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IMPORTANT POLICY NOTICE

To: Transplant Professionals

From: James B. Alcorn
Director, Policy

RE: Changes to OPTN Bylaws and Policies from actions at June Board of Directors Meeting

Date: July 1, 2014

The attached report summarizes changes to OPTN Policy and Bylaws approved by the OPTN/UNOS Board of Directors. This policy notice provides the specific Policy and Bylaws language changes and the corresponding implementation dates.

When reviewing the language changes, please note that underlined language is new and what will be in effect upon implementation and language that is ~~struck~~ will be deleted upon implementation. The policy language used to denote the approved changes reflects the most recent version of policy that has been approved, but not necessarily what is currently implemented.

This policy notice, as well as changes from previous Board of Directors meetings, can be found at optn.transplant.hrsa.gov (click on “News,” and then select “View all Policy Notices”).

The Evaluation Plan, which reviews specific details regarding how members will be assessed for compliance with OPTN policies and bylaws, has also been updated to reflect the changes resulting from the meeting. It can also be found at optn.transplant.hrsa.gov (click on “Policy Management,” and then select “Evaluation Plan”).

Thank you for your careful review of this policy notice. If you have any questions about a particular Board of Directors’ action, please contact your regional administrator at (804) 782-4800.

Changes to Policies and Bylaws to Guide Vascularized Composite Allograft (VCA) Transplantation

Sponsoring Committee: Vascularized Composite Allograft (VCA) Committee

Policies affected:

- OPTN Policy 1.2 (Definitions)
- OPTN Policy 2.2 (OPO Responsibilities)
- OPTN Policy 2.12.C (Authorization Requirement)
- OPTN Policy 5.2 (Maximum Mismatched Antigens)
- OPTN Policy 5.4.B (Order of Allocation)
- OPTN Policy 5.5.A (Receiving and Reviewing Organ Offers)
- OPTN Policy 5.5.B (Time Limit for Acceptance)
- OPTN Policy 12.1 (Waiting Time)
- OPTN Policy 12.2 (VCA Allocation)
- OPTN Policy 14.6 (Registration and Blood Type Verification of Living Donors before Donation)
- OPTN Policy 18.1 (Data Submission Requirements)
- OPTN Policy 18.2 (Timely Collection of Data)
- OPTN Policy 18.3 (Recording and Reporting the Outcomes of Organ Offers)
- OPTN Bylaws, Appendix D (Membership Requirements for Transplant Hospitals and Transplant Programs) and D.2 (Designated Transplant Program Requirement)
- OPTN Bylaws, Appendix J (Membership Requirements for Vascularized Composite (VCA) Transplant Programs)
- OPTN Bylaws, Appendix K (Transplant Program Inactivity, Withdrawal, and Termination)
- OPTN Bylaws, Appendix M (Definitions)

Distribution for Public Comment: Pending fall 2014

Amended After Public Comment: n/a

Effective Date: July 3, 2014 through September 1, 2015

Problem Statement
<p>There are no formal policies or bylaws that establish key requirements for VCA recovery or transplantation. Effective July 3, 2014, the OPTN will be responsible for oversight of VCA recovery and transplantation. As a result, substantial updates to the OPTN Policies and Bylaws are required to:</p> <ul style="list-style-type: none">• Define body parts covered by VCA policies.• Establish VCA donor authorization requirements.• Establish VCA allocation policies.• Provide membership requirements for hospitals that perform VCA transplants. <p>With the classification of VCA as an organ, interim solutions are required to collect VCA candidate registrations and removals, and to facilitate VCA allocation. This is due to significant programming requirements to Wait ListSM, DonorNet[®], and Tiedⁱ[®]. As a result, several policy and bylaws requirements contain exemptions for VCA. Many of these</p>

exemptions will be removed as elements pertaining to VCA recovery and transplantation are programmed and implemented.

Changes

All of the following changes are being made to OPTN Policies and Bylaws to establish requirements for members wishing to participate in VCA recovery and transplantation:

- New content on VCA donor authorization was added to OPTN Policy 2. This was written to avoid conflicts with the Uniform Anatomical Gift Act, applicable state laws, or the efforts of the donation community.
- New content on VCA allocation in OPTN Policy 12 ranks VCA candidates by waiting time and compatible blood type. Allocation begins within the OPO's region, then goes beyond the OPO's region.
- Bylaws Appendix D.2 was updated to reflect that a transplant hospital must have approval for a designated transplant program in addition to the VCA program designation.
- Bylaws Appendix J includes new content on membership requirements that outlines specific requirements of a VCA transplant program and the program's letter of intent.
- Policy 1.2 and Bylaws Appendix M have been updated to include "vascularized composite allografts" as an organ. Further, to be a VCA organ, a body part must meet all nine criteria from the Final Rule. These criteria appear in the definition of "Vascularized Composite Allograft."

Member Actions

Members are required to be familiar with and ensure compliance with the policies and bylaws pertaining to VCA recovery and transplantation.

Transplant programs must:

- Ensure that a body part they intend to transplant meets the criteria. This includes, but is not limited to, upper limbs, faces, and abdominal wall grafts.
- Prior to transplanting VCA organs, a transplant hospital must submit a letter of intent to perform such transplants to the OPTN Contractor in order to obtain VCA transplant program designation. The OPTN Contractor will notify the transplant hospital member of the program designation.
- Email the OPTN Contractor at VCA@unos.org and request the necessary worksheet to register candidates on the VCA candidate list once an approved as a VCA transplant program.

OPOs must:

- Separately discuss and document VCA donor authorization from solid organ donor authorization. VCA donor authorization must be documented on a separate VCA-specific authorization form. Current practices in the OPO community demonstrate the importance of discussing life-saving organ donor authorization first, then VCA donor authorization (if appropriate) *after*.
- As an interim solution, the VCA allocation system must reside outside DonorNet®. OPOs must allocate VCA organs from the VCA candidate list in Secure Enterprise and record applicable refusal, bypass, and acceptance reasons for each VCA organ consented. Each completed VCA candidate list must be returned to the OPTN Contractor via secure email to VCA@unos.org.

Affected Policy/Bylaw Language:

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

Policy 1.2 Definitions

The definitions that follow are used to define terms specific to the OPTN Policies.

O

Organ

A human kidney, liver, heart, lung, pancreas, or intestine (including the esophagus, stomach, small or large intestine, or any portion of the gastrointestinal tract), or vascularized composite allograft. Blood vessels recovered from an organ donor during the recovery of such organ(s) are considered part of an organ with which they are procured for purposes of this part if the vessels are intended for use in organ transplantation and labeled “For use in organ transplantation only.”

Organ allocation policies

OPTN Policies: *Policy 6: Allocation of Hearts and Heart-Lungs, Policy 7: Allocation of Intestines, Policy 8: Allocation of Kidneys, Policy 9: Allocation of Livers and Liver-Intestines, Policy 10: Allocation of Lungs, and Policy 11: Allocation of Pancreas, Kidney-Pancreas, and Islets, and Policy 12: Allocation of Vascularized Composite Allografts.*

V

Vascularized Composite Allograft (VCA)

A transplant involving any body parts that meet *all* nine of the following criteria:

- 1) That is vascularized and requires blood flow by surgical connection of blood vessels to function after transplantation;
- 2) Containing multiple tissue types;
- 3) Recovered from a human donor as an anatomical/structural unit;
- 4) Transplanted into a human recipient as an anatomical/structural unit;
- 5) Minimally manipulated (i.e., processing that does not alter the original relevant characteristics of the organ relating to the organ's utility for reconstruction, repair, or replacement);

- 6) For homologous use (the replacement or supplementation of a recipient's organ with an organ that performs the same basic function or functions in the recipient as in the donor);
- 7) Not combined with another article such as a device;
- 8) Susceptible to ischemia and, therefore, only stored temporarily and not cryopreserved; and
- 9) Susceptible to allograft rejection, generally requiring immunosuppression that may increase infectious disease risk to the recipient.

W

Waiting list

AThe computerized list of candidates who are waiting to be matched with specific deceased donor organs for transplant.

2.2 OPO Responsibilities

The host OPO is responsible for all of the following:

1. Identifying potential deceased donors.
2. Providing evidence of authorization for donation.
3. Evaluating deceased donors.
4. Maintaining documentation used to exclude any patient from the imminent neurological death data definition or the eligible data definition.
5. Verifying that death is pronounced according to applicable laws.
6. Establishing and then implementing a plan to address organ donation for diverse cultures and ethnic populations.
7. Clinical management of the deceased donor.
8. Assuring that the necessary tissue-typing material is procured, divided, and packaged.
9. Assessing deceased donor organ quality.
10. Preserving, packaging, and transporting the organs.
11. Reporting to the OPTN Contractor all deceased donor information required for organ placement, including the donor's human leukocyte antigen (HLA) type.
12. Executing the match run and using the resulting match for each deceased donor organ allocation. The previous sentence does not apply to VCA transplants; instead, members must allocate VCAs according to Policy 12.2: VCA Allocation.
13. Documenting and maintaining complete deceased donor information for seven years for all organs procured.
14. Ensuring that written documentation of the deceased donor evaluation, donor management, authorization for donation, death pronouncement, and organ procurement quality accompanies the organ as described in Policy 16: Organ and Vessel Packaging, Labeling, Shipping, and Storage.
15. Maintaining a serum sample for each deceased donor for at least 10 years after the date of organ transplant and ensuring the serum sample is available for retrospective testing. The host OPO must document the type of sample in the deceased donor medical record and, if possible, should use qualified specimens.

2.12.C Authorization Requirement

Organ recovery teams may only recover organs that they have received authorization to recover. An authorized organ should be recovered if it is transplantable or a transplant recipient is identified for the organ. If an authorized organ is not recovered, the host OPO must document the specific reason for non-recovery. This policy does not apply to VCA transplants.

Recovery of vascularized composite allografts for transplant must be specifically authorized from individual(s) authorizing donation whether that be the donor or a surrogate donation decision-maker consistent with applicable state law. The specific authorization for VCA must be documented by the host OPO.

5.2 Maximum Mismatched Antigens

A transplant program may also specify the maximum number of mismatched antigens it will accept and any unacceptable antigens for any of its candidates. If a transplant program specifies these mismatched antigens, the OPTN Contractor will only offer organs from deceased donors with mismatched antigens equal to or less than the maximum specified.

This policy does not apply to VCA transplants.

5.4.B Order of Allocation

The process to allocate deceased donor organs occurs with these steps:

1. The match system eliminates candidates who cannot accept the deceased donor based on size or blood type.
2. The match system ranks candidates according to the allocation sequences in the organ allocation policies.
3. OPOs must first offer organs to potential recipients in the order that the potential recipients appear on a match run.
4. If no transplant program on the initial match run accepts the organ, the host OPO may give transplant programs the opportunity to update their candidates' data with the OPTN Contractor. The host OPO may run an updated match run and allocate the organ according to the updated candidate data.
5. If no transplant program within the DSA or through an approved regional sharing arrangement accepts the organ, the Organ Center will allocate an abdominal organ first regionally and then nationally, according to allocation Policies. The Organ Center will allocate thoracic organs according to Policy 6: Allocation of Hearts and Heart-Lungs and Policy 10: Allocation of Lungs.
6. Members may export deceased donor organs to hospitals in foreign countries only after offering these organs to all potential recipients on the match run. Members must submit the Organ Export Verification Form to the OPTN Contractor prior to exporting deceased donor organs.

This policy does not apply to VCA transplants; instead, members must allocate VCAs according to Policy 12.2: VCA Allocation.

5.5.A Receiving and Reviewing Organ Offers

Transplant hospitals must view organ offers and respond to these offers through the match system. The previous sentence does not apply to VCA transplants.

The transplanting surgeon at the receiving transplant hospital is responsible for ensuring the medical suitability of organs offered for transplant to potential recipients, including compatibility of deceased donor and candidate blood types (and donor subtype, when used for allocation).

5.5.B Time Limit for Acceptance

A transplant hospital must access deceased donor information in the match system within one hour of receiving the initial organ offer notification. If the transplant hospital does not access the match system within this time, the offer will be considered refused.

Transplant hospitals must either accept or refuse the organ within one hour of accessing the deceased donor information required for an organ according to Policy 2.3: Evaluating and Screening Potential Deceased Donors. If the transplant hospital does not respond within this time, the offer expires and the organ may be offered to the transplant hospital for the candidate that appears next on the match run.

This policy does not apply to VCA transplants.

Policy 12: Allocation of Vascularized Composite Allografts

12.1 Waiting Time

Waiting time for VCA candidates begins when the candidate is registered on the waiting list. For those candidates registered prior to September 1, 2014, waiting time will begin when the transplant hospital requests that the OPO actively seek a donor for an identified VCA candidate.

12.2 VCA Allocation

The host OPO will offer VCAs to candidates with compatible blood type willing to accept a VCA with similar physical characteristics to the donor. The OPO will offer VCAs to candidates in the following order:

1. Candidates that are within the OPO's region.
2. Candidates that are beyond the OPO's region.

Within each classification, candidates are sorted by waiting time (longest to shortest). When a VCA is allocated, the host OPO must document 1) how the organ is allocated and the rationale for allocation and 2) any reason for organ offer refusals.

14.6 Registration and Blood Type Verification of Living Donors before Donation

Recovery hospitals must use source documents from both an initial and second determination blood typings and subtypings (when used to determine transplant compatibility), to enter the living donor's blood type data on the Living Donor Feedback Form. Additionally, each living donor program must develop and comply with a protocol to verify that the living donor's blood type and type was correctly entered on the Living Donor Feedback Form with both the initial and second determination blood typing and subtyping source documents by an individual other than the person initially entering the donor's blood type data.

Recovery hospitals must document that each blood typing and subtyping entry was performed according to the program's protocol and must maintain this documentation.

This policy does not apply to VCA transplants.

18.1 Data Submission Requirements

OPOs must provide donor information required for organ placement to the OPTN Contractor in an electronic data format as defined and required by the computer system. Deceased donor information required for organ placement must be submitted prior to organ allocation.

Members must report data to the OPTN using standardized forms. Table 18-1 shows the member responsible for submitting each data form and when the Member must submit the following materials to the OPTN Contractor.

This policy does not apply to VCA-only donors or VCA information for donors and recipients; however, for VCA-only procurements, Host OPOs must submit to the OPTN Contractor the Deceased donor registration (DDR) within 30 days after the procurement date.

18.2 Timely Collection of Data

Members must collect and submit timely information to the OPTN Contractor. Timely data on recipients is based on recipient status at a time as close as possible to the specified transplant event anniversary. Table 18-2: Timely Data Collection sets standards for when the member must collect the data from the patient.

This policy does not apply to VCA transplants.

18.3 Recording and Reporting the Outcomes of Organ Offers

The allocating OPO and the transplant hospitals that received organ offers share responsibility for reporting the outcomes of all organ offers. OPOs are responsible for reporting the outcomes of organ offers to the OPTN Contractor within 30 days of the match run date. OPOs, transplant hospitals, and the OPTN Contractor may report this information. The OPO or the OPTN Contractor must obtain PTR refusal codes directly from the physician, surgeon, or their designee involved with the potential recipient and not from other personnel.

If the OPO reports the refusal code, then the transplant hospital has 45 days from the match run date, to validate the refusal code by either confirming or amending the refusal code. If the OPO and transplant hospital report different refusal codes, then the OPTN Contractor will use the transplant hospital's refusal code for data analysis purposes.

If the OPTN reports the refusal code, then the transplant hospital will not be required to validate the refusal code.

This policy does not apply to VCA organ offers; instead, members must document VCA offers according to Policy 12.2: VCA Allocation.

OPTN Bylaws Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs

A transplant hospital member is any hospital that performs organ transplants and has current approval as a designated transplant program for at least one organ.

The following provisions of Appendix D do not apply to VCA transplant programs:

- *D.4: Transplant Program Director*
- *D.5: Transplant Program Key Personnel*
- *D.6: Changes in Key Transplant Program Personnel*
- *D.9: Review of Transplant Program Functional Activity*
- *D.10 A: Transplant Program Survival Rates*
- *D.10 B: Patient Notification Requirements for Waiting List Inactivation*
- *D.10 G: Relocation of Transfer of Designated Transplant Programs.*

D.2 Designated Transplant Program Requirement

In order to receive organs for transplantation, a transplant hospital member must have current approval as a designated transplant program for at least one organ. Designated transplant programs must meet at least *one* of the following requirements:

- Have approval as a transplant program by the Secretary of the U.S. Department of Health and Human Services (HSS) for reimbursement under Medicare.

- Have approval as a transplant program in a Department of Veterans Affairs, Department of Defense, or other Federal hospital.
- Qualify as a designated transplant program according to the membership requirements of these Bylaws.

The OPTN does not grant designated transplant program approval for any type of vascularized organ transplantation for which the OPTN has not established specific criteria. In order to perform vascularized organ transplantation procedures for which there are no OPTN-established criteria, including multi-visceral transplants, a hospital must be a transplant hospital member and have current approval as a designated transplant program ~~for at least one of the organ types involved in multi-visceral transplant~~. In the case of abdominal multi-visceral organ transplants, the transplant hospital must have approval as a designated liver transplant program. In the case of vascularized composite allografts (including, but not limited to, faces and upper extremities), the transplant hospital must have approval for at least one designated transplant program in addition to the vascularized composite allograft program designation.

APPENDIX J: RESERVED Membership Requirements for Vascularized Composite Allograft (VCA) Transplant Programs

This appendix describes the documentation transplant hospitals must provide when requesting approval as a designated VCA transplant program. VCAs include, but are not limited to, faces and upper extremities.

J.1 Letter of Notification

If a transplant hospital member commits to performing VCA transplants the hospital must send written notification of this intent to the OPTN Contractor. The notification to the OPTN Contractor must include a written assurance from the local OPO that it will provide organs for use in vascularized composite allografts.

The letter of notification from the transplant hospital must be signed by *all* of the following individuals:

1. The chief administrative officer for the institution
2. A reconstructive surgeon with expertise in microsurgical reconstruction, prior experience in VCA, or in lieu of actual VCA experience, extensive experience in the applicable reconstructive procedure as required, such as hand replantation or facial reconstruction
3. A transplant physician or transplant surgeon at an approved transplant program that has completed an approved transplant fellowship, or qualifies by documented transplant experience, in a medical or surgical specialty.

The OPTN Contractor will then notify the transplant hospital member of the program designation

Bylaws Appendix K: Transplant Program Inactivity, Withdrawal, and Termination

This appendix defines transplant program inactivity, withdrawal, and termination, and outlines what members must do to be in compliance with OPTN obligations during these periods.

The following provisions of Appendix D do not apply to VCA transplant programs:

- *K.1: Transplant Program Inactivity*
- *K.2: Short-term Inactive Transplant Program Status*
- *K.3: Long-term Inactive Transplant Program Status.*

Appendix M: Definitions

D

Designated Transplant Program

An organ-specific program that has been approved by the MPSC to as part of the transplant hospital membership. A transplant hospital member may have transplant programs for transplantation of hearts, lungs, liver, kidneys, pancreas, pancreas islets, ~~and~~ intestines, and vascularized composite allografts. In order to be a transplant hospital member, the transplant hospital must have current designated transplant program approval for at least one organ. A designated transplant program may also be called a transplant program in these Bylaws.

O

Organ

~~Organ means a~~ A human kidney, liver, heart, lung, pancreas, or intestine (including the esophagus, stomach, small and/or large intestine, or any portion of the gastrointestinal tract), or vascularized composite allograft. Blood vessels recovered from an organ donor during the recovery of such organ(s) are considered part of an organ with which they are procured for purposes of this part if the vessels are intended for use in organ transplantation and labeled "For use in organ transplantation only."

V

Vascularized Composite Allograft (VCA)

A transplant involving any body parts that meet *all* nine of the following criteria:

1. That is vascularized and requires blood flow by surgical connection of blood vessels to function after transplantation;
2. Containing multiple tissue types;
3. Recovered from a human donor as an anatomical/structural unit;
4. Transplanted into a human recipient as an anatomical/structural unit;
5. Minimally manipulated (i.e., processing that does not alter the original relevant characteristics of the organ relating to the organ's utility for reconstruction, repair, or replacement);
6. For homologous use (the replacement or supplementation of a recipient's organ with an organ that performs the same basic function or functions in the recipient as in the donor);
7. Not combined with another article such as a device;
8. Susceptible to ischemia and, therefore, only stored temporarily and not cryopreserved; and
9. Susceptible to allograft rejection, generally requiring immunosuppression that may increase infectious disease risk to the recipient.

Proposal for Adolescent Classification Exception for Pediatric Lung Candidates

Sponsoring Committee: Thoracic Organ Transplantation Committee

Policies Affected: Policies 10.1.D (Candidates at Least 12 Years Old – LAS) 10.1.E (LAS Values and Clinical Update Schedule for Candidates at Least 12 Years Old); 10.2.B (Lung Candidates with Exceptional Cases); and 10.2.B.i (LRB Review Process)

Distributed for Public Comment: March 2014

Amended After Public Comment: No

Effective Date: July 1, 2014

Problem Statement

On June 10, 2013, the OPTN/UNOS Executive Committee approved a temporary policy permitting lung candidates less than 12 years old to request an exception from the Lung Review Board (LRB) to be classified as an adolescent candidate for the purposes of prioritization by lung allocation score (LAS). Without further action by the Board of Directors, the “adolescent classification exception” would have expired on July 1, 2014.

Changes

These policy modifications remove the July 1, 2014 expiration date to make the adolescent classification exception a permanent policy. These modifications also clarify how candidates with approved adolescent classification exceptions will be treated for offers from donors in all three age groups (for example, such candidates will be treated as adolescents for purposes of offers from adult and adolescent donors and will be treated as children for purposes of offers from donors under 12 years of age). Lastly, the policy requires the submission of variables used to calculate the LAS for candidates with approved adolescent classification exceptions.

Member Actions

Transplant programs will be responsible for maintaining two registrations for candidates with an approved adolescent classification exception (though transplant programs will not be charged an additional registration fee for the second registration). OPTN/UNOS staff provides instructions for maintaining the candidate’s second record in the email sent to the transplant program providing notification of the LRB’s approval. For the adolescent record, transplant programs must submit to the OPTN all data required for candidates aged 12 and older.

Transplant programs should also reado first distributed on August 26, 2013, [“Recommendation for Submitting Information and Evidence in Support of Lung Review Board Exception Requests.”](#)

Affected Policy Language:

10.1.D Candidates at Least 12 Years Old - LAS

Candidates who are at least 12 years old or who have an approved adolescent classification exception receive offers for deceased donor lungs based on their calculated LAS. Candidates with a higher LAS receive higher waiting list priority within geography and blood type classifications.

10.1.E LAS Values and Clinical Data Update Schedule for Candidates at Least 12 Years Old

When registering a candidate who is at least 12 years old for a lung transplant, or when registering a candidate with an approved adolescent classification exception according to *Policy 10.2.B: Lung Candidates with Exceptional Cases*, transplant programs must report to the OPTN Contractor clinical data corresponding with to the covariates shown in *Table 10-3: Waiting List Mortality Calculation: Covariates and Their Coefficients* and *Table 10-4: Post-Transplant Survival Calculation, Covariates, and Their Coefficients*.

The data reported at the time of the candidate's registration on the lung transplant waiting list must be six months old or less from the date of the candidate's registration date. The transplant program must maintain source documentation for all laboratory values reported in the candidate's medical chart.

Except as noted in *Policy 10.1.G: Reporting Additional Data for Candidates with an LAS of 50 or Higher*, transplant programs must report to the OPTN Contractor LAS covariate clinical data for every covariate in *Table 10-3* and *Table 10-4* for each candidate at least once in every six month period after the date of the candidate's initial registration or the LRB's approval of an adolescent classification exception. The first six-month period begins six months from the date of the candidate's initial registration, or, in the case of adolescent classification exceptions, six months from the date of LRB approval, with a new six-month period occurring every six months thereafter.

A covariate's value expires if the covariate's test date is six-months older than the most recent six-month anniversary date. The LAS system considers actual values and approved estimated values for pulmonary pressures to be valid until the transplant program updates them with new actual values or new approved estimated values as described in *Policy 10.2.B.iii: Estimated Values Approved by the LRB*.

Transplant programs may report a medically reasonable estimated value if a test needed to obtain an actual value for a variable covariate cannot be performed due to the candidate's medical condition. Before entering estimated values, programs must receive approval from the LRB, which will determine whether the estimated values are appropriate according to *Policy 10.2.B.iii: Estimated Values Approved by the LRB*. Approved estimated values remain valid until an updated actual value is reported for the covariate, or until the transplant program reports a new, approved estimated value is reported.

LAS covariate data obtained by heart catheterization does not need to be reported to the OPTN Contractor every six months. For LAS covariate data that requires a heart catheterization, the transplant program may determine the frequency of updating the data. However, if a transplant program performs a heart catheterization test on the candidate during the six month interval, then it must report the data to the OPTN Contractor.

If values for certain covariates are missing, expired, or below the threshold as defined by *Table 10-1*, then the LAS calculation will substitute normal or least beneficial values to calculate the candidate's LAS. A normal value is one that a healthy individual is likely to exhibit. A least beneficial value is one that will calculate the lowest LAS for a candidate. *Table 10-1* lists the normal and least beneficial values that will be substituted.

Table 10-1: Values Substituted for Missing or Expired Actual Values in Calculating the LAS

If this covariate's value is missing, expired, or below the threshold value:	Then the LAS calculation will use this substituted value:
Bilirubin	0.7 mg/dL if the actual value is missing, expired, or less than 0.7 mg/dL
Body mass index (BMI)	100 kg/m ² if the actual value is missing or expired
Cardiac index	3.0 L/min/m ² if the actual value is missing
Central venous pressure (CVP)	5 mm Hg if the actual value is missing or less than 5 mm Hg
Continuous mechanical ventilation	No mechanical ventilation in the waiting list model if the actual value is missing or expired Continuous mechanical ventilation in the post-transplant survival measure if the actual value is missing or expired
Creatinine: serum	0.1 mg/dL in the waiting list model if the actual value is missing or expired 40 mg/dL in the post-transplant survival measure for candidates at least 18 years old if the actual value is missing or expired 0 mg/dL in the post-transplant survival measure for candidates less than 18 years old if the actual value is missing or expired
Diabetes	No diabetes if the actual value is missing or expired
Forced vital capacity (FVC)	150% for Diagnosis Group D if the actual value is missing or expired, according to <i>Policy 10.1.F.i: Lung Disease Diagnosis Groups</i>
Functional status	No assistance needed in the waiting list model if the actual value is missing or expired Some or total assistance needed in the post-transplant survival measure if the actual value is missing or expired
Oxygen needed at rest	No supplemental oxygen needed in the waiting list model if the actual value is missing or expired 26.33 L/min in the post-transplant survival measure if the actual value is missing or expired
PCO ₂	40 mm Hg if the actual value is missing, expired, or if less than 40 mm Hg
Pulmonary artery (PA) systolic pressure	20 mm Hg if the actual value is missing or less than 20 mm Hg
Six-minute-walk distance	4,000 feet in the waiting list urgency measure if the actual value is missing or expired 0 feet in the post-transplant survival measure if the actual value is missing or expired

10.2.B Lung Candidates with Exceptional Cases

The Thoracic Organ Transplantation Committee establishes guidelines for special case review by the LRB.

If a candidate's transplant program believes that a candidate's current priority or LAS does not appropriately reflect the candidate's medical urgency for transplant, the transplant program may request approval of a specific priority or LAS by the LRB. The transplant program can also ask the LRB to approve specific estimated values or diagnoses.

For lung candidates less than 12 years old, transplant programs may request classification as an adolescent candidate for the purposes of *Policy 10.4.C: Allocation of Lungs from Deceased Donors at Least 18 Years Old, and Policy 10.4.D: Allocation of Lungs from Deceased Donors 12 to Less Than 18 Years Old.* Candidates receiving this exception will also maintain their pediatric classification for the purposes of *Policy 10.4.E: Allocation of Lungs from Deceased Donors Less than 12 Years Old.*

10.2.B.i LRB Review Process

Requests for approval of estimated values, diagnoses, or specific LAS, or adolescent classification exceptions require prospective review by the LRB. The transplant hospital must submit requests for LRB review to the OPTN Contractor, and accompany each request for special review with a supporting narrative. The LRB will have seven days to reach a decision regarding the request, starting from the date that the OPTN Contractor sends the request to the LRB.

If the LRB denies a request upon initial review, then the transplant program may choose to appeal the decision and request reconsideration by the LRB. The transplant program has seven days from the date of the initial denial of the initial request to appeal. The LRB has seven days to reach a decision on the appeal, starting from the date that the OPTN Contractor sends the appealed request to the LRB. If the LRB does not complete its review of an initial request or appeal within seven days of receiving it, then the candidate will not receive the requested LAS, diagnosis, estimated value, or adolescent classification, and the OPTN Contractor will send the request or appeal to the Thoracic Organ Transplantation Committee for further review.

Requests to register a candidate less than 12 years old as priority 1 require retrospective LRB review by the LRB.

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

OPTN Bylaws Appendix L Corrections

Sponsoring Committee: Executive Committee

Bylaws Affected: Appendix L, Sections L.14 (Routine Reviews), L.15.E (Adverse Actions that Require Board Approval), L.15.F (Recommendations and Requests to the Secretary), L.17 (Interviews), and L.18 (Hearings).

Distributed for Public Comment: No

Effective Date: June 24, 2014

Problem Statement
During the substantive rewrite of Appendix L of the OPTN Bylaws, inadvertent changes were made that removed the notification requirements for members receiving the adverse action of Probation. This change corrects that inadvertent omission and related additional changes improve the members' understanding of their due process rights.

Changes
Bylaws, Appendix L, Sections L.14 (Routine Reviews), L.15.E (Adverse Actions that Require Board Approval), L.15.F (Recommendations and Requests to the Secretary), L.17 (Interviews), and L.18 (Hearings). These changes restore the notification requirements for members receiving the adverse action of Probation.

Member Actions
No action is necessary as this simply restores the requirement that was already in place. Members should ensure that they are using the most recent version of the OPTN Bylaws as posted here.

Affected Policy/Bylaw Language:

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

Appendix L: Reviews, Actions, and Due Process

L.14. Routine Reviews

A Routine Review will be conducted for any potential violation of OPTN Obligations when an Expedited Review or an Imminent Threat Review is not warranted.

A. Routine Review Investigations

The OPTN will complete a routine review investigation of the matter and refer it to the Routine Review Committee within 6 months.

B. Routine Review Committee

The Routine Review Committee will be composed of any standing subcommittee of the MPSC or, at the discretion of the MPSC Chair, the entire MPSC. The

Routine Review Committee may meet by teleconference or electronic media, as needed, for the purpose of considering any new and ongoing potential policy violations.

1. Notice after Routine Review Committee's Determinations

The Routine Review Committee will notify the member of its determination and any recommendation for a specific action. If the Committee recommends an action that would entitle the member to an interview, members will be notified of their right to an interview at the time they are informed of the Committee's determination.

C. Interviews in Routine Reviews

The member will be entitled to an interview when the Routine Review Committee is considering making a recommendation for a Letter of Reprimand or an adverse action. Interviews will be scheduled at the next in-person meeting of the MPSC or standing subcommittee of the MPSC.

1. Requesting an Interview

The member has 14 days to request an interview as described in *Section L.17.B. Requesting or Waiving the Right to an Interview* following notice of the Routine Review Committee's determination. ~~If the member waives its rights to an interview, the MPSC may proceed to issue its recommendation for an adverse action or Letter of Reprimand.~~

L.15. OPTN Determinations and Actions

E. Adverse Actions that Require Board Approval

The adverse actions of Probation and Member Not in Good Standing can only be imposed by the Board of Directors. If a member receives an adverse action, the Executive Director will give notice to the public of the adverse action as specified by the Board of Directors. This notice may include, but is not limited to, communication using the OPTN website.

1. Probation

The MPSC may recommend that the Board of Directors place a member on Probation, or the Board may do so on its own. Probation is an adverse action under these Bylaws, and the OPTN Executive Director will give notice to all members when a member is placed on Probation.

a) Corrective Action Requirements of Probation

The adverse action of Probation will require that the member adheres to corrective action requirements as specified by the MPSC, which may include, but are not limited to:

- i. Required development and submission of a corrective action plan or plan for quality improvement as specified by the MPSC, any standing subcommittee of the MPSC, the Executive Committee, or the Board of Directors. The member must demonstrate that it has adhered to the plan and that it has corrected any noncompliant activity within the Probation effective period.

- ii. Unscheduled on-site reviews by the OPTN Contractor staff or peer review teams throughout the Probation period.
- iii. Specified submission of reports, data, or other evidence to the OPTN that documents correction of the non-compliant activity throughout the period of Probation.

b) Notification Requirements of Probation

The adverse action of Probation will require that the member provide notice of the adverse action as follows:

<u>If the member is a...</u>	<u>Then notice must be provided to ...</u>
<u>Transplant hospital</u>	<u>All patients, as defined in these Bylaws, of the designated transplant program receiving the adverse action, including any new transplant program patients, during the entire effective period of the adverse action.</u>
<u>OPO</u>	<u>All hospitals that have a contractual agreement with the OPO in the OPO's Donation Service Area (DSA).</u>
<u>Histocompatibility laboratory</u>	<u>All members that have a contractual agreement with the laboratory.</u>

Members must provide notices as described above within 30 days of receiving notification from the OPTN that it has been given the adverse action of Probation. The notice to transplant program patients must be provided in writing, in each patient's spoken language, and as specified by the Executive Committee or Board of Directors.

2. Member Not in Good Standing

The MPSC may recommend that the Board of Directors declare the member to be a Member Not in Good Standing, or the Board of Directors may do so on its own. Member Not in Good Standing is an adverse action under these Bylaws.

a) Results of Member Not in Good Standing

The adverse action of Member Not in Good Standing will include:

- i. a) Formal Notice to the Secretary of HHS.
- ii. b) Loss of member voting privileges in OPTN affairs.
- iii. c) Loss of the privilege of any personnel associated with the member to serve on any Committee or the Board of Directors, or to hold office.
- iv. d) Formal notification, along with any subsequent changes in status, to the entire OPTN membership.
- v. e) Formal notification, along with any subsequent changes in status, to the member's Chief Executive Officer or Administrator.
- vi. f) Formal notification, along with any subsequent changes in status, to the state health commissioner or other appropriate state representative with oversight of health care institutions doing business in the member's state.
- vii. g) Any actions that can be taken under Probation.

3.b) Notification Requirements of Probation and Member Not in Good Standing

A member receiving the adverse action of Member Not in Good Standing must provide notice of the adverse action as follows:

If the member is a...	Then notice must be provided to ...
Transplant hospital	All transplant hospital patients as defined in these Bylaws, <u>including any new transplant hospital patients, during the entire effective period of the adverse action.</u>
OPO	All hospitals that have a contractual agreement with the OPO in the OPO's Donation Service Area (DSA).
Histocompatibility laboratory	All members that have a contractual agreement with the laboratory.

Members must provide notices as described above within 30 days of receiving notification from the OPTN that it has been given the adverse action of Member Not in Good Standing. ~~The member must send the notice to each new transplant hospital patient as defined in these Bylaws during the entire effective period of the adverse action.~~ The notice to transplant hospital patients must be provided in writing, in each patient's spoken language, and as specified by the Executive Committee or Board of Directors.

~~The Board may impose additional notification requirements regarding the form and timing.~~

F. Recommendations and Requests to the Secretary

The OPTN Board of Directors will advise the Secretary of the results of any ongoing or periodic reviews and evaluations, or Secretarial-directed reviews, of member OPOs and transplant hospitals which, in the opinion of the Board of Directors, indicate noncompliance with OPTN Obligations or indicate a risk to the health of patients or to the public safety, and will provide any recommendations for appropriate action by the Secretary. Appropriate actions, include, but are not limited to those described in the OPTN final rule, as described in *Section L.16* that follows.

At any time, the Board may make recommendations to the Secretary for specific actions, on its own or after receiving a recommendation from the MPSC.

L.17. Interviews

An interview is not a hearing, is preliminary in nature, and is not conducted according to the procedural rules followed for hearings. The member will be informed of the reasons for the interview and may present any information it considers useful and relevant.

A. Members' Right to an Interview

The member will have the right to an interview when:

1. A Letter of Reprimand is recommended.
2. An adverse action is recommended.
3. A membership application or application for designated transplant program status is rejected.

However, a member has no right to an interview when a potential violation is being reviewed through the Imminent Threat Review pathway. After the interview is completed, the MPSC will promptly provide a summary of the interview to the member.

B. Requesting or Waiving the Right to an Interview

~~A member who fails to request an interview within the specified time waives any right to an interview.~~ The member must submit its written interview request to the Executive Director using one of the approved methods described in *L.4. Methods for Correspondence and Providing Notice*.

A member may waive its right to an interview in writing. In addition, a member who fails to request an interview within the specified time waives any right to an interview. Waiver of the right to an interview means that:

1. If the recommended action is a non-adverse action, the action will be issued.
2. If the recommended action is an adverse action, the member is entitled to a hearing.

L.18. Hearings

If the MPSC makes a recommendation for an adverse action, or the Board of Directors takes an adverse action without recommendation from the MPSC, the member is entitled to a hearing.

A. Members' Right to a Hearing

The member has a right to a hearing when an adverse action is:

1. Recommended by the MPSC.
2. Recommended by a subcommittee of the MPSC, if the action is the rejection of an initial membership application or application for designated transplant program status.
3. A result of a determination regarding a potential violation undergoing an Imminent Threat Review.
4. Taken by the Board of Directors or the Executive Committee notwithstanding a favorable recommendation by the MPSC or standing subcommittee of the MPSC under circumstances where no right to a hearing existed.
5. Taken by the Board of Directors or the Executive Committee on its own without a prior recommendation by the MPSC.

If the Board of Directors determines, based on available evidence that a potential violation of OPTN Obligations may pose an urgent and severe risk to patient health or public safety, the Board may take action even if the member has not had the opportunity for a hearing.

B. Requesting or Waiving the Right to a Hearing

The member must submit its written hearing request to the OPTN using one of the approved methods described in *L.4. Methods for Correspondence and Providing Notice*. ~~A member who fails to request a hearing within the specified time waives any right to a hearing.~~

~~If the member will be represented by an attorney at the hearing, the request for a hearing must identify by name the attorney who will represent the member, and include the attorney's business address and contact information.~~

A member may waive its right to a hearing in writing. In addition, a member who fails to request a hearing within the specified time waives any right to a hearing. The failure to request a hearing Waiver of the right to a hearing means that the member accepts the adverse action or recommendation and the following outcomes will apply:

1. An adverse recommendation by the MPSC or the Executive Committee will become effective after the final decision of the Board of Directors.
2. An adverse action by the Board of Directors will become effective and considered the final decision by the Board.

If the member will be represented by an attorney at the hearing, the request for a hearing must identify by name the attorney who will represent the member, and include the attorney's business address and contact information.

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

To read the complete OPTN Bylaws language visit optn.transplant.hrsa.gov, select the "Policy Management" tab, then select "OPTN Bylaws." To read the complete UNOS Bylaws language visit www.unos.org, click on the "ABOUT US" box at the top of the screen, and then, in the left margin under "Governance," select "Bylaws."