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IMPORTANT POLICY NOTICE

To: Transplant Professionals

From: Brian M. Shepard
UNOS Director of Policy

RE: Summary of actions taken at the OPTN/UNOS Board of Directors Meeting
— June 28-29, 2011

Date: July 28, 2011

The attached report summarizes bylaw and policy changes the OPTN/UNOS Board of Directors approved at its June 2011 meeting.

This format allows you to scan the Board's actions and quickly determine what is required of you. The notice also includes the specific changes to OPTN/UNOS bylaws and policies. If you are interested in reviewing policy changes from previous board meetings, go to <http://optn.transplant.hrsa.gov>, click on "News," and then select "View all Policy Notices."

Thank you for your careful review. If you have any questions about a particular Board action, 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 **12** notices included on the grid below and share with other colleagues as appropriate.

Policy/Bylaw Change (<i>Sponsoring Committee</i>)	Directors of Organ Procurement	Lab Directors	Lab Supervisors	OPO Data Coordinators	OPO Executive Directors	OPO Medical Directors	OPO PR/Public Education Staff	OPO Procurement Coordinators	Transplant Administrators	Transplant Coordinators	Transplant Data Coordinators	Transplant Physicians	Transplant PR/Public Education Staff	Transplant Program Directors	Transplant Social Workers	Transplant Surgeons	Compliance Officers	Page #
1 Dissolution of the Organ Availability Committee (<i>Organ Availability Committee</i>)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	4
2 Model for Assessing the Effectiveness of Individual OPOs in Key Measures of Organ Recovery and Utilization (<i>Membership and Professional Standards Committee, OPO Committee</i>)	X			X	X	X	X	X	X	X		X		X		X	X	5
3 Qualifications for Director of Liver Transplant Anesthesia in the Bylaws (<i>Membership and Professional Standards Committee</i>)									X			X		X		X	X	6
4 Modifications to the Requirements for Transplant Hospitals that Perform Living Donor Kidney Recoveries (<i>Membership and Professional Standards Committee</i>)									X			X		X		X		7
5 Modifications to Clarify which Transplant Program has Responsibility for Elements of the Living Donation Process and to Reassign Reporting Responsibility for Living Donation from the Recipient Transplant Program to the Transplant Program Performing the Living Donor Nephrectomy or Hepatectomy (<i>Living Donor Committee</i>)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	8
6 Change in OPTN Patient Registration Fee (<i>Finance Committee</i>)	X	X		X	X	X		X	X	X				X				9
7 Policy Language Correction to 3.5.5.3 (Kidney Payback Debt Limit) (<i>Kidney Transplantation Committee</i>)					X				X								X	10

Overview of Policy Modifications/Board Actions and Affected Professionals

Policy/Bylaw Change (<i>Sponsoring Committee</i>)		Directors of Organ Procurement	Lab Directors	Lab Supervisors	OPO Data Coordinators	OPO Executive Directors	OPO Medical Directors	OPO PR/Public Education Staff	OPO Procurement Coordinators	Transplant Administrators	Transplant Coordinators	Transplant Data Coordinators	Transplant Physicians	Transplant PR/Public Education Staff	Transplant Program Directors	Transplant Social Workers	Transplant Surgeons	Compliance Officers	
8	Clarification to Policy 2.2.3.2 Regarding Deceased Donor HIV Screening Requirements (<i>Ad Hoc Disease Transmission Advisory Committee</i>)	X	X		X	X	X		X									X	11
9	Verification of Extra Vessel Compatibility with Recipient Prior to Transplant (<i>Operations and Safety Committee</i>)									X	X	X	X	X	X		X	X	12
10	Modifications to Require Collection of Human Leukocyte Antigen Type for Thoracic Organs (<i>Thoracic Organ Transplantation Committee</i>)	X	X		X	X	X	X	X	X	X	X	X	X	X	X	X	X	13
11	Deletion of Policy 3.7.13 (Status 1 Listing Verification) (<i>Thoracic Organ Transplantation Committee</i>)									X	X	X	X	X	X	X	X	X	14
12	Modifications to Clarify Adult Heart Status 1A Exception Language to Enable Consistent Interpretation of Policy and Reflect Current Programming in UNet (<i>Thoracic Organ Transplantation Committee</i>)									X	X	X	X	X	X	X	X	X	15

Title of Bylaw Change: Dissolution of the Organ Availability Committee

Sponsoring Committee: Organ Availability Committee

Bylaw Affected: OPTN/UNOS Bylaw Article VII, Section 7.1 (Enumeration of Committees)

Effective Date: June 29, 2011

Distributed for Public Comment: no **Amended After Public Comment:** n/a

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, and Compliance Officers.

Problem Statement	Changes	What You Need to Do
The Board of Directors recognized that issues relating to organ availability should be integrated into the efforts of other existing committees, specifically the OPO and organ-specific committees.	The bylaw was modified to reflect the dissolution of the Organ Availability Committee.	No member action is required.

Title of Bylaw Change: Model for Assessing the Effectiveness of Individual OPOs in Key Measures of Organ Recovery and Utilization

Sponsoring Committees: Membership and Professional Standards Committee (MPSC), Organ Procurement Organization (OPO) Committee

Bylaw Affected: OPTN /UNOS Bylaws, Appendix B, Section I: Organ Procurement Organizations

Effective Date: Pending programming and member notice

Distributed for Public Comment: January 2011 **Amended After Public Comment:** Yes

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, OPO Public Relations or Public Education staff, and Compliance and/or Quality Officers

Problem Statement	Changes	What You Need to Do
<p>The OPTN does not have a robust method for reviewing OPO performance.</p> <p>The OPTN (through the MPSC) monitors member performance and identifies opportunities for improvement. To assess OPOs, the MPSC primarily considers results of site surveys (audits), allocation analysis, and member reports of potential policy violations. In 2008, the Board of Directors charged the MPSC and OPO Committee with identifying performance metrics the MPSC could use to monitor OPO performance.</p>	<p>The bylaw modifications codify the MPSC’s review of OPO performance to identify opportunities for improvement at OPOs whose observed performance falls below an expected performance threshold. An OPO will be identified for MPSC review(for all organs, as well as each organ type) if <i>all three</i> of the following criteria are met:</p> <ul style="list-style-type: none"> • Observed per 100 donors- Expected per 100 donors < -10; • A ratio of observed to expected yield is less than 0.90; and • A two-sided p-value less than 0.05. 	<p>Members should review and become familiar with the bylaw changes. Once programming is complete and the donor evaluator tool is available, UNOS will notify members of the exact effective date and provide additional guidance.</p>

Title of Bylaw Change: Qualifications for Director of Liver Transplant Anesthesia in the Bylaws

Sponsoring Committee: Membership and Professional Standards Committee

Bylaw Affected: Attachment I, Appendix B of UNOS Bylaws, (Designated Transplant Program Criteria), XIII. (Transplant Programs), Section D (3)(c)

Effective Date: September 1, 2011

Distributed for Public Comment: October 2010 **Amended After Public Comment:** Yes

Professional Groups Affected by the Change: Liver Transplant Administrators, Liver Transplant Program Directors, Liver Transplant Surgeons, Liver Transplant Physicians, Transplant Anesthesiologists, Directors of Transplant Anesthesiology, Transplant Hospital Compliance Officers

Problem Statement	Changes	What You Need to Do
<p>Studies suggest that the use of a dedicated anesthesia team in liver transplantation is associated with patients spending less time in the operating room, intensive care unit, and the hospital. These studies also reflect a reduced need for blood transfusions and mechanical ventilation during and after surgery.</p> <p>Current bylaws only require liver transplant programs to provide evidence that experts in the field of anesthesiology are involved with the program. The bylaws do not provide a description of the qualifications this expert must possess or describe their expected level of involvement.</p>	<p>The bylaws specify minimum requirements for the director of liver transplant anesthesia, and provides suggested administrative responsibilities and qualifications.</p>	<p>During the late summer of 2011, each liver transplant program will receive a brief survey from the UNOS Membership Department. Your program must designate a director of liver transplant anesthesiology or, if already designated, validate the information on file.</p>

Title of Bylaw Change: Modifications to the Requirements for Transplant Hospitals that Perform Living Donor Kidney Recoveries

Sponsoring Committee: Membership and Professional Standards Committee

Bylaw Affected: Attachment I, To Appendix B of UNOS Bylaws, (Designated Transplant Program Criteria), XIII (Transplant Programs), Section D, (2)

Effective Date: August 29, 2011

Distributed for Public Comment: October 2010

Amended After Public Comment: Yes

Professional Groups Affected by the Change:

Kidney Transplant Administrators, Kidney Transplant Program Directors, Kidney Transplant Surgeons, Kidney Transplant Physicians, and Living Donor Recover Surgeons.

Problem Statement	Changes	What You Need to Do
<p>Bylaws for approving living-donor kidney programs no longer reflect the experience levels expected of recovery surgeons or the trend towards performing laparoscopic surgery rather than an open donor nephrectomy on the living kidney donor.</p>	<p>The bylaw changes make the requirements more relevant to the current practice of living kidney donation, and include:</p> <ul style="list-style-type: none"> • Eliminating the five-year time restriction from the designated primary surgeon application requirement. Surgeons must have performed 10 open donor nephrectomies before submitting their application to UNOS but not within a five year period. • Deleting bylaw language specifying that if laparoscopic and open nephrectomy expertise resides within different individuals, then the program must demonstrate how both individuals will be available to the surgical team. • Modifying the laparoscopic donor nephrectomies expertise requirements so that a minimum of seven of the required 15 laparoscopic nephrectomies procedures must have been performed as a primary surgeon. • Requiring donor procedure logs included in primary surgeon applications to indicate whether each procedure is an open or laparoscopic nephrectomy. 	<p>No action is required by the hospitals at this time.</p> <p>The UNOS Membership Department will review all applications for living donor kidney programs (new programs or changes in key personnel) that are submitted after August 28, 2011, for those items included in the modified bylaw language.</p>

Title of Policy and Bylaw Change: Modifications to Clarify which Transplant Program has Responsibility for Elements of the Living Donation Process and to Reassign Reporting Responsibility for Living Donation from the Recipient Transplant Program to the Transplant Program Performing the Living Donor Nephrectomy or Hepatectomy

Sponsoring Committee: Living Donor Committee

Policies and Bylaws Affected: Policy 7.0 (Data Submission Requirements); 12.6 (Center Acceptance of Living Donor Organs); 12.8 (Reporting Requirement); UNOS Bylaws, Appendix B, Attachment I, Section XIII (D) (2) (Kidney Transplant Programs that Perform Living Donor Kidney Transplants); and UNOS Bylaws, Appendix B, Attachment I, Section XIII (D) (4) (Liver Transplant Programs that Perform Living Donor Liver Transplants Recovery)

Effective Date: August 29, 2011

Distributed for Public Comment: October 2010

Amended After Public Comment: No

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, and Compliance Officers

Problem Statement	Changes	What You Need to Do
<p>Current policies do not clearly and consistently state which OPTN member (transplant center or recovery center) has responsibility for reporting elements of the living donation process.</p>	<p>These policy and bylaw changes will clarify and, in some cases, change which transplant program is responsible for specific elements of the living donation process. The transplant program that operates on the living donor will be responsible for all elements of the living donation process which includes the consent, medical and psychosocial evaluations, perioperative care, and required follow-up reporting on the donor.</p>	<p>Beginning August 29, 2011, if your transplant program operates on living donors, you will be responsible for all elements of the living donation process, which includes, but is not limited to, consent, medical and psychosocial evaluations, perioperative care, and required follow-up reporting on the donor to the OPTN.</p>

Title of Policy Change: Change in OPTN Patient Registration Fee

Sponsoring Committee: Finance Committee

Policy Affected: Policy 11.0 (Registration Fee)

Effective Date: October 1, 2011

Distributed for Public Comment: no **Amended After Public Comment:** n/a

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, and Lab Directors

Problem Statement	Changes	What You Need to Do
The OPTN needs additional funding for operational expenses during fiscal year 2012 (October 1, 2011 – September 30, 2012).	The OPTN Board of Directors approved an increase in the OPTN patient registration fee from \$585 to \$603, subject to final approval by HRSA.	Notify your program's finance department of this impending fee increase.

Title of Policy Change: Policy Language Correction to 3.5.5.3 (Kidney Payback Debt Limit)

Sponsoring Committee: Kidney Transplantation Committee

Policy Affected: 3.5.5.3 (Kidney Payback Debt Limit)

Effective Date: July 28, 2011

Distributed for Public Comment: no **Amended After Public Comment:** n/a

Professional Groups Affected by the Change:
OPO Executive Directors, Transplant Administrators, and Compliance Officers

Problem Statement	Changes	What You Need to Do
Policy 3.5.5.3 (Kidney Payback Debt Limit) contained outdated policy language that was no longer relevant after the Board of Directors approved modifications to Policy 3.5.3 (Mandatory Sharing of Zero Antigen Mismatched Kidneys) in June 2008 (July 2008 Policy Notice, notice #9).	The reference to reprioritization has been removed from Policy 3.5.5.3.	No action is necessary. Review and be familiar with the revised policy language.

Title of Policy Change: Clarification to Policy 2.2.3.2 Regarding Deceased Donor HIV Screening Requirements

Sponsoring Committee: Ad Hoc Disease Transmission Advisory Committee (DTAC)

Policy Affected: Policy 2.2.3.2

Effective Date: August 27, 2011

Distributed for Public Comment: no **Amended After Public Comment:** n/a

Professional Groups Affected by the Change:

OPO Executive Directors, Directors of Organ Procurement, OPO Procurement Coordinators, OPO Data Coordinators, OPO Medical Directors, Lab Directors, Lab Supervisors, and Compliance Officers

Problem Statement	Changes	What You Need to Do
Policy 2.2.3.2 currently requires OPOs to test all potential deceased donors for Human Immunodeficiency Virus (both HIV-1 and HIV-2) using a FDA licensed screening test. This policy does not, however, specify that OPOs must use antibody screening to meet the more specific requirement outlined in Policy 2.2.4.1. This inconsistency could create confusion within the OPO community.	This change clarifies that OPOs must screen all potential deceased donors for HIV-1 and HIV-2, using commonly accessible antibody testing of donor serum.	OPOs must test all potential deceased donors for HIV-1 and HIV-2 using a serological antibody screening test licensed by the FDA. Nucleic acid testing may be completed in addition to antibody screening, but by itself it is not an acceptable alternative to meet this policy requirement.

Title of Policy Change: Verification of Extra Vessel Compatibility with Recipient Prior to Transplant

Sponsoring Committee: Operations and Safety Committee

Policy Affected: Policy 5.10.1 (Vessel Recovery and Transplant)

Effective Date: August 29, 2011

Distributed for Public Comment: October 2010 **Amended After Public Comment:** Yes

Professional Groups Affected by the Change:

Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Transplant Data Coordinators, Transplant Public Relations or Public Education Staff, and Compliance Officers

Problem Statement	Changes	What You Need to Do
<p>Extra vessels recovered from living and deceased donors may be stored and later used if necessary.</p> <p>In all cases of extra vessel implant, it is a safe practice to confirm that the donor vessel is compatible with the recipient; however, current OPTN policy does not require a transplant center to verify a transplant recipient's compatibility with a donor's extra vessels before transplantation. Failure to verify compatibility could lead to a patient safety threat.</p>	<p>Language was added to Policy 5.10.1 (Vessel Recovery and Transplant) to require that transplant centers verify the vessel recipient's ABO and serologies with the donor ID, vessel container contents, vessel expiration date, donor ABO, and all donor serologies before transplanting the extra vessels. The transplant center must also document that this verification took place and make it available if requested by the OPTN.</p>	<p>Before using donor extra vessels in a transplant, transplant centers must verify the vessel recipient's ABO and serologies with the donor's ID, vessel container contents, vessel expiration date, donor ABO, and all donor serologies. The transplant center must maintain documentation that this verification has taken place and make it available to the OPTN, if requested.</p>

Title of Policy Change: Modifications to Require Collection of Human Leukocyte Antigen Type for Thoracic Organs

Sponsoring Committee: Thoracic Organ Transplantation Committee

Policy Affected: Policy 3.7.12.1 (Essential Information)

Effective Date: July 29, 2011

Distributed for Public Comment: October 2010 **Amended After Public Comment:** No

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, and Compliance Officers

Problem Statement	Changes	What You Need to Do
Knowledge of deceased donor human leukocyte antigen (HLA) type allows for a sensitized candidate to receive the most suitable thoracic organ offer. Policy does not require OPOs to provide deceased donor HLA type for thoracic organs prior to final organ acceptance.	The Board of Directors approved the addition of HLA type to Policy 3.7.12.1 (Essential Information).	If a transplant center requests HLA-typing for a thoracic organ offered, the OPO offering the thoracic organ must provide it before the organ's final acceptance. If HLA is requested, transplant centers will need to maintain documentation of this request, and the OPO will need to document provision of the information.

Title of Policy Change: Deletion of Policy 3.7.13 (Status 1 Listing Verification)

Sponsoring Committee: Thoracic Organ Transplantation Committee

Policy Affected: Policy 3.7.13 (Status 1 Listing Verification)

Effective Date: July 29, 2011

Distributed for Public Comment: no **Amended after Public Comment:** n/a

Professional Groups Affected by the Change:

Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Transplant Social Workers, Transplant Data Coordinators, Transplant Public Relations or Public Education Staff, and Compliance Officers

Problem Statement	Changes	What You Need to Do
Policy modifications and current compliance monitoring strategies have resulted in Policy 3.7.13 (Status 1 Listing Verification) becoming outdated and unnecessary.	The Board of Directors deleted Policy 3.7.13.	Members should remove references to Policy 3.7.13 from your institutional policy. Members should also note the renumbering of policies 3.7.14 (Removal of Thoracic Organ Transplant Candidates from Thoracic Organ Waiting Lists When Transplanted or Deceased) through 3.7.17 (Crossmatching for Thoracic Organs).

Title of Policy Change: Modifications to Clarify Adult Heart Status 1A Exception Language to Enable Consistent Interpretation of Policy and Reflect Current Programming in UNetSM

Sponsoring Committee: Thoracic Organ Transplantation Committee

Policy Affected: Policy 3.7.3 (Adult Candidate Status)

Effective Date: August 27, 2011; however, the list of inotropes and doses approved by the Board of Directors to be compliant with Status 1A criterion (d) that is to appear in UNetSM will be effective pending programming.

Distributed for Public Comment: October 2010 **Amended After Public Comment:** Yes

Professional Groups Affected by the Change:

Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Transplant Social Workers, Transplant Data Coordinators, Transplant Public Relations or Public Education Staff, and Compliance Officers

Problem Statement	Changes	What You Need to Do
<p>Some members have misinterpreted the requirement in Policy 3.7.3 (Adult Candidate Status) that a Status 1A-exception may only be requested for a candidate that is admitted at the transplant center hospital applying for the exception. Additionally, language in Status 1A criterion (b) does not state that an entry of an “other” mechanical circulatory support device complication is possible. Finally, only two of the four inotropes that qualify for single, high-dose usage are listed in the status justification forms in UNetSM.</p>	<p>The OPTN Board of Directors approved modifications that clearly state that a clinician may:</p> <ul style="list-style-type: none"> • Report an “other” mechanical circulatory support complication; and • Request a Status 1A-exception only for inpatient candidates. <p>The changes also include general edits that reorganize existing text in the Status 1A and Status 1B sections and enhance its readability. Pending implementation, UNetSM will include in text format all four inotropes that qualify for single, high-dose usage per Status 1A criterion (d).</p>	<p>Review the clarified policy, and become familiar with the reorganized text. UNOS will notify Members of an exact implementation date of the modification to the heart status justification form once the programming is completed.</p>

Affected Bylaw Language:**ARTICLE VII****PERMANENT STANDING COMMITTEES**

- 7.1 Enumeration of Committees.** The OPTN shall have Permanent Standing Committees on Communications, Ethics, Finance, Histocompatibility, Kidney Transplantation, Liver and Intestinal Organ Transplantation, Living Donor, Membership and Professional Standards, Minority Affairs, Operations and Safety, ~~Organ Availability~~, Organ Procurement Organization, Pancreas Transplantation, Patient Affairs, Pediatric Transplantation, Policy Oversight, Thoracic Organ Transplantation, Transplant Administrators, and Transplant Coordinators. These Committees shall provide initial review and analysis of proposed policies and initiatives based upon their unique perspectives and expertise and after collection and consideration of such information as they deem appropriate, prior to presentation to the Board of Directors. Their role in developing policies and standards is further defined in Appendix C of these Bylaws; other initiatives include matters within their respective charges relevant to the field of organ procurement and transplantation. The Committees are advisory to the Board of Directors, which is responsible for final decisions of the OPTN. Committees also may be advisory to one another in cases in which Committee perspective/expertise overlap. In such cases, Committees shall be encouraged to assess proposals jointly before presentation to the Board of Directors, presenting either common recommendations or reasons for continued disagreement.

To read the complete UNOS bylaw language visit www.unos.org, go to the "I am looking for:" box in the upper left hand corner, then select "UNOS bylaws." To read the complete OPTN bylaw language visit optn.transplant.hrsa.gov, select the "Policy Management" tab, then select "OPTN Bylaws."

Affected Bylaw Language:

**APPENDIX B TO BYLAWS
OPTN**

Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership

I. Organ Procurement Organizations.

A. General. [No change to content, only to numbering convention.]

B. Key Personnel. [No change to content, only to numbering convention.]

C. Plan for Public Education on Organ Donation. [No change to content, only to numbering convention.]

D. Communication of Information for Organ Distribution. [No change to content, only to numbering convention.]

E. Donation After Cardiac Death: [No change to content, only to numbering convention.]

F. Performance: The Membership and Professional Standards Committee (MPSC) will evaluate all OPOs to determine if the difference in observed and expected organ yield can be accounted for by some unique aspect of the Donation Service Area and/or OPO in question. The evaluation may include a peer visit to the OPO at the OPO's expense.

Those OPOs whose observed organ yield rates fall below the expected rates by more than a specified threshold will be reviewed. The absolute values of relevant parameters in the formula may be different for different organs, and may be reviewed and modified by the MPSC after distribution to the transplant community and subsequent Board approval.

The initial criteria used to identify OPOs with lower than expected organ yield, for all organs as well as for each organ type, will include all of the following:

- ~~A difference of at least 11~~ More than 10 fewer observed organs per 100 donors than expected yield (Observed per 100 donors-Expected per 100 donors < -10)
- A ratio of observed to expected yield less than 0.90.
- A two-sided p-value is less than 0.05.

All three criteria must be met for an OPO to be identified for MPSC review.

If an OPO's organ yield rate cannot be explained by donor mix or some other unique clinical aspect of the OPO or Donation Service Area in question, the Member, in cooperation with the MPSC, will adopt and promptly implement a plan for performance improvement. The Member's failure to do so will constitute a violation of OPTN requirements.

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

Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership

I. Organ Procurement Organizations.

A. General. [No change to content, only to numbering convention.]

B. Key Personnel. [No change to content, only to numbering convention.]

C. Plan for Public Education on Organ Donation. [No change to content, only to numbering convention.]

D. Communication of Information for Organ Distribution. [No change to content, only to numbering convention.]

E. Donation After Cardiac Death: [No change to content, only to numbering convention.]

F. Inactive Status. An organ procurement organization that is voluntarily inactive, declared inactive or withdrawn will no longer be allowed to list patients on the UNOS recipient list or to maintain a local recipient list in any form, and will not be allowed to provide organs to UNOS member transplant centers.

G. Performance: The Membership and Professional Standards Committee (MPSC) will evaluate all OPOs to determine if the difference in observed and expected organ yield can be accounted for by some unique aspect of the Donation Service Area and/or OPO in question. The evaluation may include a peer visit to the OPO at the OPO's expense.

Those OPOs whose observed organ yield rates fall below the expected rates by more than a specified threshold will be reviewed. The absolute values of relevant parameters in the formula may be different for different organs, and may be reviewed and modified by the MPSC after distribution to the transplant community and subsequent Board approval.

The initial criteria used to identify OPOs with lower than expected organ yield, for all organs as well as for each organ type, will include all of the following:

- A difference of at least 11. More than 10 fewer observed organs per 100 donors than expected yield (Observed per 100 donors-Expected per 100 donors < -10)
- A ratio of observed to expected yield less than 0.90.
- A two-sided p-value is less than 0.05.

All three criteria must be met for an OPO to be identified for MPSC review.

If an OPO's organ yield rate cannot be explained by donor mix or some other unique clinical aspect of the OPO or Donation Service Area in question, the Member, in cooperation with the MPSC, will adopt and promptly implement a plan for performance improvement. The Member's failure to do so will constitute a violation of UNOS requirements.

To read the complete UNOS bylaw language visit www.unos.org, go to the "I am looking for:" box in the upper left hand corner, then select "UNOS bylaws." To read the complete OPTN bylaw language visit optn.transplant.hrsa.gov, select the "Policy Management" tab, then select "OPTN Bylaws."

Affected Bylaw Language:

**ATTACHMENT I
TO APPENDIX B of UNOS BYLAWS**

Designated Transplant Program Criteria

XIII. Transplant Programs.

A – C [*No changes to these sections*]

D. In addition to the foregoing requirements, to qualify for membership in UNOS, a transplant program must have a clinical service which meets the following criteria.

(1) Kidney Transplantation [*No changes to this section*]

(2) Kidney Transplant Programs that Perform Living Donor Kidney Transplants [*No changes to this section*]

(3) Liver Transplantation

(a) Transplant Surgeon [No changes to this section]

(b) Transplant Physician [No changes to this section]

(c) Qualifications for Director of Liver Transplant Anesthesia
Liver transplant programs shall designate a Director of Liver Transplant Anesthesia who has expertise in the area of peri-operative care of ~~liver~~ ~~transplant~~ the patients undergoing liver transplantation and can serve as an advisor to other members of the team.

The Director of Liver Transplant Anesthesia shall be a Diplomate of the American Board of Anesthesiology (or hold an equivalent foreign certification).

Administrative Responsibilities:

The Director of Liver Transplant Anesthesia should be a designated member of the transplant team and will be responsible for establishing internal policies for anesthesiology participation in the peri-operative care of liver transplant patients. These policies will be developed in the context of the institutional needs, transplant volume, and quality improvement initiatives.

The policy must establish a clear communication channel between the transplant anesthesiology service and services from other disciplines that participate in the care of liver transplant patients. The types of activities to consider include peri-operative consults; participation in candidate selection, and in morbidity and mortality conferences (M&M Conferences); and development of intra-operative guidelines based on existing and published knowledge.

Clinical Responsibilities should include but are not limited to the following:

- Pre-operative assessment of transplant candidates;
- Participation in candidate selection;
- Intra-operative management;
- Post-operative visits;
- Participation on the Selection Committee;
- Consultation preoperatively with subspecialists as needed; and
- Participate in M&M Conferences

Qualifications:

1. The Director of Liver Transplant Anesthesia should have one of the following:
 - a. Fellowship training in Critical Care Medicine, Cardiac Anesthesiology, Liver Transplant Fellowship, that includes the peri-operative care of at least 10 liver transplant recipients, or
 - b. Within the last five years, experience in the peri-operative care of at least 20 liver transplant recipients in the operating room. Experience acquired during postgraduate (residency) training shall not count for this purpose.
2. The Director of Liver Transplant Anesthesia should earn a minimum of 8 hours of credit in transplant related educational activities from the Council for Continuing Medical Education (ACCME®) Category I Continuing Medical Education (CME) within the most recent 3 year period.

**(4) Liver Transplant Programs that Perform Living Donor Liver Transplants.
[No changes to this section]**

To read the complete UNOS bylaw language visit www.unos.org , go to select the “I am looking for:” box in the upper left hand corner, then select “UNOS bylaws.” To read the complete OPTN bylaw language visit optn.transplant.hrsa.gov, select the “Policy Management” tab, then select “OPTN Bylaws.”

Affected Bylaw Language:

**Please note: At its June 2011 meeting, the OPTN/UNOS Board of Directors approved two separate resolutions that modified Attachment I to Appendix B of the UNOS Bylaws. The bylaw language below reflects the changes from both of these proposals (which were sponsored by the MPSC and Living Donor Committee, respectively).*

**ATTACHMENT I
TO APPENDIX B OF UNOS BYLAWS**

Designated Transplant Program Criteria

XIII. Transplant Programs.

A. – C. [no change]

D. In addition to the foregoing requirements, to qualify for membership in UNOS, a transplant program must have a clinical service which meets the following criteria.

(1) [no change]

(2) **Kidney Transplant Programs that Perform Living Donor Kidney Recovery Recoveries Transplants:** Kidney transplant programs that perform living donor kidney ~~transplants~~ recovery (“kidney recovery hospital”) must demonstrate the following:

a. **Personnel and Resources:** Kidney recovery hospitals ~~transplant programs that perform living kidney transplants~~ must demonstrate the following regarding personnel and resources:

(i) That the ~~center~~ kidney recovery hospital meets the qualifications of a kidney transplant program as set forth above; and

(ii) In order to perform open donor nephrectomies, a qualifying kidney donor surgeon must be on site and must meet ~~either~~ one of the criteria set forth below:

(1) Completed an accredited ASTS fellowship with a certificate in kidney; or

(2) Performed no fewer than 10 open ~~donor~~ nephrectomies (to include deceased donor nephrectomy, removal of polycystic or diseased kidneys, etc.) as primary surgeon or first assistant within the prior 5 year period. ~~or~~

~~(3) Qualified under the section below (iii)(1) to perform laparoscopic donor nephrectomies.~~

(iii) If the ~~center~~ hospital wishes to perform laparoscopic donor nephrectomies, a qualifying kidney donor surgeon must be on site and must have:

- (1) Acted as primary surgeon or first assistant in performing no fewer than 15 laparoscopic nephrectomies within the prior 5-year period, seven (7) of which were performed as a primary surgeon. Role of the surgeon could be documented by a letter from fellowship program director.

~~If the laparoscopic and open nephrectomy expertise resides within different individuals then the program must demonstrate how both individuals will be available to the surgical team.~~

It is recognized that in the case of pediatric living donor or kidney paired donation transplantation, the living organ donation may occur at a hospital center that is distinct from the approved transplant hospital center.

All surgical procedures identified for the purpose of surgeon qualification must be documented. Documentation should include the date of the surgery, medical records identification and/or UNOS identification number, ~~and~~ the role of the surgeon in the operative procedure, and the type of procedure (open or laparoscopic).

- (iv) The kidney recovery hospital center must have the resources available to assess the medical condition of and specific risks to the potential living donor;
- (v) The psychosocial assessment should include an assessment of the potential donor's capacity to make an informed decision and confirmation of the voluntary nature of proceeding with the evaluation and donation; and
- (vi) That the kidney recovery hospital center has an independent donor advocate (IDA) who is not involved with the potential recipient evaluation, is independent of the decision to transplant the potential recipient and, consistent with the IDA protocol referred to below, is a knowledgeable advocate for the potential living donor. The goals of the IDA are:
- (1) to promote the best interests of the potential living donor;
 - (2) to advocate the rights of the potential living donor; and
 - (3) to assist the potential living donor in obtaining and understanding information regarding the:
 - (a) consent process;
 - (b) evaluation process;
 - (c) surgical procedure; and
 - (d) benefit and need for follow-up.

b. Protocols: Kidney ~~transplant programs that perform living donor kidney transplants~~ recovery hospitals must demonstrate that they have the following protocols:

(i) Living Donation Process: Kidney recovery hospitals ~~transplant programs that perform living donor kidney transplants~~ must develop, and once developed must comply with written protocols to address all phases of the living donation process. Specific protocols shall include the evaluation, pre-operative, operative, post-operative care, and submission of required follow-up forms at 6 months, one-year, and two-years post donation.

~~Transplant centers~~ Member Kidney recovery hospitals must document that all phases of the living donation process were performed in adherence to the hospital's center's protocol. This documentation must be maintained and made available upon request.

(ii) Independent Donor Advocate: Kidney recovery hospitals ~~transplant programs that perform living donor kidney transplants~~ must develop, and once developed, must comply with written protocols for the duties and responsibilities of Independent Donor Advocate (IDA) that include, but are not limited to, the following elements:

- (1) a description of the duties and primary responsibilities of the IDA to include procedures that ensure the IDA:
 - (a) promotes the best interests of the potential living donor;
 - (b) advocates the rights of the potential living donor; and
 - (c) assists the potential donor in obtaining and understanding information regarding the:
 - (i) consent process;
 - (ii) evaluation process;
 - (iii) surgical procedure; and
 - (iv) benefit and need for follow-up.

(iii) Medical Evaluation: Kidney recovery hospitals ~~transplant programs that perform living donor kidney transplants~~ must develop, and once developed, must comply with written protocols for the medical evaluation of the potential living donors that must include, but are not limited to, the following elements:

- (1) a thorough medical evaluation by a physician and/or surgeon experienced in living donation to assess and minimize risks to the potential donor post-donation, which shall include a screen for any evidence of occult renal and infectious disease and medical co-morbidities, which may cause renal disease;
- (2) a psychosocial evaluation of the potential living donor by a psychiatrist, psychologist, or social worker with experience in transplantation (criteria defined in Appendix B, Attachment I) to

- determine decision making capacity, screen for any pre-existing psychiatric illness, and evaluate any potential coercion;
- (3) screening for evidence of transmissible diseases such as cancers and infections; and
 - (4) anatomic assessment of the suitability of the organ for transplant purposes.
- (iv) Informed Consent: ~~Kidney recovery hospitals transplant programs that perform living donor kidney transplants~~ must develop, and once developed, must comply with written protocols for the Informed Consent for the Donor Evaluation Process and for the Donor Nephrectomy, which include, at a minimum, the following elements:
- (1) discussion of the potential risks of the procedure including the medical, psychological, and financial risks associated with being a living donor;
 - (2) assurance that all communication between the potential donor and the Transplant ~~center~~ Hospital will remain confidential;
 - (3) discussion of the potential donor's right to opt out at any time during the donation process;
 - (4) discussion that the medical evaluation or donation may impact the potential donor's ability to obtain health, life, and disability insurance;
 - (5) disclosure by the ~~member~~ kidney recovery hospital transplant center that it is required, at a minimum, to submit Living Donor Follow-up forms addressing the health information of each living donor at 6 months, one-year, and two-years post donation. The protocol must include a plan to collect the information about each donor; and
 - (6) the telephone number that is available for living donors to report concerns or grievances through the OPTN.
 - (7) documentation of disclosure by the ~~Member~~ kidney recovery hospital Transplant center to potential donors that the sale or purchase of human organs is a federal crime and that it is unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation. This documentation must be maintained in the potential donor's official medical record.

To read the complete UNOS bylaw language visit www.unos.org, go to the "I am looking for:" box in the upper left hand corner, then select "UNOS bylaws." To read the complete OPTN bylaw language visit optn.transplant.hrsa.gov, select the "Policy Management" tab, then select "OPTN Bylaws."

Affected Policy Language:**7.0 DATA SUBMISSION REQUIREMENTS**

Members must submit data to the OPTN through use of standardized forms. Data requirements include submission of information on all deceased and living donors, potential transplant recipients, and actual transplant recipients. All transplant data forms must be submitted through UNetSM, beginning January 1, 2003.

All OPOs are responsible for submission of patient level data for all consented donors, consent not recovered potential donors, imminent neurological and eligible deaths in its DSA. All OPOs are also responsible for submission of the total number of reported deaths by donor hospital. The OPO responsible for allocation of the donor organs will be responsible for submission of the Deceased Donor Feedback information, Deceased Donor Registration (DDR) Forms and Potential Transplant Recipient (PTR) Forms.

Histocompatibility laboratories will be responsible for submission of the Donor and Recipient Histocompatibility forms for each donor and actual transplant recipient typed by the laboratory.

Recipient transplant centers are responsible for submission of Recipient Feedback information, ~~Living Donor Feedback information, Living Donor Registration Forms, Living Donor Follow-up Forms,~~ Transplant Candidate Registration Forms, organ-specific Transplant Recipient Registration Forms, organ-specific Transplant Recipient Follow-up Forms, and Recipient Malignancy Forms for each recipient on the waiting list, or transplanted ~~or followed~~ at the center.

Transplant centers that recover living donor organs are responsible for submitting Living Donor feedback information, Living Donor Registration Forms, and Living Donor Follow-up Forms for each living donor whose organ was recovered at that center within the time frame established in Policy 12.8.3 or who is being followed at that center. The transplant center that intends to recover the living donor organ is responsible for generating the Donor ID and reporting whether the recovery procedure occurred.

12.6 Center 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 that are approved to perform living donor recovery for that organ. If the OPTN does not have approval criteria for a living donor recovery hospital associated with a particular organ (e.g., lung, heart, intestine, or pancreas), then Transplant Centers that perform living donor transplants must only accept and transplant living donor organs recovered at OPTN member transplant hospitals that have an approved transplant program for that organ.

12.8 Reporting Requirement. Refer to Policy 7.0 (Data Submission Requirements) for the member that is responsible for submitting living donor forms.

12.8.1 All living donors must be registered with the OPTN Contractor via the living donor feedback form prior to surgery.

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

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

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 that recover living donor organs must complete the LDR form when the donor is discharged from the hospital or ~~by~~ within six weeks following the transplant date, whichever is first. ~~The recipient~~ Transplant centers that recover living donor organs must submit LDR forms for each living donor at six months, one year and two years from the date of donation.

To read the complete policy language visit www.unos.org or optn.transplant.hrsa.gov. From the UNOS website, go to the "I am looking for:" box in the upper left hand corner, then select "Policies." From the OPTN website, select the "Policy Management" tab, then select "Policies."

Affected Bylaw Language:

**Please note: At its June 2011 meeting, the OPTN/UNOS Board of Directors approved two separate resolutions that modified Attachment I to Appendix B of the UNOS Bylaws, Section XIII, D(2) (Kidney Transplant Programs that Perform Living Donor Kidney Transplants). The bylaw language below reflects the changes from both of these proposals (which were sponsored by the MPSC and Living Donor Committee, respectively).*

**ATTACHMENT I
TO APPENDIX B OF UNOS BYLAWS**

Designated Transplant Program Criteria

XIII. Transplant Programs.

A. – C. [*no change*]

D. In addition to the foregoing requirements, to qualify for membership in UNOS, a transplant program must have a clinical service which meets the following criteria.

(1) [*no change*]

(2) **Kidney Transplant Programs that Perform Living Donor Kidney Recovery Recoveries Transplants:** Kidney transplant programs that perform living donor kidney ~~transplants~~ recovery (“kidney recovery hospital”) must demonstrate the following:

a. **Personnel and Resources:** Kidney recovery hospitals ~~transplant programs that perform living kidney transplants~~ must demonstrate the following regarding personnel and resources:

(i) That the ~~center~~ kidney recovery hospital meets the qualifications of a kidney transplant program as set forth above; and

(ii) In order to perform open donor nephrectomies, a qualifying kidney donor surgeon must be on site and must meet ~~either~~ one of the criteria set forth below:

(1) Completed an accredited ASTS fellowship with a certificate in kidney; or

(2) Performed no fewer than 10 open ~~donor~~ nephrectomies (to include deceased donor nephrectomy, removal of polycystic or diseased kidneys, etc.) as primary surgeon or first assistant within the prior 5-year period. ~~or~~

~~(3) Qualified under the section below (iii)(1) to perform laparoscopic donor nephrectomies.~~

(iii) If the ~~center~~ hospital wishes to perform laparoscopic donor nephrectomies, a qualifying kidney donor surgeon must be on site and must have:

- (1) Acted as primary surgeon or first assistant in performing no fewer than 15 laparoscopic nephrectomies within the prior 5-year period, seven (7) of which were performed as a primary surgeon. Role of the surgeon could be documented by a letter from fellowship program director.

~~If the laparoscopic and open nephrectomy expertise resides within different individuals then the program must demonstrate how both individuals will be available to the surgical team.~~

It is recognized that in the case of pediatric living donor or kidney paired donation transplantation, the living organ donation may occur at a hospital ~~center~~ that is distinct from the approved transplant hospital ~~center~~.

All surgical procedures identified for the purpose of surgeon qualification must be documented. Documentation should include the date of the surgery, medical records identification and/or UNOS identification number, ~~and~~ the role of the surgeon in the operative procedure, and the type of procedure (open or laparoscopic).

(iv) The kidney recovery hospital ~~center~~ must have the resources available to assess the medical condition of and specific risks to the potential living donor;

(v) The psychosocial assessment should include an assessment of the potential donor's capacity to make an informed decision and confirmation of the voluntary nature of proceeding with the evaluation and donation; and

(vi) That the kidney recovery hospital ~~center~~ has an independent donor advocate (IDA) who is not involved with the potential recipient evaluation, is independent of the decision to transplant the potential recipient and, consistent with the IDA protocol referred to below, is a knowledgeable advocate for the potential living donor. The goals of the IDA are:

- (1) to promote the best interests of the potential living donor;
- (2) to advocate the rights of the potential living donor; and
- (3) to assist the potential living donor in obtaining and understanding information regarding the:
 - (a) consent process;
 - (b) evaluation process;
 - (c) surgical procedure; and

(d) benefit and need for follow-up.

b. Protocols: Kidney ~~transplant programs that perform living donor kidney transplants~~ recovery hospitals must demonstrate that they have the following protocols:

(i) Living Donation Process: Kidney recovery hospitals ~~transplant programs that perform living donor kidney transplants~~ must develop, and once developed must comply with written protocols to address all phases of the living donation process. Specific protocols shall include the evaluation, pre-operative, operative, post-operative care, and submission of required follow-up forms at 6 months, one-year, and two-years post donation.

~~Transplant centers~~ Member Kidney recovery hospitals must document that all phases of the living donation process were performed in adherence to the hospital's center's protocol. This documentation must be maintained and made available upon request.

(ii) Independent Donor Advocate: Kidney recovery hospitals ~~transplant programs that perform living donor kidney transplants~~ must develop, and once developed, must comply with written protocols for the duties and responsibilities of Independent Donor Advocate (IDA) that include, but are not limited to, the following elements:

(1) a description of the duties and primary responsibilities of the IDA to include procedures that ensure the IDA:

(a) promotes the best interests of the potential living donor;

(b) advocates the rights of the potential living donor; and

(c) assists the potential donor in obtaining and understanding information regarding the:

(i) consent process;

(ii) evaluation process;

(iii) surgical procedure; and

(iv) benefit and need for follow-up.

(iii) Medical Evaluation: Kidney recovery hospitals ~~transplant programs that perform living donor kidney transplants~~ must develop, and once developed, must comply with written protocols for the medical evaluation of the potential living donors that must include, but are not limited to, the following elements:

(1) a thorough medical evaluation by a physician and/or surgeon experienced in living donation to assess and minimize risks to the potential donor post-donation, which shall include a screen for any evidence of occult renal and infectious disease and medical co-morbidities, which may cause renal disease;

- (2) a psychosocial evaluation of the potential living donor by a psychiatrist, psychologist, or social worker with experience in transplantation (criteria defined in Appendix B, Attachment I) to determine decision making capacity, screen for any pre-existing psychiatric illness, and evaluate any potential coercion;
 - (3) screening for evidence of transmissible diseases such as cancers and infections; and
 - (4) anatomic assessment of the suitability of the organ for transplant purposes.
- (iv) Informed Consent: ~~Kidney recovery hospitals transplant programs that perform living donor kidney transplants~~ must develop, and once developed, must comply with written protocols for the Informed Consent for the Donor Evaluation Process and for the Donor Nephrectomy, which include, at a minimum, the following elements:
- (1) discussion of the potential risks of the procedure including the medical, psychological, and financial risks associated with being a living donor;
 - (2) assurance that all communication between the potential donor and the ~~Transplant center~~ Hospital will remain confidential;
 - (3) discussion of the potential donor's right to opt out at any time during the donation process;
 - (4) discussion that the medical evaluation or donation may impact the potential donor's ability to obtain health, life, and disability insurance;
 - (5) disclosure by the ~~member~~ kidney recovery hospital ~~transplant center~~ that it is required, at a minimum, to submit Living Donor Follow-up forms addressing the health information of each living donor at 6 months, one-year, and two-years post donation. The protocol must include a plan to collect the information about each donor; and
 - (6) the telephone number that is available for living donors to report concerns or grievances through the OPTN.
 - (7) documentation of disclosure by the ~~Member~~ Member kidney recovery hospital ~~Transplant center~~ to potential donors that the sale or purchase of human organs is a federal crime and that it is unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation. This documentation must be maintained in the potential donor's official medical record.

(3) [no change]

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

Recovery: Liver transplant programs that perform living donor liver recovery (“liver recovery hospital”) must demonstrate the following:

a. Personnel and Resources: ~~Liver transplant programs that perform living donor liver transplants~~ recovery hospitals must demonstrate the following:

(i) That the ~~center~~ liver recovery hospital meets the qualifications of a liver transplant program as set forth above; and

(ii) That the ~~center~~ liver recovery hospital has on site no fewer than two surgeons who qualify as liver transplant surgeons under UNOS Bylaws Appendix B, Attachment I, and who have demonstrated experience as the primary surgeon or first assistant in 20 major hepatic resectional surgeries (to include living donor operations, splits, reductions, resections, etc.), 7 of which must have been live donor procedures, within the prior 5-year period. These cases must be documented. Documentation should include the date of the surgery, medical records identification and/or UNOS identification number, and the role of the surgeon in the operative procedure. It is recognized that in the case of pediatric living donor transplantation, the live organ donation may occur at a center that is distinct from the approved transplant center;

(iii) The ~~center~~ liver recovery hospital must have the resources available to assess the medical condition of and specific risks to the potential living donor;

(iv) The psychosocial assessment should include an assessment of the potential living donor’s capacity to make an informed decision and confirmation of the voluntary nature of proceeding with the evaluation and donation; and

(v) That the ~~center~~ liver recovery hospital has an independent donor advocate (IDA) who is not involved with the potential recipient evaluation, is independent of the decision to transplant the potential recipient and, consistent with the protocol referred to below, is a knowledgeable advocate for the potential living donor. The goals of the IDA are:

(1) to promote the best interests of the potential living donor;

(2) to advocate the rights of the potential living donor; and

(3) to assist the potential living donor in obtaining and understanding information regarding the:

(a) consent process;

(b) evaluation process;

- (c) surgical procedure; and
- (d) benefit and need for follow-up.

b. Protocols: Liver ~~transplant programs that perform living donor liver transplants~~ recovery hospitals must demonstrate that they have the following protocols:

- (i) Living Donation Process: Liver recovery hospitals ~~transplant programs that perform living donor liver transplants~~ must develop, and once developed must comply with written protocols to address all phases of the living donation process. Specific protocols shall include the evaluation, pre-operative, operative, post-operative care, and submission of required follow-up forms at 6 months, one-year, and two-year post donation.

~~Transplant centers~~ Liver recovery hospitals must document that all phases of the living donation process were performed in adherence to the center's protocol. This documentation must be maintained and made available upon request.

- (ii) Independent Donor Advocate: Liver recovery hospitals ~~transplant programs that perform living donor liver transplants~~ must develop, and once developed, must comply with written protocols for the duties and responsibilities of the Independent Donor Advocate that include, but are not limited, to the following elements:

- (1) a description of the duties and primary responsibilities of the IDA to include procedures that ensure that the IDA:
 - (a) promotes the best interests of the potential living donor;
 - (b) advocates the rights of the living donor; and
 - (c) assists the potential donor in obtaining and understanding information regarding the:
 - (i) consent process;
 - (ii) evaluation process;
 - (iii) surgical procedure; and
 - (iv) benefit and need for follow-up.

- (iii) Medical Evaluation: Liver recovery hospitals ~~transplant programs that perform living donor liver transplants~~ must develop, and once developed, must comply with written protocols for the medical evaluation of the potential living donors must include, but are not limited to the following elements:

- (1) a thorough medical evaluation by a physician and/or surgeon experienced in living donation to assess and minimize risks to

the potential donor post-donation, which shall include a screen for any evidence of occult liver disease;

- (2) a psychosocial evaluation of the potential living donor by a psychiatrist, psychologist or social worker with experience in transplantation (criteria defined in Appendix B, Attachment I) must also be provided to assess decision making capacity, screen for any pre-existing psychiatric illness, and evaluate potential coercion;
 - (3) screening for evidence of transmissible diseases such as cancers and infections; and
 - (4) a radiographic assessment to ensure adequate anatomy and volume of the donor and of the remnant liver.
- (iv) Informed Consent: ~~Liver recovery hospitals transplant programs that perform living donor liver transplants~~ must develop, and once developed, must comply with written protocols for the Informed Consent for the Donor Evaluation Process and for the Donor Hepatectomy, which include, at a minimum, the following elements:
- (1) discussion of the potential risks of the procedure including the medical, psychological, and financial risks associated with being a living donor;
 - (2) assurance that all communication between the potential donor and the transplant center will remain confidential;
 - (3) discussion of the potential donor's right to opt out at any time during the donation process;
 - (4) discussion that the medical evaluation or donation may impact the potential donor's ability to obtain health, life, and disability insurance;
 - (5) disclosure by the ~~liver recovery hospital transplant center~~ that it is required, at a minimum, to submit Living Donor Follow-up forms addressing the health information of each living donor at 6 months, one-year, and two-years post donation. The protocol must include a plan to collect the information about each donor; and
 - (6) the telephone number that is available for living donors to report concerns or grievances through the OPTN.
 - (7) documentation of disclosure by the ~~liver recovery hospital transplant center~~ to potential donors that the sale or purchase of human organs is a federal crime and that it is unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human

transplantation. This documentation must be maintained in the potential donor's official medical record.

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

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

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

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

The ~~program~~ liver recovery hospital's approval status shall be made available to the public.

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

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

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

To read the complete UNOS bylaw language visit www.unos.org , go to the “I am looking for:” box in the upper left hand corner, then select “UNOS bylaws.” To read the complete OPTN bylaw language visit optn.transplant.hrsa.gov, select the “Policy Management” tab, then select “OPTN B

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 UNetSM, shall be ~~\$\$\$~~ \$603.

NOTE: The amendments to Policy 11.0 (Registration Fee) shall be effective October 1, 2011.

To read the complete policy language visit www.unos.org or optn.transplant.hrsa.gov. From the UNOS website, go to the "I am looking for:" box in the upper left hand corner, then select "Policies". From the OPTN website, select the "Policy Management" tab, then select "Policies."

Affected Policy Language:

3.5.5.3 Kidney Payback Debt Limit. An OPO shall accumulate no more than nine kidney payback debts (all blood groups combined) at any point in time, effective upon implementation of this Policy 3.5.5.3. Debts accumulated prior to the effective date of this Policy 3.5.5.3 by an OPO: (i) shall be considered long-term debt, (ii) shall not apply toward the nine total debt limit effective upon implementation of this policy, and (iii) shall be reduced annually by the volume that is determined pursuant to negotiations with the Kidney and Pancreas Transplantation Committee prior to or around the effective date of this policy. A kidney shared in satisfaction of a payback debt by an OPO owing long-term debt may be applied to the OPO's short-term (*i.e.*, incurred on or after the effective date of this policy) or long-term debt balance, as directed by the OPO. Violation of either of the above provisions shall result in referral to the Membership and Professional Standards Committee as a policy violation by the OPO and all affiliated transplant centers. ~~Additionally, priority for offers of zero antigen mismatched kidneys will be adjusted as detailed in Policy 3.5.3.3.~~

To read the complete policy language visit www.unos.org or optn.transplant.hrsa.gov. From the UNOS website, go to the "I am looking for:" box in the upper left hand corner, then select "Policies." From the OPTN website, select the "Policy Management" tab, then select "Policies."

Affected Policy Language:

2.2.3.2 All potential donors are to be tested by use of a serological screening test licensed by the U.S. Food and Drug Administration (FDA) for Human Immune Deficiency Virus (Anti-HIV-1 and Anti-HIV-2).

If the sample is qualified, the screening test for HIV is negative, and blood for subsequent transfusions has been tested and found to be negative for HIV, re- testing the potential donor for HIV is not necessary.

To read the complete policy language visit www.unos.org or optn.transplant.hrsa.gov. From the UNOS website, go to the "I am looking for:" box in the upper left hand corner, then select "Policies." From the OPTN website, select the "Policy Management" tab, then select "Policies."

Affected Policy Language:**5.10.1 Vessel recovery and transplant**

- The consent forms used by the recovering OPO must include language that indicates that vessels will be used for transplant.
- The vessels cannot be used other than for the implantation or modification of a solid organ transplant.
- Vessels can be shared among transplant ~~programs~~ centers. If sharing occurs between transplant ~~programs~~ centers, the implanting program must submit to the OPTN a detailed explanation justifying the sharing. The justification will be reviewed by the Membership and Professional Standards Committee (MPSC). The implanting transplant program must notify the OPTN of subsequent disposition of the vessel(s).
- If the transplant center stores vessels and subsequently uses the vessels for the intended recipient or another transplant recipient, the OPTN must be notified.
- If vascular conduits from donors with positive serology for hepatitis are subsequently used in other than the intended recipient, the implanting transplant center must provide a detailed explanation to the OPTN for the use of this conduit. The explanation will be reviewed by the MPSC.
- The transplant center must verify the ABO, all serology results, container contents, date of expiration, and the UNOS Donor ID of the vessel with the ABO and all serology results of the recipient prior to implantation. The documentation of this verification must be maintained within the recipient medical record and made available to the OPTN contractor upon request.

To read the complete policy language visit www.unos.org or optn.transplant.hrsa.gov. From the UNOS website, go to the “I am looking for:” box in the upper left hand corner, then select “Policies.” From the OPTN website, select the “Policy Management” tab, then select “Policies.”

Affected Policy Language:

3.7.12.1 Essential Information. The Host OPO or donor center must provide the following donor information to the recipient center with each thoracic organ offer:

- (i) The cause of brain death;
- (ii) The details of any documented cardiac arrest or hypotensive episodes;
- (iii) Vital signs including blood pressure, heart rate and temperature;
- (iv) Cardiopulmonary, social, and drug activity histories;
- (v) Pre- or post-transfusion serologies as indicated in 2.2.7.1 (pre-transfusion preferred);
- (vi) Accurate height, weight, age and sex;
- (vii) ABO type;
- (viii) Interpreted electrocardiogram and chest radiograph;
- (ix) History of treatment in hospital including vasopressors and hydration;
- (x) Arterial blood gas results and ventilator settings; ~~and~~
- (xi) Echocardiogram, if the donor hospital has the facilities; ~~and~~
- (xii) Human leukocyte antigen (HLA) type if requested by the transplant center.

If a transplant center requires donor HLA type prior to submitting a final organ acceptance, it must communicate this request to the OPO; the transplant center must document this request. If a transplant center requests donor HLA type prior to submitting a final organ acceptance, the OPO must provide the following, identified splits before the organ's final acceptance: HLA-A, HLA-B, HLA-Bw4, HLA-Bw6, HLA-Cw, HLA-DR, and HLA-DQ antigens. The transplant center may request HLA-DP type, but the OPO need only provide it if its affiliated laboratory performs related testing. The OPO must document provision of HLA type to the requesting transplant center.

The thoracic organ procurement team must have the opportunity to speak directly with responsible ICU personnel or the on-site donor coordinator in order to obtain current first-hand information about the donor physiology.

To read the complete policy language visit www.unos.org or optn.transplant.hrsa.gov. From the UNOS website, go to the "I am looking for:" box in the upper left hand corner, then select "Policies." From the OPTN website, select the "Policy Management" tab, then select "Policies."

Affected Policy Language:

~~**3.7.13 Status 1 Listing Verification.** A transplant center which has demonstrated noncompliance with the Status 1 criteria specified in Policy 3.7.3 (Primary Allocation Criteria) for heart candidate registration shall be audited on a random basis and any recurrence of noncompliance will result in a recommendation to the Membership and Professional Standards Committee and Executive Committee that further Status 1 heart candidate registrations from that center shall be subject to verification by OPTN contractor of the candidates' medical status prior to their Status 1 placement on the Waiting List for a period of one year.~~

3.7.14 3.7.13 Removal of Thoracic Organ Transplant Candidates from Thoracic Organ Waiting Lists When Transplanted or Deceased. If a heart, lung, or heart-lung transplant candidate on the Waiting List has received a transplant from a deceased or living donor, or has died while awaiting a transplant, the listing center, or centers if the candidate is multiple listed, shall immediately remove that candidate from all Thoracic Organ Waiting Lists for that transplanted organ and shall notify the OPTN contractor within 24 hours of the event. If the thoracic organ recipient is again added to a Thoracic Organ Waiting List, waiting time shall begin as of the date and time the candidate is relisted.

~~**3.7.1.5 3.7.14 Local Conflicts Involving Thoracic Organ Allocation.** Regarding allocation of hearts, lungs and heart-lung combinations, locally unresolvable inequities or conflicts that arise from prevailing OPO policies may be submitted by any interested local member for review and adjudication to the Thoracic Organ Transplantation Committee and the Board of Directors.~~

~~**3.7.16 3.7.15 Allocation of Domino Donor Hearts.** A domino heart transplant occurs when the native heart of a combined heart-lung transplant recipient is procured and transplanted into a candidate who requires an isolated heart transplant. First consideration for donor hearts procured for this purpose will be given to the candidates of the participating transplant program from which the native heart was procured. If the program elects not to use the heart, then the heart will be allocated according to Policy 3.7, or an approved variance to this policy. For the purpose of Policy 3.7.16, the Local Unit of allocation for the domino heart shall be defined as the CMS-designated service area of the OPO where the domino heart is procured.~~

~~**3.7.17 3.7.16 Crossmatching for Thoracic Organs.** The transplant program and its histocompatibility laboratory must have a joint written policy that states when a crossmatch is necessary. Guidelines for policy development, including assigning risk and timing of crossmatch testing, are set out in Appendix D of Policy 3.~~

To read the complete policy language visit www.unos.org or optn.transplant.hrsa.gov. From the UNOS website, go to the "I am looking for:" box in the upper left hand corner, and select "Policies." From the OPTN website, select the "Policy Management" tab, then select "Policies."

Affected Policy Language:

3.7.3 Adult Candidate Status. Each candidate awaiting heart transplantation is assigned a status code which corresponds to how medically urgent it is that the candidate receive a transplant. Medical urgency is assigned to a heart transplant candidate who is greater than or equal to 18 years of age at the time of listing as follows:

Status	Definition
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1A	A candidate listed as Status 1A is admitted to the listing transplant center hospital (with the exception for 1A (a)(i), and 1A (b) candidates) and has at least one of the following devices or therapies in place:
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|-----|--|
| (a) | Mechanical circulatory support for acute hemodynamic decompensation that includes at least one of the following: <ul style="list-style-type: none"> (i) left and/or right ventricular assist device implanted
Candidates listed under this criterion, may be listed for 30 days at any point after being implanted as Status 1A once the treating physician determines that they are clinically stable. Admittance to the listing transplant center hospital is not required. (ii) total artificial heart; (iii) intra-aortic balloon pump; or (iv) extracorporeal membrane oxygenator (ECMO). |
|-----|--|

Qualification for Status 1A under criterion 1A(a)(ii), (iii) or (iv) is valid for 14 days and must be recertified by an attending physician every 14 days from the date of the candidate's initial listing as Status 1A to extend the Status 1A listing.

A candidate with a total artificial heart who has been discharged from the listing hospital may be listed as Status 1A for 30 days at any point in time after the discharge.

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| (b) | Mechanical circulatory support with objective medical evidence of significant device-related complications, such as thromboembolism, device infection, mechanical failure <u>and/or</u> life-threatening ventricular arrhythmias. <u>A transplant center can report a complication not listed here. The report of an "other" complication will result in a review by the respective heart regional review board.</u> (Candidate sensitization is not an appropriate device-related complication for qualification as Status 1A under this criterion. The applicability of sensitization to thoracic organ allocation is specified by Policy 3.7.1.1 (Exception for Sensitized Candidates).) |
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Admittance to the listing center transplant hospital is not required. Qualification for Status 1A under this criterion is valid for 14 days and must be recertified by an attending physician

every 14 days from the date of the candidate's initial listing as Status 1A to extend the Status 1A listing.

- (c) Continuous Mechanical ventilation. Qualification for Status 1A under this criterion is valid for 14 days and must be recertified by an attending physician every 14 days from the date of the candidate's initial listing as Status 1A to extend the Status 1A listing.
- (d) Continuous infusion of a single high-dose intravenous inotrope (~~e.g., dobutamine >= 7.5 mcg/kg/min, or milrinone >= 50 mcg/kg/min~~), or multiple intravenous inotropes, in addition to continuous hemodynamic monitoring of left ventricular filling pressures.



Qualification for Status 1A under this criterion is valid for 7 days and may be renewed for an additional 7 days for each occurrence of a Status 1A listing under this criterion for the same candidate. The OPTN contractor shall maintain in the heart status justification form in UNetSM a list of the specific inotropes and doses approved by the Board of Directors to be compliant with this criterion.

Status 1A-Exception

A candidate who does not meet ~~the~~ criteria (a), (b), (c), or (d) ~~for Status 1A~~ may nevertheless be ~~assigned to such~~ classified as ~~s~~Status 1A upon application by his/ or her transplant physician(s) and justification to the applicable Regional Review Board that the candidate is considered, using acceptable medical criteria, to have an urgency and potential for benefit comparable to that of other candidates in this status as defined above. The justification must be for a candidate admitted to his or her listing transplant center hospital and must include a rationale for incorporating the exceptional case as part of the status criteria. The justification must be reviewed and approved by the Regional Review Board. Timing of the review of these cases, whether prospective or retrospective, will be left to the discretion of each Regional Review Board. A report of the decision of the Regional Review Board and the basis for it shall be forwarded ~~to~~ for review by the Thoracic Organ Transplantation Committee to determine consistency in application among and within Regions and continued appropriateness of the candidate status criteria. A candidate's listing under this exceptional provision is valid for 14 days.

Any further extension of the Status 1A listing under this criterion requires prospective review and approval by a majority of the Regional Review Board Members. If Regional Review Board approval is not given, the candidate's transplant physician may list the candidate as Status 1A, subject to automatic referral to the Thoracic Organ Transplantation Committee. A report of the decision of the Regional Review Board and the basis for it shall be forwarded for review by the Thoracic Organ Transplantation and Membership and Professional Standards Committees to determine consistency in application among

and within Regions and continued appropriateness of the candidate status criteria.

Submission of Status 1A Justification Form

For all adult candidates listed as Status 1A, a completed Heart Status 1A Justification Form must be received-submitted to UNetSM in order to list a candidate as Status 1A, or extend-their his or her listing as Status 1A in accordance with the criteria listed above-in Policy 3.7.3. Candidates listed as Status 1A will automatically revert back to Status 1B unless they are re-listed on UNetSM by an attending physician within the time frames described in the definitions of status 1A(a)-(d) above. When a candidate's time at Status 1A expires, the candidate will automatically be classified as Status 1B unless the attending physician recertifies the candidate's qualification for a Status 1A criterion. Note: This automatic status downgrade will not require submission of a Status 1B Justification Form.

- 1B A candidate listed as Status 1B has at least one of the following devices or therapies in place:
- (aa) left and/or right ventricular assist device implanted; or
 - (bb) continuous infusion of intravenous inotropes.

A candidate with a total artificial heart who has been discharged from the listing hospital may be listed as Status 1B at any point in time after the discharge.

Status 1B-Exception

A candidate who does not meet the criteria for Status 1B may nevertheless be assigned to such status upon application by his/ or her transplant physician(s) and justification to the applicable Regional Review Board that the candidate is considered, using accepted medical criteria, to have an urgency and potential for benefit comparable to that of other candidates in this status as defined above. The justification must include a rationale for incorporating the exceptional case as part of the status criteria. A report of the decision of the Regional Review Board and the basis for it shall be forwarded for review by the Thoracic Organ Transplantation and Membership and Professional Standards Committees to determine consistency in application among and within Regions and continued appropriateness of the candidate status criteria.

Submission of Status 1B Justification Form

For all adult candidates listed as Status 1B, a completed Heart Status 1B Justification Form must be received-submitted on to UNetSM in order to list a candidate within one working day of a candidate's listing as Status 1B.

To read the complete policy language visit www.unos.org or optn.transplant.hrsa.gov. From the UNOS website, go to the "I am looking for:" box in the upper left hand corner, then select "Policies." From the OPTN website, select the "Policy Management" tab, then select "Policies."