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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 November Board of Directors Meeting

Date: December 12, 2014

The attached report summarizes changes to the OPTN Policies and Bylaws approved by the OPTN/UNOS Board of Directors at its November 2014 meeting. 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 http://optn.transplant.hrsa.gov/governance/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 http://optn.transplant.hrsa.gov/governance/compliance/optn-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.

Aligning OPTN Policies with the 2013 PHS Guideline for Reducing Transmission of HIV, HBV, and HCV through Solid Organ Transplantation

Sponsoring Committee:	**Ad Hoc Disease Transmission Advisory Committee (DTAC)**
Policies Affected:	**2.2: OPO Responsibilities; 2.4: Deceased Donor Medical and Behavioral History; 2.7: HIV Screening of Potential Deceased Donors; 2.9: Required Deceased Donor Information; 14.4.B: Living Kidney Donor Medical Evaluation Requirements; 15.3: Informed Consent of Transmissible Disease Risk; 15.3.A: Deceased Donors with Additional Risk Identified Pre-transplant; 15.3.B: Deceased Donors at Increased Risk for Blood-borne Pathogens; 16.7B: Vessel Storage**
Distributed for Public Comment:	**March 2014**
Amended After Public Comment:	**Yes**
Effective Date:	**February 1, 2015 (NAT requirements upon implementation and notice to members)**

Problem Statement

The Final Rule §121.4 (OPTN policies: Secretarial review and appeals.) notes that the OPTN Board of Directors must develop policies that are consistent with Centers for Disease Control and Prevention (CDC) recommendations to test potential organ donors and subsequent transplant recipients to prevent the spread of infectious disease. When the *PHS Guideline for Reducing Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) Through Organ Transplantation* was released, the OPTN began updating its policies to be consistent with the new recommendations.

Summary of Changes

If you're an OPO, you'll need to:

- Store donor samples appropriate for serology and nucleic acid testing (NAT), as available, for ten years
- Coordinate with donor testing laboratories to ensure that HIV NAT or HIV combination antigen/antibody (Ag/Ab) testing and HCV NAT are available, in addition to required screening tests, as part of standard donor testing orders
- Identify donors whose medical-social evaluation information cannot be obtained as having increased risk for the transmission of HIV, HBV, and HCV, and communicate this information to all transplant programs receiving organs from the donor.
- Complete HCV NAT for all donors (in addition to already required antibody screening)

- Complete HIV NAT or combination Ag/Ab testing (in addition to required screening test) for donors you identify as being at increased risk for HIV, HBV, and HCV transmission according to the U.S. Public Health (PHS) Service Guideline. (This does not apply to donors whose only increased risk factor is receiving hemodialysis within the preceding 12 months, as they are at risk only for HCV according to the *U.S. Public Health Services (PHS) Guideline*.)

If you're a living donor recovery hospital, you'll need to:
- Complete HCV NAT for all donors (in addition to already required antibody screening)
- Complete HIV NAT or combination Ag/Ab testing (in addition to required screening test) for donors you identify as being at increased risk for HIV, HBV, and HCV transmission according to the U.S. Public Health (PHS) Service Guideline. (This does not apply to donors whose only increased risk factor is receiving hemodialysis within the preceding 12 months, as they are at risk only for HCV according to the *U.S. Public Health Services (PHS) Guideline*.)
- Complete all testing for HIV, HBV, and HCV testing as close as possible, but within 28 days before organ recovery

If you're a transplant hospitals you'll need to:
- Obtain specific informed consent before you transplant any organ from a donor that meets any of the criteria for increased risk of transmitting HIV, HBV, and HCV as specified in the *U.S. Public Health Services (PHS) Guideline*.
- Develop and implement a written protocol for post-transplant testing of recipients of any organ from a donor that meets any of the criteria for increased risk of transmitting HIV, HBV, and HCV as specified in the *U.S. Public Health Services (PHS) Guideline*.
- Discard HCV Ab or NAT positive and Hepatitis B surface Ag or NAT positive vessels that are not used in the organ transplant from the same donor. Do not store them for later use.

What Members Need to Do

OPOs, living donor recovery hospitals, and transplant hospitals all need to familiarize themselves with these policy changes.

OPOs will need to do the following:
- Coordinate with donor testing laboratories to ensure that these HIV and HCV NAT are available prior to the implementation of NAT requirements.
- Prepare for ten year storage of donor samples appropriate for both serology and NAT
- Update internal procedures related to collecting donor testing and medical-social history and train staff regarding changes to policy in this area

Living donor recovery hospitals will need to do the following:
- Familiarize themselves with these policy changes
- Coordinate with donor testing laboratories to ensure that these HIV and HCV NAT are available prior to the implementation of NAT requirements.
- Update internal procedures to require completion of all testing for HIV, HBV, and HCV testing as close as possible, but within 28 days prior to organ recovery
- Train staff regarding updates to these policies

Transplant hospitals will need to do the following
- Update their internal policies and train staff regarding:
    1. Obtaining specific informed consent before transplanting any organ from a donor that meets any of the criteria for increased risk of transmitting HIV, HBV, and HCV as specified in the *U.S. Public Health Services (PHS) Guideline*.
    2. Developing and implementing a written protocol for post-transplant testing of recipients of any organ from a donor that meets any of the criteria for increased risk of transmitting HIV, HBV, and HCV as specified in the *U.S. Public Health Services (PHS) Guideline*.

3. Discarding HCV Ab or NAT positive and Hepatitis B surface Ag or NAT positive vessels that are not used in the organ transplant from the same donor. Do not store them for later use.

Affected Policy/Bylaw Language:

New language is underlined and language that will be deleted is ~~struck through~~.

Policy 2: Deceased Donor Organ Procurement

2.2 OPO Responsibilities

The host OPO is also 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 blood specimens appropriate for serologic and nucleic acid testing (NAT), as available, ~~serum sample~~ for each deceased donor for at least 10 years after the date of organ transplant, and ensuring these ~~serum~~ samples ~~is~~ are 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.

2.4 Deceased Donor Medical and Behavioral History

The medical and behavioral history for each potential deceased donor must include *all* of the following:

1. Any testing and laboratory results used to identify the presence of transmissible diseases or malignancies, treated and untreated, or any other known condition that may be transmitted by the deceased donor organ and may reasonably impact the recipient.
2. Whether the potential deceased donor has factors associated with an increased risk for disease transmission, including blood-borne pathogens ~~HIV, Hepatitis B, and Hepatitis C.~~ If the deceased donor meets the criteria for increased risk for ~~disease~~ HIV, Hepatitis B, and Hepatitis C transmission set forth in the *U.S. Public Health Services (PHS) Guideline* or the host OPO cannot obtain the

information necessary to make this determination, the host OPO must identify the donor as having increased risk for transmission of HIV, Hepatitis B, and Hepatitis C *and* communicate this information to all transplant programs receiving organs from the deceased donor.

3. Whether the potential deceased donor has a history of prior exposure or treatment with non recombinant Human Pituitary Derived Growth Hormone (HPDGH). If so, the potential deceased donor has an increased risk of prion disease and the host OPO must communicate this information to all transplant programs receiving organs from the donor.

2.7.B Informing Personnel

The host OPO ~~should~~must inform health care personnel caring for potential deceased donors or deceased donors who test positive for HIV only when it is necessary for making medical decisions.

2.9 Required Deceased Donor Infectious Disease Testing

The host OPO is responsible for ensuring that all of the following infectious disease testing is completed in CLIA-certified laboratories, or in laboratories meeting equivalent requirements as determined by the Centers for Medicare and Medicaid Services (CMS):

1. Blood and urine cultures

2. Infectious disease testing for all potential deceased organ donors using FDA licensed, approved or cleared tests, as listed below:

   a. HIV antibody (anti-HIV) donor screening test *or* HIV antigen/antibody (Ag/Ab) combination test
   b. Hepatitis B surface antigen (HBsAg) ~~*and* Hepatitis B core antibody (anti-HBc)~~ donor screening test~~s~~
   c. Hepatitis B core antibody (anti-HBc) donor screening test
   ~~c.~~d. Hepatitis C antibody donor screening test (anti-HCV)
   e. Hepatitis C ribonucleic acid (RNA) by donor screening or diagnostic nucleic acid test (NAT)
   ~~d.~~f. Cytomegalovirus (CMV) antibody (anti-CMV) donor screening *or* diagnostic test
   ~~e.~~g. Epstein-Barr Virus (EBV) antibody (anti-EBV) donor screening *or* diagnostic test
   ~~f.~~ h. Syphilis donor screening *or* diagnostic test

   If a deceased donor is identified as being at increased risk for HIV, HBV, and HCV transmission according to *the U.S. Public Health Services (PHS) Guideline*, testing must also include HIV ribonucleic acid (RNA) by donor screening or diagnostic NAT or HIV antigen/antibody (Ag/Ab) combination test. This does not apply to donors whose only increased risk factor is receiving hemodialysis within the preceding 12 months, as they are at risk only for HCV according to the *U.S. Public Health Services (PHS) Guideline*.

Additionally, if, for any reason, HIV, HBV, or HCV testing is not performed as described above in #2, the host OPO must:

1. Document in the donor record which test was used to assess the potential donor
2. Provide this information to the receiving transplant hospital before transplant
3. Report the reason for using another test to the OPTN Improving Patient Safety portal as soon as possible, but no later than 24 hours after organ recovery.

Policy 14: Living Donation

14.4.B Living Kidney Donor Medical Evaluation Requirements

A medical evaluation of the potential living kidney donor must be performed by the recovery hospital and by a physician or surgeon experienced in living donation. The goals of the medical evaluation are *all* of the following:

1. To assess the immunologic compatibility of the living donor to the recipient
2. To assess the general health and surgical risk of donation to the living donor including screening for conditions that may predict future complications from having only one kidney
3. To determine if there are diseases present that may be transmitted from the living donor to the recipient
4. To assess the anatomy and function of the living donor's kidneys

Documentation of the medical evaluation must be maintained in the donor medical record.

The medical evaluation must include *all* of the components in *Table 14-2* below.

Table 14-2: Requirements for Living Kidney Donor Medical Evaluations

This evaluation must be completed:	Including evaluation for and assessment of this information:
A general living donor history	1. A personal history of significant medical conditions which include but are not limited to: a. Hypertension b. Diabetes c. Lung disease d. Heart disease e. Gastrointestinal disease f. Autoimmune disease g. Neurologic disease h. Genitourinary disease i. Hematologic disorders j. Bleeding or clotting disorders k. History of cancer 2. History of infections 3. A kidney-specific personal history including: a. Genetic renal diseases b. Kidney disease, proteinuria, hematuria c. Kidney injury d. Diabetes including gestational diabetes e. Nephrolithiasis f. Recurrent urinary tract infections 4. Active and past medications with special consideration for known nephrotoxic medications 5. Allergies 6. An evaluation for coronary artery disease
General family history	The living donor's family history of coronary heart disease and cancer

This evaluation must be completed:	Including evaluation for and assessment of this information:
Kidney-specific family history	The living donor's family history of: • Kidney disease • Diabetes • Hypertension • Kidney Cancer
Social history	The living donor's history of: • Occupation, employment status, health insurance status, living arrangements, and social support • Smoking, alcohol and drug use and abuse • Criteria to assess increased risk for disease transmission as defined by the U.S. Public Health Services (PHS) Guideline • Psychiatric illness, depression, suicide attempts
Physical Exam	A physical exam of the living donor including: • Height • Weight • BMI • Examination of all major organ systems • Blood pressure taken on at least two different occasions or 24-hour or overnight blood pressure monitoring
General laboratory and imaging tests	• Complete blood count (CBC) with platelet count • Blood type and screen • Prothrombin Time (PT) or International Normalized Ratio (INR) • Partial Thromboplastin Time (PTT) • Metabolic testing (to include electrolytes, BUN, creatinine, transaminase levels, albumin, calcium, phosphorus, alkaline phosphatase, bilirubin) • HCG quantitative pregnancy test for premenopausal women without surgical sterilization • Chest X-Ray • Electrocardiogram (ECG)
Other metabolic testing	• Fasting blood glucose • Fasting lipid profile (cholesterol, triglycerides, HDL cholesterol, and LDL cholesterol) • Glucose tolerance test or glycosylated hemoglobin in first degree relatives of diabetics and in high risk individuals

This evaluation must be completed:	Including evaluation for and assessment of this information:

Kidney-specific tests	• Urinalysis or urine microscopy
	• Urine culture if clinically indicated
	• Measurement of urinary protein and albumin excretion
	• Measurement of glomerular filtration rate by isotopic methods or a creatinine clearance calculated from a 24-hour urine collection
	• Hospitals must develop and comply with a protocol for polycystic kidney disease or other inherited renal disease as indicated by family history
	• Patients with a history of nephrolithiasis or nephrolithiasis (>3mm) identified on radiographic imaging must have a 24-hour urine stone panel measuring:
	  ○ Calcium
	  ○ Oxalate
	  ○ Uric acid
	  ○ Citric acid
	  ○ Creatinine
	  ○ Sodium

Anatomic assessment	An assessment to determine: • Whether the kidneys are of equal size • If the kidneys have masses, cysts, or stones • If the kidneys have other anatomical defects • Which kidney is more anatomically suited for transplant. The choice of test for radiologic imaging may be determined based on the local radiological expertise and surgical preference, and may include CT angiogram or MR angiogram.

This evaluation must be completed:	Including evaluation for and assessment of this information:
Transmissible disease screening	Infectious disease testing must be performed in a CLIA-certified laboratory or in a laboratory meeting equivalent requirements as determined by Centers for Medicare and Medicaid Services (CMS) using FDA-licensed, approved, or cleared tests. Testing must include *all* the following: 1. CMV (Cytomegalovirus) antibody 2. EBV (Epstein Barr Virus) antibody 3. HIV ~~1,2 (Human Immunodeficiency Virus)~~ antibody (anti-HIV) testing *or* HIV antigen/antibody (Ag/Ab) combination test as close as possible, but within 28 days prior to organ recovery 4. ~~HepBsAg (~~Hepatitis B surface antigen (HBsAg) testing as close as possible, but within 28 days prior to organ recovery 5. ~~HepBcAB (~~Hepatitis B core antibody (anti-HBc) testing as close as possible, but within 28 days prior to organ recovery ~~6. HepBsAB (Hepatitis B surface antibody)~~ 6. ~~7. HCV (~~Hepatitis C ~~Virus)~~ antibody (anti-HCV) testing as close as possible, but within 28 days prior to organ recovery 7. HCV ribonucleic acid (RNA) by nucleic acid test (NAT) as close as possible, but within 28 days prior to organ recovery 8. ~~RPR (Rapid Plasma Reagin test for syphilis~~) Syphilis testing If a living donor is identified as being at increased risk for HIV, HBV, and HCV transmission according to the *U.S. Public Health Services (PHS) Guideline*, testing must also include HIV ribonucleic acid (RNA) by NAT or HIV antigen/antibody (Ag/Ab) combination test. This does not apply to donors whose only increased risk factor is receiving hemodialysis within the preceding 12 months, as they are at risk only for HCV according to the *U.S. Public Health Services (PHS) Guideline.* For tuberculosis (TB), ~~L~~living donor recovery hospitals must determine if the ~~potential~~ donor is at increased risk for ~~tuberculosis (TB)~~ this infection.~~and~~ ~~I~~If ~~so~~TB risk is suspected, testing must include screening for latent infection ~~TB~~ using *either*: • Intradermal PPD ~~or~~ • Interferon Gamma Release Assay (IGRA).
Endemic transmissible diseases	For the following infectious diseases, recovery hospitals must determine if the potential donor is from an endemic area, and if so must test for: • Strongyloides • Trypanosoma cruzi • West Nile

This evaluation must be completed:	Including evaluation for and assessment of this information:
Cancer screening	Recovery hospitals must develop and comply with protocols consistent with the American Cancer Society (ACS) to screen for: • Cervical cancer • Breast cancer • Prostate cancer • Colon cancer • Skin cancer • Lung cancer
Exclusion criteria	Kidney recovery hospitals may exclude a donor with any condition that, in the hospital's medical judgment, causes the donor to be unsuitable for organ donation. Kidney recovery hospitals must exclude all donors who meet *any* of the following exclusion criteria: • Is both less than 18 years old and mentally incapable of making an informed decision • Uncontrollable hypertension or history of hypertension with evidence of end stage organ damage • HIV • Diabetes • Active malignancy, or incompletely treated malignancy • High suspicion of donor coercion • High suspicion of illegal financial exchange between donor and recipient • Evidence of acute symptomatic infection (until resolved) • Diagnosable psychiatric conditions requiring treatment before donation, including any evidence of suicidality

Policy 15: Identification of Transmissible Diseases

15.3 Informed Consent of Transmissible Disease Risk

Transplant programs must obtain specific informed consent before transplant of any organ when~~, in the transplant program's medical judgment,~~ *any* of the following occurs:

- The ~~deceased~~ donor has a known medical condition that may, in the transplant hospital's medical judgment, be transmissible to the recipient, with the exception of HIV, which must be handled according to *Policy 2.7: HIV Screening of Potential Deceased Donors* or exclusionary criteria in *Table 14-2 (Requirements for Living Donor Kidney Medical Evaluations)*.
- The ~~deceased~~ donor meets any of the ~~guidelines~~ criteria for ~~an~~ increased risk of ~~transmissible disease~~ transmitting HIV, hepatitis B, and hepatitis C as specified in the *U.S. Public Health Services (PHS) Guideline.*
- When a hemodiluted specimen is used for ~~deceased~~ donor HIV, hepatitis B, or hepatitis C screening, according to *Policy 2.5: Hemodilution Assessment*.

Transplant programs must also inform potential candidates of the general risks of potential transmission of malignancies and disease from organ donors, including *all* of the following information:

1. Deceased donors are evaluated and screened as outlined in *Policy 2.3: Evaluating and Screening Potential Deceased Donors*.
2. Living donors are ~~only~~ required to undergo screening for the diseases listed in *Policy 14.4: Medical Evaluation Requirements for Living Donors*.
3. That there is no comprehensive way to screen ~~potential~~ deceased and living donors for all transmissible diseases.
4. That transmissible diseases and malignancies may be identified after transplant.

The transplant program must do *both* of the following:

1. Explain these risks and obtain informed consent from the potential candidate or candidate's agent before transplant.
2. Document consent in the potential candidate's medical record.

15.3.A ~~Deceased~~ Donors with Additional Risk Identified Pre-transplant

If additional ~~deceased~~ donor disease or malignancy transmission risk is identified pre-transplant, the transplant program must do *all* of the following:

1. Explain the risks and obtain informed consent from the potential transplant recipient or the potential recipient's agent before transplant.
2. Document this consent in the potential recipient's medical record.
3. Follow any recipient of the deceased or living donor organs for the development of potential donor-derived disease after transplantation.

15.3.B ~~Deceased~~ Donors at Increased Risk for Transmission of Blood-borne Pathogens

If a ~~deceased~~ donor is found to have an increased risk for transmitting blood borne pathogens, the transplant program must offer recipients of the donor organs *all* of the following in addition to routine post-transplant care:

1. Additional post-transplant testing for HIV, hepatitis C, and hepatitis B as appropriate based on the recipient's pre-transplant status. Every transplant hospital must develop and implement a written protocol for post-transplant testing for these diseases.
2. Treatment of or prophylaxis for the transmissible disease, when available.
~~3. Routine post-transplant follow up care.~~

Policy 16: Organ and Vessel Packaging, Labeling, Shipping, and Storage

16.7 Vessel Recovery, Transplant, and Storage

16.7.B Vessel Storage

Transplant hospitals may not store for later use any extra vessels from donors who are hepatitis C antibody positive (HCV), hepatitis C (HCV) nucleic acid test (NAT) positive, ~~or~~ hepatitis B surface antigen positive (HBsAg), or hepatitis B (HBV) NAT positive ~~extra vessels~~.

If the transplant hospital stores vessels and later uses the vessels for the intended recipient or another recipient, it must notify the OPTN Contractor.

The Transplant hospital must designate a person to do *all* of the following:

1. Monitor and maintain all records relating to the use and management of vessels
2. Monitor the refrigerator where the vessels are stored

3. Destroy expired vessels
4. Report the vessel's use or disposal to the OPTN Contractor within seven days of the transplant hospital's use or disposal of the vessels.

Additionally, the transplant hospitals must do *all* of the following:

1. Store vessels in a Food and Drug Administration (FDA) approved preservation solution
2. Package and label vessels as required by *Policy 16.4: Packaging and Labeling*
3. Store vessels in a secured refrigerator with a temperature monitor and maintain the temperature no colder than 2 degrees Celsius and no warmer than 8 degrees Celsius
4. Monitor vessels daily with documented security and temperature checks
5. Destroy unused vessels within 14 days after the recovery date
6. Maintain a log of stored vessels
7. Have accessible at all times the vessel deceased donor information for the transplant surgeon prior to using the vessels in any recipient other than the originally intended recipient

Expanding HLA Typing Requirements

Sponsoring Committee:	**Histocompatibility Committee**
Policy/Bylaws Affected:	**Policy 2.11.A: Required Information for Deceased Kidney Donors; 2.11.B: Required Information for Deceased Liver Donors; 2.11.C: Required Information for Deceased Heart Donors; 2.11.D: Required Information for Deceased Lung Donors; 2.11.E: Required Information for Deceased Pancreas Donors; 3.4.D: Candidate Human Leukocyte Antigen (HLA Information); 4.2: Requirements for Performing and Reporting HLA Typing**
Distributed for Public Comment:	**March 2014**
Amended After Public Comment:	**No**
Effective Date:	**Upon implementation and notice to members**

Problem Statement

OPTN policies were inconsistent in reporting requirements of HLA loci for deceased donors across organ types. Transplant teams needed complete deceased donor HLA typing to make decisions about organ acceptance and post-transplant monitoring.

Inconsistencies existed with the method of HLA typing required for different organ types. Molecular HLA typing provides the highest level of accuracy, but was only required for deceased kidney, kidney-pancreas, and pancreas donors.

Antibodies to HLA-DQA and –DPB are frequently observed in sensitized candidates; however, policy did not require OPOs or transplant hospitals to report this information for deceased donors and no fields existed in DonorNet® or Waitlist®. Furthermore, missing HLA information may contribute to unexpected positive crossmatches for kidneys shared regionally and nationally in the new kidney allocation system.

The Histocompatibility Committee also identified inconsistences in HLA information required for pancreas islet donors and candidates compared to those for pancreas donors and candidates. Research suggests that anti-HLA antibodies can contribute to negative outcomes in pancreas islet transplants and HLA typing can be crucial for evaluating risk from pre and post-transplant HLA antibodies; however, no HLA typing requirements existed for deceased pancreas islet donors or candidates.

Summary of Changes

The approved changes make the HLA typing methods and list of HLA loci reported consistent for deceased donors across all organ types. The required methods and list of HLA loci reported will apply both when OPTN policy requires HLA typing to be performed and reported on the deceased donors before organs (kidney, kidney-pancreas, and pancreas allocation) are allocated and in instances where HLA typing is required only if the candidate's transplant program requests it (heart, heart-lung, and lung

allocation). The policy includes new requirements for reporting HLA-DQA and HLA–DPB for deceased donors. As approved, HLA-DQA and HLA-DPB will be programmed into DonorNet® for physicians to use in making donor acceptance decisions and in Waitlist® as unacceptable antigens to automatically avoid those donors if these unacceptable antigens are listed. The period for reporting deceased donor HLA typing remains different by organ type to meet varying clinical requirements for timing of transplants. The proposal newly requires HLA typing to be performed and reported for deceased liver donors if the transplant program requests it and makes HLA typing requirements for deceased pancreas islet donors and candidates consistent with those for deceased pancreas donors and candidates.

What Members Need to Do

Histocompatibility laboratories that perform HLA typing on a deceased donor must use molecular typing methods.

Organ procurement organizations (OPOs) must enter information on DQA and DPB before making kidney, kidney-pancreas, or pancreas offers.

OPOs must provide the full list of HLA loci on deceased donors (timeframes vary based on organ type).

Thoracic and liver programs must communicate and document requests for donor HLA information.

Affected Policy/Bylaw Language:

New language is underlined and language that will be deleted is ~~struck through~~.

2.11.A Required Information for Deceased Kidney Donors

The host OPO must provide *all* the following additional information for all deceased donor kidney offers:

1. Date of admission for the current hospitalization
2. Donor name
3. Donor ID
4. Ethnicity
5. Relevant past medical or social history
6. Current history of abdominal injuries and operations
7. Current history of average blood pressure, hypotensive episodes, average urine output, and oliguria
8. Current medication and transfusion history
9. Anatomical description, including number of blood vessels, ureters, and approximate length of each
10. Human leukocyte antigen (HLA) information as follows: A, B, Bw4, Bw6, C, DR51, DR52, DR53, DQA, ~~and~~ DQB, and DPB antigens prior to organ offers. ~~The lab is encouraged to report splits for all loci as outlined in *Policy 4: Histocompatibility*~~.
11. Indications of sepsis
12. Injuries to or abnormalities of the blood
13. Assurance that final blood and urine cultures are pending
14. Final urinalysis
15. Final blood urea nitrogen (BUN) and creatinine
16. Recovery blood pressure and urine output information
17. Recovery medications
18. Type of recovery procedure, flush solution and method, and flush storage solution
19. Warm ischemia time and organ flush characteristics

2.11.B Required Information for Deceased Liver Donors

The host OPO must provide *all* the following additional information for all deceased donor liver offers:

1. Donor name
2. Donor ID
3. Ethnicity

4. Height
5. Weight
6. Vital signs, including blood pressure, heart rate and temperature
7. Social history, including drug use
8. History of treatment in hospital including current medications, vasopressors, and hydration
9. Current history of hypotensive episodes, urine output, and oliguria
10. Indications of sepsis
11. Aspartate aminotransferase (AST)
12. Bilirubin (direct)
13. Other laboratory tests within the past 12 hours including:
    a. Alanine aminotransferase (ALT)
    b. Alkaline phosphatase
    c. Total bilirubin
    d. Creatinine
    e. Hemoglobin (hgb) and hemocrit (hct)
    f. International normalized ration (INR) or Prothrombin (PT) if INR is not available, and partial thromboplastin time (PTT)
    g. White blood cell count (WBC)
14. Human leukocyte antigen (HLA) typing if requested by the transplant hospital, including A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA,DQB, and DPB antigens in the timeframe specified by the transplant program

If a transplant program requests HLA typing for a deceased liver donor, it must communicate this request to the OPO and the OPO must provide the HLA information listed above. The transplant program must document requests for donor HLA typing, including the turnaround time specified for reporting the donor HLA typing results. The OPO must document HLA typing provided to the requesting transplant program.

2.11.C Required Information for Deceased Heart Donors

The host OPO must provide *all* the following additional information for all deceased donor heart offers:

1. Height
2. Weight
3. Vital signs, including blood pressure, heart rate, and temperature
4. History of treatment in hospital including vasopressors and hydration
5. Cardiopulmonary, social, and drug activity histories
6. Details of any documented cardiac arrest or hypotensive episodes
7. 12-lead interpreted electrocardiogram
8. Arterial blood gas results and ventilator settings
9. Cardiology consult or echocardiogram, if the hospital has the facilities
10. Human leukocyte antigen (HLA) typing if requested by the transplant hospital, including A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA, ~~and~~ DQB, and DPB antigens prior to final organ acceptance
11. Toxoplasma antibody (Ab) test result or an appropriate donor sample sent with the heart for testing at the transplant hospital

For heart deceased donors, if a transplant ~~hospital~~ program requires donor HLA typing prior to submitting a final organ acceptance, it must communicate this request to the OPO and document the request. The OPO must provide the HLA information ~~required in the~~ listed above and document that the information was provided to the transplant program. ~~The transplant hospital may request HLA-DPB typing, but the OPO need only provide it if its affiliated laboratory performs related testing.~~

The heart recovery team must have the opportunity to speak directly with the responsible ICU personnel or the onsite donor coordinator in order to obtain current information about the deceased donor's physiology.

2.11.D Required Information for Deceased Lung Donors

The host OPO must provide *all* the following additional information for all deceased lung donor offers:

1. Height
2. Weight
3. Vital signs, including blood pressure, heart rate, and temperature
4. History of medical treatment in hospital including vasopressors and hydration
5. Smoking history
6. Cardiopulmonary, social, and drug activity histories
7. Arterial blood gases and ventilator settings on 5 cm/H20/PEEP including PO2/FiO2 ratio and preferably 100% FiO2, within 2 hours prior to the offer
8. Bronchoscopy results
9. Chest x-ray interpreted by a radiologist or qualified physician within 3 hours prior to the offer
10. Details of any documented cardiac arrest or hypotensive episodes
11. Sputum gram stain, with description of sputum
12. Electrocardiogram
13. Echocardiogram, if the OPO has the facilities
14. HLA typing if requested by the transplant hospital, including A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, ~~and~~ DQA, DQB, and DPB antigens prior to final organ acceptance

If the host OPO cannot perform a bronchoscopy, it must document that it is unable to provide bronchoscopy results and the receiving transplant hospital may perform it. The lung recovery team may perform a confirmatory bronchoscopy provided unreasonable delays are avoided and deceased donor stability and the time limitations in *Policy 5.5.B: Time Limit for Acceptance* are maintained.

For lung deceased donors, if a transplant ~~hospital~~ program requires donor HLA typing prior to submitting a final organ acceptance, it must communicate this request to the OPO and document the request. The OPO must provide the HLA information ~~required in the~~ listed above and document that the information was provided to the transplant program. ~~The transplant hospital may request HLA-DPB typing, but the OPO need only provide it if its affiliated laboratory performs related testing.~~

The lung recovery team must have the opportunity to speak directly with the responsible ICU personnel or the onsite OPO donor coordinator in order to obtain current information about the deceased donor's physiology.

2.11.E Required Information for Deceased Pancreas Donors

The host OPO must provide *all* the following additional information for all deceased donor pancreas offers:

1. Donor name
2. Donor ID
3. Ethnicity
4. Weight
5. Date of admission for the current hospitalization
6. Alcohol use (if known)
7. Current history of abdominal injuries and operations including pancreatic trauma
8. Current history of average blood pressure, hypotensive episodes, cardiac arrest, average urine output, and oliguria
9. Current medication and transfusion history
10. Pertinent past medical or social history including pancreatitis
11. Familial history of diabetes
12. Insulin protocol
13. Indications of sepsis
14. Serum amylase

15. HLA information as follows: A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, ~~and~~ DQA, DQB, and DPB antigens prior to organ offers ~~The lab is encouraged to report splits for all loci as outlined in *Policy 4: Histocompatibility*.~~

3.4.D Candidate Human Leukocyte Antigen (HLA) Requirements

The candidate's transplant program must report to the OPTN Contractor complete human leukocyte antigen (HLA) information (at least 1A, 1B, and 1DR antigen) according to *Table 3-1* below:

Table 3-1: HLA Requirements

If the candidate is registered for a:	Then, HLA information is:
Kidney alone	Required
Kidney–pancreas	Required
Kidney with any other non-renal organ	Not required
Pancreas alone	Required
Pancreas islet alone	Required

Transplant programs must report this HLA information using current World Health Organization (WHO) nomenclature when the candidate is registered on the waiting list.

Policy 4: Histocompatibility

4.2 Requirements for Performing and Reporting HLA Typing

Laboratories must ensure that all HLA typing is accurately determined and report HLA typing results to the OPO or Transplant Program according to the turnaround time specified in the written agreement between the laboratory and any affiliated OPO or transplant program.

4.2.A Deceased Donor HLA Typing

If the laboratory performs HLA typing on a deceased donor, the laboratory must perform molecular typing and report results at the level of serological splits to the OPO for all required HLA types on deceased donors according to Table 4-3 Deceased Donor HLA Typing Requirements.

Table 4-3 below provides the requirements of HLA typing of HLA A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA, DQB, and DPB antigens.

Table 4-3: Deceased Donor HLA Typing Requirements

If a Laboratory Performs HLA Typing on a:	Then the Laboratory Must Report Results to the OPO at the Following Times:
Deceased Kidney, Kidney-Pancreas, or Pancreas Donor	Prior to organ offers
Deceased Heart, Heart-Lung, or Lung Donors	Prior to final acceptance, if required by the transplant program
Deceased Liver Donors	Within the period specified by the transplant program

4.2.B HLA Typing for Candidates

Laboratories must perform HLA typing on a kidney, kidney-pancreas, or pancreas islet candidate and report results for HLA A, B, Bw4, Bw6, and DR to the transplant program prior to registration on the waiting list.

4.~~2~~3 Resolving Discrepant Donor and Recipient HLA Typing Results

[*Subsequent headings affected by the re-numbering of this policy will also be changed as necessary*.]

Kidney Paired Donation (KPD) Histocompatibility Testing Requirements

Sponsoring Committee:	**Kidney Transplantation Committee**
Policy/Bylaws Affected:	**Policies 13: Kidney Paired Donation (KPD); 13.5: Histocompatibility Testing; 13.6: Matching within the OPTN KPD Program; 13.7: KPD Screening Criteria; and 13.10: Crossmatching Protocol**
Distributed for Public Comment:	**March 2014**
Amended After Public Comment:	**Yes**
Effective Date:	**Upon implementation and notice to members**

Problem Statement

KPD matches can fail for a variety of reasons, but data show that a significant number of failed matches in the OPTN KPD program are due to HLA antibody related issues. These changes are designed to increase efficiency in the OPTN KPD program and prevent future match failures. Some of the changes below are simply being moved from the OPTN KPD pilot program guidelines into OPTN policy.

Summary of Changes

- HLA typing is required for donors and candidates in order to be eligible for match runs in the OPTN KPD program
- The potential donor's hospital is responsible for all HLA reporting requirements on the donor
- The transplant hospital registering the candidate in the OPTN KPD program is responsible for all HLA reporting requirements on the candidate
- HLA typing for donors and candidates must be performed using molecular methods
- The following HLA types are required to be reported for potential donors in the OPTN KPD program: HLA-A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA, DQB, and DPB
- The following types are required to be reported for candidates in the OPTN KPD program: HLA-A, B, Bw4, Bw6, and DR
- If a candidate has unacceptable antigens listed for the following, these additional types are required to be reported for the candidate: HLA-C, DR51, DR52, DR53, DQA, DQB, and DPB
- The candidate's transplant hospital is responsible for retyping a matched donor to confirm the donor's HLA information
- The candidate's transplant hospital is responsible for testing the candidate for antibodies at all of the following times:
  1. every 90 days (+/- 20 days)
  2. when a potentially sensitizing event occurs
  3. if the candidate has been reactivated after being inactive for more than 90 days
  4. if an unacceptable positive crossmatch occurs that precludes transplantation
- Candidates must be screened for antibodies using a method at least as sensitive as the crossmatch method and using a solid phase assay
- The candidate's physician or surgeon (or designee) and the affiliated histocompatibility laboratory director (or designee) must review and confirm the unacceptable antigens reported for a candidate before the candidate appears on the first KPD match run

- The candidate's transplant hospital is responsible for performing a physical crossmatch before the donor's recovery is scheduled and a final crossmatch prior to the transplant. The candidate's transplant hospital must report crossmatch results to the matched donor's hospital and the OPTN Contractor.
- If an unacceptable positive crossmatch occurs between a candidate and a matched donor, the OPTN Contractor will make the candidate ineligible for subsequent match runs until the candidate's hospital confirms that the physician or surgeon and the histocompatibility laboratory director have reviewed the candidate's unacceptable antigens.
- The candidate's hospital must report to the OPTN Contractor a reason for an unacceptable positive crossmatch within 7 days of the date that the crossmatch results were received by the candidate's transplant hospital.

What Members Need to Do

These new policies apply only to transplant programs participating in the OPTN KPD program.

Once implemented, the KPD donor hospital will be responsible for all HLA typing for donors and for arranging shipment of the donor blood sample to the candidate's hospital or lab for the crossmatch.

The KPD candidate hospital will be responsible for:
- All HLA typing for candidate and confirming the donor's HLA type.
- Performing and reporting antibody screenings at the required frequency.
- Performing crossmatches at the specified times and communicating the results to UNOS and the donor hospital.

Affected Policy/Bylaw Language:

New language is underlined and language that will be deleted is ~~struck through~~.

Policy 1: Administrative Rules and Definitions

1.2 Definitions

~~Potential~~ Paired donor's transplant hospital

The transplant hospital that enters the ~~potential living~~ paired donor in a KPD program.

Policy 13: Kidney Paired Donation (KPD)

13.5 OPTN KPD Histocompatibility Testing

~~*Reserved*~~

13.5.A HLA Typing Requirements for OPTN KPD Candidates

Before a candidate can appear on an OPTN KPD match run, the paired candidate's transplant hospital is responsible for reporting to the OPTN Contractor serological split level molecular typing results for *all* of the following:

- HLA-A
- HLA-B
- HLA-Bw4
- HLA-Bw6
- HLA-DR

If the candidate has unacceptable antigens listed for any of the following HLA types, then the paired candidate's transplant hospital is responsible for reporting to the OPTN Contractor serological split level molecular typing results for the corresponding HLA type before the candidate can appear on an OPTN

KPD match run:

- HLA-C
- HLA-DR51
- HLA-DR52
- HLA-DR53
- HLA-DPB
- HLA-DQA
- HLA-DQB

13.5.B Antibody Screening Requirements for OPTN KPD Candidates

The paired candidate's transplant hospital must complete antibody screening tests and report to the OPTN Contractor as follows:

1. Use an antibody testing method that is at least as sensitive as the crossmatch method. If antibodies are detected, then identify unacceptable antigens using a solid-phase single phenotype or solid-phase single-antigen test.
2. If no HLA antibodies or unacceptable antigens are detected, then report the paired candidate as unsensitized.
3. Report donor antigens that are considered absolute contraindications to transplant with the paired candidate as unacceptable antigens.
4. Before candidates can appear on their first OPTN KPD match run, each paired candidate's physician or surgeon or their designee and the histocompatibility laboratory director or the director's designee must review and sign a written approval of the unacceptable antigens listed for the paired candidate. The paired candidate's transplant hospital must document this review in the paired candidate's medical record.
5. Retest active candidates for antibodies according to #1 above at all of the following times:

    - At least once every 90 days (+/- 20 days) from the date of the first antibody test
    - When any potentially sensitizing event occurs
    - When a paired candidate who has been inactive for more than 90 days has been reactivated
    - When an unacceptable and positive physical crossmatch occurs that precludes transplantation of the matched candidate

If any new unacceptable antigens are identified, then the paired candidate's transplant hospital must report these antigens using the process outlined in #3 and #4 above. If no new unacceptable antigens are identified, the paired candidate's transplant hospital must document the antibody screening results in the paired candidate's medical record.

13.5.C HLA Typing Requirements for OPTN KPD Donors

Before a paired donor can appear on an OPTN KPD match run, the paired donor's transplant hospital is responsible for reporting to the OPTN Contractor serological split level molecular typing results for *all* of the following:

- HLA-A
- HLA-B
- HLA-Bw4
- HLA-Bw6
- HLA-C
- HLA-DR
- HLA-DR51
- HLA-DR52
- HLA-DR53

- HLA-DQA
- HLA-DQB
- HLA-DPB

13.5.D Responding to OPTN KPD Match Offers

1. Before declining an OPTN KPD match offer due to unacceptable antigens, the matched candidate's physician or surgeon or their designee must review the matched donor's antigens and their matched candidate's unacceptable antigens with the histocompatibility laboratory director or the director's designee. This joint review must be documented in the matched candidate's medical record.
2. When an OPTN KPD match offer is declined due to either a positive crossmatch or unacceptable antigens prior to crossmatch, the transplant hospital declining the offer must submit a written explanation to the OPTN Contractor within 7 days after declining the offer.
3. The matched candidate's transplant hospital is responsible for performing HLA typing on the matched donor and verifying the HLA information reported prior to transplant.

13.6 Matching within the OPTN KPD Program

13.6.A Requirements for Match Run Eligibility for Candidates

The OPTN KPD program will only match candidates who comply with *all* of the following requirements:

1. The candidate's transplant hospital must comply with Policies *5.5.A: Receiving and Reviewing Organ Offers* and *5.5.D: Blood Type Verification upon Receipt*
2. The candidate's transplant hospital must complete the informed consent process according to KPD Operational Guidelines
3. The candidate's transplant hospital must submit all the information for these required fields to the OPTN Contractor:

    a. Candidate details, including *all* of the following:
        - Last name
        - First name
        - SSN
        - Date of birth
        - Gender
        - Ethnicity/Race
        - ABO
        - Whether the candidate has signed an agreement to participate in the OPTN KPD program
        - Whether the candidate has signed a release of protected health information
        - Whether the candidate is a prior living donor
        - KPD status

    b. Candidate choices, including *all* of the following:
        - Whether the candidate would be willing to travel, and, if so, the transplant hospitals to which a candidate would be willing to travel
        - Whether the candidate is willing to accept a shipped kidney, and, if so, from which transplant hospitals the candidate would be willing to accept a shipped kidney
        - Minimum and maximum acceptable donor age
        - Minimum acceptable donor creatinine clearance or GFR
        - Maximum acceptable donor BMI
        - Maximum acceptable systolic and diastolic blood pressure
        - Whether the candidate is willing to accept a hepatitis B core antibody positive KPD donor, a CMV positive KPD donor, and an EBV positive KPD donor
        - Whether the candidate would be willing to accept a left kidney, right kidney, or either kidney

    c. Candidate HLA as defined in *Policy 13.5.A: Histocompatibility Requirements for KPD Candidates*

4. The candidate must have current active status in the OPTN KPD program
5. The candidate must have at least one active and eligible potential KPD donor registered in the OPTN KPD program
6. The candidate's transplant hospital must submit a response for all previous match offers for the candidate in the OPTN KPD program
7. The candidate must not be in a pending exchange in the OPTN KPD program

13.6.B Requirements for Match Run Eligibility for Potential KPD Donors

The OPTN KPD program will only match potential KPD donors that comply with *all* of the following requirements:

1. The transplant hospital registering the potential KPD donor must perform blood typing and subtyping as required by Policy 14.4.A: Living Donor Blood type Determination with the following modifications:

    a. The transplant hospital registering the potential KPD donor must report the potential KPD donor's actual blood type to the OPTN Contractor
    b. Someone, other than the person who reported the potential KPD donor's blood type to the OPTN Contractor, must compare the blood type from the two source documents, and separately report the potential KPD donor's actual blood type to the OPTN Contractor
    c. The potential KPD donor is not eligible for a KPD match run until the transplant hospital verifies and reports two identical blood types

2. The transplant hospital registering the potential KPD donor must complete the informed consent process according to KPD Operational Guidelines
3. The transplant hospital registering the potential KPD donor must complete the medical evaluation process according to *Policy 14: Living Donation*.
4. The transplant hospital registering the potential KPD donor must submit the information for the required fields below to the OPTN Contractor:

    a. Donor details, including *all* of the following:
        - Last name
        - First name
        - SSN
        - Date of birth
        - Gender
        - Ethnicity/Race
        - ABO
        - Height and weight
        - Whether the potential KPD donor is a non-directed donor or a paired donor
        - If the potential KPD donor is a paired donor, the KPD Candidate ID of the paired candidate and the potential KPD donor's relationship to the candidate
        - Whether the potential KPD donor has signed an agreement to participate in the
        - OPTN KPD program
        - Whether the potential KPD donor has signed a release of protected health information
        - Whether the potential KPD donor has signed an informed consent as required in policy
        - Whether the potential KPD donor has undergone a medical evaluation as required in Policy 14: Living Donation
        - Whether the potential KPD donor has had all age appropriate cancer screenings as defined by the American Cancer Society
        - KPD status: active, inactive or removed

    b. Clinical information, including *all* of the following:

- The number of anti-hypertensive medications the potential KPD donor is currently taking
- Systolic and diastolic blood pressure with date (either 24-hour monitoring or two measurements)
- Creatinine clearance, date, and method
- Anti-CMV, EBV, HbsAg, and Anti-HbcAb serology results

c. Donor choices, including *all* of the following:
- Whether the potential KPD donor would be willing to travel, and, if so, the transplant hospitals to which the potential KPD donor would be willing to travel
- Whether the potential KPD donor is willing to ship a kidney
- Whether the potential KPD donor is willing to donate a left kidney, right kidney, or either kidney
- Whether the KPD candidate-donor pair and the transplant hospital are willing to participate in a three-way exchange or a donor chain
- Whether the potential KPD donor and the transplant hospital are willing for the potential KPD donor to be a bridge donor

d. Donor HLA as defined in *Policy 13.5.C: Histocompatibility Requirements for KPD Donors*

5. The potential KPD donor must have current active status in the OPTN KPD program
6. The potential KPD donor must be paired to an active and eligible candidate registered in the OPTN KPD program
7. The transplant hospital registering the potential KPD donor must submit a response for all previous match offers for the potential KPD donor in the OPTN KPD program
8. The potential KPD donor must not be in a pending exchange in the OPTN KPD program.

13.7 OPTN KPD Screening Criteria

13.7.C Unacceptable Antigens

A transplant hospital ~~may~~ must specify any unacceptable antigens it will not accept for its paired candidates using the process outlined in *Policy 13.5.B: Antibody Screening Requirements for OPTN KPD Candidates*. The OPTN Contractor will not match the paired candidate with any potential KPD donor who has one of the candidate's unacceptable antigens entered as a human leukocyte antigen (HLA) value.

13.10 OPTN KPD Crossmatching Protocol

The matched candidate's transplant hospital must do *all* of the following:

1. Perform a physical crossmatch between the matched candidate and the matched donor before the matched donor's recovery is scheduled.
2. Perform a final crossmatch prior to transplant.
3. Report all crossmatching results to the OPTN Contractor and the matched donor's transplant hospital.

If, at any time, the matched candidate's transplant hospital refuses a match offer due to an unacceptable positive crossmatch between the candidate and the matched donor, then the matched candidate is ineligible for subsequent match runs. The candidate will remain ineligible until *all* of the following are completed:

1. The matched candidate's physician or surgeon or their designee and the histocompatibility laboratory director or the director's designee review the unacceptable antigens reported for the candidate.
2. The matched candidate's transplant hospital reports to the OPTN Contractor that the review has occurred.

~~The KPD candidate's transplant hospital must perform a preliminary crossmatch for candidates in the~~

~~OPTN KPD program before the matched KPD donor's recovery procedure.~~
The paired donor's transplant hospital ~~registering the potential KPD donor~~ is responsible for arranging shipment of the paired ~~potential KPD~~ donor's blood sample to the matched candidate's transplant hospital or the laboratory specified by the matched candidate's transplant hospital.

~~The KPD candidate's transplant hospital is responsible for performing the crossmatch and reporting the results to the OPTN Contractor and the matched KPD donor's transplant hospital.~~

Requiring the Reporting of Aborted Living Donor Recovery Procedures

Sponsoring Committee:	**Living Donor**
Policies Affected:	**18.5.C: Submission of Living Donor Death and Organ Failure, 18.5.D: Reporting of Non-Transplanted Living Donor Organs, 18.5.E: Reporting of Living Donor Organs Not Transplanted in the Intended Recipient, and 18.6: Reporting of Living Donor Adverse Events**
Distributed for Public Comment:	**March 2014**
Amended After Public Comment:	**Yes**
Effective Date:	**Upon implementation and notice to members**

Problem Statement

Between 2008 and 2010, a series of aborted living-donor recovery procedures occurred at a member program, resulting in non-recovery of the organ for transplant. These aborted procedures were reported to UNOS through the Living Donor Feedback form, but since patient information reported on this form is not designed to be monitored in real time, UNOS did not immediately identify the situation.

Summary of Changes

In addition to reporting aborted living-donor recovery procedures through the Living Donor Feedback form, living donor recovery hospitals must also report these events by using the new living donor adverse event category in the Improving Patient Safety Portal.

What Members Need to Do

Living donor recovery hospitals must report aborted living donor recovery procedures through the Improving Patient Safety Portal within 72 hours of the event.

Affected Policy Language:

New language is underlined and language that will be deleted is ~~struck through~~.

18.6 Reporting of Living Donor Adverse Events

18.6.A Reporting of Living Donor Adverse Events through the Improving Patient Safety Portal

Recovery hospitals must report these living donor adverse or unanticipated events through the Improving Patient Safety Portal according to *Table 18-4* below.

Table 18-4: Living Donor Adverse Event Reporting

Recovery hospitals must report to the Patient Safety System when:	To the Improving Patient Safety Portal w~~W~~ithin 72 hours after:
A living donor organ recovery procedure is aborted after the donor has begun to receive~~d~~ general anesthesia.	The aborted organ recovery procedure
A living donor dies within 2 years after organ donation	The program becomes aware
A living liver donor is listed on the liver waitlist within 2 years after organ donation	The program becomes aware
A living kidney donor is listed on the kidney wait list or begins dialysis within 2 years after organ donation	The program becomes aware
A living donor organ is recovered but not transplanted	Organ recovery
A living donor organ is recovered and transplanted into someone other than the intended recipient	Organ recovery

The Membership and Professional Standards Committee will review all cases reported ~~under *Policy 18.5.B* through *18.5.D*~~ according to *Table 18-4* above and report to the OPTN Board of Directors.

~~**18.5.C Submission of Living Donor Death and Organ Failure**~~

~~Recovery hospitals must report all instances of a living donor's death or failure of the living donor's remaining organ function within 72 hours after the hospital becomes aware of the living donor death or failure of the living donor's remaining organ function. Living donors' remaining organ failure is defined as registering for liver transplant for liver donors, and as transplant, listing for transplant, or the need for dialysis for kidney donors. Recovery hospitals must report these incidents through the OPTN Contractor's Improving Patient Safety System for a period of two years from the date of the donation. The MPSC will review and report all adverse events to the OPTN Board of Directors.~~

~~**18.5.D Reporting of Non-transplanted Living Donor Organs**~~

~~The recovery hospital must report any time a living donor organ is recovered but not transplanted into any recipients. Recovery hospitals must report these incidents through the OPTN Patient Safety System within 72 hours of organ recovery. The MPSC will review and report all cases of non-transplanted living donor organs to the OPTN Board of Directors.~~

~~**18.5.E Reporting of Living Donor Organs Not Transplanted in the Intended Recipient**~~

~~If a living donor organ is recovered for an intended recipient but ultimately redirected and transplanted to a different recipient, then all required donor and recipient information must still be reported to the OPTN Contractor.~~

~~Transplant hospitals must report these incidents through the OPTN Improving Patient Safety System within 72 hours of organ recovery. The Membership and Professional Standards Committee will review and report all cases of redirected living donor organs to the OPTN Board of Directors.~~

~~**Table 18-4: Living Donor Adverse Event Reporting**~~

~~Recovery hospitals must report to the Patient Safety System when:~~	~~Within 72 hours after:~~
~~A living donor dies within 2 years after organ donation~~	~~The program becomes aware~~
~~A living liver donor is listed on the liver waitlist within 2 years after organ donation~~	~~The program becomes aware~~

~~Recovery hospitals must report to the Patient Safety System when:~~	~~Within 72 hours after:~~
~~A living kidney donor is listed on the kidney wait list or begins dialysis within 2 years after organ donation~~	~~The program becomes aware~~
~~A living donor organ is recovered but not transplanted~~	~~Organ recovery~~
~~A living donor organ is recovered and transplanted into someone other than the intended recipient~~	~~Organ recovery~~

~~The Membership and Professional Standards Committee will review all cases reported under *Policy 18.5.B* through *18.5.D* and report to the OPTN Board of Directors.~~

Modifying or Establishing New Requirements for the Informed Consent of Living Donors

Sponsoring Committee:	**Living Donor**
Policy Affected:	**Policies 14.2.A (ILDA Requirements for Kidney Recovery Hospitals), 14.2.B (Protocols for Kidney Recovery Hospitals), 14.3 (Informed Consent Requirements)**
Distributed for Public Comment:	**March 2014**
Amended After Public Comment:	**Yes**
Effective Date:	**February 1, 2015**

Problem Statement

In 2006, the Health Resources and Services Administration (HRSA) directed the OPTN to develop living donor policies. New policies for the informed consent of living kidney donors went into effect on February 1, 2013. We still need related policies for the informed consent of other categories of living donors (liver, pancreas, intestine, and lung).

Summary of Changes

Before these new policies were approved, living liver donor recovery programs were required to develop and follow their own center-specific protocols related to the duties and responsibilities of their Independent Living Donor Advocates (ILDAs) and the informed consent of their living liver donors. Living donor (liver, pancreas, intestine, and lung) recovery hospitals will now follow new standardized requirements for the informed consent of their living donors.

What Members Need to Do

Beginning Feb. 1, 2015, living donor (liver, pancreas, intestine, and lung) recovery hospitals must follow new policy requirements for their ILDAs and for the informed consent of their living donors.

Affected Policy Language:

New language is underlined and language that will be deleted is ~~struck through~~.

14.2 Independent Living Donor Advocate (ILDA) Requirements

14.2.A ILDA Requirements for ~~Kidney~~ Living Donor Recovery Hospitals

Living donor ILDA requirements do not apply to any individual who is undergoing transplant whose native organ is suitable for transplant to another transplant candidate.

Living donor ILDA requirements apply to living kidney, liver, pancreas, intestine or lung donors.For any ~~potential~~ living ~~kidney~~ donor who is undergoing evaluation for donation, the living ~~kidney~~ donor recovery hospital must designate and provide each ~~potential~~ living donor with an ILDA who is not involved with the potential recipient evaluation and is independent of the decision to transplant the potential recipient. The ILDA may be one person or an independent living donor advocate team with multiple members. An ILDA team must designate one person from the team as the key contact for each ~~potential~~ living donor.

The ILDA must:

1. Function independently from the transplant candidate's team.

2. Advocate for the ~~rights of the potential~~ living donor ~~and the living donor~~.

3. Fulfill the qualification and training requirements specified in the recovery hospital's protocols regarding knowledge of living organ donation, transplantation, medical ethics, informed consent, and the potential impact of family or other external pressure on the ~~potential~~ living donor's decision about whether to donate. Document that each requirement has been met.

4. Review whether the ~~potential~~ living donor has received information on each of the following areas and assist the ~~potential~~ donor in obtaining additional information from other professionals as needed about the:

    - Informed ~~-~~consent process as described in *Policy 14.3: Informed Consent Requirements* ~~and its subsections~~
    - Evaluation process according to *Policies ~~14.3.A.ii~~, 14.5~~1.A~~: Living ~~Kidney~~ Donor Psychosocial Evaluation Requirements and 14.4.B*: *Living ~~Kidney~~ Donor Medical Evaluation Requirements* ~~and its subsections~~
    - Surgical procedure
    - Medical risks according to ~~*Policy 14.3.A.ii*~~ *Tables 14-1 through 14-5*
    - Psychosocial risks according to ~~*Policy 14.3.A.ii*~~ *Tables 14-1 through 14-5*
    - Follow-up requirements, and the benefit and need for participating in follow-up according to *Policies 18.1: Data Submission Requirements, 18.5.A: Reporting Requirements after Donation* and *18.5.B: Submission of Living Donor Death and Organ Failure*
    5. Document that each topic was reviewed

14.2.B ILDA Protocols for ~~Kidney~~ Living Donor Recovery Hospitals

The living ~~kidney~~ donor recovery hospital must develop, and once developed must comply with written protocols for:

1. The composition of the ILDA team, if the hospital uses a team
2. The qualifications and training (both initial and ongoing) required for the ILDA. Minimum qualifications must include knowledge of living organ donation, transplantation, medical ethics, informed consent, and the potential impact of family or other external pressures on the ~~potential~~ living donor's donation decision.
3. The duties and responsibilities of the ILDA, which must include at least the functions and duties listed throughout *Policy 14.2.A: ILDA Requirements for ~~Kidney~~ Living Donor Recovery Hospitals.*
4. The process the living donor recovery hospital will provide for the ILDA to file a grievance when necessary to protect the rights or best interests of the living donor.
5. The process the living donor recovery hospital will use to address any grievance raised by the ILDA concerning the rights or best interests of the living donor.

14.2.C ILDA Protocols for Liver Recovery Hospitals

~~Liver recovery hospitals must develop and comply with written protocols for the duties and responsibilities of the ILDA that include, but are not limited to, *all* of the following elements:~~

~~1. Promoting the best interests of the potential living donor~~
~~2. Advocating for the rights of the living donor~~
~~3. Assisting the potential donor in obtaining and understanding information about the:~~
~~a. Consent process~~
~~b. Evaluation process~~

~~c. Surgical procedure~~
~~d. Benefit of follow up~~
~~e. Need for follow up~~

14.3 Informed Consent Requirements

~~Education is important so that the potential living donor understands all aspects of the donation process, especially the risks and benefits.~~

~~14.3.A Informed Consent of Living Kidney Donors~~
~~Informed consent is required to ensure that a potential living donor understands:~~

~~1. That the living donor will undertake risk and will receive no medical benefit from donating a kidney.~~
~~2. That there are both the general risks of the surgery as well as hospital-specific risks.~~

~~14.3. A.i Living Donor Informed Consent for Evaluation of Potential Living Donors~~
~~The kidney recovery hospital must maintain documentation in the living donor's medical record that the recovery hospital informed the potential living donor of *all* of the following:~~

~~14.3.A.ii Living Donor Informed Consent Requirements~~
~~The recovery hospital must obtain informed consent from any potential living kidney donor that must include written assurance by the potential living donor of *all* of the following:~~

~~The kidney recovery hospital must document in the potential donor's medical record that the hospital provided the potential donor with *all* of the following:~~
Living donor informed consent requirements do not apply to any individual who is undergoing transplant whose native organ is suitable for transplant to another transplant candidate.

Living donor informed consent requirements apply to living kidney, liver, pancreas, and intestine or lung donors.

The recovery hospital is responsible for informed consent which must include *all* of the components in *Tables 14-1 – 14-5*.

Documentation of informed consent must be maintained in the donor medical record.

Table 14-1: Requirements for Living Donor Informed Consent

The recovery hospital must:	These elements of informed consent:
Obtain from ~~all~~ living donors	~~Written assurance by the potential donor~~ The donor's signature on a document that confirms that the donor: • ~~That the potential donor i~~Is willing to donate • ~~That the potential donor i~~Is free from inducement and coercion ~~and~~ • ~~That the potential donor h~~Has been informed that he or she may decline to donate at any time~~.~~

The recovery hospital must:	These elements of informed consent:
Provide to ~~all~~ living donors	~~The potential living donors must be offered~~ ~~a~~An opportunity to discontinue the donor consent or evaluation process in a way that is protected and confidential.The ILDA must be available to assist the ~~potential~~ donor during ~~this~~ the consent process, according to *Policy 14.2: Independent Living Donor Advocate (ILDA) Requirements.* Instruction about all phases of the living donation process, which include: • ~~c~~Consent • ~~m~~Medical and psychosocial evaluations • ~~p~~Pre and post operative care~~, and~~ • ~~r~~Required post-operative follow up according to *Policy 18.5: Living Donor Data Submission Requirements* Teaching or instructional material can include any media, one-on-one or small group interaction. Teaching or instruction must be provided in a language in which the donor is able to engage in meaningful dialogue with ~~transplant program~~ recovery hospital's staff.

The recovery hospital must:	These elements of informed consent:
Disclose to ~~all~~ living donors	~~The disclosure that~~ ~~t~~The recovery hospital will take all reasonable precautions to provide confidentiality for the donor and recipient. ~~The disclosure that~~ ~~i~~It is a federal crime for any person to knowingly acquire, obtain or otherwise transfer any human organ for anything of value including, but not limited, to cash, property, and vacations. ~~Disclosure t~~That ~~t~~he recovery hospital must provide an ILDA. ~~The disclosure of~~ ~~a~~Alternate procedures or courses of treatment for the recipient, including deceased donor transplantation, and that: A deceased donor ~~kidney~~ organ may become available for the ~~recipient~~ candidate before the recovery hospital completes the ~~potential~~ living donor's evaluation or the living donor transplant occurs. Any transplant candidate may have risk factors for increased morbidity or mortality that are not disclosed to the ~~potential~~ donor. ~~The disclosure that~~ ~~h~~Health information obtained during the evaluation is subject to the same regulations as all medical records and could reveal conditions that must be reported to local, state, or federal public health authorities. ~~The disclosure that~~ ~~t~~The recovery hospital is required to: a) Report living donor follow up information, at the time intervals specified in *Policy 18.5: Living Donor.* b) Have the ~~potential~~ donor commit to post operative follow up testing coordinated by the recovery hospital. ~~The disclosure that~~ ~~a~~Any infectious disease or malignancy pertinent to acute recipient care discovered during the ~~potential~~ donor's first two years of follow up care: ~~Will be disclosed to the donor~~ a) May need to be reported to local, state or federal public health authorities b) Will be disclosed to their recipient's transplant center c) Will be reported through the OPTN Improving Patient Safety Portal.

The recovery hospital must:	These elements of informed consent:
Disclose to ~~all~~ living donors	~~potential~~ A living donor must undergo a medical evaluation according to *Policy 14.4 (Medical Evaluation Requirements for Living Donors)* and a psychosocial evaluation as required by *Policy 14.~~5~~.1 (Psychosocial Evaluation Requirements for Living Donors)* The hospital may refuse the~~ potential~~ donor. In such cases, the recovery hospital must inform the ~~potential~~ donor that a different recovery hospital may evaluate the ~~potential~~ donor using different selection criteria. The following are inherent risks associated with evaluation for living donation: a) Allergic reactions to contrast b) Discovery of reportable infections c) Discovery of serious medical conditions d) Discovery of adverse genetic findings unknown to the donor e) Discovery of certain abnormalities that will require more testing at the donor's expense or create the need for unexpected decisions on the part of the transplant team ~~That the following~~ There are surgical, medical, psychosocial, and financial risks ~~are~~associated with living ~~kidney~~ donation~~.~~. ~~This disclosure must state that these risks~~ which may be temporary or permanent and include, but are not limited to, *all* of the following:

The recovery hospital must:	These elements of informed consent:
Disclose to ~~all~~ living donors	a. Potential medical or surgical risks: i. Death ii. Scars, <u>hernia, wound infection, blood clots, pneumonia, nerve injury,</u> pain, fatigue, and other consequences typical of any surgical procedure iii. Abdominal symptoms such as bloating, nausea, and developing bowel obstruction iv. That the morbidity and mortality of the ~~potential~~ donor may be impacted by obesity, hypertension, or other donor-specific pre-existing conditions ~~v. Decreased kidney function~~ ~~vi. Kidney failure and the need for dialysis or kidney transplant for the donor~~ b. Potential psychosocial risks: i. Problems with body image ii. Post-surgery depression or anxiety iii. Feelings of emotional distress or grief if the transplant recipient experiences any recurrent disease or if the transplant recipient dies iv. Changes to the donor's lifestyle from donation c. Potential financial impacts: i. Personal expenses of travel, housing, child care costs, and lost wages related to donation might not be reimbursed; however, resources might be available to defray some donation-related costs ii. Need for life-long follow up at the donor's expense iii. Loss of employment or income iv. Negative impact on the ability to obtain future employment v. Negative impact on the ability to obtain, maintain, or afford health insurance, disability insurance, and life insurance vi. Future health problems experienced by living donors following donation may not be covered by the recipient's insurance

Table 14-12: Required Recipient Outcome and Transplanted ~~Kidney~~ Organ Survival Data

If the recovery hospital and the recipient hospital:	Then:	Including *all* the following information:
Are the same	The recovery hospital must provide the ~~potential~~ living donor with both national and that hospital's program-specific transplant recipient outcomes from the most recent Scientific Registry of Transplant Recipients (SRTR) hospital-specific reports.	National 1-year patient and transplanted ~~kidney~~ organ survival The hospital's 1-year patient and transplanted ~~kidney~~ organ survival Notification about all Centers for Medicare and Medicaid Services (CMS) outcome requirements not being met by the transplant hospital
Will not be the same and the recipient hospital is known	The recovery hospital must provide the ~~potential~~ living donor with both national and the recipient hospital's program-specific transplant recipient outcomes from the most recent SRTR hospital-specific reports.	National 1-year patient and transplanted ~~kidney~~ organ survival The recipient hospital's 1-year patient and transplanted ~~kidney~~ organ survival Notification about all CMS outcome requirements not being met by the recipient hospital

Table 14-3: Additional Requirements for the Informed Consent of Living Kidney Donors

The recovery program must:	These additional elements as components of informed consent for living kidney donors:
Provide to all living kidney donors	Education about expected post-donation kidney function, and how chronic kidney disease (CKD) and end-stage renal disease (ESRD) might potentially impact the living donor in the future, to include: a. On average, living donors may have a 25-35% permanent loss of kidney function after donation. b. Baseline risk of ESRD for living kidney donors does not exceed that of the general population with the same demographic profile. c. Living donor risks must be interpreted in light of the known epidemiology of both CKD and ESRD. When CKD or ESRD occurs, CKD generally develops in mid-life (40-50 years old) and ESRD generally develops after age 60. The medical evaluation of a young ~~potential~~ living donor cannot predict lifetime risk of CKD or ESRD. d. Living donors may be at a higher risk for CKD if they sustain damage to the remaining kidney. The development of CKD and subsequent progression to ESRD may be faster with only one kidney. e. Dialysis is required if the donor develops ESRD. f. Current practice is to prioritize prior living kidney donors who become kidney transplant candidates according to *Policy 8.3: Points*

The recovery program must:	These additional elements as components of informed consent for living kidney donors:

Disclose to all living kidney donors	~~Disclosure that these~~ Surgical risks may be transient or permanent and include but are not limited to:
	• Potential medical or surgical risks:
	  o Decreased kidney function
	  o Kidney failure and the need for dialysis or kidney transplant for the donor

Table 14-4: Additional Requirements for the Informed Consent of Living Liver Donors

The recovery program must:	These additional elements as components of informed consent for living liver donors:
Disclose to all living liver donors	Surgical risks may be transient or permanent and include but are not limited to: • Acute liver failure with need for liver transplant. • Transient liver dysfunction with recovery. The potential for transient liver dysfunction depends upon the amount of the total liver removed for donation. • Risk of red cell transfusions or other blood products. Biliary complications, including leak or stricture that may require additional intervention. ~~Hernia, wound infection, scars, blood clots, pneumonia, nerve injury, pain, fatigue, and other consequences typical of any surgical procedure~~. Post-donation laboratory tests may result in abnormal or false positive results that may trigger additional tests that have associated risks.

Table 14-5: Additional Required Living Liver Donor Recipient Outcome and Transplanted Living Donor Liver Survival Data

If the recovery hospital and the recipient hospital:	Then:	Including *all* the following information:
Are the same	The recovery hospital must provide the living donor with the hospital's program-specific transplant recipient outcomes from the most recent Scientific Registry of Transplant Recipients (SRTR) hospital-specific reports.	The hospital's 1-year living donor recipient's survival and recipient's graft survival rates
Will not be the same and the recipient hospital is known	The recovery hospital must provide the living donor with the recipient hospital's program-specific transplant recipient outcomes from the most recent SRTR hospital-specific reports.	The recipient hospital's 1-year living donor recipient's survival and graft survival rates

14.3.B Living Liver Donor Required Protocols for Informed Consent for Evaluation

Liver recovery hospitals must develop and comply with written protocols for the informed consent process and for the living donor liver recovery that must include, but are not limited to, *all* 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. The assurance that all communication between the potential living donor and the transplant hospital will remain confidential.
3. A discussion of the potential living donor's right to opt out at any time during the donation process.
4. A discussion that the medical evaluation or donation may impact the potential donor's ability to obtain health, life, and disability insurance.
5. The disclosure by the liver recovery hospital 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.
6. A plan to collect the required follow up information about each donor.
7. Providing the toll-free Patient Services Line that is available for living donors to report concerns or grievances to the OPTN.
8. The disclosure that it is a federal crime for any person to knowingly acquire, obtain, or otherwise transfer any human organ for anything of value, including, but not limited, to cash, property, and vacations. This documentation must be maintained in the potential donor's official medical record.

Modify or Establish New Requirements for the Psychosocial and Medical Evaluation of Living Donors

Sponsoring Committee:	**Living Donor**
Policy Affected:	**14.1: Required Protocols for Recovery Hospitals, 14.5: Psychosocial Evaluations Requirements for Living Donors, 14.4: Medical Evaluation Requirements for Living Donors, 14.6: Registration and Blood Type Verification of Living Donors Before Donation, 14.7.A: Prospective Crossmatching Prior to Kidney Placement, 14.7.B: Placement of Non-directed Living Donor Kidneys, 14.7.C: Transplant Hospital Acceptance or Living Donor Organs, 14.8: Packaging, Labeling, and Transporting of Living Donor Organs, Vessels, and Tissue Typing Materials**
Distributed for Public Comment:	**March 2014**
Amended After Public Comment:	**Yes**
Effective Date:	**February 1, 2015**

Problem Statement

In 2006, the Health Resources and Services Administration (HRSA) directed the OPTN to develop living donor policies. New policies for the psychosocial and medical evaluation of living kidney donors went into effect on February 1, 2013. Related policies for the psychosocial and medical evaluation of other categories of living donors (liver, pancreas, intestine, and lung) are needed.

Summary of Changes

Before these new policies were approved, living liver donor recovery programs were required to develop and follow their own center-specific protocols for the psychosocial and medical evaluation of their living liver donors. Living donor (liver, pancreas, intestine, and lung) recovery hospitals will now follow new standardized requirements for the psychosocial and medical evaluation of their living donors.

What Members Need to Do

Before approval of these new policies, living liver donor recovery programs were required to develop and comply with center-specific protocols for psychosocial and medical evaluation of their living donors.

Living donor (liver, pancreas, intestine, and lung) recovery hospitals will now follow new standardized requirements for the psychosocial and medical evaluation of their living donors.

Affected Policy/Bylaw Language:

New language is underlined and language that will be deleted is ~~struck through~~.

~~**14.1 Required Protocols for Recovery Hospitals**~~

~~**14.1.A Required Protocols for Kidney Recovery Hospitals**~~

~~Kidney recovery hospitals must develop and comply with written protocols to address all phases of the living donation process.~~

~~**14.1.B Required Protocols for Liver Recovery Hospitals**~~

~~Liver recovery hospitals must develop and comply with written protocols to address all phases of the living donation process. Specific protocols must include the evaluation, pre-operative, operative, and post-operative care, and submission of required follow up forms at 6 months, one-year, and two-years post-donation.~~

~~Liver recovery hospitals must document that all phases of the living donation process were performed in adherence to the hospital's protocols. This documentation must be maintained by the recovery hospital.~~

14.5~~.~~1 Psychosocial Evaluation Requirements for Living Donors

14.5~~.~~1.A Living ~~Kidney~~ Donor Psychosocial Evaluation Requirements

Living donor psychosocial evaluation requirements do not apply to any individual who is undergoing transplant whose native organ is suitable for transplant to another transplant candidate.

Living donor psychosocial evaluation requirements apply to living kidney, liver, pancreas, lung or intestine donors.

The~~is~~ living ~~kidney~~ donor psychosocial evaluation must be performed by a psychiatrist, psychologist, ~~or clinical social worker~~ masters prepared social worker, or licensed clinical social worker. Documentation of the psychosocial evaluation must be maintained in the living donor record and include *all* of the following components:

1. An evaluation for any psychosocial issues, including mental health issues, that might complicate the living donor's recovery and could be identified as ~~potential~~ risks for poor psychosocial outcome
2. An evaluation for the presence of behaviors that may increase risk for disease transmission as defined by the *U.S. Public Health Service (PHS) Guideline*
3. A review of the living donor's history of smoking, alcohol, and drug use, abuse, and dependency
4. The identification of factors that warrant educational or therapeutic intervention prior to the final donation decision
5. The determination that the ~~potential~~ living donor understands the short and long-term medical and psychosocial risks for both the living donor and recipient associated with living donation

6. An assessment of whether the decision to donate is free of inducement, coercion, and other undue pressure by exploring the reasons for donating and the nature of the relationship, if any, to the transplant candidate
7. An assessment of the ~~potential~~ living donor's ability to make an informed decision and the ability to cope with the major surgery and related stress. This includes evaluating whether the ~~potential~~ donor has a realistic plan for donation and recovery, with social, emotional and financial support available as recommended
8. A review of the ~~potential~~ living donor's occupation, employment status, health insurance status, living arrangements, and social support
9. The determination that the ~~potential~~ living donor understands the potential financial implications of living donation

14.4 Medical Evaluation Requirements for Living Donors

14.4.B Living ~~Kidney~~ Donor Medical Evaluation Requirements

Living donor medical evaluation requirements do not apply to any individual who is undergoing transplant whose native organ is suitable for transplant to another transplant candidate.

Living donor medical evaluation requirements only apply to living kidney, liver, pancreas, lung or intestine donors.

A medical evaluation of the ~~potential~~ living ~~kidney~~ donor must be performed by the recovery hospital and by a physician or surgeon experienced in living donation. ~~The goals of the medical evaluation are *all* of the following:~~

~~1. To assess the immunologic compatibility of the living donor to the recipient~~
~~2. To assess the general health and surgical risk of donation to the living donor including screening for conditions that may predict future complications from having only one kidney.~~
~~3. To determine if there are diseases present that may be transmitted from the living donor to the recipient~~
~~4. To assess the anatomy and function of the living donor's kidneys~~

Documentation of the medical evaluation must be maintained in the donor medical record.

The medical evaluation must include *all* of the components in *Table*s *14-2*~~2~~6 through *14-9* ~~below~~.

Table 14-~~2~~6: Requirements for Living ~~Kidney~~ Donor Medical Evaluations

This evaluation must be completed:	Including evaluation for and assessment of this information:
A ~~L~~Ggeneral ~~living~~ donor history	1. A personal history of significant medical conditions which include but are not limited to: a. Hypertension b. Diabetes c. Lung disease d. Heart disease e. Gastrointestinal disease f. Autoimmune disease g. Neurologic disease h. Genitourinary disease i. Hematologic disorders j. Bleeding or clotting disorders k. History of cancer including melanoma 2. History of infections ~~A kidney-specific personal history including:~~ ~~a. Genetic renal diseases~~ ~~b. Kidney disease, proteinuria, hematuria~~ ~~c. Kidney injury~~ ~~d. Diabetes including gestational diabetes~~ ~~e. Nephrolithiasis~~ ~~f. Recurrent urinary tract infections~~ 3. Active and past medications with special consideration for known nephrotoxic and hepatotoxic medications or chronic use of pain medication 4. Allergies 5. An evaluation for coronary artery disease
General family history	~~The living donor's family history of coronary heart disease and cancer~~ • Coronary artery disease • Cancer
~~Kidney-specific family history~~	~~The living donor's family history of:~~ • ~~Kidney disease~~ • ~~Diabetes~~ • ~~Hypertension~~ • ~~Kidney Cancer~~

This evaluation must be completed:	Including evaluation for and assessment of this information:
Social history	~~The living donor's history of:~~ • Occupation, • Employment status~~,~~ • Health insurance status~~,~~ • Living arrangements~~, and~~ • Social support • Smoking, alcohol and drug use and abuse • Psychiatric illness, depression, suicide attempts • ~~Criteria to assess~~ iIncreased risk ~~for disease transmission~~ behavior as defined by the *U.S. Public Health Service (PHS) Guideline*
Physical Exam	~~A physical exam of the lving donor including:~~ • Height • Weight • BMI • Vital signs • Examination of all major organ systems • ~~Blood pressure taken on at least two different occasions or 24-hour or overnight blood pressure monitoring~~
General laboratory and imaging tests	• Complete blood count (CBC) with platelet count • Blood type and subtype as specified in *Policy 14.4.A (Living Donor Blood Type Determination)* and its subsections ~~screen~~ • Prothrombin Time (PT) or International Normalized Ratio (INR) • Partial Thromboplastin Time (PTT) • Metabolic testing (to include electrolytes, BUN, creatinine, albumin, calcium, phosphorus) • HCG quantitative pregnancy test for premenopausal women without surgical sterilization • Chest X-Ray • Electrocardiogram (ECG)
~~Other metabolic testing~~	~~• Fasting blood glucose~~ ~~• Fasting lipid profile (cholesterol, triglycerides, HDL cholesterol, and LDL cholesterol)~~ • ~~Glucose tolerance test or glycosylated hemoglobin in first degree relatives of diabetics and in high risk individuals~~

This evaluation must be completed:	Including evaluation for and assessment of this information:
~~Kidney-specific tests~~	~~• Urinalysis or urine microscopy~~ ~~• Urine culture if clinically indicated~~ ~~• Measurement of urinary protein and albumin excretion~~ ~~• Measurement of glomerular filtration rate by isotopic methods or a creatinine clearance calculated from a 24-hour urine collection~~ ~~• Hospitals must develop and comply with a protocol for polycystic kidney disease or other inherited renal disease as indicated by family history~~ ~~• Patients with a history of nephrolithiasis or nephrolithiasis (>3mm) identified on radiographic imaging must have a 24-hour urine stone panel measuring:~~ ~~○ Calcium~~ ~~○ Oxalate~~ ~~○ Uric acid~~ ~~○ Citric acid~~ ~~○ Creatinine~~ ~~○ Sodium~~
~~Anatomic assessment~~	~~An assessment to determine:~~ ~~• Whether the kidneys are of equal size~~ ~~• If the kidneys have masses, cysts, or stones~~ ~~• If the kidneys have other anatomical defects~~ ~~• Which kidney is more anatomically suited for transplant.~~ ~~The choice of test for radiologic imaging may be determined based on the local radiological expertise and surgical preference, and may include CT angiogram or MR angiogram.~~

This evaluation must be completed:	Including evaluation for and assessment of this information:
Transmissible disease screening	Infectious disease testing must be performed in a CLIA-certified laboratory or in a laboratory meeting equivalent requirements as determined by Centers for Medicare and Medicaid Services (CMS) using FDA-licensed, approved, or cleared tests. Testing must include *all* the following: 1. CMV (Cytomegalovirus) antibody 2. EBV (Epstein Barr Virus) antibody 3. HIV ~~1,2 (Human Immunodeficiency Virus)~~ antibody (anti-HIV) testing *or* HIV antigen/antibody (Ag/Ab) combination test as close as possible, but within 28 days prior to organ recovery 4. ~~HepBsAg (~~Hepatitis B surface antigen (HBsAg) testing as close as possible, but within 28 days prior to organ recovery 5. ~~HepBcAB (~~Hepatitis B core antibody (anti-HBc) testing as close as possible, but within 28 days prior to organ recovery ~~6. HepBsAB (Hepatitis B surface antibody)~~ 6. ~~7. HCV (~~Hepatitis C ~~Virus)~~ antibody (anti-HCV) testing as close as possible, but within 28 days prior to organ recovery 7. HCV ribonucleic acid (RNA) by nucleic acid test (NAT) as close as possible, but within 28 days prior to organ recovery 8. ~~RPR (Rapid Plasma Reagin test for syphilis~~) Syphilis testing If a living donor is identified as being at increased risk for HIV, HBV, and HCV transmission according to the *U.S. Public Health Services (PHS) Guideline*, testing must also include HIV ribonucleic acid (RNA) by NAT or HIV antigen/antibody (Ag/Ab) combination test. This does not apply to donors whose only increased risk factor is receiving hemodialysis within the preceding 12 months, as they are at risk only for HCV according to the *U.S. Public Health Services (PHS) Guideline*. For tuberculosis (TB), ~~L~~living donor recovery hospitals must determine if the ~~potential~~ donor is at increased risk for ~~tuberculosis (TB)~~ this infection.~~and~~ ~~i~~If ~~so~~TB risk is suspected, testing must include screening for latent infection ~~TB~~ using *either*: • Intradermal PPD ~~or~~ Interferon Gamma Release Assay (IGRA)

This evaluation must be completed:	Including evaluation for and assessment of this information:
Endemic transmissible diseases	Each living donor hospital must develop and follow a written protocol for identifying and testing donors at risk for transmissible seasonal or geographically defined endemic disease as part of its medical evaluation. ~~For the following infectious diseases, recovery hospitals must determine if the potential donor is from an endemic area, and if so must test for:~~ • ~~Strongyloides~~ • ~~Trypanosoma cruzi~~ • ~~West Nile~~
Cancer screening	Recovery hospitals must develop and comply with protocols consistent with the American Cancer Society (ACS) or the U.S. Preventative Services Task Force to screen for: • Cervical cancer • Breast cancer • Prostate cancer • Colon cancer • ~~Skin cancer~~ • Lung cancer
~~Exclusion criteria~~	~~Kidney recovery hospitals may exclude a donor with any condition that, in the hospital's medical judgment, causes the donor to be unsuitable for organ donation.~~ ~~Kidney recovery hospitals must exclude all donors who meet *any* of the following exclusion criteria:~~ • ~~Is both less than 18 years old and mentally incapable of making an informed decision~~ • ~~HIV~~ • ~~Diabetes~~ • ~~Uncontrollable hypertension or history of hypertension with evidence of end stage organ damage~~ • ~~Active malignancy, or incompletely treated malignancy~~ • ~~High suspicion of donor coercion~~ • ~~High suspicion of illegal financial exchange between donor and recipient~~ • ~~Evidence of acute symptomatic infection (until resolved)~~ • ~~Diagnosable psychiatric conditions requiring treatment before donation, including any evidence of suicidality~~

14.4.C ~~Required Medical Evaluation Protocols for Liver Recovery Hospitals~~ Additional Requirements for the Medical Evaluation of Living Kidney Donors

~~Liver recovery hospitals must develop and comply with written protocols for the medical evaluation of potential living donors that must include, but are not limited to, *all* the following elements:~~

~~1. A thorough medical evaluation by a physician or surgeon experienced in living donation to assess and minimize risks to the potential donor post-donation, which must 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 must be provided to assess decision making capacity, screen for any pre-existing psychiatric illness, and evaluate the potential living donor for signs of potential coercion to donate.~~
~~3. Screening for evidence of transmissible diseases such as cancers and infections.~~
4. ~~A radiographic assessment to ensure adequate anatomy and volume of the donor and the remaining liver segment.~~

Table 14-7: Additional Requirements for the Medical Evaluation of Living Kidney Donors

This evaluation must be completed:	Including evaluation for and assessment of this information:
Kidney - specific donor history	A kidney-specific personal history including: a. Genetic renal diseases b. Kidney disease, proteinuria, hematuria c. Kidney injury d. Diabetes including gestational diabetes e. Nephrolithiasis f. Recurrent urinary tract infections
Kidney-specific family history	• Kidney disease • Diabetes • Hypertension • Kidney Cancer
Physical Exam	• Blood pressure taken on at least two different occasions or 24-hour or overnight blood pressure monitoring

This evaluation must be completed:	Including evaluation for and assessment of this information:
Other metabolic testing	• Fasting blood glucose • Fasting lipid profile (cholesterol, triglycerides, HDL cholesterol, and LDL cholesterol) • Glucose tolerance test or glycosylated hemoglobin in first degree relatives of diabetics and in high risk individuals

Kidney-specific tests	• Urinalysis or urine microscopy
	• Urine culture if clinically indicated
	• Measurement of urinary protein and albumin excretion
	• Measurement of glomerular filtration rate by isotopic methods or a creatinine clearance calculated from a 24-hour urine collection
	• Hospitals must develop and comply with a written protocol for polycystic kidney disease or other inherited renal disease as indicated by family history
	• Patients with a history of nephrolithiasis or nephrolithiasis (>3 mm) identified on radiographic imaging must have a 24-hour urine stone panel measuring:
	  ○ Calcium
	  ○ Oxalate
	  ○ Uric acid
	  ○ Citric acid
	  ○ Creatinine
	  ○ Sodium

Anatomic assessment	Determine: • Whether the kidneys are of equal size • If the kidneys have masses, cysts, or stones • If the kidneys have other anatomical defects • Which kidney is more anatomically suited for transplant.

14.4.D Additional Requirements for the Medical Evaluation of Living Liver Donors

Table 14-8: Additional Requirements for the Medical Evaluation of Living Liver Donors

This evaluation must be completed:	Including evaluation for and assessment of this information:
Liver-specific family history	• Liver diseases • Bleeding or clotting disorders
General laboratory and imaging tests	• Hospitals must develop and follow a written protocol for hypercoagulable state evaluation
Liver-specific tests	• Hepatic function panel • Ceruloplasmin in a donor with a family history of Wilson's Disease • Iron, iron binding capacity, ferritin • Alpha-1-antitrypsin level: those with a low alpha-1-antitrypsin levels should have a phenotype • must develop and follow a written protocol for testing for genetic diseases • Hospitals must develop and follow a written protocol for screening for autoimmune disease • Hospitals must develop and follow a written protocol for pre-donation liver biopsy
Anatomic assessment	A radiological assessment must be performed to determine if the liver is anatomically suitable for transplantation, and to assess safety of resection for the donor. The evaluation must include at least all of the following: • Assessment of projected graft volume • Donor's remnant volume, • Vascular anatomy • Presence of steatosis

14.4 E Living Donor Exclusion Criteria

Table 14-9: Living Donor Exclusion Criteria

Exclusion criteria for all Living Donors	Living donor recovery hospitals may exclude a donor with any condition that, in the hospital's medical judgment, causes the donor to be unsuitable for organ donation. Living donor recovery hospitals must exclude all donors who meet any of the following exclusion criteria: • Is both less than 18 years old and mentally incapable of making an informed decision • HIV • Active malignancy, or incompletely treated malignancy • High suspicion of donor coercion • High suspicion of illegal financial exchange between donor and recipient • Evidence of acute symptomatic infection (until resolved) • Uncontrolled diagnosable psychiatric conditions requiring treatment before donation, including any evidence of suicidality
Additional Exclusion Criteria for Living Kidney Donor	Kidney recovery hospitals must exclude all donors who meet *any* of the following additional exclusion criteria: • Uncontrollable hypertension or history of hypertension with evidence of end organ damage • Diabetes
Additional Exclusion Criteria for Living Liver Donors	Liver recovery hospitals must exclude all donors who meet *any* of the following additional exclusion criteria: • HCV RNA positive • HBsAg positive • Donors with ZZ, Z-null, null-null and S-null alpha-1-antitrypsinphenotypes and untype-able phenotypes • Expected donor remnant volume less than 30% of native liver volume • Prior living liver donor

14.6~~5~~ Registration and Blood Type Verification of Living Donors before Donation

[*Subsequent headings affected by the re-numbering of this policy will also be changed as necessary.*]

Capping the HCC Exception Score at 34

Sponsoring Committee:	**Liver and Intestinal Organ Transplantation Committee**
Policy/Bylaws Affected:	**9.3.G.vi Extensions of HCC Exceptions**
Distributed for Public Comment:	**March 2014-June 2014**
Amended After Public Comment:	**No**
Effective Date:	**Upon Implementation and notice to members**

Problem Statement

The "Share 35 Regional" policy for deceased donor liver allocation was implemented in June 2013. Under this policy, candidates with MELD/PELD scores of 35 and higher are offered livers, first locally, then regionally, by descending MELD/PELD scores before those livers are offered to local candidates with scores less than 35. This policy intended to reduce waiting list mortality in this very sick group of patients, whose risk of mortality is similar to those in Status 1. Increasingly, there are candidates with multiple HCC exception extensions who are now receiving regional offers under the "Share 35 Regional" policy despite their lower risk of disease progression or dropout (removed from the waiting list due to death or being too sick) than those without HCC exceptions.

Summary of Changes

This proposal would cap HCC exception scores at 34, in effect giving candidates with calculated MELD/PELD scores of 35 and higher a better opportunity to receive offers under the new policy. If a candidates has an accumulated HCC exception score of 35 or higher at the time the new policy is implemented, their exception score will be reset to 34 for the duration of their time with an HCC exception as long as they continue to meet criteria. Candidates with scores greater than 34 at the time of implementation may be referred to the Regional Review Board (RRB) if they demonstrate the need for higher priority.

What Members Need to Do

Familiarize yourselves with the new policy language and process. Submission requirements have not changed but transplant hospitals should learn the new timelines to ensure you don't miss critical deadlines. You should also participate in the training UNOS is providing before the change is implemented to educate and prepare members.

Affected Policy/Bylaw Language:

New language is <u>underlined</u> and language that will be deleted is ~~struck through~~.

9.3.G.vi Extensions of HCC Exceptions

A candidate will receive additional MELD or PELD points equivalent to a 10 percentage point increase in the candidate's mortality risk every three months after receiving an HCC exception until the candidate receives a transplant or is unsuitable for transplantation based on the candidate's HCC progression. <u>The HCC exception score will be capped at 34. Upon implementation, candidates with HCC exception scores greater than 34 will receive a score of 34 for their remaining HCC exception extensions. Candidates with scores greater than 34 at the</u>

time of implementation may be referred to the RRB if they demonstrate the need for higher priority.

Delay the HCC Exception Score Assignment

Sponsoring Committee: Liver and Intestinal Organ Transplantation Committee

Policy/Bylaws Affected:	**9.3 G: Candidates with Hepatocellular Carcinoma**
Distributed for Public Comment:	**March 2014-June 2014**
Amended After Public Comment:	**No**
Effective Date:	**Upon implementation and notice to members**

Problem Statement

The priority assigned to candidates with HCC exceptions has been modified several times since it was first included in liver allocation policy in 1998. Despite modifications to increase equity among all candidates, candidates with HCC exceptions still have significantly higher transplant rates and lower dropout rates than non-HCC candidates.

Summary of Changes

Under this proposal, HCC applications are submitted as they currently are, but candidates would be registered at their calculated MELD/PELD scores for the first three months (initial application) and for the first three-month extension, as long as the candidate continues to meet the policy criteria. Currently, the median calculated MELD/PELD score at the time of an initial HCC exception application meeting policy criteria is 11. At six months (the second extension), candidates will receive a score of 28. Currently, candidates receive scores of 22, 25, and 28 at these intervals (initial application, first extension at three months, and the second extension at 6 months).

What Members Need to Do

Members should familiarize themselves with the new policy language and process. Submission requirements have not changed but transplant hospitals should learn the new timelines to prevent missing critical deadlines. Before the change is implemented, UNOS will provide a training to educate and prepare members.

Affected Policy/Bylaw Language:

New language is underlined and language that will be deleted is ~~struck through~~.

9.3.G Candidates with Hepatocellular Carcinoma (HCC)

Upon submission of the required information to the OPTN Contractor, candidates with Hepatocellular Carcinoma (HCC) that have stage T2 lesions and meet the criteria according to Policies 9.3.G.i through vi below will be listed at their calculated ~~receive an initial~~ MELD or PELD score ~~equivalent to a 15 percent risk of 3-month mortality~~.

9.3.G.vi Extensions of HCC Exceptions

In order for a candidate to maintain an HCC approved exception, the transplant program must submit an updated MELD/PELD exception application every three months. The candidate will

receive the additional priority until transplanted or is found unsuitable for transplantation based on the HCC progression. Upon submission of the first extension, the candidate will be listed at the calculated MELD/PELD score. Upon submission of the second extension, the candidate will be assigned a MELD/PELD score equivalent to a 35 percent risk of 3-month mortality (MELD 28/PELD 41). For each subsequent extension, ~~A~~ the candidate will receive additional MELD or PELD points equivalent to a 10 percentage point increase in the candidate's mortality risk every three months. ~~until the candidate receives a transplant or is unsuitable for transplantation based on the candidate's HCC progression~~.

To receive the extension, the transplant program must submit an updated MELD exception ~~application every three months~~ that contains all of the following:

1. Submit an Hepatocellular Carcinoma (HCC) MELD/PELD score exception application with an updated narrative
2. Document the tumor using a CT or MRI
3. Specify the type of treatment if the number of tumors decreased since the last application.

Invasive studies such as biopsies or ablative procedures and repeated chest CT scans are not required after the initial application is approved. If a candidate's tumors have been resected since the previous application, then the transplant program must submit the extension application to its RRB for prospective review.

Candidates with Class 5T lesions will receive a MELD or PELD equivalent to a 10 percentage point increase in the candidate's mortality risk every three months, without RRB review, even if the estimated size of residual viable tumors falls below stage T2 criteria due to ablative therapy.

Clarify Data Submission and Documentation Requirements

Sponsoring Committee:	**Membership and Professional Standards Committee**
Policy/Bylaws Affected:	**Policy 18.1 (Data Submission Requirements)**
Distributed for Public Comment:	**March 2014**
Amended After Public Comment:	**Yes**
Effective Date:	**February 1, 2015**

Problem Statement

The OPTN/UNOS Membership and Professional Standards Committee (MPSC) historically has agreed that the need for accurate data is implied within Policy 18.1. Also implied is the member's obligation to provide documentation to verify the data's accuracy, if UNOS requests it. Some members who have been cited for submitting inaccurate data believed they were complying with Policy 18.1 by submitting the required forms, noting that the policy does not state the data must be accurate. Some members have also been reluctant to submit documentation to allow the MPSC to verify the accuracy of their data.

Summary of Changes

The revised policy explicitly states that members are obligated to submit accurate data and provide documentation to support the accuracy of their data, if the MPSC requests it.

What Members Need to Do

Your organization may be asked to compile and submit documentation to support the accuracy of your data if the MPSC requests it. You will continue to submit data as required by Policy 18.1. Members will not be required to submit any new documentation or have documentation immediately available for review at all times.

Affected Policy/Bylaw Language:

New language is <u>underlined</u> and language that will be deleted is ~~struck through~~.

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 <u>accurate</u> 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. <u>Members are responsible for providing documentation upon request to verify the accuracy of all data that is submitted to the OPTN through the use of standardized forms.</u>

Requests for Exceptions Based on Geographic Isolation

Sponsoring Committee:	**Membership and Professional Standards Committee**
Bylaws Affected:	**Appendix A.3.F. (Geographically Isolated Transplant Program Applicants)**
Distributed for Public Comment:	**March 2014**
Amended After Public Comment:	**Yes**
Effective Date:	**February 1, 2015**

Problem Statement

The OPTN/UNOS Membership and Professional Standards Committee (MPSC) occasionally receives membership applications that do not meet all OPTN Bylaws key personnel requirements specifically because the hospital is located in a geographically isolated area (Alaska, Hawaii, and Puerto Rico). If the MPSC believes that the applicant is otherwise qualified to have a transplant program and that the OPTN/UNOS Board of Directors should consider approving the applicant, there is currently no mechanism in the Bylaws that allows the Board to consider this exceptional approval.

Summary of Changes

The new Bylaws establish a mechanism for the MPSC to recommend that the Board of Directors consider approving designated transplant programs located in Alaska, Hawaii, or Puerto Rico that do not meet all of the key personnel requirements in the Bylaws because of their geographic isolation. The MPSC can only make this recommendation if they conclude that the geographically-isolated applicant's key personnel have a satisfactory level of transplant experience. The applicant must also have an established history of transplant success for the specific organ type indicated in their application. Similarly, the Board will now be able to approve a geographically isolated transplant program upon recommendation from the MPSC.

What Members Need to Do

No member actions are necessary. The MPSC will continue to evaluate membership applications as it currently does. If the MPSC receives an application from Alaska, Hawaii, or Puerto Rico that does not meet all key personnel requirements due to the hospital's geographic isolation, but they are otherwise satisfied with the proposed key personnel's experience and transplant success, they may recommend the Board consider approving the designated transplant program.

Affected Policy/Bylaw Language:

New language is underlined and language that will be deleted is ~~struck through~~.

A.3.F. Geographically Isolated Transplant Program Applicants

The MPSC may recommend to the Board of Directors the approval of a designated transplant program if the prospective program cannot satisfy the current key personnel requirements due to its geographical isolation. Geographically isolated applicants must demonstrate to the MPSC that the proposed key personnel have both a satisfactory level of transplant experience and an established history of transplant success for the specific organ type indicated in the application for designated transplant program status.

MPSC recommendation of approval of a geographically isolated program that is not otherwise qualified does not give interim approval to the prospective program. The designated transplant program status of a geographically isolated program that is not otherwise qualified is effective only upon approval of the Board of Directors.

For purposes of this provision, “geographically isolated” is defined as a program located entirely within a state or commonwealth noncontiguous with the mainland United States. This includes Alaska, Hawaii, and Puerto Rico.

Effective Date Change - Modifications to the Imminent and Eligible Neurological Death Data Reporting Definitions

Sponsoring Committee:	**Organ Procurement Organization Committee**
Policy/Bylaws Affected:	**1.2 (Eligible Death Definition) and (Imminent Neurological Death)**
Distributed for Public Comment:	**September 2012**
Amended After Public Comment:	**Yes**
Effective Date:	**January 1, 2016**

Problem Statement

The OPTN/UNOS Board of Directors approved changes to the Imminent and Eligible Death Neurological Data Definitions during its June 2013 meeting and set an effective date of December 1, 2013. Implementing these policy changes on December 1, 2013, would result in organ procurement organizations (OPOs) having to report two separate sets of imminent and eligible neurological death data because of differences in the way the OPTN and CMS define imminent and eligible neurological death data reporting. The OPO Committee subsequently requested that the effective date be delayed until January 1, 2015, which was approved by the Board of Directors in November 2013. The OPO Committee again requested a change to the effective date since CMS has not made the necessary changes to adopt the OPTN definitions.

Summary of Changes

The effective date has been changed from January 1, 2015, to January 1, 2016. As a result, OPOs will not be required to report separate sets of imminent and eligible neurological death data to accommodate two different sets of definitions.

What Members Need to Do

OPO staff must review these policy changes and, once implemented, apply the new definitions when reporting imminent and eligible death data on the Death Notification Registration form.

Please note that the imminent and eligible definitions are “reporting” definitions only. They are not intended to be inclusive of all actual donors; therefore, they should not be used for screening donors, or affect allocation or acceptance of organs. These criteria are not used to exclude potential organ donors and do not prevent an OPO from pursuing a donor candidate that is not classified as an eligible death.

Affected Policy/Bylaw Language:

1.2 Definitions

Eligible death
For reporting purposes of DSA performance assessments, an eligible death for deceased organ donation is defined as the death of a patient who meets all the following characteristics:

- Is 75 years old or less

- Is legally declared dead by neurologic criteria according to the current standards of accepted medical practice and state or local law
- Has body weight of 5 kg or greater
- Has a body mass index (BMI) of 50 kg/m^2 or less
- Has at least one kidney, liver, heart or lung that is deemed to meet the eligible data definition as defined below:
    - The kidney would initially meet the eligible data definition unless the donor meets *any* of the following criteria:
        - Greater than 70 years old
        - Age 50-69 years with history of type 1 diabetes for more than 20 years
        - Polycystic kidney disease
        - Glomerulosclerosis greater than or equal to 20% by kidney biopsy
        - Terminal serum creatinine greater than 4.0 mg/dL
        - Chronic renal failure
        - No urine output for 24 hours or longer
    - The liver would initially meet the eligible data definition unless the donor meets *any* of the following criteria:
        - Cirrhosis
        - Terminal total bilirubin greater than or equal to 4 mg/dL
        - Portal hypertension
        - Macrosteatosis greater than or equal to 50%
        - Fibrosis greater than or equal to stage II
        - Fulminant hepatic failure
        - Terminal AST/ALT greater than 700 U/L
    - The heart would initially meet the eligible data definition unless the donor meets *any* of the following criteria:
        - 60 years old or older
        - 45 years old or older with a history of 10 or more years of HTN or 10 or more years of type 1 diabetes
        - History of coronary artery bypass graft (CABG)
        - History of coronary stent/intervention
        - Current or past medical history of myocardial infarction (MI)
        - Severe vessel diagnosis as supported by cardiac catheterization
        - Acute myocarditis or endocarditis, or both
        - Heart failure due to cardiomyopathy
        - Internal defibrillator or pacemaker
        - Moderate to severe single valve or 2-valve disease documented by echo or cardiac catheterization, or previous valve repair
        - Serial echo results showing severe global hypokinesis
        - Myxoma
        - Congenital defects (surgically corrected or not)
    - The lung would initially meet the eligible data definition unless the donor meets *any* of the following criteria:
        - Age 65 years or older
        - Diagnosed with COPD
        - Terminal PaO_2/FiO_2 less than 250 mmHg
        - Asthma (with daily prescription)
        - Asthma is the cause of death
        - Pulmonary fibrosis
        - Previous lobectomy
        - Multiple blebs documented on computed axial tomography (CAT) scan
        - Pneumonia as indicated on computed tomography (CT), X-ray, bronchoscopy, or cultures
        - Bilateral severe pulmonary contusions as per CT

If a deceased patient meets the above criteria they would be classified as an eligible death unless the donor meets any of the following criteria:

- The donor has no suitable organ for transplant (as defined above)
- The donor goes to the operating room with intent to recover organs for transplant and all organs are deemed not medically suitable for transplant
- The donor exhibits any of the following:
  - Active infections (with a specific diagnosis)
  - Bacterial: tuberculosis, gangrenous bowel or perforated bowel or intra-abdominal sepsis
  - Viral: HIV infection by serologic or molecular detection, rabies, reactive hepatitis B surface antigen, retroviral infections including viral encephalitis or meningitis, active herpes simplex, varicella zoster, or cytomegalovirus viremia or pneumonia, acute epstein barr virus (mononucleosis), West Nile virus infection, SARS
  - Fungal: active infection with cryptococcus, aspergillus, histoplasma, coccidioides, active candidemia or invasive yeast infection
  - Parasites: active infection with trypanosoma cruzi (Chagas'), Leishmania, strongyloides, or malaria (plasmodium sp.)
  - Prion: Creutzfeldt-Jacob disease
  - General [Exclusions to the Definition of Eligible]: aplastic anemia, agranulocytosis
  - Current malignant neoplasms, except non-melanoma skin cancers such as basal cell and squamous cell cancer and primary CNS tumors without evident metastatic disease
  - Previous malignant neoplasms with current evident metastatic disease
  - A history of melanoma
  - Hematologic malignancies: leukemia, Hodgkin's disease, lymphoma, multiple myeloma
  - Active fungal or parasitic meningitis or encephalitis
  - No discernible cause of death

Imminent neurological death
Imminent Neurological Death is defined as the death of a patient who meets both of the following criteria:

- Meets the eligible death definition with the exception that the patient has not been declared legally dead by neurologic criteria according to current standards of accepted medical practice and state or local law.
- Has a severe neurological injury requiring ventilator support who, upon clinical evaluation documented in the OPO record or donor hospital chart, has no observed spontaneous breathing and is lacking at least two of the additional brain stem reflexes that follow:

  - Pupillary reaction
  - Response to iced caloric
  - Gag Reflex
  - Cough Reflex
  - Corneal Reflex
  - Doll's eyes reflex
  - Response to painful stimuli

A patient who is unable to be assessed neurologically due to administration of sedation or hypothermia protocol does not meet the definition of an imminent neurological death.

Proposed ABO Subtyping Consistency Policy Modifications

Sponsoring Committee: Operations and Safety

Policy/Bylaws Affected: **Policy 2.6. B: Deceased Donor Blood Subtype Determination, Policy 5.3. C: Liver Acceptance Criteria), Policy 8.5. E: Allocation of Kidneys by Blood Type, Policy 9.5.B: Points Assigned by Blood Type, Policy 13.7.A: Blood Type, Policy 13.7.B: A2 and A2B Matching, Policy 14.4.A.i: Living Donor Blood Subtype Determination**

Distributed for Public Comment: **March 2014**

Amended After Public Comment: **No**

Effective Date: **May 1, 2015**

Problem Statement

In multiple sections of OPTN policy, different references are used for subtyping result categories that are intended to mean the same thing. Use of the term "A_2" is not technically correct because routine subtyping technology only tests for the presence or absence of A_1 antigens.

Summary of Changes

We will update all policies to use the same language when referring to subtyping result categories. All applicable subtyping references will be updated to either:

- Blood type A, non-A_1
- Blood type AB, non-A_1B

What Members Need to Do

By May 1, 2015, you should familiarize yourselves with the meanings of these terms: blood type A, non-A_1 and blood type AB, non-A_1B.

Affected Policy/Bylaw Language:

New language is <u>underlined</u> and language that will be deleted is ~~struck through~~.

2.6.B Deceased Donor Blood Subtype Determination

When a deceased donor is determined to be blood type A, then subtype testing must be completed. Subtype testing must be performed only on pre-transfusion blood samples. The host OPO may choose whether to perform subtype testing on deceased donors with blood type AB.

When deceased donor blood type A or AB is sub-typed and found to be ~~non-A1~~ <u>blood type A, non-A_1</u> or ~~non-A1B~~ <u>blood type AB, non-A_1B</u>, the host OPO must complete a second subtype test.

If the sample used for the second subtype test is from the same blood draw as the sample used for the first subtype test, the second sample must be tested by a different laboratory.

The host OPO must document that blood subtype determination tests have been completed to determine the deceased donor's blood subtype.

5.3.C Liver Acceptance Criteria

The responsible transplant surgeon must determine the acceptable deceased donor weight for each of its liver candidates, and the determined acceptable weight must be reported to the OPTN Contractor.

Liver transplant programs may also specify additional liver acceptance criteria, including *any* of the following:

1. The maximum number of mismatched antigens it will accept for any of its liver candidates
2. Minimal acceptance criteria for livers
3. If a blood type O candidate will accept a liver from a deceased donor with blood type A, non-A_1 ~~blood type~~
4. For status 1A or 1B candidates, if they will accept a liver from a deceased donor with any blood type
5. If a candidate with a Model for End-Stage Liver Disease (MELD) or Pediatric End Stage Liver Disease (PELD) score of at least 30 will accept a liver from a deceased donor with any blood type
6. If a candidate will accept a liver for other methods of hepatic support
7. If a candidate is willing to accept a segmental graft

8.5. E Allocation of Kidneys by Blood Type

Transplants are restricted by blood type in certain circumstances. Kidneys will be allocated to candidates according to the blood type matching requirements in *Table 8-4* below:

Table 8-4: Allocation of Kidneys by Blood Type

Kidneys from Donors with:	Are Allocated to Candidates with:
Blood Type O	Blood type O. For offers made to candidates in zero mismatch categories, blood type O kidneys may be transplanted into candidates who have blood types other than O.
Blood Type A	Blood type A or blood type AB.
Blood Type B	Blood type B. For offers made to candidates in zero mismatch categories, blood type B kidneys may be transplanted into candidates who have blood types other than B.
Blood Type AB	Blood type AB.

Kidneys from Donors with:	Are Allocated to Candidates with:
Blood ~~type~~ Types A,non-A_1 and AB,non-A_1B	Kidneys may be transplanted into candidates with blood type B who meet *all* of the following criteria: 1. The transplant program obtains written informed consent from each blood type B candidate regarding their willingness to accept a blood type A, non-A_1 or blood type AB, non-A_1B blood type kidney. 2. The transplant program establishes a written policy regarding its program's titer threshold for transplanting blood type A, non-A_1 and blood type AB, non-A_1B kidneys into candidates with blood type B. The transplant program must confirm the candidate's eligibility every 90 days (+/- 20 days).

9.5.B Points Assigned by Blood Type

For status 1A and 1B transplant candidates, those with the same blood type as the deceased liver donor will receive 10 points. Candidates with compatible but not identical blood types will receive 5 points, and candidates with incompatible types will receive 0 points.

Blood type O candidates who will accept a liver from a ~~non-A1~~ blood type A, non-A_1 blood type donor will receive 5 points for blood type incompatible matching. Within each MELD or PELD score, donor livers will be offered to transplant candidates with blood types identical to the deceased donor first, then to candidates who are blood type compatible, followed by candidates who are blood type incompatible with the deceased donor.

13.7.A Blood Type

The OPTN Contractor will only match candidates and potential donors who have identical or compatible blood types as defined in *Table 13-1* below.

Table 13-1: Allocation by Blood Type

Donors with:	Are Matched to Candidates with:
Blood Type O	Blood type O Blood types A, A_1, ~~A_2~~ or A, non-A_1
Blood Type A or A_1	Blood types A, A_1, ~~A_2~~ or A, non-A_1 Blood types AB, A_1B, or ~~A_2B~~ AB, non-A_1B
~~Blood Type A_1~~	~~Blood types A, A_1, A_2~~ ~~Blood types AB, A_1B, or A_2B~~

Donors with:	Are Matched to Candidates with:
Blood Type ~~A_2~~ A, non-A_1	Blood types A, A_1, ~~A_2~~,or A, non-A_1 Blood types AB, A_1B, or ~~A_2B~~ AB, non-A_1B Blood type O or B if the candidate meets the requirements in *Policy 13.7.B: ~~A_2~~ Blood Type A, non-$A_1$and ~~A_2B~~ Blood Type AB, non-A_1B Matching*.
Blood Type B	Blood type B Blood types AB, A_1B, or ~~A_2B~~ AB, non-A_1B
Blood Type AB	Blood types AB, A_1B, or ~~A_2B~~ AB, non-A_1B
Blood Type A_1B	Blood types AB, A_1B, or ~~A_2B~~ AB, non-A_1B
Blood Type ~~A_2B~~ AB, non-A_1B	Blood types AB, A_1B, or ~~A_2B~~ AB, non-A_1B Blood type B if the candidate meets the requirements in *Policy 13.7.B: ~~A_2~~ Blood Type A, non-$A_1$and ~~A_2B~~ Blood Type AB, non-A_1B Matching*.

13.7.B ~~A_2~~ Blood Type A, non-A_1 and Blood Type AB,non-A_1B ~~A_2B~~ Matching

In order for a blood type B candidate to be eligible to be matched to a blood type ~~A2~~ A,non-A_1 or ~~A2B~~ blood type AB,non-A_1B potential donor, or for a blood type O candidate to be eligible to match to a blood type ~~A2~~ A,non-A_1 potential donor in the OPTN KPD Program, the candidate must meet *both* of these conditions:

1. The candidate must have an IgG antibody titer value less than 1:8
2. The candidate's transplant hospital must report to the OPTN Contractor the candidate's titer value and date of the test.

14.4.A.i Living Donor Blood Subtype Determination

The recovery hospital subtyping a living donor whose initial subtype test indicates the donor to be ~~non-A1 (negative for A1)~~ blood type A, non-A_1 or ~~non-A1B (negative for A1B)~~ blood type AB,non-A_1B must ensure a second determination test is performed prior to living donation to assess the accuracy of the result. Blood samples for subtype testing must be taken on two separate occasions, defined as two samples taken at different times. Samples tested must not be taken after a blood transfusion. When the initial and second determination subtypings are the same result, the result can be used to determine transplant compatibility with the intended recipient or any other potential recipient. If the initial and second determination subtyping results are not the same, the donor must be allocated based on the primary blood type, A or AB.

Require the Collection of Serum Lipase for Pancreas Donors

Sponsoring Committee:	**Pancreas Transplantation Committee**
Policy/Bylaws Affected:	**Policy 2.11.E Required Information for Deceased Pancreas Donors**
Distributed for Public Comment:	**March 2014**
Amended After Public Comment:	**No**
Effective Date:	**Upon implementation and notice to members**

Problem Statement

Policy 2.11.E: lists required information for deceased pancreas donors. The required list currently does not include serum lipase results but does include serum amylase results. Compared to serum amylase analysis, serum lipase analysis is more sensitive and specific, and thus a better indicator of pancreas quality. In turn, transplant professionals need to know the pancreas' quality to determine whether or not to accept the offer.

Currently, serum lipase is a requested field in DonorNet® but it's not required in order to make pancreas offers. Some OPOs do not provide a serum lipase value, which makes assessing pancreas quality more challenging.

Summary of Changes

The proposal makes serum lipase a required field for all pancreas donors. It also creates another required new field, the upper limit of normal serum lipase value.

What Members Need to Do

OPOs will have to report serum lipase tests results and the upper limit of normal at the time of the pancreas offer and for all pancreas offers.

Affected Policy/Bylaw Language:

New language is <u>underlined</u> and language that will be deleted is ~~struck through~~.

2.11 Required Deceased Donor Information

2.11.E Required Information for Deceased Pancreas Donors

The host OPO must provide *all* the following additional information for all deceased donor pancreas offers:

1. Donor name
2. Donor ID
3. Ethnicity
4. Weight
5. Date of admission for the current hospitalization
6. Alcohol use (if known)
7. Current history of abdominal injuries and operations including pancreatic trauma

8. Current history of average blood pressure, hypotensive episodes, cardiac arrest, average urine output, and oliguria
9. Current medication and transfusion history
10. Pertinent past medical or social history including pancreatitis
11. Familial history of diabetes
12. Insulin protocol
13. Indications of sepsis
14. Serum amylase
15. Serum lipase
16. HLA information as follows: A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, and DQB antigens. The lab is encouraged to report splits for all loci as outlined in *Policy 4: Histocompatibility.*

Allow Non-substantive Changes to the OPTN Policies and Bylaws

Sponsoring Committee:	**Policy Oversight (POC)**
Policy/Bylaws Affected:	**Bylaws Article X: Amendment of Charter and Article XI: Adoption of Policies**
Distributed for Public Comment:	**March 2014**
Amended After Public Comment:	**No**
Effective Date:	**February 1, 2015**

Problem Statement

On occasion, clerical errors are identified in the Policies and Bylaws. These clerical errors are non-controversial things like obvious misspellings and mis-numbering of lists. These changes must be approved by the Executive Committee or Board because there is nothing in the Bylaws or Policies that allow staff to make these non-substantive corrections. This proposal would allow staff to make non-substantive corrections without needing approval by the Executive Committee or Board of Directors. The Executive Committee would review these changes retrospectively.

Summary of Changes

Two sections are added to the *OPTN Bylaws Article X: Amendment of Charter* and *Article XI: Adoption of Policies*:

- 10.3: Non-substantive Changes to Bylaws
- 11.5 Non-substantive Changes to Policy

These additions allow staff to make these non-substantive corrections such as:

- Capitalization or punctuation, as needed to maintain consistency with current policy
- Typographical, spelling, or grammatical errors
- Lettering and numbering of a rule or the subparts of a rule, according to style conventions in current policy
- Cross-references to rules or sections that are cited incorrectly because of subsequent repeal, amendment, or reorganization of the sections cited

What Members Need to Do

This proposal will not require that members do anything or change their procedures. If members print out copies of the Bylaws or Policies, they should print out the new, corrected version.

Affected Policy/Bylaw Language:

New language is <u>underlined</u> and language that will be deleted is ~~struck through~~.

OPTN Bylaws Article X: Amendment of Charter and Bylaws

10.3 Non-substantive Changes to Bylaws

The OPTN Contractor may correct *any* of the following:

- Capitalization or punctuation, as needed to maintain consistency with current policy
- Typographical, spelling, or grammatical errors
- Lettering and numbering of a rule or the subparts of a rule, according to style conventions in current policy
- Cross-references to rules or sections that are cited incorrectly because of subsequent repeal, amendment, or reorganization of the sections cited

The Executive Committee will retrospectively review any of these changes made to policy by the OPTN Contractor. The OPTN Contractor may not make any substantive changes to policy without approval of the Board of Directors.

OPTN Bylaws Article XI: Adoption of Policies

11.5 ~~Adoption of Policies~~ Non-substantive Changes to Policy

The OPTN Contractor may correct *any* of the following:

- Capitalization or punctuation, as needed to maintain consistency with current policy
- Typographical, spelling, or grammatical errors
- Lettering and numbering of a rule or the subparts of a rule, according to style conventions in current policy
- Cross-references to rules or sections that are cited incorrectly because of subsequent repeal, amendment, or reorganization of the sections cited

The Executive Committee will retrospectively review any corrections made to policy by the OPTN Contractor. The OPTN Contractor may not make any substantive changes to policy without approval of the Board of Directors.

11.~~5~~6 Adoption of Policies

New policy or changes to existing policy adopted by the Board of Directors may periodically be incorporated into these Bylaws by amendment to the Bylaws. Members must comply with all policies after adoption by the Board of Directors and after receiving written notice, even if the policies have not been incorporated as amendments to these Bylaws.

11.~~6~~7 Developing Organ Allocation Policies

Policy proposals affecting organ allocation must specify the organ or combination of organs addressed in the policy and summarize how the proposal meets requirements of the OPTN Final Rule, *42 CFR Part 121*.

Clarification to Policy 10.1.G: Reporting Additional Data for Candidates with an LAS of 50 or Higher

Sponsoring Committee:	**Thoracic Organ Transplantation Committee**
Policy/Bylaws Affected:	**10.1.G: Reporting Additional Data for Candidates with an LAS of 50 or Higher**
Distributed for Public Comment:	**No**
Amended After Public Comment:	**N/A**
Effective Date:	**February 1, 2015**

Problem Statement

In November 2011, the Board of Directors adopted the Thoracic Committee's proposal "Requiring Updates of Certain Clinical Factors Every 14 Days for Lung Transplant Candidates with Lung Allocation Scores of at Least 50." That policy requires transplant programs to report values for assisted ventilation, supplemental oxygen, and current PCO_2 every 14 days from the date a candidate's LAS becomes 50 or higher. However, UNOS cannot effectively monitor the policy the way it is currently written. Current policy is not clear whether programs need to assess and report new data every 14 days regardless of a change in the variables, or assess and only report observed changes every 14 days.

Summary of Changes

The changes clarify, but do not change, the reporting requirements for transplant programs with candidates with an LAS of 50 or higher. Even if there is no observed change, a transplant program must assess and report these variables every 14 days once a lung transplant candidate's LAS becomes 50 or higher, but the program is not required to provide information about every observed change in these variables over the course of each 14 day reporting period. Additionally, programs must report data for all fields associated with assisted ventilation, supplemental oxygen, and current PCO_2.

What Members Need to Do

If you're a transplant program and your candidate's LAS becomes 50 or higher, within 14 days you must report data for all fields associated with assisted ventilation, supplemental oxygen, and current PCO_2. As long as your candidate's LAS remains 50 or higher, you must report these data every 14 days, starting with the date their LAS became 50 or higher. If your program does not perform a heart catheterization for your candidate during a 14-day reporting period, you are not required to update the PCO_2 data.

Affected Policy/Bylaw Language:

New language is <u>underlined</u> and language that will be deleted is ~~struck through~~.

10.1.G Reporting Additional Data for Candidates with an LAS of 50 or Higher

<u>Within 14 days of the date a candidate's LAS becomes 50 or higher</u>, ~~A~~ <u>the candidate's</u> transplant program must <u>assess and</u> report ~~data for three key variables~~ to the OPTN Contractor <u>the following variables</u> ~~no more than 14 days after a candidate's LAS becomes 50 or higher~~:

1. Assisted ventilation
2. Supplemental oxygen
3. Current PCO_2

~~The transplant program is only required to report an updated PCO_2 value if the test was performed within those 14 days.~~ While the candidate's LAS ~~score~~ remains 50 or higher, the transplant program must continue to assess and report ~~any observed changes in the three clinical key variables~~ assisted ventilation and supplemental oxygen data every 14 days. The transplant program is only required to report updated PCO_2 data if the assessment was performed during the previous 14 day interval.

The transplant program must maintain documentation of each assessment in the candidate's medical chart.

Modifications to Approved Lung Allocation Policy

Sponsoring Committee:	**Thoracic Organ Transplantation Committee**
Policy/Bylaws Affected:	**Policies 10.1.C: Priority and Clinical Data Update Schedule for Candidates less than 12 Years Old; 10.1.E: LAS Values and Clinical Data Update Schedule for Candidates at Least 12 Years Old; 10.1.F: The LAS Calculation; 10.1.F.i: Lung Disease Diagnosis Groups; 10.1.F.ii: PCO2 in the LAS; 10.1.F.iii: Bilirubin in the LAS; 10.1.F.iv: Creatinine in the LAS; 10.2.B.iv: LAS Values and Diagnoses Approved by the LRB; 10.3 Waiting Time; and 10.5: Probability Data Used in the LAS Calculation**
Distributed for Public Comment:	**No**
Amended After Public Comment:	**N/A**
Effective Date:	**Upon implementation and notice to members**

Problem Statement

In February 2015, UNOS will implement a modified LAS policy, based on Board-approved modifications from June 2009, October 2009, November 2009, November 2012, May 2013, and April 2014. During the programming process, UNOS staff has identified areas in which the policy can be improved, clarified, or changed to accurately reflect how the Lung Allocation Score (LAS) is calculated.

Summary of Changes

Issue	Solution
The organization of *Table 10-1: Values Substituted for Missing or Expired Actual Values in Calculating the LAS* may lead to multiple interpretations.	Reorganize Table 10-1 by adding a column and changing the column titles.
When the value "continuous mechanical ventilation" (CMV) is programmed, transplant programs will have the option of selecting CMV "while hospitalized" or CMV without a qualifier. The default value will only apply if the candidate is hospitalized, but the description in Table 10-1 does not explicitly explain this.	Add "while hospitalized" to the description of CMV in the substituted value column of Table 10-1.

Issue	Solution
The coefficient for oxygen needed to maintain minimum oxygen saturation at rest, in both *Table 10-3: Waiting List Mortality Calculation: Covariates and their Coefficients*, and *Table 10-4: Post-Transplant Survival Calculation: Covariates and Their Coefficients*, is missing the multiplier that is necessary to make the calculation operable.	Add "*O_2" to this covariate in Tables 10-3 and 10-4.
The description of the coefficient for creatinine increase of at least 150% in *Table 10-4: Post-Transplant Survival Calculation: Covariates and Their Coefficients* is misleading as written.	Remove "or creatinine decreases" from the description of the coefficient for creatinine increase of less than 150%.
The description of the coefficient for functional status in *Table 10-4: Post-Transplant Survival Calculation: Covariates and Their Coefficients* uses incorrect phrasing for "activities of daily living."	Change "or" to "of" for the phrase "activities of daily living."
The coefficient for six-minute-walk-distance in *Table 10-4: Post-Transplant Survival Calculation: Covariates and Their Coefficients* is not clear because it is not spelled out.	Change "6mw" to "six-minute-walk-distance" for clarity.
The diagnosis for BAC is misspelled in Diagnosis Group D	Change the spelling to bronchioloalveolar carcinoma (BAC).
The diagnosis pulmonary lymphangiectasia (PL) is missing from the lists of diagnoses in Diagnosis Group D. It was added as a result of the "other diagnosis" project approved by the Board in November 2009.	Add pulmonary lymphangiectasia (PL) to the list of Group D diagnoses.
During the plain language rewrite, the term for the threshold change calculation was replaced with "increase in…" for PCO_2, bilirubin and creatinine. Describing the calculation as a threshold change is more accurate than describing it as an "increase," because the values for PCO_2, creatinine and bilirubin could increase but the calculation would still not apply unless the threshold was met.	Change the title of the calculation back to "threshold change."
The definition of Current PCO_2 is missing the time component. Current PCO_2 was programmed in 2010, and uses most recent date only; if there are multiple tests from the same date, it will choose an arterial test over a venous or capillary test. Current bilirubin and current serum creatinine, on the other hand, use the value with the most recent date and time.	Add "and time" to the definition of current PCO_2 so that it is consistent with the definitions for current bilirubin and current serum creatinine, and delete the section of policy that indicates arterial values should be chosen over other test types if the dates are the same.
The description of current bilirubin, which states that a current bilirubin value of at least 1.0 mg/dL will impact a candidate's LAS, is mathematically incorrect. The current bilirubin value must be greater than 1.0 mg/dL to impact the LAS.	Change the description from "at least 1.0 mg/dL" to "greater than 1.0 mg/dL."
The section title for *10.2.B.iv: LAS Values and Diagnoses Approved by the LRB* is misleading, because the section only discusses diagnoses approved by the LRB.	Remove "Values and" from the section title.
***Policy 10.3: Waiting Time* does not correctly describe the waiting time policies for lung candidates less than 12 years old. These candidates do accrue waiting time while inactive.**	Add the waiting time accrual policy for candidates less than 12 years old in this section.

Issue	Solution
The values in the *Table 10-8: Baseline Waiting List Survival (SWL(t)) Probability* and *Table 10-9: Baseline Post-Transplant Survival (STX(t)) Probability* are only rounded to the sixth digit. The LAS calculation uses these values to the tenth digit.	Include the values to the tenth digit in Tables 10-8 and 10-9.
For both serum creatinine and bilirubin, the least beneficial values provided in *Table 10-1: Values Substituted for Missing or Expired Actual Values in Calculating* are both less than 1. However, in the threshold change calculation for both bilirubin and serum creatinine, the high value must be at least 1. If the high value for serum creatinine is 150% greater than the low value used in the threshold change calculation (and 50% greater than the low value used in the threshold change calculation for bilirubin), then the threshold change maintenance is awarded. If 0.1 is the low value used in the threshold change calculation for serum creatinine, the high value used in the threshold change could be 150% higher than 0.1 but still not be 1 – which is the requirement for the threshold change calculation. The same holds true for bilirubin; if 0.7 is the low value used in the threshold change calculation, the high value used in the threshold change could be 50% higher than 0.7 but still not be 1.	In the description of the threshold change maintenance calculation in both the bilirubin and serum creatinine sections, modify the description to require the current bilirubin and current serum creatinine values to be at least 1.0 mg/dL, in addition to meeting the respective percentage increase to maintain the impact of the threshold change calculation.

What Members Need to Do

These modifications do not change the way members must prepare their lung candidates for the upcoming implementation of the modified LAS policy. Professionals at transplant hospitals should become familiar with the new data reporting requirements, including what must be reported and when, and participate in UNOS training sessions in order to learn the policy requirements and systems changes.

Affected Policy/Bylaw Language:

New language is <u>underlined</u> and language that will be deleted is ~~struck through~~.

10.1.C Priority and Clinical Data Update Schedule for Candidates Less than 12 Years Old

A transplant program may update the reported clinical data to justify a candidate's priority at any time. When a candidate meets the requirements for priority 1 the candidate will remain at priority 1 for six months from the date first registered as priority 1 on the lung transplant waiting list.

To remain as priority 1, the transplant program must then update the required clinical data, except data that requires a heart cathe<u>te</u>rization, every six months following the first six months as a priority 1 candidate. The updates must occur in each six month period following the initial six months at priority 1 to remain at priority 1. The transplant program may determine the frequency of performing the heart catheterization.

If the data used to justify the priority 1 criteria are more than 6 months old at the 6-month anniversary date, other than data requiring a heart catheterization, the candidate will automatically be assigned priority 2.

Lung candidates registered on the waiting list at inactive status are subject to these same requirements for updating clinical data.

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~~:	**Is:**	**Then the LAS calculation will use this substituted value:**
Bilirubin	Missing, expired, or less than 0.7 mg/dL	0.7 mg/dL ~~if the actual value is missing, expired, or less than 0.7 mg/dL~~
Body mass index (BMI)	Missing or expired	100 kg/m^2 ~~if the actual value is missing or expired~~
Cardiac index	Missing	3.0 L/min/m^2 ~~if the actual value is missing~~
Central venous pressure (CVP)	Missing or less than 5 mm Hg	5 mm Hg ~~if the actual value is missing or less than 5 mm Hg~~
Continuous mechanical ventilation	Missing or expired	No mechanical ventilation in the waiting list model ~~if the actual value is missing or expired~~ Continuous mechanical ventilation while hospitalized in the post-transplant survival measure ~~if the actual value is missing or expired~~
Creatinine: serum	Missing or expired	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	Missing or expired	No diabetes ~~if the actual value is missing or expired~~
Forced vital capacity (FVC)	Missing or expired	150% for Diagnosis Group D ~~if the actual value is missing or expired, according to *Policy 10.1.F.i: Lung Disease Diagnosis Groups*~~

If this covariate's value ~~is missing, expired, or below the threshold value~~:	Is:	Then the LAS calculation will use this substituted value:
Functional status	Missing or expired	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	Missing or expired	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	Missing, expired, or less than 40 mm Hg	40 mm Hg ~~if the actual value is missing, expired, or if less than 40 mm Hg~~
Pulmonary artery (PA) systolic pressure	Missing or less than 20 mm Hg	20 mm Hg ~~if the actual value is missing or less than 20 mm Hg~~
Six-minute-walk distance	Missing or expired	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~~

10.1.F. The LAS Calculation

The LAS calculation uses *all* of the following measures:

- Waiting List Urgency Measure, which is the expected number of days a candidate will live without a transplant during an additional year on the waiting list.
- Post-transplant Survival Measure, which is the expected number of days a candidate will live during the first year post-transplant.
- Transplant Benefit Measure, which is the difference between the Post-transplant Survival Measure and the Waiting List Urgency Measure.
- Raw Allocation Score, which is the difference between Transplant Benefit Measure and Waiting List Urgency Measure.

To determine a candidate's LAS, the Raw Allocation Score is normalized to a continuous scale of zero to 100.

The equation for the LAS calculation is:

$$LAS = \frac{100 * [PTAUC - 2 * WLAUC + 730]}{1095}$$

Table 10-2: LAS Calculation Values

Where…	Includes…
$PTAUC = \sum_{k=0}^{364} S_{TX}(k)$	PTAUC = the area under the post-transplant survival probability curve during the first post-transplant year. β_I = the coefficient for characteristic i from the waiting list measure, according to *Table 10-3: Waiting List Mortality Calculation: Covariates and their Coefficients.*
$S_{TX}(t) = S_{TX,0}(t)^{e^{\alpha_1 Y_1 + \alpha_2 Y_2 + \ldots + \alpha_q Y_q}}$	$S_{TX}(t)$ = the expected post-transplant survival probability at time t for an individual candidate. Y_i = the value of the j^{th} characteristic for an individual candidate $\propto_j$ = the coefficient for characteristic j from the post-transplant survival measure, according to *Table 10-4: Post-Transplant Survival Calculation, Covariates, and Their Coefficients*.
$WLAUC = \sum_{k=0}^{364} S_{WL}(k)$	WLAUC = the area under the waiting list survival probability curve during the next year.
$S_{WL}(t) = S_{WL,0}(t)^{e^{\beta_1 X_1 + \beta_2 X_2 + \ldots + \beta_p X_p}}$	$S_{WL,0}(t)$ = the baseline waiting list survival probability at time t, according to *Table 10-5: Baseline Waiting List Survival (SWL(t)) Probability*. $S_{TX,0}(t)$ = the baseline post-transplant survival probability at time t, according to *Table 10-6: Baseline Post-Transplant Survival ($S_{TX}(t)$) Probability*. $S_{WL}(t)$ = the expected waiting list survival probability at time t for an individual candidate X_i = the value of the i^{th} characteristic for an individual candidate.

Table 10-3 provides the covariates and their coefficients for the waiting list mortality calculation. See *Policy 10.1.F.i: Lung Disease Diagnosis Groups* for specific information on each diagnosis group.

Table 10-3: Waiting List Mortality Calculation: Covariates and their Coefficients

For this covariate:	The following coefficient is used in the LAS calculation:
1. Age (year)	0.0083990318885565*age
2. Bilirubin (mg/dL)	0.0431682188302477*(bilirubin – 1) if bilirubin is more than 1.0 mg/dL 0 when bilirubin is 1.0 mg/dL or less
3. Bilirubin increase of at least 50%	1.4144058906830200 for Diagnosis Group B 0 for Diagnosis Groups A, C, and D
4. Body mass index (BMI) (kg/m^2)	0.1261444133358100*(20 – BMI) for BMI less than 20 kg/m^2 0 if BMI is at least 20 kg/m^2
5. Cardiac index prior to any exercise	0.5435368888028200 if the cardiac index is less than 2 $L/min/m^2$ 0 if the cardiac index is at least 2 $L/min/m^2$
6. Central venous pressure (CVP) (mm Hg) at rest, prior to any exercise	0.0173841981251578*(CVP – 7) for CVP greater than 7 mm Hg (Diagnosis Group B only) 0 if less than or equal to 7 mm Hg for Diagnosis Group B 0 for candidates in Diagnosis Groups A, C, and D
7. Ventilation status if candidate is hospitalized	1.6771121096052300 if continuous mechanical ventilation needed 0 if no continuous mechanical ventilation needed
8. Creatinine (serum) (mg/dL)	0.5034346761960600* creatinine if candidate is at least 18 years old 0 if candidate is less than 18 years old
9. Diabetes	0.4680254026735700 if diabetic 0 if not diabetic
10. Diagnosis Group A	0
11. Diagnosis Group B	1.5774243292137200
12. Diagnosis Group C	1.2313926484343600
13. Diagnosis Group D	0.6259577164157700
14. Detailed diagnosis: Bronchiectasis (Diagnosis Group A only)	0.6680518055684700
15. Detailed diagnosis: Eisenmenger's syndrome (Diagnosis Group B only)	-0.6278657824830000

For this covariate:	The following coefficient is used in the LAS calculation:
16. Detailed diagnosis: Lymphangioleiomyomatosis (Diagnosis Group A only)	-0.3162937838984600
17. Detailed Diagnosis: Obliterative bronchiolitis (not-retransplant) (Diagnosis Group D only)	0.4453284411081100
18. Detailed Diagnosis: Pulmonary fibrosis, not idiopathic (Diagnosis Group D only)	-0.2091170018125500
19. Detailed Diagnosis: Sarcoidosis with PA mean pressure greater than 30 mm Hg (Diagnosis Group D only)	-0.4577749354638600
20. Detailed Diagnosis: Sarcoidosis with PA mean pressure of 30 mm Hg or less (Diagnosis Group A only)	0.9330846239906700
21. Forced vital capacity (FVC)	0.1829476350587400*(80 – FVC)/10 if FVC is less than 80% for Diagnosis Group D 0 if FVC is greater than or equal to 80% for Diagnosis Group D 0 for candidates in Diagnosis Groups A, B, and C
22. Functional Status	-0.4471034284458400 if no assistance needed with activities of daily living 0 if some or total assistance needed with activities of daily living
23. Oxygen needed to maintain adequate oxygen saturation (88% or greater) at rest (L/min)	0.0213187586203456*O_2 for Diagnosis Group B 0.1188479817592500*O_2 for Diagnosis Groups A, C, and D
24. PCO_2 (mm Hg): current	0.1104609835819100*PCO_2/10 if PCO_2 is at least 40 mm Hg
25. PCO_2 increase of at least 15%	0.2331149280428300 if PCO_2 increase is at least 15% 0 if PCO_2 increase is less than 15%
26. Pulmonary artery (PA) systolic pressure (10 mm Hg) at rest, prior to any exercise	0.4155116686114300*(PA systolic – 40)/10 for Diagnosis Group A if the PA systolic pressure is greater than 40 mm Hg 0 for Diagnosis Group A if the PA systolic pressure is 40 mm Hg or less 0.0462410402627318*PA systolic/10 for Diagnosis Groups B, C, and D

For this covariate:	The following coefficient is used in the LAS calculation:
27. Six-minute-walk distance (feet) obtained while the candidate is receiving supplemental oxygen required to maintain an oxygen saturation of 88% or greater at rest. Increase in supplemental oxygen during this test is at the discretion of the center performing the test.	-0.0844896372724000*Six-minute-walk distance/100

Table 10-4 lists the covariates and corresponding coefficients in the waiting list and post-transplant survival measures. See *Policy 10.1.F.i: Lung Disease Diagnosis Groups* for specific information on each diagnosis group.

Table10-4: Post-Transplant Survival Calculation: Covariates and Their Coefficients

For this variable:	The following is used in the LAS calculation:
1. Age (years)	0.0246579831271869*(age–45) if candidate is greater than 45 years old 0 if candidate is 45 years old or younger
2. Creatinine (serum) at transplant (mg/dL)	0.0895569900508900*creatinine if candidate is at least 18 years old 0 if candidate is less than 18 years old
3. Creatinine increase of at least 150%	0.7708616024698100 if increase in creatinine is at least 150%, and ~~when~~ the higher value determining this increase is at least 1 mg/dL 0 if increase in creatinine of 150% if the higher value determining this increase is less than 1 mg/dL 0 if increase in creatinine less than 150% ~~or creatinine decreases~~
4. Cardiac index (L/min/m^2) at rest, prior to any exercise	0.3499381679822400 if less than 2 L/min/m^2 0 if at least 2 L/min/m^2
5. Ventilation status if candidate is hospitalized	0.6094478988424900 if continuous mechanical ventilation needed 0 if no continuous mechanical ventilation needed
6. Diagnosis Group A	0
7. Diagnosis Group B	0.6115547319209300
8. Diagnosis Group C	0.3627014422464200
9. Diagnosis Group D	0.4641392063023200

For this variable:	The following is used in the LAS calculation:
10. Detailed diagnosis: Bronchiectasis (Diagnosis Group A only)	0.1889100379099400
11. Detailed diagnosis: Eisenmenger's syndrome (Diagnosis Group B only)	0.9146727886744700
12. Detailed diagnosis: Lymphangioleiomyomatosis (Diagnosis Group A only)	-1.5194416206749400
13. Detailed diagnosis: Obliterative bronchiolitis (not-retransplant, Diagnosis Group D only)	-1.2050508750702600
14. Detailed diagnosis: Pulmonary fibrosis, not idiopathic (Diagnosis Group D only)	-0.0723596761367600
15. Detailed diagnosis: Sarcoidosis with PA mean pressure greater than 30 mm Hg (Diagnosis Group D only)	-0.0437880049066331
16. Detailed diagnosis: Sarcoidosis with PA mean pressure of 30 mm Hg or less (Diagnosis Group A only)	-0.1389363636019300
17. Oxygen needed to maintain adequate oxygen saturation (88% or greater) at rest (L/min)	0.0747978926517300*O_2 for Diagnosis Group A 0.0164276945879309*O_2 for Diagnosis Groups B, C, and D
18. Functional Status	-0.1900086366785100 if no assistance needed with activities ~~or~~of daily living 0 if some or total assistance needed with activities ~~or~~of daily living
19. Six-minute-walk-distance (feet) obtained while candidate is receiving supplemental oxygen required to maintain an oxygen saturation of 88% or greater at rest. Increase in supplemental oxygen during this test is at the discretion of the center performing the test.	0.0004594953809594*(1200-Six-minute-walk distance ~~6mw~~) 0 if six-minute-distance-walked is at least 1,200 feet

See *Policy 10.5: Probability Data Used in the LAS Calculation* for *Tables 10-8* and *10-9* that provide data used in the LAS calculation.

10.1.F.i Lung Disease Diagnosis Groups

The LAS calculation uses diagnosis Groups A, B, C, and D as listed below.

Group A

A candidate is in Group A if the candidate has *any* of the following diagnoses:

- Allergic bronchopulmonary aspergillosis
- Alpha-1 antitrypsin deficiency

- Bronchiectasis
- Bronchopulmonary dysplasia
- Chronic obstructive pulmonary disease/emphysema
- Ehlers-Danlos syndrome
- Granulomatous lung disease
- Inhalation burns/trauma
- Kartagener's syndrome
- Lymphangioleiomyomatosis
- Obstructive lung disease
- Primary ciliary dyskinesia;
- Sarcoidosis with mean pulmonary artery pressure of 30 mm Hg or less
- Tuberous sclerosis
- Wegener's granuloma – bronchiectasis

Group B

A candidate is in Group B if the candidate has any of the following diagnoses:

- Congenital malformation
- CREST – pulmonary hypertension
- Eisenmenger's syndrome: atrial septal defect (ASD)
- Eisenmenger's syndrome: multi-congenital anomalies
- Eisenmenger's syndrome: other specify
- Eisenmenger's syndrome: patent ductus arteriosus (PDA)
- Eisenmenger's syndrome: ventricular septal defect (VSD)
- Portopulmonary hypertension
- Primary pulmonary hypertension/pulmonary arterial hypertension
- Pulmonary capillary hemangiomatosis
- Pulmonary telangiectasia – pulmonary hypertension
- Pulmonary thromboembolic disease
- Pulmonary vascular disease
- Pulmonary veno-occlusive disease
- Pulmonic stenosis
- Right hypoplastic lung
- Scleroderma – pulmonary hypertension
- Secondary pulmonary hypertension
- Thromboembolic pulmonary hypertension

Group C

A candidate is in Group C if the candidate has *any* of the following diagnoses:

- Common variable immune deficiency
- Cystic fibrosis
- Fibrocavitary lung disease
- Hypogammaglobulinemia
- Schwachman-Diamond syndrome

Group D

A candidate is in Group D if the candidate has *any* of the following diagnoses:

- ABCA3 transporter mutation
- Alveolar proteinosis
- Amyloidosis
- Acute respiratory distress syndrome or pneumonia
- Bronchioloalveolar carcinoma (BAC)
- Carcinoid tumorlets
- Chronic pneumonitis of infancy
- Constrictive bronchiolitis
- CREST – Restrictive
- Eosinophilic granuloma
- Fibrosing Mediastinitis
- Graft versus host disease (GVHD)
- Hermansky Pudlak syndrome
- Hypersensitivity pneumonitis
- Idiopathic interstitial pneumonia, with at least one or more of the following disease entities:
  - Acute interstitial pneumonia
  - Cryptogenic organizing pneumonia/Bronchiolitis obliterans with organizing pneumonia (BOOP)
  - Desquamative interstitial pneumonia
  - Idiopathic pulmonary fibrosis (IPF)
  - Nonspecific interstitial pneumonia
  - Lymphocytic interstitial pneumonia (LIP)
  - Respiratory bronchiolitis-associated interstitial lung disease
- Idiopathic pulmonary hemosiderosis
- Lung retransplant or graft failure: acute rejection
- Lung retransplant or graft failure: non-specific
- Lung retransplant or graft failure: obliterative bronchiolitis-obstructive
- Lung retransplant or graft failure: obliterative bronchiolitis-restrictive
- Lung retransplant or graft failure: obstructive
- Lung retransplant or graft failure: other specify
- Lung retransplant or graft failure: primary graft failure
- Lung retransplant or graft failure: restrictive
- Lupus
- Mixed connective tissue disease
- Obliterative bronchiolitis: non-retransplant
- Occupational lung disease: other specify
- Paraneoplastic pemphigus associated Castleman's disease
- Polymyositis
- Pulmonary fibrosis: other specify cause
- Pulmonary hyalinizing granuloma
- Pulmonary lymphangiectasia (PL)
- Pulmonary telangiectasia – restrictive
- Rheumatoid disease
- Sarcoidosis with mean pulmonary artery pressure higher than 30 mm Hg
- Scleroderma – restrictive
- Secondary pulmonary fibrosis: (specify cause)

- Silicosis
- Sjogren's syndrome
- Surfactant protein B mutation
- Surfactant protein C mutation
- Teratoma
- Wegener's granuloma – restrictive

10.1.F.ii PCO_2 in the LAS

The LAS calculation uses two measures of PCO_2:

1. Current PCO_2
2. ~~Increase in~~ PCO_2 Threshold Change

Current PCO_2

Current PCO_2 is the PCO_2 value reported to the OPTN Contractor with the most recent test date and time. A program may report a PCO_2 value from an arterial, venous, or capillary blood gas test. All blood gas values will be converted to an arterial value as follows:

- A capillary value will equal an arterial value.
- A venous value minus 6 mmHg equals an arterial value.

~~The LAS calculation uses the PCO_2 value with the most recent test date. If an arterial value and either a venous value, or an arterial value and a capillary value, have the same test date, the LAS calculation will use the arterial value.~~

~~Increase in~~PCO_2 Threshold Change ~~Calculations~~

There are two ~~increase in~~ PCO_2 threshold change calculations:

- The ~~Increase in~~-PCO_2 Threshold Change Calculation
- The Threshold Change Maintenance Calculation

The ~~Increase in~~-PCO_2 Threshold Change Calculation

An increase in PCO_2 that is at least 15% will impact a candidate's LAS. If a value is less than 40 mmHg, the system will substitute the normal clinical value of 40 mmHg before calculating change. The ~~increase in~~-PCO_2 threshold change calculation uses the highest and lowest values of PCO_2 as follows:

- The test date and time of the lowest value reported to the OPTN Contractor used in the PCO_2 threshold change calculation must be earlier than the test date and time of the highest value used in the PCO_2 threshold change calculation.
- Test dates of these highest and lowest values cannot be more than six months apart.
- The ~~increase in~~-PCO_2 threshold change calculation ~~will~~ can use an expired lowest value, but cannot use an expired highest value.

If a current PCO_2 value expires according *to Policy 10.1.E: LAS Values and*

Clinical Data Update Schedule for Candidates at Least 12 Years Old, the candidate's LAS will lose the impact from the ~~increase in~~ PCO_2 threshold change calculation. The equation for the ~~increase in~~ PCO_2 threshold change calculation is:

$$\frac{\text{Highest } PCO_2 - Lowest\ PCO_2}{Lowest\ PCO_2}$$

The Threshold Change Maintenance Calculation

When a 15% or greater ~~increase in~~ PCO_2 threshold change calculation impacts a candidate's LAS, the LAS threshold change maintenance calculation assesses whether to maintain that impact. To maintain the impact of the PCO_2 increase, the candidate's current PCO_2 value must be at least 15% higher than the lowest value used in the ~~increase in~~ PCO_2 threshold change calculation. The equation for this threshold change maintenance calculation is:

$$\frac{\text{Current } PCO_2 - Lowest\ PCO_2}{Lowest\ PCO_2}$$

The threshold change maintenance calculation occurs either when the current PCO_2 value expires, according to *Policy 10.1.E: LAS Values and Clinical Data Update Schedule for Candidates at Least 12 Years Old*, or a new current PCO_2 value is entered ~~reported to the OPTN Contractor~~. For this calculation, the lowest and highest values that were used in the ~~increase in~~ PCO_2 threshold change calculation can be expired. The current PCO_2 value can be the highest one that was used in the ~~increase in~~ PCO_2 threshold change calculation. If a current PCO_2 value expires, the candidate's LAS will no longer be affected by the ~~increase in~~ PCO_2 threshold change.

If a transplant hospital reports a new current PCO_2 value for a candidate who has lost the impact from the ~~increase in~~ PCO_2 threshold change calculation, the LAS will perform the threshold change maintenance calculation. If the new current PCO_2 value is at least 15% higher than the lowest value used in the ~~increase in~~ PCO_2 threshold change calculation, the candidate's LAS will again be affected by the ~~increase in~~ PCO_2 threshold change calculation.

Normal PCO_2 Value

The normal clinical PCO_2 value is 40mmHg. If a current PCO_2 value is below 40 mmHg, or if the current PCO_2 value is missing or expired, the LAS calculation will use the normal clinical PCO_2 value.

10.1.F.iii Bilirubin in the ~~Lung Allocation Score~~ LAS

The LAS calculation uses two measures of total bilirubin:

- Current bilirubin (for all candidates)
- ~~Increase in b~~Bilirubin Threshold Change (for diagnosis Group B only)

Current Bilirubin
Current bilirubin is the total bilirubin value with the most recent test date and time reported to the OPTN Contractor. A current bilirubin value greater than ~~of at least~~ 1.0 mg/dL will impact candidate's LAS.

~~Increase in~~ Bilirubin Threshold Change (Diagnosis Group B Only)
There are two ~~Increase in~~ Bilirubin threshold change calculations:

- ~~Increase in~~ Bilirubin Threshold Change Calculation
- Threshold Change Maintenance Calculation

~~Increase in~~ Bilirubin Threshold Change Calculation
For candidates in diagnosis Group B, an increase in bilirubin that is at least 50% impacts the candidate's LAS. The ~~increase in~~ bilirubin threshold change calculation uses the highest and lowest values of bilirubin as follows:~~.~~

- The test date and time of the lowest bilirubin value reported to the OPTN Contractor used in the ~~increase in~~ bilirubin threshold change calculation must be earlier than the test date and time of the highest bilirubin value ~~reported~~ used in the bilirubin threshold change calculation.
- The highest value must be at least 1.0 mg/dL.
- Test dates of these highest and lowest values cannot be more than six ~~6~~ months apart.
- The ~~increase in~~ bilirubin threshold calculation can~~will~~ use an expired lowest value, but cannot use an expired highest value.
- If a value is less than 0.7 mg/dL, the ~~increase in~~ bilirubin threshold change calculation will use the normal clinical value of 0.7 mg/dL.

The equation for this ~~increase in~~ bilirubin threshold change calculation is:

$$\frac{\text{Highest Bilirubin} - \text{Lowest Bilirubin}}{\textit{Lowest Bilirubin}}$$

Threshold Change Maintenance Calculation
When a 50% or greater increase in bilirubin impacts a candidate's LAS, the LAS threshold change maintenance calculation assesses whether to maintain that impact. To maintain the impact of the bilirubin increase, the candidate's current bilirubin value must be at least 1.0 mg/dL and at least 50% higher than the lowest value used in the ~~increase in~~ bilirubin threshold change calculation. The equation for the threshold change maintenance calculation is:

$$\frac{\text{Current } \textit{Bilirubin} - \textit{Lowest Bilirubin}}{\textit{Lowest Bilirubin}}$$

The ~~increase~~ threshold change maintenance calculation occurs either when the current bilirubin value expires, according to *Policy 10.1.E: LAS Values and Clinical Data Update Schedule for Candidates at Least 12 Years Old*, or

a new current bilirubin value is entered. For this calculation, the lowest and highest values that were used in the ~~increase in~~ bilirubin threshold change calculation can be expired. The current bilirubin value can be the highest one that was used in the ~~increase in~~ bilirubin threshold change calculation. If a current bilirubin value expires, the candidate's LAS will no longer be affected by the ~~increase in~~ bilirubin threshold change.

If a transplant hospital reports a new current bilirubin value for a candidate who has lost the impact from the ~~increase in~~ bilirubin threshold change calculation, the LAS will perform the threshold change maintenance calculation. If the new current bilirubin value is at least 50% higher than the lowest value used in the ~~increase in~~ bilirubin threshold change calculation, the candidate's LAS will again be affected by the ~~increase in~~ bilirubin threshold change calculation.

Normal Bilirubin Value

The normal clinical current bilirubin value is 0.7 mg/dL. If a current bilirubin value is below 0.7 mg/dL, or if the current bilirubin value is missing or expired, the LAS calculation will use the normal clinical current bilirubin value.

10.1.F.iv~~.~~ Creatinine in the LAS

The LAS calculation uses two measures of creatinine:

1. Current creatinine (only for candidates who are at least 18 years old)
2. ~~Increase in~~ cCreatinine Threshold Change (for all candidates)

Current Creatinine

Current creatinine is the serum creatinine value with the most recent test date and time reported to the OPTN Contractor for candidates who are at least 18 years old.

~~Increase in~~ Creatinine Threshold Change Calculations

There are two ~~Increase in~~ Creatinine threshold change calculations:

1. ~~Increase in~~ Creatinine Threshold Change Calculation
2. Threshold Change Maintenance Calculation

The ~~Increase in~~ Creatinine Threshold Change Calculation

An increase in creatinine that is at least 150% will impact a candidate's LAS. The ~~increase in~~ creatinine threshold change calculation uses the highest and lowest values of creatinine~~.~~ as follows:

- ~~For this variable to impact a candidate's LAS, t~~The test date and time of the lowest creatinine value reported to the OPTN Contractor used in the ~~increase in~~ creatinine threshold change calculation must be earlier than the test date and time of the highest creatinine value used in the ~~increase in~~ creatinine threshold change calculation.
- The highest value must be at least 1.0 mg/dL.
- Test dates of these highest and lowest values cannot be more than ~~6~~six months apart.

- The ~~increase in~~ creatinine threshold change calculation ~~will~~can use an expired lowest value, but cannot use an expired highest value.

The equation for this ~~increase in~~ creatinine threshold change calculation is:

$$\frac{\text{Highest Creatinine} - \text{Lowest Creatinine}}{\textit{Lowest Creatinine}}$$

The Threshold Change Maintenance Calculation

When a~~n increase in~~ creatinine threshold change calculation impacts ~~a~~ a candidate's LAS, the threshold change maintenance calculation assesses whether to maintain that impact. To maintain the impact of the increase in creatinine, the candidate's current creatinine value must be at least 1.0 mg/dL and at least 150% higher than the lowest value used in the ~~increase in~~ creatinine threshold change calculation. The equation for the threshold change maintenance calculation is:

$$\frac{\text{Current Creatinine} - \text{Lowest Creatinine}}{\textit{Lowest Creatinine}}$$

If the current creatinine value expires or a new creatinine value is entered, then the ~~increase~~ threshold change maintenance calculation will occur.

10.2.B.iv LAS ~~Values and~~ Diagnoses Approved by the LRB

A diagnosis that has been approved by the LRB or the Thoracic Organ Transplantation Committee is valid indefinitely, or until an adjustment is requested and, if necessary, approved by the LRB.

10.3 Waiting Time

Waiting time for lung candidates begins when the candidate is registered on the waiting list. Candidates at least 12 years old awaiting a lung transplant on the waiting list at inactive status will not accrue any waiting time while at inactive status. Lung candidates less than 12 years old accrue waiting time when registered at inactive status.

When waiting time is used for lung allocation, a candidate will receive a preference over other candidates who have accumulated less waiting time within the same priority or LAS.

10.5 Probability Data Used in the LAS Calculation

~~Table 10-8: Baseline Waiting List Survival (SWL(t)) Probability~~

~~Time (days): t~~	~~$S_{WL}(t)$~~	~~Time (days): t~~	~~$S_{WL}(t)$~~	~~Time (days): t~~	~~$S_{WL}(t)$~~	~~Time (days): t~~	~~$S_{WL}(t)$~~	~~Time (days): t~~	~~$S_{WL}(t)$~~
~~0~~	~~1.000000~~	~~49~~	~~0.996644~~	~~98~~	~~0.993160~~	~~147~~	~~0.990540~~	~~196~~	~~0.987299~~
~~1~~	~~0.999991~~	~~50~~	~~0.996543~~	~~99~~	~~0.993098~~	~~148~~	~~0.990540~~	~~197~~	~~0.987263~~
~~2~~	~~0.999925~~	~~51~~	~~0.996518~~	~~100~~	~~0.993061~~	~~149~~	~~0.990540~~	~~198~~	~~0.987155~~
~~3~~	~~0.999867~~	~~52~~	~~0.996397~~	~~101~~	~~0.993005~~	~~150~~	~~0.990540~~	~~199~~	~~0.987122~~
~~4~~	~~0.999746~~	~~53~~	~~0.996397~~	~~102~~	~~0.993005~~	~~151~~	~~0.990540~~	~~200~~	~~0.986530~~
~~5~~	~~0.999598~~	~~54~~	~~0.996363~~	~~103~~	~~0.992938~~	~~152~~	~~0.990384~~	~~201~~	~~0.986530~~
~~6~~	~~0.999499~~	~~55~~	~~0.996305~~	~~104~~	~~0.992938~~	~~153~~	~~0.990333~~	~~202~~	~~0.986480~~

Time (days): t	$S_{WL}(t)$	Time (days): t	$S_{WL}(t)$	Time (days): t	$S_{WL}(t)$	Time (days): t	$S_{WL}(t)$	Time (days): t	$S_{WL}(t)$
7	0.999371	56	0.996191	105	0.992883	154	0.990333	203	0.985963
8	0.999305	57	0.996119	106	0.992883	155	0.990333	204	0.985926
9	0.999218	58	0.995942	107	0.992851	156	0.990245	205	0.985926
10	0.999085	59	0.995942	108	0.992762	157	0.990245	206	0.985820
11	0.998990	60	0.995909	109	0.992724	158	0.990245	207	0.985820
12	0.998887	61	0.995909	110	0.992643	159	0.990145	208	0.985742
13	0.998816	62	0.995873	111	0.992643	160	0.989689	209	0.985742
14	0.998730	63	0.995846	112	0.992562	161	0.989689	210	0.985742
15	0.998660	64	0.995846	113	0.992089	162	0.989652	211	0.985708
16	0.998588	65	0.995614	114	0.992064	163	0.989575	212	0.985708
17	0.998455	66	0.995553	115	0.992040	164	0.989575	213	0.985541
18	0.998362	67	0.995553	116	0.991997	165	0.988903	214	0.985541
19	0.998259	68	0.995553	117	0.991966	166	0.988873	215	0.985541
20	0.998220	69	0.995500	118	0.991940	167	0.988873	216	0.985450
21	0.998068	70	0.995479	119	0.991940	168	0.988784	217	0.985450
22	0.998036	71	0.995349	120	0.991940	169	0.988722	218	0.985450
23	0.997972	72	0.995293	121	0.991514	170	0.988695	219	0.985330
24	0.997868	73	0.995136	122	0.991514	171	0.988695	220	0.985265
25	0.997770	74	0.994965	123	0.991514	172	0.988695	221	0.985265
26	0.997742	75	0.994821	124	0.991514	173	0.988655	222	0.985265
27	0.997667	76	0.994774	125	0.991488	174	0.988655	223	0.985265
28	0.997626	77	0.994702	126	0.991462	175	0.988655	224	0.985265
29	0.997540	78	0.994702	127	0.991393	176	0.988625	225	0.984621
30	0.997473	79	0.994634	128	0.991307	177	0.988548	226	0.984549
31	0.997391	80	0.994565	129	0.991307	178	0.988548	227	0.984549
32	0.997327	81	0.994547	130	0.991270	179	0.988548	228	0.984549
33	0.997297	82	0.994465	131	0.991236	180	0.988062	229	0.984549
34	0.997274	83	0.994465	132	0.991236	181	0.988062	230	0.984489
35	0.997242	84	0.994297	133	0.991053	182	0.988062	231	0.984489
36	0.997242	85	0.994297	134	0.991012	183	0.988021	232	0.984396
37	0.997181	86	0.994297	135	0.991012	184	0.987934	233	0.984324
38	0.997137	87	0.994297	136	0.990978	185	0.987885	234	0.984280
39	0.997121	88	0.994181	137	0.990978	186	0.987885	235	0.984079
40	0.997121	89	0.994077	138	0.990978	187	0.987885	236	0.984079
41	0.997019	90	0.994035	139	0.990936	188	0.987885	237	0.984015
42	0.996946	91	0.994008	140	0.990901	189	0.987856	238	0.984015
43	0.996916	92	0.993866	141	0.990901	190	0.987856	239	0.984015
44	0.996849	93	0.993831	142	0.990811	191	0.987856	240	0.984015
45	0.996849	94	0.993807	143	0.990739	192	0.987856	241	0.983835
46	0.996820	95	0.993715	144	0.990595	193	0.987856	242	0.983835
47	0.996780	96	0.993308	145	0.990595	194	0.987608	243	0.983792
48	0.996731	97	0.993220	146	0.990540	195	0.987359	244	0.983753

Table 10-8: Baseline Waiting List Survival ($S_{WL}(t)$) Probability (Continued)

Time (days): t	$S_{WL}(t)$	Time (days): t	$S_{WL}(t)$	Time (days): t	$S_{WL}(t)$	Time (days): t	$S_{WL}(t)$	Time (days): t	$S_{WL}(t)$
245	0.983753	269	0.982960	293	0.981827	317	0.980218	341	0.978597
246	0.983753	270	0.982960	294	0.981827	318	0.980129	342	0.978597
247	0.983697	271	0.982797	295	0.981573	319	0.980129	343	0.978301
248	0.983636	272	0.982797	296	0.981319	320	0.980016	344	0.978250
249	0.983636	273	0.982797	297	0.980775	321	0.980016	345	0.978250
250	0.983636	274	0.982797	298	0.980775	322	0.980016	346	0.978250

Time (days): t	$S_{WL}(t)$	Time (days): t	$S_{WL}(t)$	Time (days): t	$S_{WL}(t)$	Time (days): t	$S_{WL}(t)$	Time (days): t	$S_{WL}(t)$
251	0.983636	275	0.982700	299	0.980519	323	0.979773	347	0.978117
252	0.983243	276	0.982603	300	0.980397	324	0.979773	348	0.978037
253	0.983243	277	0.982603	301	0.980397	325	0.979671	349	0.978037
254	0.983243	278	0.982511	302	0.980397	326	0.979671	350	0.978037
255	0.983097	279	0.982457	303	0.980397	327	0.979164	351	0.978037
256	0.983097	280	0.982457	304	0.980397	328	0.979164	352	0.977937
257	0.983097	281	0.982457	305	0.980397	329	0.979164	353	0.977937
258	0.983097	282	0.982413	306	0.980397	330	0.979164	354	0.977937
259	0.983097	283	0.982323	307	0.980339	331	0.979100	355	0.977855
260	0.983097	284	0.982323	308	0.980339	332	0.979100	356	0.977855
261	0.983097	285	0.982323	309	0.980339	333	0.978935	357	0.977855
262	0.983052	286	0.982323	310	0.980339	334	0.978935	358	0.977710
263	0.983052	287	0.982323	311	0.980339	335	0.978817	359	0.977710
264	0.983052	288	0.982323	312	0.980339	336	0.978817	360	0.976881
265	0.983052	289	0.982323	313	0.980339	337	0.978817	361	0.976881
266	0.983052	290	0.982323	314	0.980339	338	0.978817	362	0.976881
267	0.983052	291	0.981916	315	0.980218	339	0.978817	363	0.976709
268	0.982960	292	0.981878	316	0.980218	340	0.978817	364	0.976709

Table 10-9: Baseline Post-Transplant Survival ($S_{TX}(t)$) Probability

Time (days): t	$S_{TX}(t)$	Time (days): t	$S_{TX}(t)$	Time (days): t	$S_{TX}(t)$	Time (days): t	$S_{TX}(t)$	Time (days): t	$S_{TX}(t)$
0	1.000000	48	0.981882	97	0.972415	146	0.965165	195	0.958585
0	0.998946	49	0.981394	98	0.972415	147	0.965018	196	0.958585
1	0.997558	50	0.981115	99	0.972128	148	0.965018	197	0.958511
2	0.996895	51	0.980836	100	0.971984	149	0.964724	198	0.958361
3	0.996364	52	0.980416	101	0.971769	150	0.964651	199	0.958062
4	0.995498	53	0.980207	102	0.971697	151	0.964504	200	0.958062
5	0.995165	54	0.980137	103	0.971553	152	0.964357	201	0.957987
6	0.994565	55	0.979926	104	0.971337	153	0.964063	202	0.957987
7	0.994164	56	0.979646	105	0.971265	154	0.963843	203	0.957913
8	0.993963	57	0.979436	106	0.971193	155	0.963696	204	0.957763
9	0.993360	58	0.979085	107	0.971121	156	0.963475	205	0.957613
10	0.993159	59	0.978874	108	0.971049	157	0.963328	206	0.957538
11	0.992487	60	0.978733	109	0.970977	158	0.963107	207	0.957388
12	0.992353	61	0.978452	110	0.970761	159	0.962738	208	0.957313
13	0.991949	62	0.978382	111	0.970689	160	0.962517	209	0.957238
14	0.991679	63	0.978170	112	0.970617	161	0.962443	210	0.957163
15	0.991207	64	0.978100	113	0.970545	162	0.962296	211	0.957163
16	0.990531	65	0.977959	114	0.970473	163	0.962074	212	0.956938
17	0.990260	66	0.977818	115	0.970329	164	0.961927	213	0.956863
18	0.989921	67	0.977818	116	0.969968	165	0.961705	214	0.956788
19	0.989582	68	0.977536	117	0.969824	166	0.961631	215	0.956713
20	0.989514	69	0.977254	118	0.969679	167	0.961557	216	0.956638
21	0.988902	70	0.977042	119	0.969607	168	0.961483	217	0.956488
22	0.988220	71	0.976971	120	0.969390	169	0.961483	218	0.956263
23	0.987810	72	0.976901	121	0.969101	170	0.961409	219	0.956263
24	0.987469	73	0.976759	122	0.968956	171	0.961113	220	0.956187
25	0.987263	74	0.976547	123	0.968667	172	0.961113	221	0.956112
26	0.987058	75	0.976476	124	0.968594	173	0.961039	222	0.956037
27	0.986578	76	0.976193	125	0.968377	174	0.960965	223	0.955887
28	0.986304	77	0.975909	126	0.968159	175	0.960891	224	0.955736

Time (days): t	$S_{TX}(t)$	Time (days): t	$S_{TX}(t)$	Time (days): t	$S_{TX}(t)$	Time (days): t	$S_{TX}(t)$	Time (days): t	$S_{TX}(t)$
29	0.986030	78	0.975767	127	0.968086	176	0.960743	225	0.955736
30	0.985961	79	0.975625	128	0.967868	177	0.960595	226	0.955736
31	0.985755	80	0.975483	129	0.967796	178	0.960446	227	0.955661
32	0.985480	81	0.975483	130	0.967504	179	0.960446	228	0.955661
33	0.985136	82	0.975483	131	0.967359	180	0.960372	229	0.955510
34	0.984929	83	0.974985	132	0.967140	181	0.960298	230	0.955510
35	0.984515	84	0.974985	133	0.967140	182	0.960149	231	0.955209
36	0.984446	85	0.974700	134	0.966994	183	0.960075	232	0.955209
37	0.984170	86	0.974700	135	0.966702	184	0.959852	233	0.955134
38	0.983825	87	0.974415	136	0.966483	185	0.959778	234	0.954983
39	0.983479	88	0.973987	137	0.966483	186	0.959703	235	0.954832
40	0.983202	89	0.973845	138	0.966410	187	0.959629	236	0.954681
41	0.983063	90	0.973630	139	0.966263	188	0.959554	237	0.954530
42	0.982855	91	0.973416	140	0.966190	189	0.959480	238	0.954455
43	0.982716	92	0.973416	141	0.966190	190	0.959256	239	0.954228
44	0.982578	93	0.973202	142	0.965971	191	0.959107	240	0.954228
45	0.982300	94	0.973059	143	0.965751	192	0.959033	241	0.954077
46	0.982160	95	0.972916	144	0.965678	193	0.959033	242	0.954077
47	0.981952	96	0.972629	145	0.965311	194	0.958735	243	0.953925

Table 10-9: Baseline Post-Transplant Survival ($S_{TX}(t)$) Probability (Continued)

Time (days): t	$S_{TX}(t)$	Time (days): t	$S_{TX}(t)$	Time (days): t	$S_{TX}(t)$	Time (days): t	$S_{TX}(t)$	Time (days): t	$S_{TX}(t)$
244	0.953850	269	0.951190	293	0.948589	317	0.946359	341	0.943729
245	0.953850	270	0.950961	294	0.948359	318	0.946359	342	0.943651
246	0.953774	271	0.950656	295	0.948282	319	0.946204	343	0.943573
247	0.953774	272	0.950579	296	0.948128	320	0.946204	344	0.943418
248	0.953698	273	0.950427	297	0.948052	321	0.946127	345	0.943341
249	0.953623	274	0.950274	298	0.947975	322	0.946050	346	0.943108
250	0.953395	275	0.950121	299	0.947821	323	0.946050	347	0.943030
251	0.953319	276	0.950121	300	0.947667	324	0.945896	348	0.943030
252	0.953016	277	0.949815	301	0.947667	325	0.945818	349	0.942952
253	0.953016	278	0.949662	302	0.947360	326	0.945587	350	0.942719
254	0.952712	279	0.949662	303	0.947360	327	0.945432	351	0.942719
255	0.952712	280	0.949585	304	0.947360	328	0.945432	352	0.942719
256	0.952712	281	0.949585	305	0.947360	329	0.945355	353	0.942641
257	0.952484	282	0.949432	306	0.947283	330	0.945278	354	0.942485
258	0.952408	283	0.949355	307	0.947283	331	0.945123	355	0.942485
259	0.952332	284	0.949279	308	0.947206	332	0.945123	356	0.942173
260	0.952256	285	0.949279	309	0.947129	333	0.944968	357	0.942017
261	0.952180	286	0.949202	310	0.946975	334	0.944891	358	0.941783
262	0.952104	287	0.949202	311	0.946821	335	0.944736	359	0.941705
263	0.951876	288	0.949126	312	0.946821	336	0.944581	360	0.941627
264	0.951800	289	0.949049	313	0.946821	337	0.944504	361	0.941549
265	0.951648	290	0.948896	314	0.946744	338	0.944194	362	0.941549
266	0.951648	291	0.948819	315	0.946590	339	0.944039	363	0.941315
267	0.951572	292	0.948819	316	0.946436	340	0.943961	364	0.941315
268	0.951495								

Table 10-8: Baseline Waiting List Survival (SWL(t)) Probability Where t=Time in Days

t	$S_{WL}(t)$	t	$S_{WL}(t)$	t	$S_{WL}(t)$	t	$S_{WL}(t)$	t	$S_{WL}(t)$
0	1.0000000000	49	0.9966437334	98	0.9931596573	147	0.9905400510	196	0.9872991723
1	0.9999907157	50	0.9965433845	99	0.9930980163	148	0.9905400510	197	0.9872626749
2	0.9999254055	51	0.9965175429	100	0.9930607383	149	0.9905400510	198	0.9871552755
3	0.9998674170	52	0.9963972737	101	0.9930052489	150	0.9905400510	199	0.9871220338
4	0.9997455435	53	0.9963972737	102	0.9930052489	151	0.9905400510	200	0.9865302072
5	0.9995975343	54	0.9963631304	103	0.9929378277	152	0.9903840245	201	0.9865302072
6	0.9994989961	55	0.9963053385	104	0.9929378277	153	0.9903328361	202	0.9864801346
7	0.9993713802	56	0.9961914895	105	0.9928829296	154	0.9903328361	203	0.9859628001
8	0.9993046242	57	0.9961189511	106	0.9928829296	155	0.9903328361	204	0.9859256159
9	0.9992177050	58	0.9959421227	107	0.9928506946	156	0.9902446847	205	0.9859256159
10	0.9990851999	59	0.9959421227	108	0.9927619069	157	0.9902446847	206	0.9858198690
11	0.9989901794	60	0.9959092500	109	0.9927244496	158	0.9902446847	207	0.9858198690
12	0.9988873318	61	0.9959092500	110	0.9926433860	159	0.9901449203	208	0.9857415923
13	0.9988160788	62	0.9958731922	111	0.9926433860	160	0.9896887318	209	0.9857415923
14	0.9987295863	63	0.9958457969	112	0.9925624932	161	0.9896887318	210	0.9857415923
15	0.9986602768	64	0.9958457969	113	0.9920885646	162	0.9896520090	211	0.9857075131
16	0.9985875403	65	0.9956136053	114	0.9920640055	163	0.9895745634	212	0.9857075131
17	0.9984554393	66	0.9955529860	115	0.9920400127	164	0.9895745634	213	0.9855411680
18	0.9983616851	67	0.9955529860	116	0.9919966080	165	0.9889025189	214	0.9855411680
19	0.9982588046	68	0.9955529860	117	0.9919660469	166	0.9888730124	215	0.9855411680
20	0.9982200289	69	0.9955000986	118	0.9919399263	167	0.9888730124	216	0.9854501485
21	0.9980677506	70	0.9954789372	119	0.9919399263	168	0.9887838841	217	0.9854501485
22	0.9980357372	71	0.9953493820	120	0.9919399263	169	0.9887222824	218	0.9854501485
23	0.9979724590	72	0.9952934145	121	0.9915144847	170	0.9886945957	219	0.9853304718
24	0.9978684291	73	0.9951363273	122	0.9915144847	171	0.9886945957	220	0.9852652088
25	0.9977699910	74	0.9949654223	123	0.9915144847	172	0.9886945957	221	0.9852652088
26	0.9977420222	75	0.9948209678	124	0.9915144847	173	0.9886549235	222	0.9852652088
27	0.9976665328	76	0.9947736691	125	0.9914883902	174	0.9886549235	223	0.9852652088
28	0.9976255053	77	0.9947021905	126	0.9914618560	175	0.9886549235	224	0.9852652088
29	0.9975404117	78	0.9947021905	127	0.9913925084	176	0.9886246774	225	0.9846212073
30	0.9974725579	79	0.9946337898	128	0.9913069760	177	0.9885475245	226	0.9845486667
31	0.9973914097	80	0.9945649862	129	0.9913069760	178	0.9885475245	227	0.9845486667
32	0.9973268946	81	0.9945465023	130	0.9912697831	179	0.9885475245	228	0.9845486667
33	0.9972974521	82	0.9944645092	131	0.9912361687	180	0.9880619575	229	0.9845486667
34	0.9972743143	83	0.9944645092	132	0.9912361687	181	0.9880619575	230	0.9844886959
35	0.9972419197	84	0.9942969766	133	0.9910529687	182	0.9880619575	231	0.9844886959
36	0.9972419197	85	0.9942969766	134	0.9910121623	183	0.9880212199	232	0.9843962284
37	0.9971814314	86	0.9942969766	135	0.9910121623	184	0.9879335450	233	0.9843236173
38	0.9971367830	87	0.9942969766	136	0.9909776544	185	0.9878851712	234	0.9842799561
39	0.9971209292	88	0.9941805902	137	0.9909776544	186	0.9878851712	235	0.9840794709
40	0.9971209292	89	0.9940771789	138	0.9909776544	187	0.9878851712	236	0.9840794709
41	0.9970189115	90	0.9940345018	139	0.9909355857	188	0.9878851712	237	0.9840145629
42	0.9969461979	91	0.9940082090	140	0.9909011142	189	0.9878560942	238	0.9840145629
43	0.9969159237	92	0.9938663826	141	0.9909011142	190	0.9878560942	239	0.9840145629
44	0.9968488001	93	0.9938313146	142	0.9908111395	191	0.9878560942	240	0.9840145629
45	0.9968488001	94	0.9938070978	143	0.9907387924	192	0.9878560942	241	0.9838347625
46	0.9968199961	95	0.9937145919	144	0.9905945464	193	0.9878560942	242	0.9838347625
47	0.9967799694	96	0.9933077154	145	0.9905945464	194	0.9876077782	243	0.9837917116
48	0.9967313053	97	0.9932199214	146	0.9905400510	195	0.9873585581	244	0.9837534417

Table 10-8: Baseline Waiting List Survival ($S_{WL}(t)$) Probability Where t=Time in Days (Continued)

t	$S_{WL}(t)$	t	$S_{WL}(t)$	t	$S_{WL}(t)$	t	$S_{WL}(t)$	t	$S_{WL}(t)$
245	0.9837534417	269	0.9829597020	293	0.9818267812	317	0.9802178676	341	0.9785965606
246	0.9837534417	270	0.9829597020	294	0.9818267812	318	0.9801289145	342	0.9785965606
247	0.9836972199	271	0.9827972342	295	0.9815730256	319	0.9801289145	343	0.9783012252
248	0.9836363251	272	0.9827972342	296	0.9813194319	320	0.9800157994	344	0.9782502701
249	0.9836363251	273	0.9827972342	297	0.9807747475	321	0.9800157994	345	0.9782502701

t	$S_{WL}(t)$	t	$S_{WL}(t)$	t	$S_{WL}(t)$	t	$S_{WL}(t)$	t	$S_{WL}(t)$
250	0.9836363251	274	0.9827972342	298	0.9807747475	322	0.9800157994	346	0.9782502701
251	0.9836363251	275	0.9827004206	299	0.9805186284	323	0.9797725024	347	0.9781167565
252	0.9832432776	276	0.9826027019	300	0.9803970706	324	0.9797725024	348	0.9780370471
253	0.9832432776	277	0.9826027019	301	0.9803970706	325	0.9796706377	349	0.9780370471
254	0.9832432776	278	0.9825107450	302	0.9803970706	326	0.9796706377	350	0.9780370471
255	0.9830967678	279	0.9824570403	303	0.9803970706	327	0.9791639481	351	0.9780370471
256	0.9830967678	280	0.9824570403	304	0.9803970706	328	0.9791639481	352	0.9779370209
257	0.9830967678	281	0.9824570403	305	0.9803970706	329	0.9791639481	353	0.9779370209
258	0.9830967678	282	0.9824128485	306	0.9803970706	330	0.9791639481	354	0.9779370209
259	0.9830967678	283	0.9823232942	307	0.9803390799	331	0.9791001516	355	0.9778553245
260	0.9830967678	284	0.9823232942	308	0.9803390799	332	0.9791001516	356	0.9778553245
261	0.9830967678	285	0.9823232942	309	0.9803390799	333	0.9789346942	357	0.9778553245
262	0.9830516708	286	0.9823232942	310	0.9803390799	334	0.9789346942	358	0.9777099092
263	0.9830516708	287	0.9823232942	311	0.9803390799	335	0.9788174060	359	0.9777099092
264	0.9830516708	288	0.9823232942	312	0.9803390799	336	0.9788174060	360	0.9768812539
265	0.9830516708	289	0.9823232942	313	0.9803390799	337	0.9788174060	361	0.9768812539
266	0.9830516708	290	0.9823232942	314	0.9803390799	338	0.9788174060	362	0.9768812539
267	0.9830516708	291	0.9819156574	315	0.9802178676	339	0.9788174060	363	0.9767085255
268	0.9829597020	292	0.9818779459	316	0.9802178676	340	0.9788174060	364	0.9767085255

Table 10-9: Baseline Post-Transplant Survival ($S_{TX}(t)$) Probability Where t=Time in Days

t	$S_{TX}(t)$	t	$S_{TX}(t)$	t	$S_{TX}(t)$	t	$S_{TX}(t)$	t	$S_{TX}(t)$
0	1.0000000000	48	0.9818819454	97	0.9724145650	146	0.9651646731	195	0.9585852831
0	0.9989463518	49	0.9813940581	98	0.9724145650	147	0.9650179741	196	0.9585852831
1	0.9975582572	50	0.9811149797	99	0.9721278916	148	0.9650179741	197	0.9585106153
2	0.9968950221	51	0.9808357071	100	0.9719843820	149	0.9647244778	198	0.9583612369
3	0.9963635815	52	0.9804163818	101	0.9717688365	150	0.9646510762	199	0.9580621750
4	0.9954983869	53	0.9802065044	102	0.9716969486	151	0.9645042403	200	0.9580621750
5	0.9951651492	54	0.9801365116	103	0.9715531365	152	0.9643573707	201	0.9579873451
6	0.9945645668	55	0.9799264755	104	0.9713373330	153	0.9640634927	202	0.9579873451
7	0.9941636334	56	0.9796462096	105	0.9712653813	154	0.9638429283	203	0.9579125074
8	0.9939630137	57	0.9794358024	106	0.9711934225	155	0.9636958085	204	0.9577628083
9	0.9933601591	58	0.9790847785	107	0.9711214419	156	0.9634750547	205	0.9576130592
10	0.9931589002	59	0.9788739877	108	0.9710494372	157	0.9633278327	206	0.9575381540
11	0.9924871748	60	0.9787334069	109	0.9709774209	158	0.9631069028	207	0.9573882873
12	0.9923526429	61	0.9784520623	110	0.9707613132	159	0.9627384081	208	0.9573133332
13	0.9919487360	62	0.9783816832	111	0.9706892585	160	0.9625171483	209	0.9572383663
14	0.9916792045	63	0.9781704820	112	0.9706171946	161	0.9624433701	210	0.9571633895
15	0.9912068471	64	0.9781000588	113	0.9705451162	162	0.9622957853	211	0.9571633895
16	0.9905308509	65	0.9779591798	114	0.9704730247	163	0.9620743353	212	0.9569383725
17	0.9902600814	66	0.9778182436	115	0.9703288079	164	0.9619266457	213	0.9568633391
18	0.9899212765	67	0.9778182436	116	0.9699680182	165	0.9617049921	214	0.9567883006
19	0.9895819543	68	0.9775361418	117	0.9698236079	166	0.9616310727	215	0.9567132550
20	0.9895140131	69	0.9772537901	118	0.9696791597	167	0.9615571395	216	0.9566381918
21	0.9889017936	70	0.9770418835	119	0.9696069224	168	0.9614831983	217	0.9564880147
22	0.9882201168	71	0.9769712231	120	0.9693901236	169	0.9614831983	218	0.9562625865
23	0.9878104319	72	0.9769005466	121	0.9691008601	170	0.9614092449	219	0.9562625865
24	0.9874685977	73	0.9767590709	122	0.9689561390	171	0.9611132339	220	0.9561873965
25	0.9872633504	74	0.9765466782	123	0.9686665562	172	0.9611132339	221	0.9561121949
26	0.9870579950	75	0.9764758630	124	0.9685941382	173	0.9610391867	222	0.9560369867
27	0.9865784176	76	0.9761925132	125	0.9683767411	174	0.9609651281	223	0.9558865533
28	0.9863040866	77	0.9759089522	126	0.9681590825	175	0.9608910582	224	0.9557360679
29	0.9860295071	78	0.9757670435	127	0.9680864781	176	0.9607428635	225	0.9557360679
30	0.9859608276	79	0.9756250284	128	0.9678684348	177	0.9605945954	226	0.9557360679
31	0.9857547158	80	0.9754829371	129	0.9677956729	178	0.9604462255	227	0.9556608016
32	0.9854796626	81	0.9754829371	130	0.9675043666	179	0.9604462255	228	0.9556608016
33	0.9851355094	82	0.9754829371	131	0.9673585766	180	0.9603719931	229	0.9555102388
34	0.9849288641	83	0.9749850268	132	0.9671398110	181	0.9602977341	230	0.9555102388
35	0.9845152420	84	0.9749850268	133	0.9671398110	182	0.9601491697	231	0.9552089409
36	0.9844462708	85	0.9747001806	134	0.9669939177	183	0.9600748710	232	0.9552089409
37	0.9841701925	86	0.9747001806	135	0.9667019115	184	0.9598519074	233	0.9551335669

t	$S_{TX}(t)$	t	$S_{TX}(t)$	t	$S_{TX}(t)$	t	$S_{TX}(t)$	t	$S_{TX}(t)$
38	0.9838247337	87	0.9744152006	136	0.9664827327	185	0.9597775675	234	0.9549827718
39	0.9834789109	88	0.9739873157	137	0.9664827327	186	0.9597032090	235	0.9548319320
40	0.9832019349	89	0.9738445742	138	0.9664096522	187	0.9596288106	236	0.9546810412
41	0.9830633211	90	0.9736303735	139	0.9662634193	188	0.9595543795	237	0.9545300840
42	0.9828552725	91	0.9734160812	140	0.9661902639	189	0.9594799325	238	0.9544545732
43	0.9827164882	92	0.9734160812	141	0.9661902639	190	0.9592564778	239	0.9542279182
44	0.9825775890	93	0.9732016972	142	0.9659707159	191	0.9591074222	240	0.9542279182
45	0.9822995280	94	0.9730587142	143	0.9657510525	192	0.9590328768	241	0.9540767061
46	0.9821604041	95	0.9729156920	144	0.9656778054	193	0.9590328768	242	0.9540767061
47	0.9819515885	96	0.9726294362	145	0.9653113457	194	0.9587345577	243	0.9539254009

Table 10-9: Baseline Post-Transplant Survival ($S_{TX}(t)$) Probability Where t=Time in Days (Continued)

t	$S_{TX}(t)$	t	$S_{TX}(t)$	t	$S_{TX}(t)$	t	$S_{TX}(t)$	t	$S_{TX}(t)$
244	0.9538497172	269	0.9511902217	293	0.9485888127	317	0.9463585089	341	0.9437285938
245	0.9538497172	270	0.9509612738	294	0.9483586281	318	0.9463585089	342	0.9436509982
246	0.9537740199	271	0.9506558210	295	0.9482818803	319	0.9462042511	343	0.9435733917
247	0.9537740199	272	0.9505794198	296	0.9481283428	320	0.9462042511	344	0.9434181618
248	0.9536983112	273	0.9504265693	297	0.9480515582	321	0.9461270863	345	0.9433405390
249	0.9536225901	274	0.9502736813	298	0.9479747621	322	0.9460499065	346	0.9431075841
250	0.9533952367	275	0.9501207590	299	0.9478210865	323	0.9460499065	347	0.9430298440
251	0.9533193886	276	0.9501207590	300	0.9476673351	324	0.9458955253	348	0.9430298440
252	0.9530158831	277	0.9498147874	301	0.9476673351	325	0.9458183199	349	0.9429520371
253	0.9530158831	278	0.9496617253	302	0.9473596856	326	0.9455866228	350	0.9427185272
254	0.9527122194	279	0.9496617253	303	0.9473596856	327	0.9454321012	351	0.9427185272
255	0.9527122194	280	0.9495851653	304	0.9473596856	328	0.9454321012	352	0.9427185272
256	0.9527122194	281	0.9495851653	305	0.9473596856	329	0.9453548209	353	0.9426406582
257	0.9524843651	282	0.9494319939	306	0.9472827362	330	0.9452775175	354	0.9424848995
258	0.9524083896	283	0.9493553886	307	0.9472827362	331	0.9451228653	355	0.9424848995
259	0.9523323977	284	0.9492787721	308	0.9472057776	332	0.9451228653	356	0.9421732641
260	0.9522563886	285	0.9492787721	309	0.9471288083	333	0.9449681796	357	0.9420173651
261	0.9521803676	286	0.9492021461	310	0.9469748345	334	0.9448908227	358	0.9417833903
262	0.9521043365	287	0.9492021461	311	0.9468208245	335	0.9447360580	359	0.9417053586
263	0.9518761834	288	0.9491255112	312	0.9468208245	336	0.9445812189	360	0.9416273052
264	0.9518000820	289	0.9490488687	313	0.9468208245	337	0.9445037758	361	0.9415492338
265	0.9516477499	290	0.9488955575	314	0.9467438071	338	0.9441938892	362	0.9415492338
266	0.9516477499	291	0.9488188902	315	0.9465897325	339	0.9440388525	363	0.9413148953
267	0.9515715365	292	0.9488188902	316	0.9464356005	340	0.9439613054	364	0.9413148953
268	0.9514952979								

Clarification to Membership and Personnel Requirements for VCA Programs

Sponsoring Committee:	**VCA Committee**
Policy/Bylaws Affected:	**OPTN Bylaws, Appendix J.1**
Distributed for Public Comment:	**No**
Amended After Public Comment:	**N/A**
Effective Date:	**February 1, 2015**

Problem Statement

In June 2014, the OPTN/UNOS Board of Directors approved membership requirements for VCA transplant programs, and distributed them for public comment in the fall of 2014. As a part of the public comment process, it was brought to the Committee's attention that transplant hospitals do not have to specify the type or types of VCAs the hospital will transplant. As written, the membership requirements allow an OPTN-approved VCA program to transplant any type of VCA.

Summary of Changes

This technical clarification will promote patient safety and ensure transplant hospital accountability to the OPTN. The transplant hospital's letter of intent must now include the type or types of VCAs they will transplant. Additionally, the local OPO must specify the type or types of VCAs they will provide from deceased donors. The transplant hospital must specify the reconstructive surgeon, and transplant physician or surgeon responsible for each VCA program type. UNOS staff will contact VCA programs that were approved by the OPTN prior to the effective date of this bylaw change to gather the required information.

What Members Need to Do

If you're a transplant hospital applying for a VCA program, you must specify the type or types of VCAs you will transplant. If you want to expand transplant services to include another VCA type in the future, you must contact UNOS to get approval for this additional VCA type before you list candidates for or transplant organs of that type. If you're an OPO, you must also specify the types of deceased donor VCAs you'll provide.

Affected Policy/Bylaw Language:

New language is underlined and language that will be deleted is ~~struck through~~.

OPTN Bylaws, Appendix J - Membership Requirements for Vascularized Composite Allograft (VCA) Transplant Programs

J.1 Letter of Notification

If a transplant hospital member commits to performing VCA transplants, the hospital must send a written notification ~~of this intent~~ to the OPTN Contractor that includes *both* of the following: ~~. 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.~~

1. The specific type or types of VCA transplant the hospital will perform.

2. If the member will perform deceased donor VCA transplants, assurance from the local OPO that it will provide the same type or types of VCA for transplantation.

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~~ The reconstructive surgeon for each type of VCA transplant 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~~ The transplant physician or transplant surgeon for each type of VCA transplant 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 for each type of VCA transplant.