIX B OF UNOS BYLAWS

### Designated Transplant Program Criteria

~~**H. Inactive Program Status.** Designated transplant programs qualified in accordance with these Attachment I criteria that fail to remain functionally active shall voluntarily stop transplantation at that transplant program for a period of up to twelve months by notice to the Executive Director, or may relinquish designated transplant program status for the program. This voluntary action to stop transplantation may be extended beyond twelve months upon request to the MPSC and demonstration to the MPSC's satisfaction of the benefit of such extension, together with a plan and timeline for re-starting transplantation at the program which shall include assurance that all OPTN membership criteria will be met at the time of re-starting transplantation. The MPSC may also require, at its discretion, that the Member participate in a discussion regarding a performance review. The discussion may be with the MPSC, a subcommittee or work group, as the MPSC may direct.~~

~~The discussion referenced above will be conducted according to the principles of confidential medical peer review, as described in Section 2.07A of Appendix A to the Bylaws. The discussion is not an adverse action or an element of due process. A Member who participates in a discussion with the MPSC is entitled to receive a summary of the discussion.~~

For purposes of these Bylaws, "functionally inactive" is defined as:

- ~~(2) — The inability to serve patients, as a group, for a sustained and significant time period, where a period of 15 days or more is presumed to be sustained and significant, or~~
- ~~(2) — No transplant performed for a period of time defined as:
 
  - ~~(i) — No transplant performed in three months in the case of kidney, liver, and heart transplant programs,~~~~

- ~~(ii) No transplant performed in six months in the case of pancreas and lung programs, and~~
- ~~(iii) No transplant performed in one year in the case of transplant programs located in stand alone pediatric transplant hospitals, with no explanation deemed satisfactory by the MPSC that the program remains qualified pursuant to the criteria defined in this Appendix B to provide transplant services.~~

~~If the program fails to take either action voluntarily, the Membership and Professional Standards Committee may recommend that the Board of Directors take appropriate action in accordance with Appendix A of these Bylaws which action may include those defined as adverse under Section 3.01A. Program inactivation or relinquishment of designated transplant program status involves (i) prompt suspension of transplantation, (ii) notice to patients (with a of the need to inactivate, removal of these patients from the program's waiting list, or if the patient desires transfer of the patient to the list of another Member Transplant Hospital, and (iii) assistance for patients in identifying the designated transplant programs to which they can transfer. Upon submission and review of information establishing that the Member has again become active in human organ transplantation and that all other criteria for membership are met, the Membership and Professional Standards Committee shall recommend to the Board of Directors take appropriate action.~~

~~To assure equity in waiting times, and facilitate smooth transfer of patients from the waiting list of a program that is inactivated or relinquishes designated transplant status, patients on the waiting list of a designated transplant program at the time of inactivation or relinquishment of designated status may retain existing waiting time and continue to accrue waiting time appropriate to their status on the waiting list at the time of inactivation or relinquishment of designated status of their program for a maximum of 90 days following that program's inactivation or relinquishment of designated status. This total acquired waiting time may be, with agreement of the accepting center, transferred to the patient's credit when s(he) is listed with a new program.~~

~~It is expected that all designated transplant programs will duly inform their patients on the waiting list if there will be an extended period of time when the program will be unable to perform transplants. Programs that are not able to serve patients, as a group, for a period of 15 consecutive days or more are further expected to notify UNOS and their patients as described above.~~

To read the complete policy language visit [www.unos.org](http://www.unos.org) or [optn.transplant.hrsa.gov](http://optn.transplant.hrsa.gov). From the UNOS Web site, select Resources from the main menu, and then select Policies. From the OPTN Web site, select Policy Management, and then select Policies.