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IMPORTANT POLICY NOTICE

To: Transplant Professionals

From: James B. Alcorn
Director, Policy

RE: Summary of actions taken at OPTN/UNOS Board of Directors Meeting (November 12-13, 2012) and OPTN/UNOS Executive Committee Meetings (August 28, 2012; October 19, 2012; and November 12, 2012)

Date: December 13, 2012

The attached report summarizes OPTN policy, bylaw, and Review Board Operational Guidelines changes approved by the OPTN/UNOS Board of Directors or the OPTN/UNOS Executive Committee at their August 28, October 19, and November 12-13 meetings. This policy notice provides the specific bylaw and policy 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. This policy notice, and those reviewing changes from previous Board of Directors meetings, can be found at optn.transplant.hrsa.gov (click on "News," and then select "View all Policy Notices").

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

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

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Modifying Review Board Policy and Operational Guidelines to Standardize the Heart, Liver, and Lung Review Board Processes

Sponsoring Committees: Thoracic Organ Transplantation & Liver and Intestinal Organ Transplantation Committees

Policies Affected: 3.7.3 (Adult Candidate Status), 3.7.4 (Pediatric Candidate Status), 3.7.6.2 (Candidates Age 0-11), and 3.7.6.4 (Lung Candidates With Exceptional Cases)

Distributed for Public Comment: No

Effective Date: To be determined, implementation pending programming

Problem Statement
Existing OPTN policy and Review Board operational guidelines create over two dozen different permutations for the review of status and score exceptions. This creates unnecessary variability, complexity, and cost in the system.

Changes
The Executive Committee recently approved changes to Review Board operational guidelines. These changes will make managing exception requests submitted to the organ specific review boards more efficient. The changes to the operational guidelines also made it necessary to change OPTN policy. The operational guidelines and policy changes standardize individual components of the heart, lung, and liver review boards, and do not impact those aspects that vary across organ type for clinical reasons. Specific changes include: • Clearly defining the two distinct exception review processes - retrospective reviews for the most urgent requests (Heart and Liver Status 1A exceptions) and prospective reviews for less urgent requests (MELD/PELD score and Lung Allocation Score exceptions). • Establishing voting procedures, such as defining and requiring a quorum for all votes. • Setting more stringent and consistent timeframes for each phase of the retrospective and prospective review processes. • Clarifying that overrides will be retrospectively reviewed by the respective organ specific OPTN/UNOS subcommittees. • Clearly detailing those actions that may result in subcommittee or Membership and Professional Standards Committee review.

Member Actions
Members should familiarize themselves with the new policy language, which specifies the type of review process that will be applied to each exception request. Members should also review the new Heart Regional Review Board, Liver Regional Review Board, and Lung Review Board operational guidelines that are provided below. Submission requirements have not changed, but transplant centers should learn the new timelines to prevent missing critical deadlines. Before the change is implemented, UNOS staff will provide training to educate and prepare members.

Click Here to View the Modified Policy Language

Click Here to View the Modified Review Board Guidelines

Modifications to OPTN Bylaws to Correct Inadvertent Substantive Changes

Sponsoring Committee: Membership and Professional Standards Committee (MPSC)

Bylaws Affected: OPTN Bylaws Appendices E through I

Distributed for Public Comment: No

Effective Date: December 13, 2012

Problem Statement
After the rewritten OPTN Bylaws were released on September 1, 2012, UNOS staff discovered that some substantive changes to the OPTN Bylaws requirements had been made inadvertently. These inadvertent changes included: • Excluding a phrase that defines the period a primary transplant surgeon has to perform the required number of transplant procedures for kidney and lung transplant programs. • Incorrectly rewording the fellowship training requirement that qualify surgeons for predominantly pediatric transplant programs. • Adding the requirement that primary kidney physicians must observe organ procurements involving **multiple** organs for the 12-month transplant nephrology pathway. • Incorrectly using the redundant term "kidney nephrectomies."

Changes
At its October 2012 meeting, the OPTN/UNOS Executive Committee approved changes to the Appendices E through I of the OPTN Bylaws to address these problems. These changes include: • Including a phrase to define that a primary transplant surgeon for kidney and lung transplant programs, respectively, has a two- to five-year period to perform the required number of transplant procedures. • Correcting the wording of fellowship training requirements that qualify surgeons for predominantly pediatric transplant programs. • Eliminating the term "multiple" from the 12-month transplant nephrology pathway for primary kidney physicians, which currently requires that physicians "should have observed at least 3 multiple organ procurements and 3 kidney transplants." • Eliminating use of the redundant term "kidney nephrectomies."

Member Actions
Members should familiarize themselves with the rewritten OPTN bylaws. View the rewritten bylaws here.

Click Here to View the Modified Bylaw Language

Revisions to the Waiting Time Modification Policy

Sponsoring Committee: Kidney Transplantation Committee

Policy Affected: 3.2.1.8 (Waiting Time Modification) through 3.2.1.8.4 (Modifications of Waiting Time), and 3.2.7 (Waiting Time Adjustment for Candidates Needing a Life-Saving Organ Transplant When the Need for a Second Organ Transplant Arises)

Distributed for Public Comment: September 2011

Amended After Public Comment: Yes

Effective Date: February 1, 2013

Problem Statement
Current OPTN policies for submitting waiting time modification requests are not clear. This leads to wasted time for the transplant centers that submit requests, for OPTN Contractor staff who process requests, and for the committees that review requests. Required documentation is often missing, which means transplant candidates may not quickly receive the waiting time that they are entitled to under OPTN policy.

Changes
The existing requirements and process for submitting a waiting time modification request have not substantially changed. OPTN Policy 3.2.1.8 (Waiting Time Modification) has primarily been edited to state this process more clearly. The new policy language also explicitly states which committee will review each waiting time modification request. Finally, the new policy language standardizes the processes for the application and implementation of waiting time modifications. The OPTN/UNOS Board of Directors originally approved changes to Policy 3.2.1.8 at its June 2012 meeting. Prior to implementation, UNOS staff recognized unintended consequences that would result from these policy changes. In response, the OPTN/UNOS Executive Committee voted to delay implementing these policy changes at its August 2012 meeting. In October 2012, the Executive Committee approved additional policy modifications to address these unintended consequences. The policy language below provides how the policy will read upon implementation. It incorporates the original edits approved by the Board of Directors and the subsequent edits approved by the Executive Committee.

Member Actions
Transplant center staff who submit waiting time modification requests to the OPTN Contractor should familiarize themselves with the new policy language. The application to be completed for waiting time modifications can be found under the “Resources” tab in Waitlist℠.

Click Here to View the Modified Policy Language

Policy Clarification of the Allocation Sequence for Liver-Intestine Candidates

Sponsoring Committee: Executive Committee

Policy Affected: 3.6 (Adult Donor Liver Allocation Algorithm)

Distributed for Public Comment: No

Effective Date: To be determined, implementation pending programming

Problem Statement
In November 2011, the OPTN/UNOS Board of Directors approved a proposal intended to reduce the death rate on the waiting list for adult combined liver-intestine candidates by giving these candidates national access to donor organs. As written, Status 1 candidates who are outside the region of the donor's DSA would receive organ offers *after* candidates listed with a MELD/PELD score who are outside the region of the donor DSA (i.e., listed in classification 8 rather than classification 5 in the adult donor liver allocation algorithm). While this would be rare, it is possible for a candidate waiting for an adult donor combined liver-intestine allograft to meet the criteria for Status 1A, which is reserved for candidates with fulminant liver failure. It is also possible that a candidate would be listed in Status 1B, which is reserved for chronically ill pediatric candidates. Although both scenarios are unlikely, the policy and corresponding programming should accommodate these occurrences.

Changes
This oversight was corrected by adding the words "Status and" to classification 5 before the phrase "mortality risk score" as shown in the adult donor liver allocation algorithm.

Member Actions
Members should become familiar with the policy change. UNOS will send a system notice when these changes have been programmed in UNet[SM].

Click Here to View the Modified Policy Language

Minimum Requirements for Living Kidney Donor Follow-up

Sponsoring Committee: Living Donor Committee

Policies Affected: 7.2 (General Submission of Forms), 12.8.3 (Reporting Requirements), 12.8.3.1, and 12.10 (Required Protocols for Kidney Recovery Hospitals)

Distributed for Public Comment: September 2011

Amended After Public Comment: Yes

Effective Date: February 1, 2013

Problem Statement
Living donor recovery hospital performance metrics cannot be established because the data submitted on Living Donor Follow-up (LDF) forms are often incomplete and unsuitable for analysis. OPTN data show that 21% of living donor recovery hospitals failed to report donor status (alive or dead) and any clinical data at one year post-donation for any living kidney donor who donated at that hospital between January 1 and December 31, 2010.

Changes

The OPTN/UNOS Board of Directors approved policy changes that require living kidney donor recovery hospitals to report accurate, complete, and timely data pertaining to the donor's status, clinical information, and kidney laboratory data. Follow-up data collected within 60 days of the six-month, one-year, and two-year anniversary of donation is considered timely and reported data are to include:

Donor Status and Clinical Information

- Patient status
- Cause of death, if applicable and known
- Working for income, and if not working, reason for not working
- Loss of medical (health, life) insurance due to donation*
- Has the donor been readmitted since last LDF form was submitted?
- Kidney complications
- Maintenance dialysis
- Donor developed hypertension requiring medication
- Diabetes

Kidney Laboratory Data

- Serum creatinine
- Urine protein

* Not yet on the LDF form, and will not be required until it is added.

Member Actions
For all potential living kidney donors whose evaluations are initiated on or after February 1, 2013, transplant hospitals that perform living donor recoveries will be required to submit accurate, complete, and timely LDF forms. Living kidney donor recovery hospitals will be required to provide donor status and clinical information using the LDF form for at least: • 60% of their living kidney donors who donate between February 1, 2013, and December 31, 2013 • 70% of their living kidney donors who donate between January 1, 2014, and December 31, 2014 • 80% of their living kidney donors who donate after December 31, 2014. Living kidney donor recovery hospitals will be required to provide kidney laboratory data using the LDF form for at least: • 50% of their living kidney donors who donate between February 1, 2013, and December 31, 2013 • 60% of their living kidney donors who donate between January 1, 2014, and December 31, 2014 • 70% of their living kidney donors who donate after December 31, 2014. For those donors who donate after February 1, 2013, living donor recovery hospitals would first be required to report the new living donor follow-up requirements beginning in August 2013 (when the six month LDF forms are due for donors who donated after February 1, 2013). The first cohort of donors to be reviewed will include donors who donate from February 2013 through July 2013. The six month LDF forms for the last donor in this cohort will be due in at the end of January 2014. Living kidney donor recovery hospitals must submit 100% of their forms within 6 months of their due date (Policy 7.8.1), so no living kidney donor recovery hospital could be out of compliance for failing to report required follow-up elements prior to **August 2014**. Professionals at transplant hospitals may participate in a web-based education session focused on the new policies. More information and registration details may be found here.

Click Here to View the Modified Policy Language

Requirements for the Informed Consent of Living Kidney Donors

Sponsoring Committee: Living Donor Committee

Policies Affected: 12.2 (Informed Consent of Living Donors), 12.2.1 (Living Kidney Donor Evaluation Consent), 12.4 (Independent Donor Advocates), 12.4.1, 12.7.10.1 (Vessel recovery and transplant), and 12.10 (Required Protocols for Kidney Recovery Hospitals)

Distributed for Public Comment: September 2011

Amended After Public Comment: Yes

Effective Date: February 1, 2013

Problem Statement
National standards for the informed consent of living kidney donors have not been established. This contributes to variability in the informed consent of potential living kidney donors throughout the country. In response to a directive from the Health Resources and Services Administration (HRSA) to develop policies for living organ donors and their recipients, the OPTN/UNOS Living Donor Committee proposed minimum standard requirements for informed consent to improve the care of all future living kidney donors.

Changes
The new policies detail minimum requirements that all living donor recovery hospitals must follow for the informed consent of living kidney donors. Required elements now include medical and psychosocial evaluations, as well as explicit disclosure of certain risks and other relevant information. The policy changes also eliminate the requirement that all living kidney donor consent forms indicate that extra vessels may be used for transplant. Instead, a living donor recovery hospital will only need to obtain consent for vessel recovery in those cases where it intends to recover extra vessels from the living kidney donor.

Member Actions
Living donor transplant hospitals must follow new standard requirements for the informed consent of any potential living kidney donor whose evaluation is initiated on or after February 1, 2013. The minimum standard requirements are detailed in policies 12.2 (Informed Consent of Living Kidney Donors) and 12.4 (Independent Donor Advocate). Professionals at transplant hospitals may participate in a web-based education session focused on the new policies. More information and registration details may be found here.

Click Here to View the Modified Policy Language

Requirements for the Medical Evaluation of Living Kidney Donors

Sponsoring Committee: Living Donor Committee

Policies Affected: 12.3.3 (Psychosocial Evaluation of the Living Kidney Donor), 12.3.4 (Medical Evaluation of the Living Kidney Donor), and 12.10 (Required Protocols for Kidney Recovery Hospitals)

Distributed for Public Comment: September 2011

Amended After Public Comment: Yes

Effective Date: February 1, 2013

Problem Statement
National standards for the medical and psychosocial evaluations of living kidney donors have not been established. This contributes to variability in the medical and psychosocial evaluations of potential living kidney donors throughout the country. In response to a directive from the Health Resources and Services Administration (HRSA) to develop policies for living organ donors and their recipients, the OPTN/UNOS Living Donor Committee proposed minimum standard requirements for medical and psychosocial evaluations to improve the care of all future living kidney donors.

Changes
The OPTN/UNOS Board of Directors adopted new policies detailing the minimum requirements that transplant hospitals must incorporate into the medical and psychosocial evaluation of every potential living kidney donor.

Member Actions
Living donor transplant hospitals must follow new minimum standard requirements for the medical and psychosocial evaluations of any potential living kidney donor whose evaluation is initiated on or after February 1, 2013. The minimum standard requirements are detailed in policies 12.3.3 (Psychosocial Evaluation of the Living Kidney Donor) and 12.3.4 (Medical Evaluation of the Living Kidney Donor). Professionals at transplant hospitals may participate in a web-based education session focused on the new policies. More information and registration details may be found here.

Click Here to View the Modified Policy Language

Reporting Unexpected Potential and Proven Disease Transmission Involving Living Donors

Sponsoring Committee: Living Donor Committee

Policies Affected: 4.5 (Post-Transplant Reporting of Potential Transmission of Disease or Medical Conditions, Including Malignancies), 4.5.1(Host OPO Responsibilities), 4.5.2 (Transplant Program Responsibilities) and 12.2 (Informed Consent of Living Donors).

Distributed for Public Comment: March 2012

Amended After Public Comment: No

Effective Date: February 1, 2013

Problem Statement
In November 2010, the OPTN/UNOS Board of Directors approved revisions to OPTN Policies 2.0 (Minimum Procurement Standards for an Organ Procurement Organization (OPO)) and 4.0 (Identification of Transmissible Diseases in Organ Recipients). The revisions included rules for communicating and reporting all unexpected potential or proven disease transmissions, including infections or malignancies. Since implementation, there has been confusion about whether these revisions also apply to living donation.

Changes
OPTN policy will now explicitly require that any unexpected potential or proven disease transmission involving a living donor must be communicated between the organ recipient's transplant hospital and the living donor recovery hospital, as well as to the OPTN Contractor.

Member Actions
Beginning February 1, 2013, transplant hospitals caring for living donor organ transplant recipients must inform the living donor recovery hospital and report in the OPTN Improving Patient Safety portal all potential or actual unexpected disease transmissions. Recipient transplant hospitals must communicate this information within 24 hours of the time that they become aware of the risk of potential disease transmission. Similarly, beginning February 1, 2013, if a living donor recovery hospital becomes aware of an unexpected potential disease transmission risk through follow-up with a donor during the first two years after donation, then it must inform the recipient transplant hospital and report in the OPTN Improving Patient Safety portal all potential unexpected disease transmissions involving a living donor. Living donor recovery hospitals must report this information within 24 hours of the time that they become aware of an unexpected potential disease transmission risk.

Click Here to View the Modified Policy Language

OPTN Kidney Paired Donation (KPD) Policy

Sponsoring Committee: Kidney Transplantation Committee

Policies/Bylaw Affected: 13.0 (Kidney Paired Donation) through 13.10 (Definitions) including all subsections, and OPTN Bylaws, Appendix E

Distributed for Public Comment: March 2012

Amended After Public Comment: Yes

Effective Date: Changes to Policies 13.6.1 (Requirements for Match Run Eligibility for Candidates), 13.6.6.1 (Chain Size), and those changes resulting from the inclusion of bridge donors (13.6.2, 13.6.6.2, and 13.6.6.3) and reviewed in the following notice, will be implemented and effective pending programming. The remaining changes will be effective February 1, 2013.

Problem Statement
Rules for the OPTN KPD Pilot Program are currently governed by operational guidelines. In December 2009, the Health Resources and Services Administration (HRSA) directed the OPTN to establish interim policies to govern the OPTN KPD Pilot Program and replace the operational guidelines. Converting operational guidelines to policy will allow the Membership and Professional Standards Committee (MPSC) to follow its standard processes for potential violations of KPD policy with the full range of adverse actions.

Changes
This proposal converts "Requirements for Participation in the OPTN KPD Program;" "Crossmatching Protocol;" "Transportation of Kidneys;" and "Rules for When Donors and Recipients Can Meet" of the existing OPTN KPD Pilot Program Operational Guidelines into OPTN policy. The policy also includes requirements for how the OPTN Contractor will conduct matching in the OPTN KPD Pilot Program. The operational guidelines have not been completely eliminated; some aspects of the OPTN KPD Pilot Program remain in the operational guideline format.

Member Actions
Transplant hospitals participating in the OPTN KPD Pilot Program will be required to abide by OPTN KPD policy. Transplant hospital staff should become familiar with the new policies, as well as the remaining operational guidelines.

Click Here to View the Modified Policy Language & Bylaw Language

Including Bridge Donors in the OPTN Kidney Paired Donation (KPD) Program

Sponsoring Committee: Kidney Transplantation Committee

Policies Affected: 13.6.2 (Requirements for Match Run Eligibility for Potential Donors), 13.6.6.2 (Logistical Requirements), 13.6.6.3 (What to Do When a Chain Breaks), and 13.10 (Definitions)

Distributed for Public Comment: March 2012

Amended After Public Comment: Yes

Effective Date: To be determined, implementation pending programming

Problem Statement
Currently, the OPTN KPD Pilot Program requires that donor chains end with a donation to a candidate on the deceased donor waiting list. As a result, donor chains could end when there may be the potential to extend the chain and transplant more candidates. Additionally, many transplant hospitals have expressed a desire for the OPTN KPD Pilot Program to include bridge donors.

Changes
The OPTN/UNOS Board of Directors voted to allow bridge donors in the OPTN KPD Pilot Program.

Member Actions
When entering a paired donor into the OPTN KPD Pilot Program, the potential donor and the transplant hospital must decide if they are willing for the potential donor to be a bridge donor. When entering a non-directed donor into the OPTN KPD Pilot Program, the transplant hospital must decide if the chain should end with a donation to a candidate on the deceased donor waiting list or with a bridge donor.

Click Here to View the Modified Policy Language

Clarifying Priority Status for Prior Living Organ Donors Who Later Require a Kidney Transplant

Sponsoring Committee: Kidney Transplantation Committee

Policies Affected: 3.5.11.6 (Donation Status) and 12.9.3 (Priority on the Waitlist)

Distributed for Public Comment: March 2012

Amended After Public Comment: No

Effective Date: February 1, 2013

Problem Statement
Under current policy, prior living organ donors who later require a kidney transplant receive local priority and four additional allocation points at the regional and national levels of allocation. Policy is unclear whether a prior living organ donor receives this priority with each registration or only the first registration.

Changes
The OPTN/UNOS Board of Directors adopted policy changes that clarify the allocation priority assigned to prior living organ donors who later require a kidney transplant applies to their first, and each subsequent, kidney transplant registration.

Member Actions
Transplant hospital staff responsible for registering kidney transplantation candidates will need to request priority for candidates who are prior living organ donors through the UNOS Organ Center. This process remains the same, but is required for each kidney transplant registration for that candidate.

Click Here to View the Modified Policy Language

Require Extra Vessels Disposition Reporting to the OPTN within Seven Calendar Days

Sponsoring Committee: Operations and Safety Committee

Policy Affected: 5.10.2 (Vessel storage)

Distributed for Public Comment: March 2012

Amended After Public Comment: Yes

Effective Date: To be determined, implementation pending programming

Problem Statement
Transmitting infectious diseases through organ transplant is a patient safety issue and is significant to public health. It is important for the OPTN to know quickly if extra vessels are used for an intended or secondary recipient. Analysis of OPTN data shows that transplant hospitals do not regularly report the disposition of extra vessels to the OPTN. Many transplant hospitals sporadically report dispositions or may not provide information on the use or disposal of extra vessels until the time of a site survey.

Changes
The policy changes will require transplant hospitals to report the disposition (use or disposal) of extra vessels they have received within seven calendar days of the disposition.

Member Actions
Transplant hospital professionals should: • become familiar with the new vessel disposition reporting timeline, and • participate in upcoming UNOS training sessions to learn how to report vessel dispositions in UNet^{SM}.

Click Here to View the Modified Policy Language

Required Documentation of All Unique Identifiers Used to Label Tissue Typing Specimens

Sponsoring Committee: Organ Procurement Organization Committee

Policies Affected: 5.4.2 (Tissue typing materials) & 12.7.4.2 (Tissue typing materials)

Distributed for Public Comment: March 2012

Amended After Public Comment: Yes

Effective Date: February 1, 2013

Problem Statement
During preliminary donor evaluation, if the UNOS donor ID or blood type is not available, policy permits OPOs to use their own unique identifiers to identify tissue typing specimens. When these unique identifiers are not documented in the donor record, it is impossible for transplant hospitals to validate the tissue typing specimens.

Changes
Policy will require OPOs to document in the donor record all unique identifiers used to label tissue typing specimens.

Member Actions
Beginning February 1, 2013, OPOs must document in the donor record all unique identifiers used to label tissue typing specimens.

Click Here to View the Modified Policy Language

Revisions to the Lung Allocation Score (LAS) System

Sponsoring Committee: Thoracic Organ Transplantation Committee

Policies Affected: 3.7.6 (Lung Allocation) through 3.7.6.1.5 (Creatinine in the Lung Allocation Score (LAS)), 3.7.6.3 (Candidate Variables in UNet℠), 3.7.6.3.1 (Updating Candidate Variables), and 3.7.9.2 (Waiting Time Accrual for Lung Candidates Age 12 and Older Following Implementation of Lung Allocation Scores Described in Policy 3.7.6)

Distributed for Public Comment: March 2012

Amended After Public Comment: Yes

Effective Date: To be determined, implementation pending programming

Problem Statement
The LAS system prioritizes candidates who are at least 12 years of age for allocation of deceased donor lungs. The LAS does not include risk factors that allow for accurate calculation of waiting list urgency and post-transplant survival, particularly for candidates in Diagnosis Group B. Additionally, the LAS calculation is currently based on candidates waiting for transplant over ten years ago, rather than reflecting the current patient population and clinical practices of managing these candidates. The OPTN/UNOS Thoracic Organ Transplantation Committee (the Committee) intended for the LAS system to be dynamic to address disease severity and post-transplant survival for a given current candidate population. However, except for adding partial pressure of carbon dioxide (PCO_2) as a covariate to the LAS system's waiting list model, the Committee has not thoroughly revised the LAS system since its implementation in 2005.

Changes
The LAS policy revision modifies covariates in the system's statistical models, and updates the baseline survival rates and coefficients to reflect the current waiting list population. The revision includes modifications to the covariates in the waiting list and post-transplant survival models, coefficients of the covariates, and baseline waiting list and post-transplant survival rates used in the LAS calculation. Additionally, the revision includes plain language edits, guidance to transplant hospitals for reporting data, and the complete LAS calculation and its components for transparency.

Member Actions
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 changes to UNet℠ resulting from the new policy.

Click Here to View the Modified Policy Language

Affected Policy Language:

3.7 ALLOCATION OF THORACIC ORGANS.

3.7.3 Adult Candidate Status.

[…]

Status 1A by Exception
A candidate who does not meet criterion (a), (b), (c), or (d) may nevertheless be Status 1A upon application by his or her transplant physician. The transplant physician must justify to the applicable Regional Review Board why the candidate is considered, using acceptable medical criteria, to have an urgency and potential for benefit as other candidates in Status 1A. The justification must be for a candidate admitted to his or her listing transplant center hospital and must include a rationale for incorporating the exceptional case as part of Status 1A. The justification must be reviewed and approved by the Regional Review Board. ~~Timing of the review of these cases, whether prospective or retrospective, will be left to the discretion of each Regional Review Board.~~ Regional Review Boards will retrospectively review requests for Status 1A-exceptions.

A candidate's listing under this exceptional provision is valid for 14 days. Any further extension of the Status 1A listing by exception requires ~~prospective~~ retrospective review and approval by ~~a majority of~~ the Regional Review Board ~~Members.~~ If Regional Review Board approval is not given, the candidate's transplant physician may override the Regional Review Board and list the candidate as Status 1A~~, subject to automatic referral to the Thoracic Organ Transplantation Committee~~. A report of the decision of the Regional Review Board and the basis for it ~~shall~~ may be forwarded for review by the Thoracic Organ Transplantation Committee. The Thoracic Organ Transplantation Committee may refer the case to the Membership and Professional Standards Committee.

Submission of Status 1A Justification Form
A completed Heart Status 1A Justification Form must be submitted ~~to~~in UNet^{SM} in order to list a candidate as Status 1A, or extend his or her listing as Status 1A in accordance with the criteria listed above. When a candidate's time at Status 1A expires, the candidate will automatically be classified as Status 1B. The attending physician must classify the candidate as Status 2 or 7 if the candidate's medical condition does not qualify for Status 1A or Status 1B.

Status 1B A candidate listed as Status 1B has at least one of the

following devices or therapies in place:

(aa) left and/or right ventricular assist device implanted; or
(bb) continuous infusion of intravenous inotropes.

Status 1B by Exception
A candidate who does not meet the criteria for Status 1B may nevertheless be listed as Status 1B upon application by his or her transplant physician. The transplant physician must justify to the applicable Regional Review Board why the candidate is considered, using acceptable medical criteria, to have an urgency and potential for benefit as other Status 1B candidates. The justification must include a rationale for incorporating the exceptional case as part of Status 1A. Regional Review Boards will retrospectively review requests for Status 1B exceptions. A report of the decision of the Regional Review Board and the basis for it ~~shall~~ may be forwarded for review by the Thoracic Organ Transplantation Committee. The Thoracic Organ Transplantation Committee may refer the case to the Membership and Professional Standards Committee.

Submission of Status 1B Justification Form
A completed Heart Status 1B Justification Form must be submitted to UNet℠ in order to list a candidate as Status 1B.

Status 2 A candidate who does not meet the criteria for Status 1A or 1B is listed as Status 2.

Status 7 A candidate listed as Status 7 is considered temporarily unsuitable to receive a thoracic organ transplant.

Change in Status 1A or 1B Criterion or Eligibility
If a change in the candidate's medical condition makes the criterion used to justify a candidate's Status 1A or 1B no longer accurate, the transplant program must report the accurate information in UNet℠ within 24 hours of the change in medical condition.

3.7.4 **Pediatric Candidate Status.** Each candidate awaiting heart transplantation receives a status code corresponding to the candidate's medical urgency for transplant. Pediatric heart transplant candidates who have not received a heart transplant before their 18th birthday shall continue to qualify for medical urgency status based on Policy 3.7.4. A heart transplant candidate who is less than 18 years of age at the time of listing receives a status code as follows:

Status	Definition
Status 1A	A candidate listed as Status 1A meets at least one of the

following criteria:

(a) Requires assistance with a ventilator;

(b) Requires assistance with a mechanical assist device (e.g., ECMO);

(c) Requires assistance with a balloon pump;

(d) A candidate less than six months old with congenital or acquired heart disease exhibiting reactive pulmonary hypertension at greater than 50% of systemic level. Such a candidate may be treated with prostaglandin E (PGE) to maintain patency of the ductus arteriosus;

(e) Requires infusion of high dose or multiple inotropes (The OPTN contractor shall maintain in the heart status justification form in UNet℠ a list of the specific inotropes and doses approved by the Board of Directors to be compliant with this criterion.); or,

(f) A candidate who does not meet the criteria specified in (a), (b), (c), (d), or (e) may be listed as Status 1A if the candidate has a life expectancy without a heart transplant of less than 14 days, such as due to refractory arrhythmia. Qualification for Status 1A under this criterion is valid for 14 days and may be recertified by an attending physician for one additional 14-day period. Any further extension of the Status 1A listing under this criterion requires a retrospective conference with the applicable Regional Review Board. If Regional Review Board approval is not given, the candidate's transplant physician may list the candidate as Status 1A, subject to automatic referral to the Thoracic Organ Transplantation Committee. A report of the decision of the Regional Review Board and the basis for it shall be forwarded for review by the Thoracic Organ Transplantation Committee. The Thoracic Organ Transplantation Committee may refer the case to the Membership and Professional Standards Committee.

Qualification for Status 1A under criteria (a) through (e) is valid for 14 days and must be recertified by an attending physician every 14 days from the date of the candidate's initial listing as Status 1A to extend the Status 1A listing.

Submission of Status 1A Justification Form
A completed Heart Status 1A Justification Form must be submitted in UNet^{SM} in order to list a candidate as Status 1A, or extend his or her listing as Status 1A in accordance with the criteria listed above in Policy 3.7.4. When a candidate's time at Status 1A expires, the candidate will automatically be classified as Status 1B. The attending physician must classify the candidate as Status 2 or 7 if the candidate's medical condition does not qualify for Status 1A or Status 1B.

Status 1B A candidate listed as Status 1B meets at least one of the following criteria:

(a) Requires infusion of low dose single inotropes (The OPTN contractor shall maintain in the heart status justification form in UNet^{SM} a list of the specific inotropes and doses approved by the Board of Directors to be compliant with this criterion.);

(b) Less than six months old and does not meet the criteria for Status 1A; or

(c) Growth failure *i.e.,* less than 5th percentile for weight and/or height, or loss of 1.5 standard deviations of expected growth (height or weight) based on the National Center for Health Statistics for pediatric growth curves.

Note: This criterion defines growth failure as either < 5th percentile for weight and/or height, or loss of 1.5 standard deviation score of expected growth (height or weight). The first measure looks at relative growth as of a single point in time. The second alternative accounts for cases in which a substantial loss in growth occurs between two points in time. Assessment of growth failure using the standard deviation score decrease can be derived by, first, measuring (or using a measure of) the candidate's growth at two different times, second, calculating the candidate's growth velocity between these times, and, third, using the growth velocity to calculate the standard deviation score (*i.e.,* (candidate's growth rate - mean growth rate for age and sex) divided by standard deviation of growth rate for age and sex).

Status 1B by Exception
A candidate who does not meet the criteria for Status 1B may be listed as Status 1B upon application by his transplant physician to the applicable Regional Review Board. The transplant physician must justify why the candidate is considered, using acceptable medical criteria, to have an urgency and potential for benefit as other candidates listed as Status 1B. The justification must include a rationale for incorporating the exceptional case as part of Status 1B. A report of the decision of the Regional Review Board and the basis for it ~~shall~~ may be forwarded for review by the Thoracic Organ Transplantation Committee~~s~~. The Thoracic Organ Transplantation Committee may refer the case to the Membership and Professional Standards Committee.

Submission of Status 1B Justification Form
A completed Heart Status 1B Justification Form must be submitted in UNet℠ to list a candidate as Status 1B.

Status 2 A candidate who does not meet the criteria for Status 1A or 1B is listed as Status 2.

Status 7 A candidate listed as Status 7 is considered temporarily unsuitable to receive a thoracic organ transplant.

Change in Status 1A or 1B Criterion or Eligibility
If a change in the candidate's medical condition makes the criterion used to justify a candidate's Status 1A or 1B no longer accurate, the transplant program must report the accurate information in UNet℠ within 24 hours of the change in medical condition.

3.7.6.2 **Candidates Age 0 - 11**. UNet℠ ranks candidates who are 0 – 11 years old for lung offers according to the priorities defined below. Within each priority, UNet℠ will rank candidates by ABO (according to Policy 3.7.8.2) and then by waiting time, in descending order. For Priority 1, UNet℠ will only consider the most current period of time a candidate has spent as Priority 1, i.e, UNet℠ will not tally the time waiting during multiple Priority 1 periods. For Priority 2, and if there is ever a tie among Priority 1 candidates, UNet℠ will use these candidates' total waiting time to determine the order for receiving lung offers. Total waiting time includes time spent waiting as Priority 1, Priority 2, and inactive.

A program may update clinical data used to justify a candidate's priority at any time it believes a candidate's medical condition warrants such modifications. For a candidate listed as Priority 1, a program must update each qualifying criterion, except that which is obtained only by heart catheterization, at least once in each six month period following the candidate's registration on the lung Waitlist℠. If more than six months elapse without data updates after the candidate's last six-month "anniversary" of his or her Waitlist℠ registration, then the candidate's

Priority 1will revert to Priority 2. UNet^{SM} will assess the currency of lung variables for each candidate on every six-month "anniversary" date. (For example, if a candidate is first registered on the Waitlist^{SM} on January 1, 2011, and the most recent six-month "anniversary" is January 1, 2012, then UNet^{SM} will consider any variables collected on or after July 1, 2011 as current until June 30, 2012. UNet^{SM} will reassess the currency of the lung variables on July 1, 2012, and then any variables with test dates that are on or after January 1, 2012 would be considered current.)

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

- **Respiratory failure, defined as:**
  - Requiring continuous mechanical ventilation; ***or***
  - Requiring supplemental oxygen delivered by any means to achieve FiO_2 greater than 50% in order to maintain oxygen saturation levels greater than 90%; ***or,***
  - Having an arterial or capillary PCO_2 greater than 50 mmHg, or a venous PCO_2 greater than 56mmHg.

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

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

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

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

3.7.6.4 **Lung Candidates With Exceptional Cases**. Special cases require prospective review by the Lung Review Board. Transplant programs may request approval of estimated values, diagnosis, or a specific Lung Allocation Score. The transplant hospital will accompany each request for special case review with a supporting narrative. Once complete, the request must be sent to the OPTN contractor. The Lung Review Board will have seven (7) calendar days to reach a decision, starting from the date that the contractor sends the request to the Lung Review Board. If a request is denied by the Lung Review Board upon initial review, then the hospital may choose to appeal the decision for reconsideration by the

Lung Review Board. The hospital will have seven (7) calendar days from the date of the initial request denial to appeal. The Lung Review Board will have seven (7) calendar days to reach a decision on the appeal, starting from the date that the contractor sends the appealed request to the Lung Review Board. If the Lung Review Board has not completed its review of an initial request or an appeal within seven (7) calendar days of receiving it, then the candidate will not receive the requested Lung Allocation Score, diagnosis, or estimated value, and the request or appeal will be forwarded to the Thoracic Organ Transplantation Committee for further review.

Should the Lung Review Board deny a transplant hospital's initial request or appealed request for an estimated value or a specific Lung Allocation Score, the transplant hospital has the option to override the decision of the LRB. If the transplant hospital elects to override the decision of the Lung Review Board, then the request or appeal will be automatically referred to the Thoracic Organ Transplantation Committee for review; this review by the Thoracic Organ Transplantation Committee may result in further referral of the matter to the Membership and Professional Standards Committee for appropriate action in accordance with Appendix A of the Bylaws.

Estimated values will remain valid until an actual value is entered in the system or a new estimated value is entered pursuant to the procedures described in this policy. A diagnosis that has been approved by the Lung Review Board or the Thoracic Organ Transplantation Committee will remain valid indefinitely or until an adjustment is requested and, if necessary, approved by the Lung Review Board. Lung Allocation Scores will remain valid for six (6) months from the entry date (or the candidate's twelfth birthday, whichever occurs later). If the candidate continues to be on the Waiting List six months after the entry date, then the candidate's Lung Allocation Score will be computed as described in Policy 3.7.6.1 and Policy 3.7.6.3 unless a new Lung Allocation Score request is entered pursuant to the procedures described in this policy or the hospital chooses to use the computed Lung Allocation Score instead.

The Thoracic Committee shall establish guidelines for special case review by the Lung Review Board.

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

OPTN/UNOS Heart Regional Review Board (RRB) Guidelines for Reviewing Adult and Pediatric Heart Status 1A- and 1B-Exception Cases

1. Purpose of the RRB

The RRB provides prompt peer review of Status 1A-Exception and Status 1B-Exception candidate registrations on the heart transplant waiting list.

2. Representation on the RRB

A. There will be a minimum of 3 physicians on the RRB representing active adult and pediatric heart transplant programs. Each active heart transplant program will have the opportunity to be represented. The region may choose to include the regional representative to the OPTN/UNOS Thoracic Organ Transplantation Committee (the Committee) on the RRB as an organizational or continuity measure. The Regional Councilor, or his designee, chooses the RRB Chair, who is a heart transplant physician or surgeon affiliated with an active heart transplant program; but, the RRB Chair must not simultaneously represent his or her transplant program as an RRB member.

B. On a national basis, RRBs vary in number. Since larger RRBs may pose operational or administrative problems, some of the RRBs rotate membership to ensure that each transplant program is represented on the RRB for one term each year. Frequency of rotation will be determined by each region.

C. Each RRB member must identify one or more alternate representatives to the OPTN Contractor. It is the responsibility of each transplant program to provide the OPTN Contractor with the contact information for both the RRB member and the alternate representative. Should an RRB member leave his or her transplant program, then the transplant program's alternate representative will become the permanent RRB member, and must provide the OPTN Contractor with the contact information for another alternate representative from his transplant program.

D. If a heart transplant program becomes inactive, it is no longer entitled to representation on the RRB. The term of the transplant program's representative on the RRB ends upon program's withdrawal or inactivation from the OPTN. Should a program reactivate, it may again have representation on the RRB.

3. Responsibilities of the RRB Members

RRB members and alternates must:

A. Evaluate the appropriateness of applying the requested status to the specified candidate.

B. Vote on cases according to the timelines specified in the OPTN/UNOS policies and guidelines.

C. Participate on conference calls as they are scheduled.

D. Sign an OPTN/UNOS Confidentiality/Conflict of Interest Statement prior to serving on the RRB.

4. Voting Procedures

A. Eligibility to Vote

An RRB member or alternate's vote will not be valid and will not count towards quorum in any case in which he has a conflict of interest. The vote of an RRB member on cases originating from the member's transplant program or hospital where he has an affiliation will be excluded from the final vote.

B. Retrospective Review of Status Exceptions

The RRB will retrospectively review Status 1A Exception or 1B Exception applications. The review will address the appropriateness of the Status assignment.

During the entirety of the retrospective review and appeal process, the candidate's status will be equal to the requested status and the requesting program must follow all OPTN policies that apply to the requested status.

At the termination of the application and appeal process, if the requested status is not approved, then the requesting program must either change the candidate's status to the status for which the candidate qualifies under policy, or follow the requirements for an override, as described below.

C. Prospective Review of Score Exceptions

During the prospective review and appeal process, the candidate will be registered according to the status for which he qualifies under policy, until the OPTN Contractor notifies the requesting program that the request is approved. Alternatively, the requesting program may follow the requirements for an override, as described below.

The prospective review process is not applicable to Status 1A exception and Status 1B exception registrations.

D. Initial RRB Case Review and Vote

The OPTN Contractor will send the application or appeal to RRB members. If the RRB member has not voted within 3 days of when the OPTN Contractor sends the application or appeal to the RRB, then the OPTN Contractor will send the case to the alternate. Thereafter, both the RRB member and alternate may vote on the application within 7 days of when the OPTN Contractor originally sent the application to the RRB. If the RRB member and the alternate both submit votes for the same application, then the OPTN Contractor will count the vote from whoever voted first.

Initial applications are decided as follows: vote

If the vote is…	**And the case is prospectively reviewed,* then the...**	**Or the case is retrospectively reviewed, then the…**
Majority vote to approve the request	Application is granted	Application is granted
Majority vote to deny the request	Application is not granted	Application is not granted
Tie Vote	Application is not granted	Application is granted
No Quorum	Application is not granted	Application is granted

*Not applicable to Status 1A-exception and Status 1B-exception registrations.

In order for a vote to be valid, quorum must be reached. To reach quorum, a majority of all RRB members, or their alternates in cases where the RRB member cannot or does not vote, eligible to vote must vote within the allotted timeframe.

A majority vote is calculated by dividing the total number of eligible RRB members that vote on each case by half and then adding one.

Voting will close at the earliest of when:

- all eligible voters have voted;
- a majority of all eligible voters have voted to approve or deny a request; or

- 7 days after the OPTN Contractor sends the request to the RRB.

Once voting has closed on a case, a RRB member or alternate can no longer vote on that case.

The OPTN Contractor will send the results of the RRB's vote to the requesting program. The OPTN Contractor must not reveal the vote of any specific RRB member, but may provide the requesting program with comments or questions made by the RRB members.

5. Appeals

A. Appeal to the Review Board

If the RRB does not grant the exception, then the requesting program may appeal the decision of the RRB. Individual candidates are not eligible to submit exception applications or appeal RRB rulings. Only transplant programs may submit applications and appeals.

The requesting program must notify the OPTN Contractor of its intent to appeal within 7 days of when the OPTN Contractor sent the requesting program notice of the initial RRB decision, and submit additional information justifying the requested exception status, as well as responses to written comments of dissenting RRB members. This additional information will be submitted to RRB members for further consideration.

If the appeal is not approved, the requesting program may request a conference call with the RRB. A teleconference is considered an additional appeal.

If the RRB fails to reach quorum, or the vote results in a tie, within 7 days of the date the requesting program initially sent the appeal request to the OPTN Contractor, the OPTN Contractor will notify the requesting program of the result, and the requesting program may list the candidate at the requested status.
Appealed applications are decided as follows:

If the vote is…	**And the case is prospectively reviewed,* then the...**	**Or the case is retrospectively reviewed, then the…**
Majority vote to approve the request	Appeal is granted	Appeal is granted

If the vote is…	And the case is prospectively reviewed,* then the...	Or the case is retrospectively reviewed, then the…
Majority vote to deny the request	Appeal is not granted	Appeal is not granted
Tie Vote	Appeal is granted	Appeal is granted
No Quorum	Appeal is granted	Appeal is granted

*Not applicable to Status 1A-exception and Status 1B-exception registrations.

B. Appeals of RRB Denials to the Committee

If the RRB votes to deny the request for the entirety of 7 days from the date the OPTN Contractor sends the transplant program's request for appeal to the RRB, then the requesting program may request a final appeal to the Committee. The requesting program must request an appeal to the Committee within 14 days of when the OPTN Contractor sent the requesting program notice of the RRB appeal decision.

The requesting program may provide the OPTN Contractor with additional information about the case, which the OPTN Contractor will send to the Committee or Heart Subcommittee. At its next scheduled meeting, the Committee or Heart Subcommittee will compare the eligibility criterion of other approved exceptional cases to achieve consistency in approved exception requests and to determine whether this candidate meets similar levels of medical urgency. The Committee will approve or deny each appeal according to its own procedures.

C. Overrides

If the RRB or Committee does not grant a request or appeal, then the requesting program may implement the requested status. The requesting program must notify the OPTN Contract of its intent to do so. The OPTN Contractor will notify the Committee of the transplant program's decision to override and provide any available details about the case.

The Committee will retrospectively discuss any overrides at its next scheduled full committee meeting or heart subcommittee meeting. The Committee or subcommittee will determine whether candidates registered using the override process exhibited similar medical urgencies as other candidates registered at the requested status. If the Committee or

subcommittee determines any of these cases were not comparable to the other candidates registered at the same status, then the Committee may refer the registering hospital to the Membership and Professional Standards Committee (MPSC) for action as outlined in *Appendix L: Reviews, Actions, and Due Process* of the OPTN Bylaws.

D. Referrals for Committee Discussion and MPSC Review

The RRB may refer a case to the Committee if the final outcome of the RRB appeal is a denial of the request, a lack of quorum, or a tie vote. The RRB may also refer a case to the Committee if the transplant program does not respond to the OPTN Contractor's requests for a statement of intent to appeal, or to subsequent requests to submit additional information in support of the appeal.

Referral of cases to the Committee will include information about the number of previous case referrals from that transplant program and the outcome of those referrals. If the Committee or Heart Subcommittee determines any of these cases were not comparable to the other candidates registered at the same status, then the Committee may refer the registering hospital to the Membership and Professional Standards Committee (MPSC) for action as outlined in *Appendix L: Reviews, Actions, and Due Process* of the OPTN Bylaws.

Additionally, the OPTN Contractor will refer the cases that result in a lack of quorum to the Committee or Heart Subcommittee. The Committee or Heart Subcommittee will review these cases to ensure that RRB members are properly executing their responsibilities outlined in Section 3.

6. Extensions

The RRB will retrospectively review extension requests for status exceptions. In compliance with OPTN/UNOS Policy 7.2(B), second and subsequent extensions of pediatric Status 1A-Exception listings will be reviewed retrospectively.

If an unapproved status exception will expire before the deadline for an RRB or Committee to decide an appeal for that exception, and the requesting program submits a request for an extension of that exception, then the RRB or Committee will vote on the exception extension request, and the appeal for the unapproved status exception will automatically close out.

7. Administration

The central office for each RRB is maintained by the OPTN Contractor. The RRB efforts are coordinated by the OPTN Contractor with the help of the Chairs of the RRBs.

Data sent to the RRBs for action or review will not contain hospital, program or candidate identifying information.

Responses may be shared with the transplant program if a RRB member specifically asks that comments be shared with the program, regardless of the voting outcome.

When a new group of RRB members are identified, all heart transplant programs in the region are notified of the roster. However, the only time a RRB member's identity as a reviewer is disclosed is during conference calls.

OPTN/UNOS Lung Review Board (LRB) Guidelines for Reviewing LAS and Priority Exceptions

1. Purpose of the LRB

The LRB provides prompt peer review of candidate priority and score exceptions on the lung transplant waiting list.

2. Representation on the LRB

A. The LRB is composed of 7 individual lung transplant surgeons or lung transplant physicians, a pediatric member, and an ad hoc pediatric member randomly selected from a national pool of active lung transplant programs that have agreed to participate on the LRB. Seven LRB members represent active adult lung transplant programs and 1 member represents an active pediatric lung transplant program. The pediatric member will only be sent cases involving pediatric lung transplant candidates, and may only vote on those cases. The chair of the OPTN/UNOS Thoracic Organ Transplantation Committee (the Committee) shall appoint a primary LRB member from among those selected to serve as the LRB Chair for a 2-year term. Each active lung transplant program shall have the opportunity to rotate onto the LRB.

B. LRB members serve a term of 2 years. Service terms will be staggered among the LRB members to ensure that at no time more than 4 terms will end. This requirement is to preserve the continuity of the LRB and the efficiency of its operation. Initial terms upon establishment of the LRB will be 4 members with 2 year terms and 4 members with a term of 1 year. The Chair of the OPTN/UNOS Committee will determine the terms, consistent with this requirement, for the initial LRB composition.

C. Each LRB member is required to appoint an alternate representative from his transplant program. In addition to the primary pediatric LRB member and his alternate, there will be an alternate ad-hoc pediatric member from another transplant program who will also be required to have an alternate. This will ensure that if a case from the primary pediatric member's program requires review there will still be an opportunity for a pediatric member to review the case without a conflict of interest.

It is the responsibility of each transplant program to provide the OPTN Contractor with the contact information for the both the primary LRB representative and the alternate from their program. Should a representative leave his transplant program, then the program's alternate representative will become the LRB member and another alternate will be appointed. The departing member is no longer a member of the LRB.

D. If a lung program is inactivated, it is no longer entitled to representation on the LRB. The term of the transplant program's representative on the LRB ends upon withdrawal or inactivation. Another eligible transplant program will be contacted at random and requested to put forth a representative and an alternate to replace the departed member. Should a transplant program reactivate, it may again have the opportunity to be represented on the LRB during future rotations.

3. Responsibilities of the LRB Members

LRB members and alternates must:

A. Evaluate the appropriateness of applying the requested status or score to the specified candidate.

B. Vote on cases according to the timelines specified in the OPTN/UNOS policies and guidelines.

C. Participate on conference calls as they are scheduled.

D. Sign an OPTN/UNOS Confidentiality/Conflict of Interest Statement prior to serving on the LRB.

4. Voting Procedures

A. Eligibility to Vote

An LRB member or alternate's vote will not be valid and will not count towards quorum in any case in which he has a conflict of interest. The vote of an LRB member on cases originating from his transplant program or hospitals where he has an affiliation will be excluded from the final vote count.

Should a case come from the pediatric program that is represented on the LRB be submitted for review, that case shall be forwarded to the pediatric ad-hoc LRB member who is from another transplant program.

B. Retrospective Review of Status Exceptions

The LRB will retrospectively review each Priority exception application. The review will address the appropriateness of the Priority assignment.

During the entirety of the retrospective review and appeal process, the candidate's priority will be equal to the requested priority, and the requesting program must follow all OPTN policies that apply to the requested priority.

At the termination of the application and appeal process, if the requested priority is not approved, then the requesting program must either change the

candidate's priority to the priority for which the candidate qualifies under policy or follow the requirements for an override, as described below.

C. Prospective Review of Score Exceptions

The LRB will prospectively review requests for LAS scores, estimated clinical values, diagnoses, and cases where the LAS is in dispute. The review will address both the appropriateness of the existing LAS and the appropriateness of the requested value or LAS.

During the prospective review and appeal process, the candidate will be registered according to the score for which he qualifies under policy, until the OPTN Contractor notifies the requesting program that the request is approved by the LRB. Alternatively, the requesting program may follow the requirements for an override, as described below.

D. Initial LRB Case Review and Vote

The OPTN Contractor will send the application or appeal to LRB members. If the LRB member has not voted within 3 days of when the OPTN Contractor sends the application or appeal to the LRB, then the OPTN Contractor will send the case to the alternate. Thereafter, both the LRB member and alternate may vote on the application within 7 days of when the OPTN Contractor originally sent the application to the LRB. If the LRB member and the alternate both submit votes for the same application, then the OPTN Contractor will count the vote from whoever voted first.

Initial applications are decided as follows:

If the vote is…	**And the case is prospectively reviewed, then the...**	**Or the case is retrospectively reviewed, then the…**
Majority vote to approve the request	Application is granted	Application is granted
Majority vote to deny the request	Application is not granted	Application is not granted
Tie Vote	Application is not granted	Application is granted

If the vote is…	And the case is prospectively reviewed, then the...	Or the case is retrospectively reviewed, then the…
No Quorum	Application is not granted	Application is granted

In order for a vote to be valid, quorum must be reached. To reach quorum, a majority of all LRB members, or their alternates in cases where the LRB member cannot or does not vote, eligible to vote must vote within the allotted timeframe.

A majority vote is calculated by dividing the total number of eligible LRB members that vote on each case by half and then adding one.

Voting will close at the earliest of when:

- all eligible voters have voted;
- a majority of all eligible voters have voted to approve or deny a request; or
- 7 days after the OPTN Contractor sends the request to the LRB.

Once voting has closed on a case, an LRB member or alternate can no longer vote on that case.

The OPTN Contractor will send the results of the LRB's vote to the requesting program. The OPTN Contractor must not reveal the vote of any specific LRB member, but may provide the requesting program with comments or questions made by the LRB members.

5. Appeals

A. Appeal to the Review Board

If the LRB does not grant the exception, then the requesting program may appeal the decision of the LRB. Individual candidates are not eligible to submit exception applications or appeal LRB rulings. Only transplant programs may submit applications and appeals.

The requesting program must notify the OPTN Contractor of its intent to appeal within 7 days of when the OPTN Contractor sent the requesting program notice of the initial RRB decision, and submit additional information justifying the requested exception, as well as responses to written comments of dissenting LRB members. This additional information will be submitted to LRB members for further consideration.

If the appeal is not approved, the requesting program may request a conference call with the LRB. A teleconference is considered an additional appeal.

If the LRB fails to reach quorum, or the vote results in a tie, within 7 days of the date the requesting program initially sent the appeal request to the OPTN Contractor, the OPTN Contractor will notify the requesting program of the result, and the requesting program may list the candidate at the requested priority or score.

Appealed applications are decided as follows:

If the vote is…	**And the case is prospectively reviewed, then the...**	**Or the case is retrospectively reviewed, then the…**
Majority vote to approve the request	Appeal is granted	Appeal is granted
Majority vote to deny the request	Appeal is not granted	Appeal is not granted
Tie Vote	Appeal is granted	Appeal is granted
No Quorum	Appeal is granted	Appeal is granted

B. <u>Appeals of Denials to the Committee</u>

If the LRB votes to deny the request for the entirety of 7 days from the date the OPTN Contractor sends the transplant program's request for appeal to the LRB, then the requesting program may request a final appeal to the Committee. The requesting program must request the Committee appeal within 14 days of when the OPTN Contractor sent the requesting program notice of the LRB appeal decision.

The requesting program may provide the OPTN Contractor with additional information about the case, which the OPTN Contractor will send to the Committee or Lung Subcommittee. At its next scheduled meeting, the Committee or Lung Subcommittee will compare the eligibility criterion of other approved exceptional cases to achieve consistency in approved exception requests and to determine whether this candidate meets similar levels of

medical urgency. The Committee will approve or deny each appeal according to its own procedures.

C. Overrides

If the LRB or Committee does not grant a request or appeal, then the requesting program may nonetheless implement the requested exception. The transplant program must notify the OPTN Contractor of its intent to do so. The OPTN Contractor will notify the Committee of the requesting program's decision to override and provide any available details about the case.

The Committee will retrospectively discuss any overrides at its next scheduled full committee meeting or lung subcommittee meeting. The Committee or subcommittee will determine whether candidates the transplant program registered using the override process exhibited similar medical urgencies as other candidates registered at the requested score or priority. If the Committee or subcommittee determines any of these cases were not comparable to the other candidates registered at the same score or priority, then the Committee may refer the transplant program to the Membership and Professional Standards Committee (MPSC) for action as outlined in *Appendix L: Reviews, Actions, and Due Process* of the OPTN Bylaws.

D. Referrals for Committee Discussion and MPSC Review

The LRB may refer a case to the Committee if the final outcome of the LRB appeal is a denial of the request, a lack of quorum, or a tie vote. The Committee will discuss LRB cases that end in ties or quorum with the purpose of looking at LRB policies, guidelines and procedures. The LRB may refer a case to the Committee if the transplant program does not respond to requests for a statement of intent to appeal, or to subsequent requests to submit additional information in support of the appeal.

Referral of cases to the Committee will include information about the number of previous case referrals from that program and the outcome of those referrals. If the Committee or subcommittee determines any of these cases were not comparable to the other candidates registered at the same status, then the Committee may refer the registering hospital to the Membership and Professional Standards Committee (MPSC) for action as outlined in *Appendix L: Reviews, Actions, and Due Process* of the OPTN Bylaws.

Additionally, the OPTN Contractor will refer the cases that result in a lack of quorum to the Committee or Lung Subcommittee. The Committee or Lung Subcommittee will review these cases to ensure that RRB members are properly executing their responsibilities outlined in Section 3.

6. Extensions

If an unapproved exception will expire before the deadline for an LRB or Committee to decide an appeal for that exception, and the program submits a request for an extension of that exception, then the LRB or Committee will vote on the exception extension request, and the appeal for the unapproved exception will automatically close out.

7. Administration

The central office for each LRB is maintained by the OPTN Contractor. The LRB efforts are coordinated by the OPTN Contractor with the help of the Chair of the LRB.

Data sent to the LRB for action or review will not contain transplant program, hospital or candidate identifying information.

Responses may be shared with the requesting program if an LRB member specifically asks that comments be shared with the program, regardless of the voting outcome.

When a new group of LRB members are identified, all lung transplant programs are notified of the roster. However, the only time an LRB member's identity as a reviewer is disclosed is during conference calls.

OPTN/UNOS Guidelines for Liver Regional Review Board (RRB) Review of Adult and Pediatric MELD/PELD Cases and Status 1 Subcommittee Review of Status 1A and 1B Exception Cases

1. Purpose of the RRB and Liver Status 1 Review Subcommittee

The RRB provides prompt peer review of MELD/PELD exceptions for candidates on the liver transplant waiting list.

Status 1 exceptions are referred to the Liver and Intestinal Organ Transplantation Committee (the Committee) for retrospective review. Operationally, these reviews are conducted by the Status 1 Review Subcommittee acting on behalf of the full Committee.

2. Representation on the RRB

A. There will be a minimum of 3 physicians on the RRB representing active adult and pediatric liver transplant programs. Each active liver transplant program shall have the opportunity to be represented on the RRB. On a national basis, the representatives on the RRBs vary in number. There should be representation from both hepatology and surgery on the RRB. An individual involved in pediatric transplantation should also be included on pediatric cases; although the logistics of such representation may be challenging. The region may choose to include the regional representative to the Committee on the RRB as an organizational and continuity measure. In most cases, the regional representative to the Committee will serve as the RRB Chair. Each RRB Chair shall be an active liver transplant practitioner but may not be required to represent his transplant program as a RRB member.

B. Since larger RRBs may pose operational or administrative problems, some of the RRBs rotate the membership to ensure that each program is represented on the RRB for one term. Each region shall determine the length of a term. The frequency of rotation will be determined by each region.

C. At the time of their appointment to the RRB, each RRB member must identify one or more alternate representatives to the OPTN Contractor and to the RRB chair, to be contacted if the RRB member is not available for more than 72 hours. It is the responsibility of each transplant program to provide the OPTN Contractor with the contact information for the RRB member by providing the information for both the RRB member and the alternate representative. Should a RRB member leave their transplant program, then the program's alternate representative will become the RRB member. If a regional chair should leave his transplant program, the alternate still becomes the RRB member and a new alternate is chosen. A transplant program may also appoint a new RRB member and

continue with the same alternate. An alternate member replacing a chair does not serve out the term as chair unless designated by the Regional Councilor or the RRB as described in 2A. It is recommended that immediate past Review Board chair serve as the alternate chair.

D. If a liver program is inactivated, it is no longer entitled to representation on the RRB. The term of the transplant program's representative on the RRB ends upon withdrawal or inactivation. Should a program reactivate, the transplant program may again have representation on the RRB during future rotations.

3. Responsibilities of the RRB Members

RRB members and alternates must:

A. Evaluate the appropriateness of applying the requested MELD/PELD score to the specified candidate.

B. Vote on cases according to the timelines specified in the OPTN/UNOS policies and guidelines.

C. Participate on conference calls as they are scheduled.

D. Sign an OPTN/UNOS Confidentiality/Conflict of Interest Statement prior to serving on the RRB.

4. Voting Procedures

A. Eligibility to Vote

An RRB member or alternate's vote will not be valid and will not count towards quorum in any case in which he has a conflict of interest. The vote of an RRB member on cases originating from his transplant program or hopsitals where he has an affiliation will be excluded from the final vote count.

B. Retrospective Review of Status Exceptions

The Status 1 Review Subcommittee will retrospectively review the status justification form for each Status 1A or 1B exception. The review will address the appropriateness of the status assignment.

During the entirety of the retrospective review and appeal process, the candidate's status will be equal to the requested status, and the requesting program must follow all OPTN policies that apply to the requested status.

At the termination of the application and appeal process, if the requested status is not approved, then the requesting program must either change the candidate's

status to the score or status for which the candidate qualifies under policy, or follow the requirements for an override, as described below.

C. Prospective Review of Score Exceptions

The RRB will prospectively review requests for MELD/PELD exceptions. The RRB will assess (a) whether the candidate is considered to have an urgency and potential for benefit comparable to that of other candidates having the requested MELD score; or (b) whether the candidate meets criteria previously agreed upon by the RRB.

During the prospective review and appeal process, the candidate will be registered with his or her calculated MELD or PELD score, until the OPTN Contractor notifies the requesting program that the request is approved. Alternatively, the requesting program follows the requirements for an override, as described below.

D. Initial RRB Case Review and Vote

The OPTN Contractor will send the application or appeal to RRB members. If the RRB member has not voted within 3 days of when the OPTN Contractor sends the application or appeal to the RRB, then the OPTN Contractor will send the case to the alternate. Thereafter, both the RRB member and alternate may vote on the application within 7 days of when the OPTN Contractor originally sent the application to the RRB. If the RRB member and the alternate both submit votes for the same application, then the OPTN Contractor will count the vote from whoever voted first.

Initial applications are decided as follows:

If the vote is…	**And the case is prospectively reviewed, then the...**	**Or the case is retrospectively reviewed, then the…**
Majority vote to approve the request	Application is granted	Application is granted
Majority vote to deny the request	Application is not granted	Application is not granted

Tie Vote	Application is not granted	Application is granted
No Quorum	Application is not granted	Application is granted

In order for a vote to be valid, quorum must be reached. To reach quorum, a majority of all RRB members, or their alternates in cases where the RRB member cannot or does not vote, eligible to vote must vote within the allotted timeframe.

A majority vote is calculated by dividing the total number of eligible review board members that vote on each case by half and then adding one.

Voting will close at the earliest of when:

- all eligible voters have voted;
- a majority of all eligible voters have voted to approve or deny a request; or
- 7 days after the OPTN Contractor sends the request to the RRB.

Once voting has closed on a case, an RRB member or alternate can no longer vote on that case.

The OPTN Contractor will send the results of the RRB's vote to the requesting program. The OPTN Contractor must not reveal the vote of any specific RRB member, but may provide the requesting program with comments or questions made by the RRB members.

5. Appeals

A. Appeal to the Review Board

If the RRB does not approve the exception request, then the requesting program may appeal the decision of the RRB. Individual candidates are not eligible to submit exception applications or appeal RRB rulings. Only transplant programs may submit applications and appeals.

The requesting program must notify the OPTN Contractor of its intent to appeal, and submit additional information justifying the requested exception, as well as responses to written comments of dissenting RRB members. This additional information will be submitted to RRB members for further consideration.

MELD/PELD exception application appeals may be submitted an indefinite number of times as long as the appeal is submitted within 21 days of the date the OPTN Contractor received the initial application for the MELD/PELD exception.

If the appeal is not approved, the requesting program may request a conference call with the RRB. If the requesting program requests a conference call with the RRB, it must also be requested within 21 days of the date the OPTN Contractor received the initial application for the MELD/PELD exception. If a pediatric case is appealed, pediatric representation is required on the conference call. If no pediatric surgeon or physician is eligible to vote on the case in the Region, one may be selected from another region to assist in the RRB's deliberation in a non-voting capacity at the request of the Review Board chair.

If the appeal is not approved, the requesting program may request a conference call with the RRB. A teleconference is considered an additional appeal.

If the RRB fails to reach quorum, or the vote results in a tie, within 21 days of the date the requesting program initially sent the exception request to the OPTN Contractor, the OPTN Contractor will notify the requesting program of the result, and the requesting program may list the candidate at the requested status or score.

Appealed applications are decided as follows:

If the vote is…	**And the case is prospectively reviewed, then the...**	**Or the case is retrospectively reviewed, then the…**
Majority vote to approve the request	Appeal is granted	Appeal is granted
Majority vote to deny the request	Appeal is not granted	Appeal is not granted
Tie Vote	Appeal is granted	Appeal is granted
No Quorum	Appeal is granted	Appeal is granted

B. <u>Appeals of Denials to the Committee</u>

If the RRB votes to deny the request for the entirety of 21 days of the date the requesting program initially sent an exception request to the OPTN Contractor, then the requesting program may request a final appeal to the Committee. The requesting program must request the Committee appeal within 14 days of when the OPTN Contractor sent the requesting program notice of the RRB appeal decision.

The requesting program may provide the OPTN Contractor with additional information about the case, which the OPTN Contractor will send to the Committee or Status Review Subcommittee. At its next scheduled meeting, the Committee or Status Review Subcommittee will compare the eligibility criterion of other approved exceptional cases to achieve consistency in approved exception requests and to determine whether this candidate meets similar levels of medical urgency. The Committee will approve or deny each appeal according to its own procedures.

C. Overrides

If the RRB or Committee does not grant a request or appeal, then the requesting program may nonetheless implement the requested exception. The requesting physician and the RRB must meet to review the case prior to overriding the RRB's decision. If it chooses to proceed with the override, the requesting program must notify the OPTN Contractor of its intent to do so. The OPTN Contractor will notify the Committee of the transplant program's decision to override and provide any available details about the case.

The Committee will retrospectively discuss any overrides which led to the candidate being transplanted while registered at that exception score or status at its next scheduled full committee meeting or liver subcommittee meeting. The Committee or subcommittee will determine whether the candidate(s) registered by the transplant program using the override process exhibited similar medical urgencies as other candidates registered at the requested score or status. If the Committee or subcommittee determines any of these cases were not comparable to the other candidates registered at the same score or status, then the Committee may refer the transplant program to the Membership and Professional Standards Committee (MPSC) for action as outlined in *Appendix L: Reviews, Actions, and Due Process* of the OPTN Bylaws.

D. Referrals for Committee Discussion and MPSC Review

The RRB may refer a case to the Committee if the final outcome of the RRB appeal is a denial of the request, a lack of quorum, or a tie vote. The RRB may also refer a case to the Committee if the requesting program does not respond to requests for a statement of intent to appeal, or to subsequent requests to submit additional information in support of the appeal. Additionally, if the Status Review Subcommittee determines that a status registration is inappropriate, and the candidate is transplanted at that status, the case will be referred to the Liver Committee. Transplant programs with more than one inappropriate Status 1 registration resulting in a transplant over a rolling two-year period will be referred to the Committee for possible referral to the MPSC.

Referral of cases to the Committee will include information about the number of previous case referrals from that program and the outcome of those referrals. If the Committee or subcommittee determines any of these cases were not comparable to the other candidates registered at the same status, then the Committee may refer the registering hospital to the Membership and Professional Standards Committee (MPSC) for action as outlined in *Appendix L: Reviews, Actions, and Due Process* of the OPTN Bylaws.

Additionally, the OPTN Contractor will refer the cases that result in a lack of quorum to the Committee or Status Review Subcommittee. The Committee or Status Review Subcommittee will review these cases to to ensure that RRB members are properly executing their responsibilities outlined in Section 3.

6. Extensions

The RRB will prospectively review extensions of MELD/PELD exceptions.

The Review Subcommittee will retrospectively review extension requests for candidates registered as Status 1A or 1B by exception.

If an unapproved exception will expire before the deadline for an RRB or Committee to decide an appeal for that exception, and the program submits a request for an extension of that exception, then the RRB or Committee will vote on the exception extension request, and the appeal for the unapproved exception will automatically close out.

7. Administration

The central office for each RRB is maintained by the OPTN Contractor. The RRB efforts are coordinated by the OPTN Contractor with the help of the Chairs of the RRBs.

Data sent to the RRBs for action or review will not contain transplant program or candidate identifying information.

Responses may be shared with the transplant program if an RRB member specifically asks that comments be shared with the program, regardless of the voting outcome.

When a new group of RRB members are identified, all liver transplant programs in the region are notified of the roster. However, the only time an RRB member's identity as a reviewer is disclosed is during a conference call.

Affected Bylaws Language:

Appendix E:

Membership and Personnel Requirements for Kidney Transplant Programs

(No changes to E.1)

E.2 Primary Kidney Transplant Surgeon Requirements

(No changes to E.2.A)

B. Clinical Experience Pathway

Surgeons can meet the requirements for primary kidney transplant surgeon through clinical experience gained post-fellowship if the following conditions are met:

1. The surgeon has performed 45 or more kidney transplants <u>over a 2 to 5-year period</u> as primary surgeon or first assistant at a designated kidney transplant program, or its foreign equivalent. The transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and medical record number or other unique identifier that can be verified by the OPTN Contractor. The log should be signed by the program director, division chief, or department chair from the program where the experience was gained. Each year of the surgeon's experience must be substantive and relevant and include pre-operative assessment of kidney transplant candidates, performance of transplants as primary surgeon or first assistant, and post-operative care of kidney recipients.
2. The surgeon has performed at least 15 kidney procurements as primary surgeon or first assistant. At least 3 of these procurements must be multiple organ procurements and at least 10 must be from deceased donors. These cases must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
3. The surgeon has maintained a current working knowledge of kidney transplantation, defined as direct involvement in kidney transplant patient care in the last 2 years. This includes the management of patients with end stage renal disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, performing the transplant operation, immediate postoperative and continuing inpatient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long term outpatient care.
4. The following letters are submitted directly to the OPTN Contractor:
   a. A letter from the director of the transplant program and Chairman of the department or hospital credentialing committee verifying that the surgeon has met the above qualifications and is qualified to direct a kidney transplant program.

b. A letter of recommendation from the primary surgeon and transplant program director at the transplant program last served by the surgeon outlining the surgeon's overall qualifications to act as a primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
c. A letter from the surgeon that details the training and experience the surgeon has gained in kidney transplantation.

C. Alternative Pathway for Predominantly Pediatric Programs

If a surgeon does not meet the requirements for primary kidney transplant surgeon through either the transplant fellowship pathway or clinical experience pathway as described above, transplant programs that serve predominantly pediatric patients may petition the MPSC in writing to consider the surgeon for primary transplant surgeon if the program can demonstrate that the following conditions are met:

1. The surgeon's kidney transplant training or experience is equivalent to the fellowship or clinical experience pathways as described in *Sections E.2.A or E.2.B* above.
2. The surgeon has maintained a current working knowledge of all aspects of kidney transplantation and patient care, defined as direct involvement in kidney transplant patient care within the last 2 years.
3. The surgeon submits a letter of recommendation from the ~~fellowship training~~ primary surgeon and transplant program director of the fellowship training program or transplant program last served by the surgeon outlining the surgeon's overall qualifications to act as a primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
4. The hospital participates in an informal discussion with the MPSC.

The MPSC or an Ad Hoc Subcommittee of at least 4 MPSC members appointed by the MPSC Chair is authorized to conduct the informal discussion and make an interim determination. Interim determinations are:

- Advisory to the MPSC, Board of Directors, or both, who have the final authority to grant approval of a designated transplant program.
- Effective temporarily, pending final decision by the MPSC or Board of Directors.

Any application recommended for rejection by the MPSC or the Board of Directors may entitle the applicant to due process as specified in *Appendix L* of these Bylaws.

E.3 Primary Kidney Transplant Physician Requirements

A. Twelve-month Transplant Nephrology Fellowship Pathway

Physicians can meet the training requirements for a primary kidney transplant physician during a separate 12-month transplant nephrology fellowship if the following conditions are met:

1. The physician has current board certification in nephrology by the American Board of Internal Medicine or the foreign equivalent.
2. The physician completed 12 consecutive months of specialized training in transplantation under the direct supervision of a qualified kidney transplant physician and along with a kidney transplant surgeon at a kidney transplant program that performs 30 or more transplants each year. The training must have included at least 6 months of clinical transplant service. The remaining time must have consisted of transplant-related experience, such as experience in a tissue typing laboratory, on another solid organ transplant service, or conducting basic or clinical transplant research.
3. During the fellowship period, the physician was directly involved in the primary care of 30 or more newly transplanted kidney recipients and continued to follow these recipients for a minimum of 3 months from the time of transplant. The care must be documented in a log that includes the date of transplant and the recipient medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log must be signed by the director of the training program or the transplant program's primary transplant physician.
4. The physician has maintained a current working knowledge of kidney transplantation, defined as direct involvement in kidney transplant care in the last 2 years. This includes the management of patients with end stage renal disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate postoperative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long term outpatient care. The curriculum for obtaining this knowledge should be approved by the Residency Review Committee for Internal Medicine (RRC-IM) of the Accreditation Council for Graduate Medical Education (ACGME).
5. The physician should have observed at least 3 ~~multiple~~ organ procurements and 3 kidney transplants. The physician should also have observed the evaluation, the donation process, and management of at least 3 multiple organ donors who donated a kidney. If the physician has completed these observations, they must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
6. The following letters are submitted directly to the OPTN Contractor:
   a. A letter from the director of the training program and ~~Chairman of the department or hospital credentialing committee~~ the supervising qualified kidney transplant physician verifying that the ~~surgeon~~ physician has met the above requirements and is qualified to direct a kidney transplant program.
   b. A letter of recommendation from the fellowship training program's primary physician and transplant program director outlining the physician's overall qualifications to act as a primary transplant physician, as well as the

physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician ~~surgeon~~, at its discretion.

c. A letter from the physician that details the training and experience the physician has gained in kidney transplantation.

The training requirements outlined above are in addition to other clinical requirements for general nephrology training.

B. Clinical Experience Pathway

A physician can meet the requirements for a primary kidney transplant physician through acquired clinical experience if the following conditions are met:

1. The physician has been directly involved in the primary care of 45 or more newly transplanted kidney recipients and continued to follow these recipients for a minimum of 3 months from the time of transplant. This patient care must have been provided over a 2 to 5-year period on an active kidney transplant service as the primary kidney transplant physician or under the direct supervision of a qualified transplant physician and in conjunction with a kidney transplant surgeon at a kidney transplant program or the foreign equivalent. The care must be documented in a log that includes the date of transplant and recipient medical record number or other unique identifier that can be verified by the OPTN Contractor. The recipient log should be signed by the program director, division Chief, or department Chair from the program where the physician gained this experience.
2. The physician has maintained a current working knowledge of kidney transplantation, defined as direct involvement in kidney transplant patient care over the last 2 years. This includes the management of patients with end stage renal disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate postoperative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long term outpatient care.
3. The physician should have observed at least 3 organ procurements and 3 kidney transplants. The physician should also have observed the evaluation, the donation process, and management of at least 3 multiple organ donors who donated a kidney. If the physician has completed these observations, they must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
4. The following letters are submitted directly to the OPTN Contractor:
   a. A letter from the qualified transplant physician or the kidney transplant surgeon who has been directly involved with the proposed physician documenting the physician's experience and competence.

b. A letter of recommendation from the primary physician and transplant program director at the transplant program last served by the ~~surgeon~~ physician outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician ~~surgeon~~, at its discretion.
c. A letter from the physician that details the training and experience the physician has gained in kidney transplantation.

(No Changes to E.3.C, E.3.D, or E.3.E)

F. Alternative Pathway for Predominantly Pediatric Programs

If a physician does not meet the requirements for primary physician through any of the transplant fellowship or clinical experience pathways as described above, transplant programs that serve predominantly pediatric patients may petition the MPSC in writing to consider the physician for primary transplant physician if the program can demonstrate that the following conditions are met:

1. That the physician's kidney transplant training or experience is equivalent to the fellowship or clinical experience pathways as described in *Sections E.3.A* through *E.3.E* above.
2. The physician has maintained a current working knowledge of all aspects of kidney transplantation, defined as direct involvement in kidney transplant patient care within the last 2 years.
3. The physician receives a letter of recommendation from the primary physician and transplant program director of the fellowship training program or transplant program last served by the physician outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
4. The hospital participates in an informal discussion with the MPSC.

The MPSC or an Ad Hoc Subcommittee of at least 4 MPSC members appointed by the MPSC Chair is authorized to conduct the informal discussion and make an interim determination. Interim decisions are:

- Advisory to the MPSC, Board of Directors, or both, which has the final authority to grant approval of a designated transplant program.
- Effective temporarily, pending final decision by the MPSC or Board.

Any application recommended for rejection by the MPSC or the Board of Directors may entitle the applicant to due process as specified in *Appendix L* of these Bylaws.

(No changes to E.4.)

E.5 Kidney Transplant Programs that Perform Living Donor Recovery

No changes to E.5.A, E.5.B, or E.5.C.

D. Primary Open Living Donor Kidney Surgeon

A kidney donor surgeon who performs open living donor nephrectomies must be on site and must meet *one* of the following criteria:

- Completion of an accredited American Society of Transplant Surgeons (ASTS) fellowship with kidney certification.
- Completion of at least 10 open ~~kidney~~ nephrectomies, including deceased donor ~~kidney~~ nephrectomies or the removal of diseased kidneys, as primary surgeon or First Assistant. The open ~~kidney~~ nephrectomies must be documented in a log that includes the date of recovery, the role of the surgeon in the procedure, the type of procedure (open or laparoscopic), and the medical record number or Donor ID.

E. Primary Laparoscopic Living Donor Kidney Surgeon

A surgeon who performs laparoscopic living donor kidney recoveries must be on site and must have completed at least 15 laparoscopic kidney nephrectomies in the last 5 years as primary surgeon or first assistant. Seven of these nephrectomies must have been performed as the primary surgeon, and this role should be documented by a letter from the fellowship program director. The laparoscopic nephrectomies must be documented in a log that includes the date of the surgery, the role of the surgeon in the procedure, the type of procedure (open or laparoscopic), and the medical record number or Donor ID.

(No further changes to Appendix E)

Appendix F:
Membership and Personnel Requirements for Liver Transplant Programs

(No changes to F.1 or F.2)

F.3 Primary Liver Transplant Physician Requirements

(No changes to F.3.A.)

B. Clinical Experience Pathway

A physician can meet the requirements for a primary liver transplant physician through acquired clinical experience if the following conditions are met:

1. The physician has been directly involved in the primary care of 50 or more newly transplanted liver recipients and continued to follow these recipients for a minimum of 3 months from the time of transplant. This patient care must have been provided over a 2 to 5-year period on an active liver transplant service as the primary liver transplant physician or under the direct supervision of a qualified liver transplant physician and in conjunction with a liver transplant surgeon at a liver transplant program or the foreign equivalent. This care must be documented in a log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log should be signed by the program director, division chief, or department chair from the program where the physician gained this experience.
2. The physician has maintained a current working knowledge of liver transplantation, defined as direct involvement in liver transplant patient care within the last 2 years. This includes the management of patients with end stage liver disease, acute liver failure, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of liver allograft dysfunction, histologic interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long term outpatient care.
3. The physician should have observed at least 3 organ procurements and 3 liver transplants. The physician should also have observed the evaluation, the donation process, and management of at least 3 multiple organ donors who donated a liver. If the physician has completed these observations, they must be documented in a log that includes the date of procurement, the location of the donor, and Donor ID.
4. The following letters are submitted directly to the OPTN Contractor:
   a. A letter from the qualified transplant physician or the liver transplant surgeon who has been directly involved with the proposed physician documenting the physician's experience and competence.

b. A letter of recommendation from the primary ~~surgeon~~ physician and transplant program director at the transplant program last served by the physician outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
c. A letter from the physician that details the training and experience the physician gained in liver transplantation.

(No changes to F.3.C, F.3.D, or F.3.E.)

F. Alternative Pathway for Predominantly Pediatric Programs

If a physician does not meet the requirements for primary physician through any of the transplant fellowship or clinical experience pathways as described above, transplant programs that serve predominantly pediatric patients may petition the MPSC in writing to consider the physician for primary transplant physician if the program can demonstrate that the following conditions are met:

1. That the physician's liver transplant training or experience is equivalent to the fellowship or clinical experience pathways as described in *Sections F.3.A through F.3.E* above.
2. The physician has maintained a current working knowledge of all aspects of liver transplantation, defined as direct involvement in liver transplant patient care within the last 2 years.
3. The physician submits a letter of recommendation from the primary physician ~~surgeon~~ and transplant program director at the fellowship training program or transplant program last served by the physician outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
4. The hospital participates in an informal discussion with the MPSC.

The MPSC or an Ad Hoc Subcommittee of at least 4 MPSC members appointed by the MPSC Chair is authorized to conduct the informal discussion and make an interim determination. Interim decisions are:

- Advisory to the MPSC, Board of Directors, or both, which has the final authority to grant approval of a designated transplant program.
- Effective temporarily, pending final decision by the MPSC or Board.

Any application recommended for rejection by the MPSC or the Board of Directors may entitle the applicant to due process as specified in *Appendix L* of these Bylaws.

G. Conditional Approval for Primary Transplant Physician

If the primary liver transplant physician changes at an approved liver transplant program, a physician can serve as the primary liver transplant physician for a maximum of 12 months if the following conditions are met:

1. The physician has current board certification in gastroenterology by the American Board of Internal Medicine, the American Board of Pediatrics, or the foreign equivalent.
2. The physician has been involved in the primary care of 25 or more newly transplanted liver recipients, and has followed these patients for at least 3 months from the time of their transplant. This care must be documented in a recipient log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair from the transplant program where the experience was gained.
3. The physician has maintained a current working knowledge of liver transplantation, defined as direct involvement in liver transplant patient care during the last 2 years. This includes the management of patients with end stage liver disease, acute liver failure, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of liver allograft dysfunction, histologic interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long term outpatient care.
4. The physician has 12 months experience on an active liver transplant service as the primary liver transplant physician or under the direct supervision of a qualified liver transplant physician along with a liver transplant surgeon at a designated liver transplant program, or the foreign equivalent. These 12 months of experience must be acquired within a 2-year period.
5. The physician should have observed at least 3 organ procurements and 3 liver transplants. The physician should also have observed the evaluation, the donation process, and management of at least 3 multiple organ donors who are donating a liver. If the physician has completed these observations, they must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
6. The transplant program submits activity reports to the OPTN Contractor every 2 months describing the transplant activity, transplant outcomes, physician recruitment efforts, and other operating conditions as required by the MPSC to demonstrate the ongoing quality and efficient patient care at the program. The activity reports must also demonstrate that the physician is making sufficient progress to meet the required involvement in the primary care of 50 or more liver transplant recipients, or that the program is making sufficient progress in recruiting a physician who meets all requirements for primary liver

transplant physician and who will be on site and approved by the MPSC to assume the role of primary physician by the end of the 12 month conditional approval period.

7. The program has established and documented a consulting relationship with counterparts at another liver transplant program.
8. The following letters are submitted directly to the OPTN Contractor:
   a. A letter from the qualified liver transplant physician and surgeon who were directly involved with the physician verifying that the physician has satisfactorily met the above requirements to become the primary transplant physician of a liver transplant program.
   b. A letter of recommendation from the ~~fellowship training program's~~ primary physician and transplant program director at the transplant program last served by the physician outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
   c. A letter from the physician sends that details the training and experience the physician gained in liver transplantation.

The 12-month conditional approval period begins on the first approval date granted to the personnel change application, whether it is interim approval granted by the MPSC subcommittee, or approval granted by the full MPSC. The conditional approval period ends 12 months after the first approval date of the personnel change application.

If the program is unable to demonstrate that it has an individual on site who can meet the requirements as described in *Sections F.3.A through F.3.F* above at the end of the 12 month conditional approval period, it must inactivate.

The MPSC may consider on a case-by-case basis and grant a 6-month extension to a transplant program that provides substantial evidence of progress toward fulfilling the requirements but is unable to complete the requirements within one year.

(No changes to F.4 or F.5)

F.6 Liver Transplant Programs that Perform Living Donor Recovery

(No Changes to F.6.A, F.6.B, F.6.C, or F.6.D)

E. Conditional Program Approval Status

If the program does not have a second surgeon on site who has performed at least 7 living donor liver ~~transplants~~ recoveries within the past 5-years, the program may be eligible for conditional approval status if the surgeon:

1. Has completed the requirement for obtaining experience in 20 major liver resection surgeries as described in *Section F.6.A* above.
2. Meets all other requirements of a primary liver transplant surgeon.

The transplant program may be granted one year to fully comply with applicable membership criteria with a possible one year extension. This option will be available to new programs as well as previously approved programs that experience a change in key personnel. During this period of conditional approval, both of the designated surgeons must be present at all living donor liver recoveries.

The program must comply with interim operating policies and procedures as required by the MPSC. This may include submitting reports describing the surgeon's progress towards meeting the requirements, and any other operating conditions as requested by the MPSC to demonstrate ongoing quality and efficient patient care. The program must provide a report prior to the end of the first year of conditional approval documenting that the surgeon has met or is making sufficient progress toward performing 7 living donor liver recoveries or that the program is making sufficient progress in employing a transplant surgeon who meets this as well as all other criteria for a qualified live donor liver surgeon.

Should the surgeon meet the requirements before the conditional approval period ends, the program may submit a progress report and request review by the MPSC. The program's approval status will be made available to the public.

F. Rejection of Conditional Approval

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

1. Inactivating the living donor component of the program for a period up to 12 months.
2. Relinquishing the living donor component of the liver transplant program until it can meet the requirements for full approval.

Appendix G:

Membership and Personnel Requirements for Pancreas and Pancreatic Islet Transplant Programs

(No Changes to G.1 or G.2)

G.3 Primary Pancreas Transplant Physician Requirements

(No changes to G.3.A, G.3.B, or G.3.C)

D. Conditional Approval for Primary Transplant Physician

If the primary pancreas transplant physician changes at an approved pancreas transplant program, a physician can serve as the primary pancreas transplant physician for a maximum of 12 months if the following conditions are met:

1. The physician has been involved in the primary care of 8 or more newly transplanted pancreas recipients, and has followed these patients for at least 3 months from the time of their transplant. This care must be documented in a recipient log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log ~~must~~ should be signed by the program director, division chief, or department chair from the transplant program where the experience was gained.
2. The physician has maintained a current working knowledge of pancreas transplantation, defined as direct involvement in pancreas transplant patient care within the last 2 years. This includes the management of patients with end stage pancreas disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of pancreas dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for pancreas dysfunction, and long term outpatient care.
3. The physician has 12 months experience on an active pancreas transplant service as the primary pancreas transplant physician or under the direct supervision of a qualified pancreas transplant physician along with a pancreas transplant surgeon at a designated pancreas transplant program, or its foreign equivalent. This 12-month period of experience on the transplant service must have been acquired over a maximum of 2 years.
4. The physician should have observed at least 3 organ procurements and 3 pancreas transplants. The physician should also have observed the evaluation, the donation process, and management of at least 3 multiple organ donors who are donating a pancreas. If the physician has completed these observations, they must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.

5. The program has established and documented a consulting relationship with counterparts at another pancreas transplant program.
6. The transplant program submits activity reports to the OPTN Contractor every 2 months describing the transplant activity, transplant outcomes, physician recruitment efforts, and other operating conditions as required by the MPSC to demonstrate the ongoing quality and efficient patient care at the program. The activity reports must also demonstrate that the physician is making sufficient progress in meeting the required involvement in the primary care of 15 or more pancreas transplant recipients, or that the program is making sufficient progress in recruiting a physician who will be on site and approved by the MPSC to assume the role of Primary Physician by the end of the 12 month conditional approval period.
7. The following letters are submitted directly to the OPTN Contractor:
   a. A letter from the qualified pancreas transplant physician and surgeon who were directly involved with the physician documenting the physician's experience and competence.
   b. A letter of recommendation from the ~~fellowship training program's~~ primary physician and director at the transplant program last served by the physician outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
   c. A letter from the physician that details the training and experience the physician has gained in pancreas transplantation.

The 12-month conditional approval period begins on the initial approval date granted to the personnel change application, whether it is interim approval granted by the MPSC subcommittee, or approval granted by the full MPSC. The conditional approval period ends 12 months after the first approval date of the personnel change application.

If the transplant program is unable to demonstrate that it has an individual on site who can meet the requirements as described in *Sections G.3.A through G.3.C* above at the end of the 12-month conditional approval period, it must inactivate. The requirements for program inactivation are described in *Appendix K: Transplant Program Inactivity, Withdrawal and Termination* of these Bylaws.

The MPSC may consider on a case-by-case basis and grant a 6-month extension to a transplant program that provides substantial evidence of progress toward fulfilling the requirements but is unable to complete the requirements within one year.

(No further changes to Appendix G)

Appendix H:
Membership and Personnel Requirements for Heart Transplant Programs

No changes to H.1.

H.2 Primary Heart Transplant Surgeon Requirements

(No changes to H.2.A or H.2.B)

C. Clinical Experience Pathway

Surgeons can meet the requirements for primary heart transplant surgeon through clinical experience gained post-fellowship if the following conditions are met:

1. The surgeon has performed 20 or more heart or heart/lung transplants as primary surgeon or first assistant at a designated heart transplant program or its foreign equivalent. These transplants must have been completed over a 2 to 5-year period and include at least 15 of these procedures performed as the primary surgeon. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and medical record number or other unique identifier that can be verified by the OPTN Contractor. This log should be signed by the program director, division chief, or department chair from program where the experience was gained. Transplants performed during board qualifying surgical residency or fellowship do not count.
2. The surgeon has performed at least 10 heart or heart/lung procurements as primary surgeon or first assistant under the supervision of a qualified heart transplant surgeon. These procedures must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
3. The surgeon has maintained a current working knowledge of all aspects of heart transplantation, defined as a direct involvement in heart transplant patient care within the last 2 years. This includes performing the transplant operation, donor selection, the use of mechanical assist devices, recipient selection, post-operative hemodynamic care, postoperative immunosuppressive therapy, and outpatient follow-up.
4. The following letters are submitted directly to the OPTN Contractor:
   a. A letter from the director of the program where the surgeon acquired transplant experience verifying that the surgeon has met the above requirements and is qualified to direct a heart transplant program.
   b. A letter of recommendation from the ~~program's~~ primary surgeon and transplant program director <u>at the transplant program last served by the surgeon</u> outlining the <u>surgeon's</u> overall qualifications to act as primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon,

director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.

c. A letter from the surgeon that details the training and experience the surgeon has gained in heart transplantation.

(No further changes to Appendix H)

Appendix I:
Membership and Personnel Requirements for Lung Transplant Programs

(No changes to I.1)

I.2 Primary Lung Transplant Surgeon Requirements

(No changes to I.2.A)

B. Twelve-month Lung Transplant Fellowship Pathway

Surgeons can meet the training requirements for primary lung transplant surgeon by completing a 12-month lung transplant fellowship if the following conditions are met:

1. The surgeon has performed at least 15 lung or heart/lung transplants under the direct supervision of a qualified lung transplant surgeon and in conjunction with a qualified lung transplant physician as primary surgeon or first assistant during the 12-month lung transplant fellowship. At least half of these transplants must be lung procedures. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the director of the program.
2. The surgeon has performed at least 10 lung procurements as primary surgeon or first assistant under the supervision of a qualified lung transplant surgeon during the 12-month lung transplant fellowship. These procedures must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
3. The surgeon has maintained a current working knowledge of all aspects of lung transplantation, defined as a direct involvement in lung transplant patient care within the last 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass, donor selection, recipient selection, pre- and postoperative ventilator care, postoperative immunosuppressive therapy, histological interpretation and grading of lung biopsies for rejection, and long-term outpatient follow-up.
4. This training was completed at a hospital with a cardiothoracic training program approved by the American Board of Thoracic Surgery, or its foreign equivalent. Foreign programs must have a recommendation from the Thoracic Organ Transplantation Committee and be accepted as equivalent by the MPSC.
5. The following letters are submitted directly to the OPTN Contractor:
    a. A letter from the director of the training program verifying that the surgeon has met the above requirements and is qualified to direct a lung transplant program.

b. A letter of recommendation from the training program's primary surgeon and transplant program director outlining the individual's overall qualifications to act as primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
c. A letter from the surgeon that details the training and experience the surgeon has gained in lung transplantation.

C. Clinical Experience Pathway

Surgeons can meet the requirements for primary lung transplant surgeon through clinical experience gained post-fellowship if the following conditions are met:

1. The surgeon has performed 15 or more lung or heart/lung transplants over a 2 to 5-year period as primary surgeon or first assistant at a designated lung transplant program, or its foreign equivalent. At least half of these transplants must be lung procedures, and at least 10 must be performed as the primary surgeon. The surgeon must also have been actively involved with cardiothoracic surgery. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log should be signed by the program director, division chief, or department chair from program where the experience was gained.
2. The surgeon has performed at least 10 lung procurements. These procedures must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
3. The surgeon has maintained a current working knowledge of all aspects of lung transplantation, defined as a direct involvement in lung transplant patient care within the last 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass, donor selection, recipient selection, pre- and postoperative ventilator care, postoperative immunosuppressive therapy, histological interpretation and grading of lung biopsies for rejection, and long-term outpatient follow-up.
4. The following letters are submitted directly to the OPTN Contractor:
   a. A letter from the director of the program where the surgeon gained experience verifying that the surgeon has met the above requirements and is qualified to direct a lung transplant program.
   b. A letter of recommendation from the ~~training program's~~ primary surgeon and director at the transplant program last served by the surgeon outlining the surgeon's overall qualifications to act as primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.

c. A letter from the surgeon that details the training and experience the surgeon has gained in lung transplantation.

D. Alternative Pathway for Predominantly Pediatric Programs

If a surgeon does not meet the requirements for primary lung transplant surgeon through either the training or clinical experience pathways described above, hospitals that serve predominantly pediatric patients may petition the MPSC in writing to consider the surgeon for primary transplant surgeon if the program can demonstrate that the following conditions are met:

1. The surgeon's lung transplant training or experience is equivalent to the residency, fellowship, or clinical experience pathways as described in *Sections I.2.A* through *I.2.C* above.
2. The surgeon has maintained a current working knowledge of all aspects of lung transplantation and patient care, defined as direct involvement in lung transplant patient care within the last 2 years.
3. The surgeon submits a letter of recommendation from the ~~fellowship training program's~~ primary surgeon and transplant program director <u>of the fellowship training program or transplant program last served by the surgeon</u> outlining the surgeon's overall qualifications to act as a primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
4. The hospital participates in an informal discussion with the MPSC.

The MPSC or an Ad Hoc Subcommittee of at least 4 MPSC members appointed by the MPSC Chair is authorized to conduct the informal discussion and make an interim determination. Interim determinations are:

- Advisory to the MPSC, Board of Directors, or both, who have the final authority to grant approval of a designated transplant program.
- Effective temporarily, pending final decision by the MPSC or Board.

Any application recommended for rejection by the MPSC or the Board of Directors may entitle the applicant to due process as specified in *Appendix L* of these Bylaws.

I.3 Primary Lung Transplant Physician Requirements

A designated lung transplant program must have a primary physician who meets *all* the following requirements:

1. The physician must have an M.D., D.O., or equivalent degree from another country, with a current license to practice medicine in the hospital's state or jurisdiction.

2. The physician must be accepted onto the hospital's medical staff, and be practicing on site at this hospital.
3. The physician must have documentation from the hospital credentialing committee that it has verified the physician's state license, board certification, training, and transplant continuing medical education and that the physician is currently a member in good standing of the hospital's medical staff.
4. The lung transplant physician must have current board certification or have achieved eligibility in adult or pediatric pulmonary medicine by the American Board of Internal Medicine, the American Board of Pediatrics, or their foreign equivalent.

In addition, the primary transplant physician must have completed at least one of the training or experience pathways listed below:

- The 12-month transplant pulmonary fellowship pathway, as described in *Section I.3.A. Twelve-month Transplant Pulmonary Fellowship* **Pathway** below.
- The clinical experience pathway, as described in *Section I.3.B. Clinical* Experience **Pathway** below.

A. Twelve-month Transplant Pulmonary Fellowship Pathway

Physicians can meet the training requirements for primary lung transplant physician during a 12-month transplant pulmonary fellowship if the following conditions are met:

1. The physician was directly involved in the primary and follow-up care of at least 15 newly transplanted lung or heart/lung recipients. This training will have been under the direct supervision of a qualified lung transplant physician and in conjunction with a lung transplant surgeon. At least half of these patients must be single or double-lung transplant recipients. This care must be documented in a log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log must be signed by the director of the training program or the primary transplant physician at the transplant program.
2. The physician has maintained a current working knowledge of all aspects of lung transplantation, defined as a direct involvement in lung transplant patient care within the last 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass, donor selection, recipient selection, pre- and postoperative ventilator care, postoperative immunosuppressive therapy, histological interpretation and grading of lung biopsies for rejection, and long-term outpatient follow-up.
3. The physician should have observed at least 3 lung or heart/lung procurements and 3 lung transplants. The physician should also have observed the evaluation, the donation process, and management of 3 multiple organ donors who are donating a lung or heart/lungs. If the physician has completed these observations, they must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
4. This training was completed at a hospital with an American Board of Internal Medicine certified fellowship training program in adult pulmonary medicine,

an American Board of Pediatrics-certified fellowship training program in pediatric medicine, or its foreign equivalent. Foreign programs must have a recommendation from the Thoracic Organ Transplantation Committee and be accepted as equivalent by the MPSC.

5. The following letters are submitted directly to the OPTN Contractor:
   a. A letter from the director of the training program verifying that the physician has met the above requirements and is qualified to direct a lung transplant program.
   b. A letter of recommendation from the training program's primary physician and transplant program director outlining the physician's overall qualifications to act as primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
   c. A letter from the physician that details the training and experience the ~~surgeon~~ physician has gained in lung transplantation.

B. Clinical Experience Pathway

A physician can meet the requirements for primary lung transplant physician through acquired clinical experience if the following conditions are met.

1. The physician has been directly involved in the primary care of 15 or more newly transplanted lung or heart/lung recipients and continued to follow these recipients for a minimum of 3 months from the time of transplant. At least half of these transplant must be lung transplants. This patient care must have been provided over a 2 to 5-year period on an active lung transplant program or its foreign equivalent. This care must have been provided as the lung transplant physician or directly supervised by a qualified lung transplant physician along with a lung transplant surgeon. This care must be documented in a log that includes the date of transplant and medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log should be signed by the director or the primary transplant physician at the transplant program where the physician gained this experience.
2. The physician has maintained a current working knowledge of all aspects of lung transplantation, defined as a direct involvement in lung transplant patient care within the last 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass, donor selection, recipient selection, pre- and postoperative ventilator care, postoperative immunosuppressive therapy, histological interpretation and grading of lung biopsies for rejection, and long-term outpatient follow-up.
3. The physician should have observed at least 3 lung or heart/lung procurements and 3 lung transplants. The physician should also have observed the evaluation, the donation process, and management of 3 multiple organ donors who are donating a lung or heart/lungs. If the physician has completed these observations, they must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.

4. The following letters are submitted directly to the OPTN Contractor:
   a. A letter from the lung transplant physician or surgeon of the training program who has been directly involved with the physician documenting the physician's competence.
   b. A letter of recommendation from the ~~training program's~~ primary physician and transplant program director at the transplant program last served by the physician outlining the physician's overall qualifications to act as primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
   c. A letter from the physician that details the training and experience the physician has gained in lung transplantation.

(No further changes to Appendix I)

To read the complete OPTN bylaw language visit optn.transplant.hrsa.gov, select the "Policy Management" tab, then select "OPTN Bylaws."

Affected Policy Language:

3.2.1.8 Waiting Time Modification

3.2.1.8.1 Permissible Modifications

Applications for waiting time modifications that meet *any* of the following qualifications must follow the procedures for expedited modifications of waiting time in Policy 3.2.1.8.3 below.

- An error occurred in removing the candidate's waiting list record and the Transplant Program requests a modified waiting time to include time accrued under the previous registration, in addition to any time lost by the error.
- An error occurred in listing, modifying, or renewing the candidate's waiting list record for a Status 1 liver, Status 1A heart, or Priority 1 pediatric lung candidate and the Transplant Program requests a modified waiting time to correct any time lost by the error.
- The candidate was removed from the waiting list for medical reasons, other than receiving a transplant, was subsequently relisted for the same organ with the same diagnosis, and the Transplant Program requests a modified waiting time to only include the time accrued under the previous registration without the time interval when the candidate was removed from the waiting list.
- The candidate needs a second organ while waiting for a heart, liver, or lung, and the Transplant Program requests a modified waiting time for the second organ that includes the waiting time accrued for the first organ.
- The candidate needs a second organ while waiting for a kidney, pancreas, or intestine, routine alternative therapies are not possible, the other Transplant Programs within the OPO and the OPO itself agree to the modified waiting time, and the Transplant Program requests a modified waiting time for the second organ that includes the waiting time for the first organ.

Applications to modify a candidate's registration date and all other applications for waiting time modifications must follow the procedures for modifications of waiting time in Policy 3.2.1.8.4 below. Additionally, applications must meet any additional requirements stipulated in the organ-specific allocation policies. If an application does not comply with the requirements of Policy 3.2.1.8, then the OPTN Contractor will neither implement the requested waiting time modifications nor forward the application for review.

3.2.1.8.2 Application

To apply for a waiting time modification, a candidate's Transplant Program must submit an application to the OPTN Contractor with *all* of the following information:

1. The requested listing date and documentation showing an intent to register the candidate at the requested listing date.
2. That the candidate met applicable waiting time qualifying criteria in the organ specific policies (Policy 3.0 *et seq.*).
3. A corrective action plan, if the application is due to an error.
4. The name and signature of the candidate's physician or surgeon.
5. Signatures indicating agreement from all applicable transplant programs in the OPO. If a signature cannot be obtained from a transplant program, the submitting program must explain the efforts it made to obtain a signature and include any stated reasons for disagreement with the request.

3.2.1.8.3 Expedited Modifications of Waiting Time

Applications eligible for expedited modifications of waiting time must use the following process:

1. Upon receipt of a complete application, the OPTN Contractor will implement the waiting time modification.
2. The OPTN Contractor will report the modification, without person-identified data, to the relevant organ specific Committee.
3. The Committee will report the modification, without person-identified data, to the Board of Directors.

3.2.1.8.4 Modifications of Waiting Time

All other applications for waiting time modifications must use the following process:

1. Upon receipt of a complete application and approval or explanation of disagreements from all applicable Transplant Programs within the local unit where the candidate is registered, the OPTN Contractor will forward the application, without person-identified data, as follows:

If the candidate requests a modification on the following organ waiting list:	Then the application will be reviewed by the:
Kidney	Kidney Waiting Time Modifications Subcommittee
Liver	A subcommittee of the Liver and Intestinal Organ Transplantation Committee, appointed by the Chair of the Liver and Intestinal Organ Transplantation Committee
Thoracic	A subcommittee of the Thoracic Transplantation Committee, appointed by the Chair of the Thoracic Transplantation Committee
Pancreas	Pancreas Waiting Time Modifications Subcommittee
Intestine	A subcommittee of the Liver and Intestinal Organ Transplantation Committee, appointed by the Chair of the Liver and Intestinal Organ Transplantation Committee

Review of Waiting List Modification Applications

2. The reviewer will determine if it is appropriate to modify the candidate's waiting time as requested in the application and notify the OPTN Contractor of the decision.
3. Upon notice, the OPTN Contractor will implement the waiting time modification.
4. The reviewer will report the modification, without person-identified data, to the relevant organ specific Committee.

5. The Committee will report the modification, without person-identified data, to the Board of Directors.

3.2.1.8 Waiting Time Modification. Transplant candidates on the Waiting List may have waiting time accrued under a previous Waiting List registration reinstated under the following circumstances:

i. The candidate was incorrectly removed from the Waiting List, as a result of errors and/or miscommunication between clinical/clerical personnel. The reinstated waiting time shall include time accrued under the previous registration, in addition to the time interval during which the candidate was removed from the Waiting List.

ii. The candidate was removed from the Waiting List for medical reasons other than having received a transplant and subsequently was relisted for the same organ with the same diagnosis. The reinstated waiting time only shall include time accrued under the previous registration and not the time interval during which the candidate was removed from the Waiting List.

Upon receipt by the Organ Center of a completed Waiting Time Modification Form (with all required information) and verification of the information through review of the candidate's history, Organ Center staff may reinstate the candidate's waiting time.

All other requests for waiting time reinstatement that are not specified under Policy 3.2.3.2 (Waiting Time Reinstatement for Kidney Recipients), or other policies which describe permissible waiting time adjustments, shall be first approved by unanimous agreement among the hospitals (with transplant programs for the applicable organ) within the local area in which the candidate is listed, and then submitted to the appropriate organ-specific committees and Board of Directors for review with appropriate supporting documentation. Notwithstanding the above, however, upon demonstration to the appropriate organ-specific committee that unanimous agreement among the relevant parties cannot be obtained despite efforts to do so, such a request may be submitted with appropriate supporting documentation, including without limitation, reasons provided by the dissenting party(ies) for any disagreement, for consideration despite the lack of unanimous approval. Modification requests for isolated kidney and combined kidney/pancreas waiting time shall indicate and substantiate with supporting documentation that the candidate met waiting time criteria as defined in Policy 3.5.11.1 (Time of Waiting), or Policy 3.5.12.1 (Time of Waiting), or Policy 3.8.4.3 (Waiting time) as of the listing date requested. Under the circumstances described in this paragraph, waiting time modifications will be made, in the case of requests for modifying kidney or pancreas waiting time, after consideration and approval by the Kidney Transplantation Committee (for kidney and kidney/pancrease candidates) or& Pancreas Transplantation Committee (for kidney/pancreas and pancreas candidates), or, in the case of pediatric (*i.e.,* less than 18 years old) kidney candidates, with approval from the Chair of the Kidney & Pancreas Transplantation Committee to proceed to a subcommittee of the full Committee followed by consideration and unanimous approval by this subcommittee. Pediatric candidate cases addressed by a subcommittee of the Kidney &

~~Pancreas Transplantation Committee will subsequently be referred to the full Committee for consideration of final action as determined appropriate by the Committee and in the case of requests for modifying waiting time for organs other than kidney, kidney-pancreas, and pancreas (except as provided in Policy 3.2.1.8.1 (Waiting Time Modification for Urgent Status Candidates)) only upon approval by the Board of Directors, or by the Executive Committee subject to ratification by the Board of Directors. Requests for modifying kidney or pancreas waiting time, along with decisions of the Kidney Transplantation Committee & Pancreas Transplantation Committee or subcommittee in the case of pediatric candidates and Pancreas Transplantation Committee, shall be reported to the Board of Directors retrospectively.~~

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

~~**3.2.107 Waiting Time Adjustment for Candidates Needing a Life-Saving Organ Transplant When the Need for a Second Organ Transplant Arises.** Waiting time accrued by a candidate for a transplant of a life-saving organ while waiting on the Waiting List may also be accrued for a second organ, when it is determined that the candidate requires a multiple-organ transplant. For purposes of this policy, a life-saving organ shall be defined as the heart, lung or liver. Kidney, pancreas or intestine may qualify as life-saving organs if routine alternative therapies are not possible and demonstrable and after all transplant centers and programs within those centers, the other transplant programs within the OPO and the OPO itself agree to the waiting time adjustment.~~

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

Affected Policy Language:

** Please note: Amendments to the Adult Donor Liver Allocation Algorithm in Policy 3.6 that the Board of Directors approved at its November 2011 and June 2012 meetings are still awaiting programming for implementation. The complete allocation algorithm for adult donor livers upon the implementation of the approved policy changes from the November 2011 and June 2012 Board of Directors meetings, and the November 2012 Executive Committee meeting are provided below. To distinguish the changes to Policy 3.6 that the Board of Directors approved in November 2011 and June 2012 but not yet implemented, that language is not underlined and is instead written in *italics*. Policy language changes from the November 2012 Executive Committee meeting are marked with a single underline, following the conventional policy change notation.

3.6 Allocation of Livers

Adult Donor Liver Allocation Algorithm

Combined Local and Regional

1. Status 1A candidates in descending point order

2. Status 1B candidates in descending order

Local and Regional

3. Candidates with MELD/PELD Scores >=35 in descending order of mortality risk (MELD) scores, with Local candidates ranked above Regional candidates at each level of MELD score

Local

~~*34.*~~ Candidates with MELD/PELD Scores ~~*>=15*~~ *29-34* in descending order of mortality risk scores (probability of candidate death)

National

~~*45.*~~ *Liver-Intestine Candidates in descending order of* Status and *mortality risk scores (probability of candidate death)*

Local

~~*5*~~*6. Candidates with MELD/PELD Scores 15-28 in descending order of mortality risk scores (probability of candidate death)*

Regional

~~*46*~~*7*. Candidates with MELD/PELD Scores ~~*>=*~~*15-34* in descending order of mortality risk scores (probability of candidate death)

National

8. Status 1A candidates in descending point order

9. Status 1B candidates in descending point order

10. Candidates with MELD/PELD Scores >=15 in descending order of mortality risk scores (probability of candidate death)

Local

~~57~~11. Candidates with MELD/PELD Scores < 15 in descending order of mortality risk scores (probability of candidate death)

Regional

~~68~~12. Candidates with MELD/PELD Scores < 15 in descending order of mortality risk scores (probability of candidate death)

National

~~79 Status 1A candidates in descending point order~~

~~810 Status 1B candidates in descending point order~~

*~~91~~113. ~~All other~~ ~~c~~*Candidates *with MELD/PELD Scores < 15* in descending order of mortality risk scores (probability of candidate death)

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Affected Policy Language:

** Please note: At its November 2012 meeting, the OPTN/UNOS Board of Directors approved three separate resolutions that modified Policy 12.10 (Required Protocols for Kidney Recovery Hospitals). Below, Policy 12.10 reflects the changes from all three of these proposals: Proposal to Establish Minimum Requirements for Living Kidney Donor Follow-Up, Proposal to Establish Requirements for the Informed Consent of Living Kidney Donors, and Proposal to Require Reporting of Unexpected Potential and Proven Disease Transmission Involving Living Organ Donors.

7.2 General Submission of Forms

The Transplant Candidate Registration, Deceased Donor Registration, ~~Living Donor Follow-up,~~ Recipient Histocompatibility, Donor Histocompatibility, and Recipient Malignancy Forms must be submitted to the OPTN within 30 days of the form generation date. The Living Donor Follow-up Form must be submitted to the OPTN within 60 days of the form generation date.

12.8.3 Reporting Requirements

Transplant centers that recover living donor organs must complete the LDR form when the donor the donor is discharged from the hospital or within six weeks following the transplant date, whichever is first. Living Donor Registration Forms (LDR) must be submitted to the OPTN within 60 days of the form generation date. ~~Transplant centers that recover living donor organs must complete the LDR form when the donor is discharged from the hospital or within six weeks following the transplant date, whichever is first. Transplant centers that recover living donor organs must submit LDF forms for each living donor at six months, one years and two years from the date of donation~~

12.8.3.1

Transplant centers that recover living donor organs must submit Living Donor Follow-up (LDF) forms for each living donor at six months, one year, and two years from the date of donation.

The transplant center must report accurate, complete, and timely follow-up data for Donor Status and Clinical Information using the LDF form for at least:

- 60% of their living kidney donors who donate between February 1, 2013 and December 31, 2013
- 70% of their living kidney donors who donate between January 1, 2014 and December 31, 2014
- 80% of their living kidney donors who donate after December 31, 2014.

The transplant center must report accurate, complete, and timely follow-up Kidney Laboratory Data using the LDF form for at least:

- 50% of their living kidney donors who donate between February 1, 2013 and December 31, 2013
- 60% of their living kidney donors who donate between January 1, 2014 and December 31, 2014
- 70% of their living kidney donors who donate after December 31, 2014.

- Donor Status and Clinical Information
  - Patient status
  - Cause of death, if applicable and known
  - Working for income, and if not working, reason for not working
  - Loss of medical (health, life) insurance due to donation
  - Has the donor been readmitted since last LDF form was submitted?
  - Kidney complications
  - Maintenance dialysis
  - Donor developed hypertension requiring medication
  - Diabetes
- Kidney Laboratory Data
  - Serum creatinine
  - Urine protein

Living donor follow-up data collected within 60 days of the six-month, one-year, and two-year anniversary of donation is considered timely.

Follow-up rates will be calculated separately, and at least annually, for the submission of the six-month, one-year, and two-year LDF forms.

12.10 Required Protocols for Kidney Recovery Hospitals

Kidney recovery hospitals must demonstrate that they have the following protocols:

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

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

~~(ii) Independent Donor Advocate Protocols: Kidney transplant programs that perform living donor kidney transplants must develop, and once developed, must comply with~~

~~written protocols for the duties and responsibilities of Independent Donor Advocate (IDA) that include, but are not limited to, the following elements:~~

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

~~(a) promotes the best interests of the potential living donor;~~
~~(b) advocates the rights of the potential living donor; and~~
~~(c) assists the potential donor in obtaining and understanding information regarding the:~~

~~1. consent process;~~
~~2. evaluation process;~~
~~3. surgical procedure; and~~
~~4. benefit and need for follow-up.~~

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

~~(1) a thorough medical evaluation by a physician and/or surgeon experienced in living donation to assess and minimize risks to the potential donor post-donation, which shall include a screen for any evidence of occult renal and infectious disease and medical co-morbidities, which may cause renal disease;~~
~~(2) a psychosocial evaluation of the potential living donor by a psychiatrist, psychologist, or social worker with experience in transplantation (criteria defined in Appendix B, Attachment I) to determine decision making capacity, screen for any pre-existing psychiatric illness, and evaluate any potential coercion;~~
~~(3) screening for evidence of transmissible diseases such as cancers and infections; and~~
~~(4) anatomic assessment of the suitability of the organ for transplant purposes.~~

~~(iv) Informed Consent Protocols: Kidney recovery hospitals must develop, and once developed, must comply with written protocols for the Informed Consent for the Donor Evaluation Process and for the Donor Nephrectomy, which include, at a minimum, the following elements:~~

~~(1) discussion of the potential risks of the procedure including the medical, psychological, and financial risks associated with being a living donor;~~
~~(2) assurance that all communication between the potential donor and the transplant center will remain confidential;~~
~~(3) discussion of the potential donor's right to opt out at any time during the donation process;~~
~~(4) discussion that the medical evaluation or donation may impact the potential donor's ability to obtain health, life, and disability insurance;~~
~~(5) disclosure by the kidney 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. The protocol must include a plan to collect the information about each donor; and~~

~~(6) the telephone number that is available for living donors to report concerns or grievances through the OPTN.~~

~~(7) documentation of disclosure by the kidney recovery hospital to potential donors that the sale or purchase of human organs is a federal crime and that it is unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation. This documentation must be maintained in the potential donor's official medical record.~~

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Affected Policy Language:

** Please note: At its November 2012 meeting, the OPTN/UNOS Board of Directors approved two separate resolutions that modified Policy 12.2 (Informed Consent of Living Donors). Below, Policy 12.2 reflects the changes from both of these proposals: Proposal to Require Reporting of Unexpected Potential and Proven Disease Transmission Involving Living Organ Donors and Proposal to Establish Minimum Requirements for Living Kidney Donor Follow (both sponsored by the Living Donor Committee).

Additionally, the OPTN/UNOS Board of Directors approved three separate resolutions that modified Policy 12.10 (Required Protocols for Kidney Recovery Hospitals) at its November 2012 meeting. Below, Policy 12.10 reflects the changes from all three of these proposals: Proposal to Establish Minimum Requirements for Living Kidney Donor Follow-Up, Proposal to Establish Requirements for the Informed Consent of Living Kidney Donors, and Proposal to Require Reporting of Unexpected Potential and Proven Disease Transmission Involving Living Organ Donors.

12.2 Informed Consent of Living Kidney Donors.

~~*Reserved.*~~

Introduction:

Education is important to enable the potential donor to understand all aspects of the donation process, especially the risks and benefits.

The goal of informed consent is to ensure that a potential donor understands:

1) That he or she will undertake risk and will receive no medical benefit from the donor nephrectomy.
2) That there are both general risks of the operation as well as center specific risks.

Living Kidney Donor Consent

The recovery hospital must obtain informed consent from any potential living kidney donor which must include, but is not limited to, documentation in the donor chart of the following:

a. Written assurance by the potential donor that he or she is willing to donate, free from inducement and coercion, and has been informed that he or she may decline to donate at any time. Potential donors must be offered an opportunity to discontinue the donor consent or evaluation process and to do so in a way that is protected and confidential. The independent donor advocate (IDA) must be available to assist the potential donor during this process. (see Policy 12.4)

b. Instruction about all phases of the living donation process, which include consent, medical and psychosocial evaluations, pre- and post-operative

care, and required post-operative follow-up. (Policy 7.3.2) Teaching or instructional material can include any media (e.g., written, video, audio) or 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 a meaningful dialogue with the transplant program staff.

c. Disclosure that the recovery hospital will take all reasonable precautions to provide confidentiality for the donor and recipient.

d. Disclosure that it is a federal crime for any person to knowingly acquire, obtain or otherwise transfer any human organ for valuable consideration (i.e., for anything of value such as cash, property, vacations).

e. Disclosure that the recovery hospitals must provide an Independent Donor Advocate (IDA).

f.

If the recovery hospital and the recipient hospital…	Then…	Including *all* the following information….
Are the same	The recovery hospital must provide the potential donor with both national and that hospital's program-specific transplant recipient outcomes from the most recent SRTR center-specific reports.	1. National 1-year patient graft survival 2. The hospital's 1-year patient and graft survival 3. Notification about all 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 donor with both national and the recipient hospital's program-specific transplant recipient outcomes from the most recent SRTR center-specific reports.	1. National 1-year patient and graft survival 2. The recipient hospital's 1-year patient and graft survival 3. Notification about all CMS outcome requirements not being met by the recipient hospital

g. Education about expected post-donation kidney function and how chronic kidney disease (CKD) and end-stage renal disease (ESRD) might potentially impact the donor in the future to include:

1) On average, donors will have a 25-35% permanent loss of kidney function at donation.

2) Baseline risk or ESRD does not exceed that of members of the general population with the same demographic profile.

3) Donor risks must be interpreted in light of the known epidemiology of both CKD and ESRD. When CKD or ESRD occur, CKD generally develops in mid-life (40-50 years old) and ESRD generally develops after age 60. The medical evaluation of a young potential donor cannot predict lifetime risk of CKD or ESRD.

4) 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 more rapid with only one kidney.

5) Dialysis is required when reaching ESRD.

6) Current practice is to prioritize prior living kidney donors who become kidney transplant candidates. (Policy 12.9.3)

h. Disclosure of alternate procedures or courses of treatment for the recipient including deceased donor transplantation.

- The donor must be informed that a deceased donor kidney might become available for the recipient before the donor evaluation is completed or the living donor transplant occurs.

- The donor must be informed that any transplant candidate might have-risk factors for increased morbidity or mortality that are not disclosed to the potential donor.

i. The disclosure that the donor will receive a thorough medical and psychosocial evaluation.

j. Inform the donor that health information obtained during their evaluation will be subject to the same regulations as all records and could reveal conditions that the transplant center must report to local, state or federal public health authorities.

k. Disclosure that recovery hospitals are required to report living donor follow-up information at the time intervals specified in Policy 12.8.3, and have the potential donor commit to post-operative follow-up testing coordinated by the living donor recovery hospital.

l. Disclosure that any infectious disease or malignancy pertinent to acute recipient care discovered during the potential donor's first two years of post-operative follow-up care:

- will be disclosed to the donor;
- may need to be reported to local, state or federal public health authorities;
- will be disclosed to their recipient's transplant center; and
- will be reported through the OPTN Improving Patient Safety Portal.

12.2.1 Living Kidney Donor Evaluation Consent

The recovery center must maintain documentation in the donor chart that it informed the potential donor of the following:

- That the potential donor must undergo a medical and psychosocial evaluation as required in Policy 12.3

- That the transplant hospital may refuse the potential donor. In such cases, potential donors must be informed that they could be evaluated by another transplant program that may have different selection criteria.

- That the following are inherent risks associated with evaluation for living donation:

  i. allergic reactions to contrast,
  ii. discovery of reportable infections,
  iii. discovery of serious medical conditions,
  iv. discovery of adverse genetic findings unknown to the donor, and 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.

- The following surgical, medical, psychosocial, and financial risks are associated with living kidney donation. This disclosure must state that these risks may be transient or permanent and include, but are not limited to the following:

  i) Potential Medical or Surgical Risks:
  - Death;

  - Scars, pain, fatigue, and other consequences typical of any surgical procedure;

  - Decreased kidney function;

  - Abdominal or bowel symptoms such as bloating and nausea and developing bowel obstruction;

  - Kidney failure and the need for dialysis or kidney transplant for the donor; and

- Impact of obesity, hypertension, or other donor-specific medical condition on morbidity and mortality of the potential donor.

ii) Potential Psychosocial Risks:

- Problems with body image;
- Post-surgery depression or anxiety;
- Feelings of emotional distress or bereavement if the transplant recipient experiences any recurrent disease or in the event of the transplant recipient's death; and
- Impact of donation on the donor's lifestyle.

iii) Potential Financial Impacts:

- 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;
- Need for life-long follow-up at the donor's expense;
- Loss of employment or income;
- Negative impact on the ability to obtain future employment;
- Negative impact on the ability to obtain, maintain, or afford health, disability, and life insurance; and,
- Future health problems experienced by living donors following donation may not be covered by the recipient's insurance.

12.4 Independent Donor Advocates.

~~*Reserved.*~~

The living kidney donor recovery hospital must provide an independent donor advocate (IDA) who is not involved with the potential recipient evaluation and is independent of the decision to transplant the potential recipient.

12.4.1 The IDA must assist the potential living kidney donor with the evaluation process and focus on their needs and questions. The IDA must be knowledgeable about risks and benefits associated with all phases of the donation process. IDA responsibilities include, but are not limited to the following:

- Promote the best interests of the potential living donor
- Advocate for the rights of the potential donor
- Assist the potential donor in obtaining and understanding information regarding the:

  i. Consent process;
  ii. Evaluation process;
  iii. Surgical procedure;
  iv. Medical and psychosocial risks;
  v. Benefit and need for follow-up.

12.7.10.1 Vessel recovery and transplant

- A recovery hospital may only recover extra vessels for transplant if the living donor consents to the removal of extra vessels for transplant. ~~The consent forms used by the donor recovery transplant center must include language that indicates that vessels may be used for transplant.~~
- The vessels from a living donor can only be used for the implantation or modification of a solid organ transplant for the original intended recipient.

12.10 Required Protocols for Kidney Recovery Hospitals

Kidney recovery hospitals must demonstrate that they have the following protocols:

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

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

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

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

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

~~(1) a thorough medical evaluation by a physician and/or surgeon experienced in living donation to assess and minimize risks to the potential donor post-donation, which shall include a screen for any evidence of occult renal and infectious disease and medical co-morbidities, which may cause renal disease;~~
~~(2) a psychosocial evaluation of the potential living donor by a psychiatrist, psychologist, or social worker with experience in transplantation (criteria defined in Appendix B, Attachment I) to determine decision making capacity, screen for any pre-existing psychiatric illness, and evaluate any potential coercion;~~
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~~(3) discussion of the potential donor's right to opt out at any time during the donation process;~~
~~(4) discussion that the medical evaluation or donation may impact the potential donor's ability to obtain health, life, and disability insurance;~~
~~(5) disclosure by the kidney 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. The protocol must include a plan to collect the information about each donor; and~~

~~(6) the telephone number that is available for living donors to report concerns or grievances through the OPTN.~~

~~(7) documentation of disclosure by the kidney recovery hospital to potential donors that the sale or purchase of human organs is a federal crime and that it is unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation. This documentation must be maintained in the potential donor's official medical record.~~

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12.3.3 Psychosocial Evaluation of the Living Kidney Donor

This psychosocial evaluation must be performed by a psychiatrist, psychologist, and/or clinical social worker. Documentation of the psychosocial evaluation must be maintained in the donor record. The psychosocial evaluation must include the following components:

- Assess for any psychosocial (including mental health) issues that might complicate the living donor's recovery and identify potential risks for poor psychosocial outcome;
- Assess for the presence of high-risk behaviors as defined by the US Public Health Service (PHS) that have the potential to increase the risk of disease transmission to the recipient;
- Assess history of smoking, alcohol, and drug use/abuse and dependency;
- Identify factors that warrant educational or therapeutic intervention prior to final donation decision;
- Determine that the potential donor understands the short and long-term medical and psychosocial risks associated with living donation, for both donor and recipient;
- Assess whether the decision to donate is free of inducement, coercion, and other undue pressure; by exploring the reason(s) for volunteering to donate and the nature of the relationship (if any) to the transplant candidate;
- Assess the potential donor's ability to make an informed decision and the ability to cope with the major surgery and related stress. This includes the potential donor having a realistic plan for donation and recovery, with social, emotional and financial support available as recommended; and
- Review the occupation, employment status, health insurance status, living arrangements, and social support of the potential donor and determine if the potential donor understands the potential financial implications of living donation.

12.3.4 Medical Evaluation of the Living Kidney Donor The medical evaluation must be performed by the recovery hospital and by a physician or surgeon experienced in living donation. The goal of the medical evaluation is to:

- Assess the immunologic compatibility of the donor to the recipient;
- Assess the general health and surgical risk of the donor including screening for conditions that may predict complications from having one kidney in the future;
- Determine if there are diseases present that may be transmitted from donor to recipient; and
- Assess the anatomy and function of the kidneys.

Documentation of the medical evaluation must be maintained in the donor record. The medical evaluation must include the following components:

A) General History:

- Evaluate for a personal history of significant medical conditions which include but are not limited to hypertension, diabetes, genetic renal diseases, lung disease, heart disease, gastrointestinal disease, autoimmune disease, neurologic disease, genitourinary disease, hematologic disorders, bleeding or clotting disorders, history of cancer and history of infections.

- Evaluate for Kidney Specific Personal History:
  - Kidney disease, proteinuria, hematuria
  - Kidney injury
  - Diabetes including gestational diabetes
  - Nephrolithiasis
  - Recurrent urinary tract infections
  - Active and past medications with special consideration for known nephrotoxic medications
- Allergies
- Evaluation for coronary artery disease

B) Family history of coronary artery disease and cancer

C) Kidney Specific Family History:

- Kidney disease
- Diabetes
- Hypertension
- Kidney Cancer

D) Social History:

The medical evaluation must determine:

- Occupation, employment status, health insurance status, living arrangements, and social support
- Smoking, alcohol and drug use/abuse
- High risk behavior as defined by the US PHS

- Psychiatric illness, depression, suicide attempts

E) Physical Exam:

- Height, weight, BMI
- Examination of all major organ systems
- Blood pressure
  - Taken on at least two different occasions; or
  - Perform 24-hour or overnight blood pressure monitoring

F) General Laboratory Tests:

- Complete Blood Count (CBC) with platelet count
- Blood Type and Screen
- Prothrombin Time (PT)
- International Normalized Ratio (INR) or 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)

G) Other Metabolic Testing:

- Fasting blood glucose
- Fasting lipid profile (Cholesterol, Triglycerides, HDL Cholesterol, and LDL Cholesterol)
- Glucose Tolerance Test and/or Glycosylated Hemoglobin in first degree relatives of diabetics and in high risk individuals

H) Kidney-Specific Tests:

- Urinalysis; 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.
- Centers must establish a protocol and follow their protocol for screening for Polycystic Kidney Disease or other inherited renal disease as guided 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 and sodium excretion

I) Anatomic Assessment:

An assessment to determine whether the kidneys are of equal size or have masses, cysts, or stones or other anatomical defects and to determine which kidney is more anatomically suitable for transplantation.

- The choice of test for radiologic imaging may be determined based upon the local radiological expertise and surgical preference, and may include CT angiogram or MR angiogram.

J) Screening for transmissible diseases:

Infectious disease testing must include:

- CMV (Cytomegalovirus) Antibody
- EBV (Epstein Barr Virus) Antibody
- HIV 1,2 (Human Immunodeficiency Virus) antibody testing
- HepBsAg (Hepatitis B surface antigen)
- HepBcAB (Hepatitis B core antibody)
- HepBsAB (Hepatitis B surface antibody)
- HCV (Hepatitis C Virus) antibody testing
- RPR (Rapid Plasma Reagin Test for Syphilis)

For tuberculosis (TB), living donor recovery centers must determine if the potential donor is at increased risk for this infection, and if so testing must include:

- Screening for latent TB using either intradermal PPD or Interferon Gamma Release Assay (IGRA)

For the following infectious diseases, transplant centers must determine if the potential donor is from an endemic area, and if so testing must include:

- Strongyloides
- Trypanosoma cruzi
- West Nile

K) Cancer screening:

Centers must develop protocols consistent with the American Cancer Society (ACS), and once developed follow their own protocols for screening:

- Cervical Cancer
- Breast Cancer
- Prostate Cancer
- Colon Cancer
- Skin Cancer
- Lung cancer

L) Exclusion Criteria:

Transplant programs that perform living kidney donor recoveries may exclude a donor with any condition that, in the Transplant Program's medical judgment, causes the donor to be unsuitable for organ donation.

Transplant programs that perform living kidney donor recoveries must exclude all donors who meet any of the following exclusion criteria:

- Both age less than 18 years 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

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Affected Policy Language:

** Please note: At its November 2012 meeting, the OPTN/UNOS Board of Directors approved two separate resolutions that modified Policy 12.2 (Informed Consent of Living Donors). Below, Policy12.2 reflects the changes from both of these proposals: Proposal to Require Reporting of Unexpected Potential and Proven Disease Transmission Involving Living Organ Donors and Proposal to Establish Minimum Requirements for Living Kidney Donor Follow (both sponsored by the Living Donor Committee).

4.5 POST-TRANSPLANT REPORTING OF POTENTIAL TRANSMISSION OF DISEASE OR MEDICAL CONDITIONS, INCLUDING MALIGNANCIES. In order to promote prompt notification of potential risk of disease transmission through organ transplantation, all events involving unexpected potential or proven transmission of a medical condition, including infections and malignancies, discovered after procurement of a deceased donor organ or recovery and transplant of a living donor organ must be reported to the OPTN Improving Patient Safety Portal ~~System~~℠.

- When an organ recipient is suspected to have, is confirmed positive for, or has died from a potential transmissible disease or medical condition for which there is substantial concern that it could be from donor origin, then the transplant program must notify the Living Donor Recovery Center (for living donor recipients) or Host OPO (for deceased donor recipients) by phone and provide available documentation to the Living Donor Recovery Center or Host OPO as soon as possible, but, at the latest, within ~~and not to exceed~~ 24 hours of ~~this~~ their knowledge~~/concern~~ of the event. The transplant center that suspects potential transmission should not wait for all medical documentation that may eventually be available, but must inform: ~~the Host OPO and/or the OPTN Patient Safety System to transfer knowledge/concern as soon as possible to all other centers that received organs from the same donor.~~

    - the Living Donor Recovery Center or Host OPO and
    - the OPTN Improving Patient Safety Portal .

- If ~~When~~ a Host OPO learns ~~of~~ new information regarding a deceased donor (~~i.e.~~ including but not limited to final culture results, information from autopsy report~~, etc.~~) as part of its donor follow-up (See Policy 2.2.5) that indicates risk of potential transmission of disease or malignancy, the Host OPO must report the donor result through the OPTN Patient Safety Portal ~~System~~℠.

- If a Recovery Center learns new information regarding a living donor, during the first two years post donation, (including but not limited to new or follow-up testing results, donor death or autopsy reports) that indicates risk of potential transmission of disease or malignancy, then the Recovery Center:

    - may need to report the new information to local, state or federal public health authorities;
    - must disclose to the living donor that a potential disease transmission or malignancy must be reported to the recipient transplant center and the OPTN Improving Patient Safety Portal;
    - must notify the recipient transplant center; and

- must report the potential transmission through the OPTN Improving Patient Safety Portal.

4.5.1 Living Donor Recovery Center and Host OPO Responsibilities. The Living Donor Recovery Center or Host OPO shall be responsible for:

i. Communication of test results and diagnosis from a suspected donor and/or affected recipient(s) that may be pertinent to acute patient care as soon as practicable, not to exceed 24 hours, to any transplant program(s) Patient Safety Contact and tissue bank(s) that received an organ(s) or tissue from the donor who is the subject of the investigation. This includes results of all tests that were not available at the time of procurement or recovery (i.e. cultures, final pathology, etc) or subsequently performed after recovery and documenting that this information is shared with all recipient centers and tissue banks.

ii. Notification of the event to the OPTN Improving Patient Safety ~~System℠~~ Portal as soon as possible, not to exceed 24 hours.

iii. Follow-up Communication of Potential Disease Transmission

- For deceased donors, ~~C~~completion and submission of the Potential Disease Transmission Report Form (a form that will be sent to the Host OPO after OPTN staff receives the electronic notification from the OPTN Patient Safety ~~System~~ Portal) to OPTN Patient Safety Staff within 24 hours of reporting the event through the Patient Safety ~~System℠~~ Portal to identify:

  - The specific Patient Safety Contact at the recipient transplant program(s) and tissue bank(s) personnel that were notified of the potential transmission;

  - Disposition of all organs, tissues and vessels; and

  - Any preliminary information available regarding any remaining donor samples for additional testing, notification to state or local health department as appropriate for nationally notifiable infectious diseases, and whether an autopsy was performed on the donor.

- For all donors, ~~If requested by~~ the Ad Hoc Disease Transmission Advisory Committee~~,~~ may request submission of a Potential Disease Transmission Donor Follow-Up Report (a form that will be sent ~~to the Host OPO~~ by OPTN contractor staff) 45 days after the initial reporting date; OPTN Patient Safety Staff may request additional information related to the donor beyond 45 days, including pending test results depending on the potentially transmitted disease or condition.

iv. Management of the review, in partnership with OPTN Patient Safety Staff, to determine whether the organ donor was diagnosed with a potentially transmissible disease or condition;

4.5.2 Transplant Program Responsibilities. Any transplant program treating recipient(s) that received organ(s) from a donor who is the subject of a potential disease transmission report is responsible for:

i. Responding to Host OPO, Living Donor Recovery Center, and OPTN Patient Safety Staff requests for information regarding recipient(s) in a timely fashion and communicating updated information regarding recipient condition, test results, diagnosis, and plans for treatment and follow-up.

ii. Submitting copies of any pertinent test results (including cultures, serologies, imaging studies, autopsy results, etc.) to OPTN Patient Safety Staff.

iii. Notifying recipient(s) involved in cases of confirmed transmissions and documenting this notification in the recipient medical record as required in Policy 4.3.

iv. If requested by the Ad Hoc Disease Transmission Advisory Committee, submission of a Potential Disease Transmission Recipient Follow-Up Report (a form that will be sent to the transplant program by OPTN staff) within 45 days of the initial reporting date.

OPTN Patient Safety Staff may request additional information related to the recipient beyond 45 days, (including pending test results, long term follow-up testing, and/or screening results, etc.) depending on the potentially transmitted disease or condition in an effort to determine the probability of donor-derived

12.2 Informed Consent of Living Kidney Donors.

~~*Reserved.*~~

Introduction:

Education is important to enable the potential donor to understand all aspects of the donation process, especially the risks and benefits.

The goal of informed consent is to ensure that a potential donor understands:

1) That he or she will undertake risk and will receive no medical benefit from the donor nephrectomy.
2) That there are both general risks of the operation as well as center specific risks.

Living Kidney Donor Consent

The recovery hospital must obtain informed consent from any potential living kidney donor which must include, but is not limited to, documentation in the donor chart of the following:

a. Written assurance by the potential donor that he or she is willing to donate, free from inducement and coercion, and has been informed that he or she may decline to donate at any time. Potential donors must be offered an opportunity to discontinue the donor consent or evaluation process and to do so in a way that is protected and confidential. The independent donor advocate (IDA) must be available to assist the potential donor during this process. (see Policy 12.4)

b. Instruction about all phases of the living donation process, which include consent, medical and psychosocial evaluations, pre- and post-operative care, and required post-operative follow-up. (Policy 7.3.2) Teaching or instructional material can include any media (e.g., written, video, audio) or 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 a meaningful dialogue with the transplant program staff.

c. Disclosure that the recovery hospital will take all reasonable precautions to provide confidentiality for the donor and recipient.

d. Disclosure that it is a federal crime for any person to knowingly acquire, obtain or otherwise transfer any human organ for valuable consideration (i.e., for anything of value such as cash, property, vacations).

e. Disclosure that the recovery hospitals must provide an Independent Donor Advocate (IDA).

f.

If the recovery hospital and the recipient hospital…	Then…	Including *all* the following information….
Are the same	The recovery hospital must provide the potential donor with both national and that hospital's program-specific transplant recipient outcomes from the most recent SRTR center-specific reports.	1. National 1-year patient graft survival 2. The hospital's 1-year patient and graft survival 3. Notification about all 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 donor with both national and the recipient hospital's program-specific transplant recipient outcomes from the most recent SRTR	1. National 1-year patient and graft survival 2. The recipient hospital's 1-year patient and graft survival 3. Notification about all

	center-specific reports.	CMS outcome requirements not being met by the recipient hospital

g. Education about expected post-donation kidney function and how chronic kidney disease (CKD) and end-stage renal disease (ESRD) might potentially impact the donor in the future to include:

1) On average, donors will have a 25-35% permanent loss of kidney function at donation.

2) Baseline risk or ESRD does not exceed that of members of the general population with the same demographic profile.

3) Donor risks must be interpreted in light of the known epidemiology of both CKD and ESRD. When CKD or ESRD occur, CKD generally develops in mid-life (40-50 years old) and ESRD generally develops after age 60. The medical evaluation of a young potential donor cannot predict lifetime risk of CKD or ESRD.

4) 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 more rapid with only one kidney.

5) Dialysis is required when reaching ESRD.

6) Current practice is to prioritize prior living kidney donors who become kidney transplant candidates. (Policy 12.9.3)

h. Disclosure of alternate procedures or courses of treatment for the recipient including deceased donor transplantation.

- The donor must be informed that a deceased donor kidney might become available for the recipient before the donor evaluation is completed or the living donor transplant occurs.

- The donor must be informed that any transplant candidate might have-risk factors for increased morbidity or mortality that are not disclosed to the potential donor.

i. The disclosure that the donor will receive a thorough medical and psychosocial evaluation.

j. Inform the donor that health information obtained during their evaluation will be subject to the same regulations as all records and could reveal conditions that the transplant center must report to local, state or federal public health authorities.

k. Disclosure that recovery hospitals are required to report living donor follow-up information at the time intervals specified in Policy 12.8.3, and have the potential donor commit to post-operative follow-up testing coordinated by the living donor recovery hospital.

l. Disclosure that any infectious disease or malignancy pertinent to acute recipient care discovered during the potential donor's first two years of post-operative follow-up care:

- will be disclosed to the donor;
- may need to be reported to local, state or federal public health authorities;
- will be disclosed to their recipient's transplant center; and
- will be reported through the OPTN Improving Patient Safety Portal.

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

Affected Policy/Bylaw Language:

** Please note: At its November 2012 meeting, the OPTN/UNOS Board of Directors approved two separate resolutions that established, and then modified, Policy 13 (KIDNEY PAIRED DONATION). Below, Policy 13 reflects the changes from both of these proposals: Proposal to Establish Kidney Paired Donation (KPD) Policy and Proposal to Include Bridge Donors in the OPTN Kidney Paired Donation (KPD) Program (both sponsored by the Kidney Transplantation Committee). All of Policy 13 is new OPTN policy. To distinguish those policies that require programming prior to implementation, policy language that will be implemented on February 1, 2013, is not underlined and is instead written in *italics*. Policy language that requires programming for implementation, and the changes to the OPTN Bylaws Appendix E, are marked with a ~~single strikethrough~~ or a single underline, following the conventional policy change notation.

13 KIDNEY PAIRED DONATION

13.1 Scope of Policy

Unless otherwise stated, references to potential donors and donors within this policy are specific to KPD potential donors and donors and references to candidates and recipients are specific to KPD candidates and recipients.

13.2 Requirements for Participation in the OPTN KPD Program

13.2.1 Candidates

In order to participate in the OPTN KPD program, candidates must be registered on the deceased donor kidney waiting list at the Transplant Hospital that wishes to enroll the candidate in the OPTN KPD Program.

13.2.2 Potential Donors

In order to participate in OPTN KPD Program, potential donors must comply with all of the following requirements:

1. *Be aged at least 18 years old*
2. *Not be currently listed as a potential donor for any other candidate registered in the OPTN KPD Program*

13.3 Informed Consent for Candidates

Reserved

13.4 Informed Consent for Potential Donors

Reserved

13.5 Histocompatibility Testing

Reserved

13.6 Matching Within the OPTN KPD Program

13.6.1 Requirements for Match Run Eligibility for Candidates

The OPTN KPD Program will only match candidates that comply with all of the following requirements:

1. *The candidate's Transplant Hospital must comply with Policy 3.1.2*
2. *The candidate's Transplant Hospital must complete the informed consent process per KPD Operational Guidelines*
3. *The candidate's Transplant Hospital must submit the required fields below to the OPTN Contractor*

   a. *Candidate Details*
      - *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*
      - *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*
      - *Maximum acceptable donor BMI*
      - *Maximum acceptable systolic and diastolic blood pressure*
      - *Whether the candidate is willing to accept a hepatitis B core antibody positive donor, a CMV positive donor, and an EBV positive donor*
      - *Whether the candidate would be willing to accept a left kidney, right kidney, or either kidney*

4. *The candidate must be in an active status in the OPTN KPD Program*
5. *The candidate must have at least one ~~and no more than two~~ active and eligible potential 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*

13.6.2 Requirements for Match Run Eligibility for Potential Donors

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

1. *The Transplant Hospital registering the potential donor in KPD must perform ABO typing and sub-typing as required by Policy 12.3.1 and 12.3.2 with the following modifications*

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

2. *The Transplant Hospital registering the potential donor in KPD must complete the informed consent process per KPD Operational Guidelines*
3. *The Transplant Hospital registering the potential donor in KPD must complete the medical evaluation process per KPD Operational Guidelines*
4. *The Transplant Hospital registering the potential donor in KPD must submit the required fields below to the OPTN Contractor*

    a. *Donor Details*
        - *Last name*
        - *First name*
        - *SSN*
        - *Date of birth*
        - *Gender*
        - *Ethnicity/Race*
        - *ABO*
        - *Height and weight*
        - *Whether the potential donor is a non-directed donor;*

- *If the potential donor is a paired donor, the KPD Candidate ID of the paired candidate and the potential donor's relationship to the candidate*
- *Whether the potential donor has signed an agreement to participate in the OPTN KPD Program*
- *Whether the potential donor has signed a release of protected health information*
- *Whether the potential donor has signed an informed consent as required in policy*
- *Whether the potential donor has undergone a medical evaluation as required in policy*
- *Whether the potential donor has had all age appropriate cancer screenings as defined by the American Cancer Society*
- *KPD status*

b. *Clinical Information*
- *The number of anti-hypertensive medications the donor is on*
- *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*
- *Whether the potential donor would be willing to travel, and, if so, the Transplant Hospitals to which the potential donor would be willing to travel*
- *Whether the potential donor is willing to ship a kidney*
- *Whether the potential donor is willing to donate a left kidney, right kidney, or either kidney*
- *Whether the candidate-donor pair and the Transplant Hospital are willing to participate in a three-way exchange or a donor chain*
- <u>Whether the potential donor and the Transplant Hospital are willing for the potential donor to be a bridge donor</u>

5. *The potential donor must be in an active status in the OPTN KPD Program*
6. *The potential donor must be paired to an active and eligible candidate registered in the OPTN KPD Program*
7. *The Transplant Hospital registering the potential donor in KPD must submit a response for all previous match offers for the potential donor in the OPTN KPD Program*
8. *The potential donor must not be in a pending exchange in the OPTN KPD Program.*

13.6.3 Screening Criteria

13.6.3.1 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. Fields with a "●" indicate identical blood type matches. Fields with a "◑" indicate permissible blood type matches. Fields with a "◑" indicate permissible blood type matches providing the candidates meets the requirements in Policy 13.6.3.2. Fields with a "○" indicate impermissible blood type matches.*

		Candidate's Blood Type			
		O	A or A_1 or A_2	B	AB or A_1B or A_2B
Donor's Blood Type	O	●	◑	◑	◑
	A	○	●	○	◑
	A_1	○	●	○	◑
	A_2	◑*	●	◑*	◑
	B	○	○	●	◑
	AB	○	○	○	●
	A_1B	○	○	○	●
	A_2B	○	○	◑*	●

Table 13-1: Blood Typing for KPD

13.6.3.2 A_2 and A_2B Matching

In order for a blood type B candidate to be eligible to be matched to a blood type A_2 or A_2B potential donor, or for a blood type O candidate to be eligible to match to a blood type A_2 potential donor in the OPTN KPD Program, all of the following conditions must be met:

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.*

13.6.3.3 Unacceptable Antigens

A Transplant Hospital may specify any unacceptable antigens it will not accept for its candidates. The OPTN Contractor will not match the candidate with any potential donor who has one of the candidate's unacceptable antigens entered as an HLA value.

13.6.3.4 Candidate and Potential Donor Choices

A Transplant Hospital may specify criteria it will not accept for any of its candidates as outlined in Policy 13.6.1-3(b) or potential donors as outlined in Policy 13.6.2-6(c). The OPTN Contractor will not match the candidates with potential donors who fall outside the specified criteria or potential donors with candidates who fall outside the specified criteria.

13.6.4 Prioritization Points

Reserved

13.6.5 Two- and Three-Way Matches

13.6.5.1 Match Size

The OPTN Contractor will match donor-candidate pairs only in two-way or three-way exchanges unless the exchange includes a non-directed donor as outlined in Policy 13.6.6.

13.6.5.2 Logistical Requirements

In two-way or three-way exchanges in the OPTN KPD Program, all donor surgeries involved in the exchange must begin on the same day and only after all donor surgeons involved in the exchange agree to proceed.

13.6.6 Donor Chains

13.6.6.1 Chain Size

In the OPTN KPD Program, ~~donor chains will be limited to 20 donor-candidate pairs~~ there is no limit on the length of the donor chains.

13.6.6.2 Logistical Requirements

In donor chains in the OPTN KPD Program, surgeries may or may not occur simultaneously. A candidate will receive a kidney before or the same day his paired donor donates. A candidate-donor pair will always have the option to have surgery on the same day. Donor surgeries must be scheduled to occur within 3 weeks of the day the paired candidate receives a transplant.

A chain must end with a donation to a candidate on the deceased donor waiting list at the Transplant Hospital that entered the non-directed donor (NDD) that started that chain or with a bridge donor who will be included in a later match run. The Transplant Hospital that enters the NDD can choose whether the chain can end with a bridge donor or whether the chain must end with a donation to a candidate on the waiting list at that Transplant Hospital. The Transplant Hospital registering the potential donor in KPD may refuse to allow the potential donor to serve as a bridge donor at any point in the process.

13.6.6.3 What to Do When a Chain Breaks

In the OPTN KPD Program, a donor chain will proceed until a candidate or potential donor refuses a match offer.

If a candidate or potential donor in a chain refuses a match offer, then the chain's last donor, who is in a match that has been accepted before a candidate or potential donor refuses a match, may donate to the deceased donor waiting list or may be a bridge donor as outlined in Policy 13.6.6.2. ~~*may be entered in the next match run to repair the donor chain if all of the following conditions are met:*~~

~~1. *The operating room dates are not set for a chain at the time of the next match run*~~
~~2. *The crossmatches have been performed for all matches up to the point where a candidate or a potential donor refuses a match*~~
~~3. *The potential donors have been approved for all matches up to the point where a candidate or potential donor refuses a match.*~~

13.7 Crossmatching Protocol

The candidate's Transplant Hospital must perform a preliminary crossmatch for candidates in the OPTN KPD Program before the matched donor's recovery procedure.

The Transplant Hospital registering the potential donor in KPD is responsible for shipping the potential donor's blood sample to the matched candidate's Transplant Hospital or the laboratory specified by the matched candidate's Transplant Hospital.

The candidate's Transplant Hospital is responsible for running the crossmatch and reporting the results to the OPTN Contractor and the matched donor's Transplant Hospital.

13.8 Transportation of Kidneys

For any KPD exchange, the recovery Transplant Hospital is responsible for packaging, labeling, and transporting kidneys from donors as provided in Policy 12.7.

In the OPTN KPD Program, the recipient's Transplant Hospital must specify the location where the recovery Transplant Hospital must deliver the kidney. The recovery Transplant Hospital must then document the name and telephone number of every person or company who will package, label, or transport the kidney from the time that the kidney is recovered until the kidney is delivered to the location specified by the recipient's Transplant Hospital along with the date and time that the name is documented. The recovery Transplant Hospital must complete this documentation before the potential donor enters the operating room for the kidney recovery surgery and must maintain this documentation in the donor's medical record.

13.9 Rules for When Donors and Recipients Can Meet

The following rules apply to meetings facilitated by an OPTN Member between donors and matched recipients that participated in an OPTN KPD Program exchange. These rules do not apply to meetings between potential donors and paired candidates.

Members can facilitate a meeting between donors and recipients that participated in an OPTN KPD Program exchange only if all of the follow conditions are met:

1. *All the donors and recipients participating in the meeting agree to meet*
2. *The meeting occurs after the transplant concludes*
3. *The Transplant Hospital establishes a written protocol for when donors and recipients can meet. This protocol must include, at a minimum, the timing of the meeting and what staff must attend the meeting.*
4. *Transplant Hospital complies with their written protocol for when donors and recipients can meet. The Transplant Hospital must maintain documentation of compliance in the donor's or recipient's medical record.*

13.10 Definitions

- *Bridge donor- a donor who does not have a match identified during the same match run as his paired candidate.*
- *Chain – a set of matches that begins with a donation from a non-directed donor to his matched candidate. This candidate's paired donor then donates to his matched candidate. A chain continues until a donor donates to a waiting list candidate or is a bridge donor.*
- *Exchange – a set of matches that form a chain, a two-way exchange, or a three-way exchange.*
- *Match –a donor and his matched candidate*
- *Match Run – procedure used to generate a set of exchanges*
- *Matched candidate – the candidate that a KPD match run identifies as a potential recipient of a donor's kidney*

- *Matched donor – a donor identified by a KPD match run as a potential donor for a candidate*
- *Matched recipient – a matched candidate that has received a transplant*
- *Non-Directed Donor (NDD) - a donor that enters KPD without a paired candidate*
- *Other antibody specificities- antigens that may result in a positive or negative crossmatch. The rate of positive crossmatches would be expected to be higher against donors who express these antigens.*
- *Pair – a donor and his paired candidate*
- *Paired candidate – the candidate to whom a donor intended to donate his organ before entering into KPD*
- *Paired Donation of Human Kidneys (KPD) – the donation and receipt of human kidneys under the following circumstances:*
    - *An individual (the first donor) desires to make a living donation of a kidney specifically to a particular patient (the first patient), but such donor is biologically incompatible as a donor for such patient.*
    - *A second individual (the second donor) desires to make a living donation of a kidney specifically to a second particular patient (the second patient), but such donor is biologically incompatible as a donor for such patient.*
    - *The first donor is biologically compatible as a donor of a kidney for the second patient, and the second donor is biologically compatible as a donor of a kidney for the first patient.*
    - *If there are any additional donor-patient pair as described above, each donor in the group of donor-patient pairs is biologically compatible as a donor of a kidney for a patient in such group.*
    - *All donors and patients in the group of donor-patient pairs enter into a single agreement to donate and receive such kidneys, respectively, according to such biological compatibility in the group.*
    - *Other than described as above, no valuable consideration is knowingly acquired, received, or otherwise transferred with respect to the kidneys referred to.*

- *Paired donor –a donor who intended to donate his organ, before entering into KPD, to his paired candidate*
- *Paired Recipient- a paired candidate that has received a transplant*
- *Transplant Hospital registering the potential donor in KPD - the Transplant Hospital that enters the potential donor in a KPD program*
- *Three-way exchange- a set of matches that includes three donor-candidate pairs where each donor donates a kidney to a candidate in one of the other pairs.*
- *Two-way exchange – a set of matches that includes two donor-candidate pairs where each donor donates a kidney to the candidate in the other pair.*
- *Unacceptable antigens- antigens to which the patient is sensitized and would preclude transplantation at the candidate's center with a donor having any one of those antigens.*

OPTN Bylaws, Appendix E

E.5. Kidney Transplant Programs that Perform Living Donor Recovery

~~**F. Kidney Paired Donation**~~

~~Members that choose to participate in any OPTN kidney paired donation program must agree to follow the kidney paired donation program rules. Potential violations may be forwarded by the Kidney Transplantation Committee to the MPSC for review.~~

F. Kidney Paired Donation (KPD)

Members that choose to participate in the OPTN KPD program must do *all* of the following:

1. Meet all the requirements of *Section E.5: Kidney Transplant Programs that Perform Living Donor Recovery* above.
2. Notify the OPTN Contractor in writing if the transplant hospital decides to participate in the OPTN KPD program. A transplant hospital must notify the OPTN Contractor in writing if it decides to quit its participation in the OPTN KPD program.
3. Provide to the OPTN Contractor a primary and alternate kidney paired donation contact that is a member of the hospital's staff.
4. Members that choose to participate in any OPTN kidney paired donation program must agree to follow the kidney paired donation program rules (Operational Guidelines). Potential violations may be forwarded by the Kidney Transplantation Committee to the MPSC for review.

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

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

Affected Policy Language:

** Please note: At its November 2012 meeting, the OPTN/UNOS Board of Directors approved two separate resolutions that modified Policy 13 (KIDNEY PAIRED DONATION). Below, Policy 13 reflects the changes from both of these proposals: Proposal to Establish Kidney Paired Donation (KPD) Policy and Proposal to Include Bridge Donors in the OPTN Kidney Paired Donation (KPD) Program (both sponsored by the Kidney Transplantation Committee). All of Policy 13 is new OPTN policy. To distinguish the policy changes corresponding to the inclusion of bridge donors in the OPTN KPD Pilot Program that require programming prior to implementation, policy language that will be implemented on February 1, 2013, is not underlined and is instead written in *italics*. The policy language changes that include bridge donors in the OPTN KPD Pilot Program, which require programming prior to implementation, are marked with a ~~single strikethrough~~ or a single underline, following the conventional policy change notation.

13.6.2 Requirements for Match Run Eligibility for Potential Donors

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

1. *The Transplant Hospital registering the potential donor in KPD must perform ABO typing and sub-typing as required by Policy 12.3.1 and 12.3.2 with the following modifications*

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

2. *The Transplant Hospital registering the potential donor in KPD must complete the informed consent process per KPD Operational Guidelines*
3. *The Transplant Hospital registering the potential donor in KPD must complete the medical evaluation process per KPD Operational Guidelines*
4. *The Transplant Hospital registering the potential donor in KPD must submit the required fields below to the OPTN Contractor*

    a. *Donor Details*
        - *Last name*
        - *First name*
        - *SSN*

- *Date of birth*
- *Gender*
- *Ethnicity/Race*
- *ABO*
- *Height and weight*
- *Whether the potential donor is a non-directed donor;*
- *If the potential donor is a paired donor, the KPD Candidate ID of the paired candidate and the potential donor's relationship to the candidate*
- *Whether the potential donor has signed an agreement to participate in the OPTN KPD Program*
- *Whether the potential donor has signed a release of protected health information*
- *Whether the potential donor has signed an informed consent as required in policy*
- *Whether the potential donor has undergone a medical evaluation as required in policy*
- *Whether the potential donor has had all age appropriate cancer screenings as defined by the American Cancer Society*
- *KPD status*

b. *Clinical Information*
- *The number of anti-hypertensive medications the donor is on*
- *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*
- *Whether the potential donor would be willing to travel, and, if so, the Transplant Hospitals to which the potential donor would be willing to travel*
- *Whether the potential donor is willing to ship a kidney*
- *Whether the potential donor is willing to donate a left kidney, right kidney, or either kidney*
- *Whether the candidate-donor pair and the Transplant Hospital are willing to participate in a three-way exchange or a donor chain*
- <u>Whether the potential donor and the Transplant Hospital are willing for the potential donor to be a bridge donor</u>

5. *The potential donor must be in an active status in the OPTN KPD Program*
6. *The potential donor must be paired to an active and eligible candidate registered in the OPTN KPD Program*

7. *The Transplant Hospital registering the potential donor in KPD must submit a response for all previous match offers for the potential donor in the OPTN KPD Program*
8. *The potential donor must not be in a pending exchange in the OPTN KPD Program.*

13.6.6.2 Logistical Requirements

In donor chains in the OPTN KPD Program, surgeries may or may not occur simultaneously. A candidate will receive a kidney before or the same day his paired donor donates. A candidate-donor pair will always have the option to have surgery on the same day. Donor surgeries must be scheduled to occur within 3 weeks of the day the paired candidate receives a transplant.

A chain must end with a donation to a candidate on the deceased donor waiting list at the Transplant Hospital that entered the non-directed donor (NDD) that started that chain or with a bridge donor who will be included in a later match run. The Transplant Hospital that enters the NDD can choose whether the chain can end with a bridge donor or whether the chain must end with a donation to a candidate on the waiting list at that Transplant Hospital. The Transplant Hospital registering the potential donor in KPD may refuse to allow the potential donor to serve as a bridge donor at any point in the process.

13.6.6.3 What to Do When a Chain Breaks

In the OPTN KPD Program, a donor chain will proceed until a candidate or potential donor refuses a match offer.

If a candidate or potential donor in a chain refuses a match offer, then the chain's last donor, who is in a match that has been accepted before a candidate or potential donor refuses a match, may donate to the deceased donor waiting list or may be a bridge donor as outlined in Policy 13.6.6.2. ~~*may be entered in the next match run to repair the donor chain if all of the following conditions are met:*~~

~~1. *The operating room dates are not set for a chain at the time of the next match run*~~
~~2. *The crossmatches have been performed for all matches up to the point where a candidate or a potential donor refuses a match*~~
~~3. *The potential donors have been approved for all matches up to the point where a candidate or potential donor refuses a match.*~~

13.10 Definitions

- Bridge donor- a donor who does not have a match identified during the same match run as his paired candidate.
- *Chain – a set of matches that begins with a donation from a non-directed donor to his matched candidate. This candidate's paired donor then donates to his matched candidate. A chain continues until a donor donates to a waiting list candidate or is a bridge donor.*
- *Exchange – a set of matches that form a chain, a two-way exchange, or a three-way exchange.*
- *Match –a donor and his matched candidate*
- *Match Run – procedure used to generate a set of exchanges*
- *Matched candidate – the candidate that a KPD match run identifies as a potential recipient of a donor's kidney*
- *Matched donor – a donor identified by a KPD match run as a potential donor for a candidate*
- *Matched recipient – a matched candidate that has received a transplant*
- *Non-Directed Donor (NDD) - a donor that enters KPD without a paired candidate*
- *Other antibody specificities- antigens that may result in a positive or negative crossmatch. The rate of positive crossmatches would be expected to be higher against donors who express these antigens.*
- *Pair – a donor and his paired candidate*
- *Paired candidate – the candidate to whom a donor intended to donate his organ before entering into KPD*
- *Paired Donation of Human Kidneys (KPD) – the donation and receipt of human kidneys under the following circumstances:*
    - *An individual (the first donor) desires to make a living donation of a kidney specifically to a particular patient (the first patient), but such donor is biologically incompatible as a donor for such patient.*
    - *A second individual (the second donor) desires to make a living donation of a kidney specifically to a second particular patient (the second patient), but such donor is biologically incompatible as a donor for such patient.*
    - *The first donor is biologically compatible as a donor of a kidney for the second patient, and the second donor is biologically compatible as a donor of a kidney for the first patient.*
    - *If there are any additional donor-patient pair as described above, each donor in the group of donor-patient pairs is biologically compatible as a donor of a kidney for a patient in such group.*
    - *All donors and patients in the group of donor-patient pairs enter into a single agreement to donate and receive such kidneys, respectively, according to such biological compatibility in the group.*
    - *Other than described as above, no valuable consideration is knowingly acquired, received, or otherwise transferred with respect to the kidneys referred to.*

- *Paired donor –a donor who intended to donate his organ, before entering into KPD, to his paired candidate*
- *Paired Recipient- a paired candidate that has received a transplant*
- *Transplant Hospital registering the potential donor in KPD - the Transplant Hospital that enters the potential donor in a KPD program*
- *Three-way exchange- a set of matches that includes three donor-candidate pairs where each donor donates a kidney to a candidate in one of the other pairs.*
- *Two-way exchange – a set of matches that includes two donor-candidate pairs where each donor donates a kidney to the candidate in the other pair.*
- *Unacceptable antigens- antigens to which the patient is sensitized and would preclude transplantation at the candidate's center with a donor having any one of those antigens.*

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

Affected Policy Language:

3.5.11.6 Prior Living Organ Donors

A candidate will receive 4 points and local priority for kidneys that are not shared for 0 HLA mismatching or for renal/non-renal allocation if all of the following conditions are met:

1. The candidate donated for transplantation within the United States or its territories at least one of the following:
   - Kidney
   - Liver segment
   - Lung segment
   - Partial pancreas
   - Small bowel segment.

2. The candidate's physician provides all of the following information to the OPTN Contractor:
   - The name of the recipient of the donated organ or organ segment
   - The name of the recipient's Transplant Program
   - The date of the transplant of the donated organ.

Candidates receive these points and priority for each kidney registration when the above requirements are met.

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

12.9.3 Priority on the Waiting List

A candidate will receive 4 points and local priority for kidneys that are not shared for 0 HLA mismatching or for renal/non-renal allocation if all of the following conditions are met:

1. The candidate donated for transplantation within the United States or its territories at least one of the following:
   - Kidney
   - Liver segment
   - Lung segment
   - Partial pancreas
   - Small bowel segment.
2. The candidate's physician provides all of the following information to the OPTN Contractor:
   - The name of the recipient of the donated organ or organ segment
   - The names of the recipient's Transplant Program
   - The date of the transplant of the donated organ.

Candidates receive these points and priority for each kidney registration when the above requirements are met.

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

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

Affected Policy Language:

5.10.2 Vessel storage

The Transplant Center must designate a person to monitor and maintain records, destroy, and notify the OPTN of outcome and/or use of vessels. This designated person must maintain information on all donor vessels including monitoring and maintaining all records relating to the use and management of donor vessels (e.g. subsequent positive serology testing, monitor inventory of stored ~~vascular conduits~~ extra vessels). This person must monitor the refrigerator, ensure records are up to date and available with the ~~conduits~~ vessels, destroy the vessels when expired, and ~~notify~~ report the vessel's use or disposal to the OPTN ~~of its use or disposal~~ within 7 calendar days.

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

Affected Policy Language:

5.4.2 Tissue typing materials

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

12.7.4.2 Tissue typing materials

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

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

Affected Policy Language:

** Please note: The Board of Directors approved changes to Policy 3.7.6.1.c (Bilirubin in the Lung Allocation Score) at its June 2009 meeting that are pending programming for implementation. Policy 3.7.6.1 is provided below in its entirety, including changes from the June 2009 and the November 2012 meetings. Policy 3.7.9.2 is also provided below in its entirety, and includes changes approved in the June 2005 and November 2012 Board meetings. The previously approved changes to Policy 3.7.6.1.c and Policy 3.7.9.2 that are not yet implemented are written in *italics*. Language in Policy 3.7.9.2 that is currently in effect, but that will be deleted upon the implementation of the changes approved in June 2005, is marked with a ~~double strikethrough~~. All other italicized text found in the policy below reflects the formatting of current policy. Policy language changes from the November 2012 Board of Directors meeting are marked with a ~~single strikethrough~~ or a single underline, following the conventional policy change notation.

3.7.6 Lung Allocation. Candidates waiting for lung transplants receive priority for deceased donor lung offers based on Lung Allocation Score (LAS) if they are at least 12 years of age. Candidates less than 12 years of age receive deceased donor lung offers based on medical urgency priority. ~~Candidates are assigned priority in lung allocation as follows:~~

3.7.6.1 Lung Allocation Score (LAS) System for Candidates at Least 12 Years of Age

Candidates who are at least 12 years of age receive offers for deceased donor lungs based on LAS, as well as geography and blood type. Candidates with higher LASs receive higher waiting list priority.

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

~~intervals of approximately six months and will propose changes to Tables 1 and 2 as appropriate.~~

3.7.6.1.1 The LAS Calculation

The LAS calculation uses *all of* the following:

- Waitlist 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 Waitlist Urgency Measure

The LAS is determined by normalizing the Raw Allocation Score to a continuous scale of 0 to 100. The Raw Allocation Score is the difference between the Transplant Benefit Measure and the Waitlist Urgency Measure.

The equation for the LAS calculation is:

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

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 model, according to Table 1.

Where…	**Includes…**
$S_{TX}(t) = S_{TX,0}(t)^{e^{\alpha_1 Y_1 + \alpha_2 Y_2 + \ldots + \alpha_q Y_q}}$	$S_{TX}(t)$ = the expected post-transplant survival probability at time t for an individual candidate. Y_j = the value of the jth characteristic for an individual candidate α_j = the coefficient for characteristic j from the post-transplant model, according to Table 2.
$WLAUC = \sum_{k=0}^{364} S_{WL}(k)$	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 3. $S_{TX,0}(t)$ = the baseline post-transplant survival probability at time t, according to Table 4. $S_{WL}(t)$ = the expected waiting list survival probability at time t for an individual candidate X_j = the value of the ith characteristic for an individual candidate.

Table 1

Factors Used in the Waiting List Morality 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 (see Policy 3.7.6.1.4) 0 when bilirubin is 1.0 mg/dL or less

For this covariate:	**The following coefficient is used in the LAS calculation:**
3. Bilirubin increase of at least 50%	1.4144058906830200 for Group B (see Policy 3.7.6.1.4) 0 for Groups A, C, and D (see Policy 3.7.6.1.2)
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 (Group B only – see Policy 3.7.6.1.2.b) 0 if less than or equal to 7 mm Hg for Group B (see Policy 3.7.6.1.2.b) 0 for candidates in Groups A, C, and D (see Policy 3.7.6.1.2)
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 at least 18 years of age (see Policy 3.7.6.1.5) 0 if less than 18 years of age

For this covariate:	**The following coefficient is used in the LAS calculation:**
9. Diabetes	0.4680254026735700 if diabetic 0 if not diabetic
10. Diagnosis Group A (see Policy 3.7.6.1.2.a for the diseases included in this group)	0
Diagnosis Group B (see Policy 3.7.6.1.2.b for the diseases included in this group)	1.5774243292137200
Diagnosis Group C (see Policy 3.7.6.1.2.c for the diseases included in this group)	1.2313926484343600
Diagnosis Group D (see Policy 3.7.6.1.2.d for the diseases included in this group)	0.6259577164157700
11. Detailed diagnosis: Bronchiectasis (Group A – see Policy 3.7.6.1.2.a)	0.6680518055684700
Detailed diagnosis: Eisenmenger's syndrome (Group B – see Policy 3.7.6.1.2.b)	-0.6278657824830000
Detailed diagnosis: Lymphangioleiomyomatosis (Group A – see Policy 3.7.6.1.2.a)	-0.3162937838984600
Detailed Diagnosis: Obliterative bronchiolitis (not-retransplant) (Group D – see Policy 3.7.6.1.2.d)	0.4453284411081100

For this covariate:	**The following coefficient is used in the LAS calculation:**
Detailed Diagnosis: Pulmonary fibrosis, not idiopathic (Group D – see Policy 3.7.6.1.2.d)	-0.2091170018125500
Detailed Diagnosis: Sarcoidosis with PA mean pressure greater than 30 mm Hg (Group D – see Policy 3.7.6.1.2.d)	-0.4577749354638600
Detailed Diagnosis: Sarcoidosis with PA mean pressure of 30 mm Hg or less (Group A – see Policy 3.7.6.1.2.a)	0.9330846239906700
12. Forced vital capacity (FVC)	0.1829476350587400*(80 – FVC)/10 if FVC is less than 80% for Group D (see Policy 3.7.6.1.2.d) 0 if FVC is greater than or equal to 80% for Group D (see Policy 3.7.6.1.2.d) 0 for candidates in Groups A, B, and C (see Policy 3.7.6.1.2)
13. 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
14. Oxygen needed to maintain adequate oxygen saturation (80% or greater) at rest (L/min)	0.0213187586203456*O_2 for Group B (see Policy 3.7.6.1.2.b) 0.1188479817592500 for Groups A, C, and D (see Policy 3.7.6.1.2)

For this covariate:	**The following coefficient is used in the LAS calculation:**
15. PCO_2 (mm Hg): current	0.1104609835819100*PCO_2/10 if PCO_2 is at least 40 mm Hg (see Policy 3.7.6.1.3)
16. PCO_2 increase of at least 15% (see Policy 3.7.6.1.3)	0.2331149280428300 if PCO_2 increase is at least 15% (see Policy 3.7.6.1.3) 0 if PCO_2 increase is less than 15% (see Policy 3.7.6.1.3)
17. Pulmonary artery (PA) systolic pressure (10 mm Hg) at rest, prior to any exercise	0.4155116686114300*(PA systolic – 40)/10 for Group A if the PA systolic pressure is greater than 40 mm Hg (see Policy 3.7.6.1.2.a) 0 for Group A if the PA systolic pressure is 40 mm Hg or less (see Policy 3.7.6.1.2.a) 0.0462410402627318*PA systolic/10 for Groups B, C, and D (see Policy 3.7.6.1.2)
18. 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 1~~

~~Factors Used to Predict Risk of Death on the Lung Transplant Waitlist~~

~~1. Forced vital capacity (FVC)~~ ~~2. Pulmonary artery (PA) systolic pressure (Groups A, C, and D[1] — see 3.7.6.1.a)~~

~~3. O_2 required at rest (Groups A, C, and D[4] – see 3.7.6.1.a)~~
~~4. Age~~
~~5. Body mass index (BMI)~~
~~6. Diabetes~~
~~7. Functional Status~~
~~8. Six-minute walk distance~~
~~9. Continuous mechanical ventilation~~
~~10. Diagnosis~~
~~11. PCO_2 (see 3.7.6.1.b)~~
~~12. Bilirubin (current bilirubin – all gGroups; change in bilirubin – Group B; see 3.7.6.1.c)~~

Table 2

Factors Used in the Post-Transplant Survival Calculation: Covariates and their Coefficients

For this covariate:	**The following coefficient is used in the LAS calculation:**
1. Age (years)	0.0246579831271869*(age – 45) if greater than 45 years of age 0 if 45 years of age or younger
2. Creatinine (serum) at transplant (mg/dL)	0.0895569900508900*creatinine if at least 18 years of age (see Policy 3.7.6.1.5) 0 if less than 18 years of age

For this covariate:	**The following coefficient is used in the LAS calculation:**
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 (see Policy 3.7.6.1.5) 0 if increase in creatinine of 150% if the higher value determining this increase is less than 1 mg/dL (see Policy 3.7.6.1.5) 0 if increase in creatinine less than 150% or creatinine decreases (see Policy 3.7.6.1.5)
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 (see Policy 3.7.6.1.2.a for the diseases included in this group)	0
Diagnosis Group B (see Policy 3.7.6.1.2.b for the diseases included in this group)	0.6115547319209300
Diagnosis Group C (see Policy 3.7.6.1.2.c for the diseases included in this group)	0.3627014422464200

For this covariate:	The following coefficient is used in the LAS calculation:
Diagnosis Group D (see Policy 3.7.6.1.2.d for the diseases included in this group)	0.4641392063023200
7. Detailed diagnosis: Bronchiectasis (Group A – see Policy 3.7.6.1.2.a)	0.1889100379099400
Detailed diagnosis: Eisenmenger's syndrome (Group B – see Policy 3.7.6.1.2.b)	0.9146727886744700
Detailed diagnosis: Lymphangioleiomyomatosis (Group A – see Policy 3.7.6.1.2.a)	-1.5194416206749400
Detailed Diagnosis: Obliterative bronchiolitis (not-retransplant) (Group D – see Policy 3.7.6.1.2.d)	-1.2050508750702600
Detailed Diagnosis: Pulmonary fibrosis, not idiopathic (Group D – see Policy 3.7.6.1.2.d)	-0.0723596761367600
Detailed Diagnosis: Sarcoidosis with PA mean pressure greater than 30 mm Hg (Group D – see Policy 3.7.6.1.2.d)	-0.0437880049066331
Detailed Diagnosis: Sarcoidosis with PA mean pressure of 30 mm Hg or less (Group A – see Policy 3.7.6.1.2.a)	-0.1389363636019300

For this covariate:	**The following coefficient is used in the LAS calculation:**
8. Oxygen needed to maintain adequate oxygen saturation (80% or greater) at rest (L/min)	0.0747978926517300*O_2 for Group A (see Policy 3.7.6.1.2.a) 0.0164276945879309 for Groups B, C, and D (see Policy 3.7.6.1.2)
9. Functional Status	-0.1900086366785100 if no assistance needed with activities for daily living 0 if some or total assistance needed with activities for daily living
10. 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*(1200-6mw) 0 if six-minute-distance-walked is at least 1200 feet

~~**Table 2**~~

~~**Factors that Predict Survival after Lung Transplant**~~

~~1. FVC (Groups B and D – see 3.7.6.1.a)~~
~~2. PCW pressure ≥ 20 (Group D – see 3.7.6.1.a)~~
~~3. Continuous mechanical ventilation~~
~~4. Age~~
~~5. Serum Creatinine~~
~~6. Functional Status~~
~~7. Diagnosis~~

~~The calculations define the difference between transplant benefit and waitlist urgency: Raw Allocation Score = Transplant Benefit Measure – Waitlist Urgency Measure.~~

~~Raw allocation scores range from –730 days up to +365 days, and are normalized to a continuous scale from 0 – 100 to determine Lung Allocation Scores. The higher the score, the higher the priority for receiving lung offers. Lung Allocation Scores are calculated to sufficient decimal places to avoid assigning the same score to multiple candidates.~~

~~As an example, assume that a donor lung is available, and both Candidate X and Candidate Y are on the Waiting List. Taking into account all diagnostic and prognostic factors, Candidate X is expected to live 101.1 days during the following year without transplant. Also using available predictive factors, Candidate X is expected to live 286.3 days during the following year if transplanted today. On the other hand, Candidate Y is expected to live 69.2 days during the following year on the waitlist and 262.9 days post-transplant during the following year if transplanted today. Computationally, the proposed system would prioritize candidates based on the difference between each candidate's transplant benefit measure and the waitlist urgency as measured by the expected days of life lived during the next year.~~

~~Table 3~~

~~Example Illustrating the LAS Calculation~~

~~Parts of the Score Equation~~	~~Candidate X~~	~~Candidate Y~~
~~a. Post-transplant survival (days)~~	~~286.3~~	~~262.9~~
~~b. Waitlist survival (days)~~	~~101.1~~	~~69.2~~
~~c. Transplant benefit (a-b)~~	~~185.2~~	~~193.7~~
~~d. Raw allocation score (c-b)~~	~~84.1~~	~~124.5~~
~~e. **Lung Allocation Score**~~	**~~74.3~~**	**~~78.0~~**

~~In the example here, Candidate X's raw allocation score would be 84.1 and Candidate Y's raw allocation score would be 124.5.~~

~~Similar to the mathematical conversion of temperature from Fahrenheit to Centigrade, once the raw score is computed, it will be normalized to a continuous scale from 0-100 for easier interpretation by candidates and caregivers (see formula above). A higher score on this scale indicates a higher priority for a lung~~

~~offer. Conversely, a lower score on this scale indicates a lower priority for organ offers. Therefore, in the example above, Candidate X's raw allocation score of 84.1 normalizes to a Lung Allocation Score of 74.3. Candidate Y's raw score of 124.5 normalizes to a Lung Allocation Score of 78.0. As in the example of raw allocation scores, Candidate Y has a higher Lung Allocation Score and will therefore receive a higher priority for a lung offer than Candidate X.~~

Tables 3 and 4 provide the baseline waiting list and post-transplant survival probabilities, which are used in the LAS calculation.

Table 3: Baseline Waiting List Survival ($S_{WL}(t)$) 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
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 3: 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
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 4: 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
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 4: 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								

3.7.6.1.2 Lung Disease Diagnosis Group Classification in the Lung Allocation Score (LAS)

The LAS calculation includes four diagnosis groups: A, B, C, and D. The diagnoses that comprise each group are:

a. Group A
- 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

b. Group B
- Congenital malformation
- CREST – pulmonary hypertension
- Eisenmenger's syndrome: atrial septal defect
- 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

c. Group C
- Common variable immune deficiency
- Cystic fibrosis
- Fibrocavitary lung disease
- Hypogammaglobulinemia
- Schwachman-Diamond syndrome

d. Group D
- ABCA3 transporter mutation
- Alveolar proteinosis
- Amyloidosis
- Acute respiratory distress syndrome or pneumonia
- Bronchoalveolar 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 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
  - Nonspecific interstitial pneumonia
  - Lymphocytic interstitial pneumonia
  - 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 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

~~a. Lung Disease Diagnosis Groups~~

~~The following are some of the diagnoses included in groups A, B, C, and D.~~

~~(i) *Group A*~~
~~Includes candidates with obstructive lung disease, including without limitation, chronic obstructive pulmonary disease (COPD), alpha-1-antitrypsin deficiency, emphysema, lymphangioleiomyomatosis, bronchiectasis, and sarcoidosis with mean pulmonary artery (PA) pressure ≤ 30 mmHg~~

~~(ii) *Group B*~~
~~Includes candidates with pulmonary vascular disease, including without limitation, primary pulmonary hypertension (PPH), Eisenmenger's syndrome, and other uncommon pulmonary vascular diseases~~

~~(iii) *Group C*~~
~~Includes, without limitation, candidates with cystic fibrosis (CF) and immunodeficiency disorders such as hypogammaglobulinemia~~

~~(iv) *Group D*~~
~~Includes candidates with restrictive lung diseases, including without limitation, idiopathic pulmonary fibrosis (IPF), pulmonary fibrosis (other causes), sarcoidosis with mean PA pressure > 30 mmHg, and obliterative bronchiolitis (non-retransplant)~~

3.7.6.1.3 PCO_2 in the Lung Allocation Score (LAS)

~~b. PCO_2 in the Lung Allocation Score~~

UNet[SM] will use two measures of PCO_2 in a candidate's lung allocation score calculation: current PCO_2, and change in PCO_2. There are two types of PCO_2 change calculations: "threshold change" and "threshold change maintenance." The following explanations (a-f) ~~(i-vi)~~ and illustrations (Figures 1-3) detail how UNet[SM] uses PCO_2 in the lung allocation score.

a.~~(i)~~*Use of Arterial, Venous, or Capillary PCO_2 Values*

In UNet[SM], a center may enter a PCO_2 value from an arterial, venous, or capillary blood gas test. UNet[SM] will convert a venous or capillary value to estimate an arterial value as follows:

- a capillary value will equal an arterial value; and,
- UNet[SM] will subtract 6 mmHg from a venous value to equal an arterial value.

In the lung allocation score calculation, UNet[SM] will use the PCO_2 value with the most recent test date, regardless of the blood gas type. Exception: if an arterial value and either a venous or capillary value have the same test date, UNet[SM] will use the arterial value in the lung allocation score calculation.

b.~~(ii)~~*Definition of Current PCO_2*

Current PCO_2 is the PCO_2 value with the most recent test date entered in UNet[SM].

c.~~(iii)~~*Expiration of Current PCO_2 Value*

UNet[SM] will evaluate a current PCO_2 value as expired according to Policy 3.7.6.3.~~2.~~

d.~~(iv)~~*Use of Normal Clinical Value for Current PCO_2*

The normal clinical value of PCO_2 is 40 mmHg. UNet[SM] will substitute this normal clinical value in the lung allocation score calculation when the value of current PCO_2 is less than 40 mmHg, missing, or expired.

e.~~(v)~~*PCO_2 Values Used in the Change Calculations*

There are two types of PCO_2 change calculations: threshold change and threshold change maintenance.

The threshold change calculation evaluates whether the PCO_2 change is 15% or higher. In this calculation, UNet[SM] will use highest and lowest values of PCO_2. The test date of the lowest value must be earlier than the test date of the highest value. Test dates of these highest and lowest values cannot be more than 6 months apart. If necessary, UNet[SM] will use an expired lowest value, but not an expired highest value. If a value is less than 40 mmHg, UNet[SM] will substitute the normal clinical value of 40 mmHg before calculating change. The equation for threshold change is: ~~**[(highest PCO_2 – lowest PCO_2)/lowest PCO_2]**~~

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The threshold change maintenance calculation occurs *after* the candidate receives the impact from threshold change in the lung allocation score. This maintenance calculation determines the candidate's eligibility for retaining the impact from threshold change in the lung allocation score. To maintain the impact from threshold change in the lung allocation score, the current PCO_2 value must be at least 15% higher than the lowest value used in the threshold change calculation. The equation for threshold change maintenance is: ~~**[(current PCO_2 – lowest PCO_2)/lowest PCO_2]**~~.

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UNet[SM] will perform the threshold change maintenance calculation either when the current PCO_2 value expires (Policy 3.7.6.3~~.2~~) or a new current PCO_2 value is entered. For this calculation, the lowest and highest values that were used in the threshold change calculation can be expired. The current PCO_2 value can be the highest one that was used in the threshold change calculation. If a current PCO_2 value expires, the candidate's lung allocation score will lose the impact from threshold change. The reason for this loss is that when a current PCO_2 value expires, UNet[SM] will substitute that expired value with the normal clinical value of 40 mmHg. This normal value, therefore, cannot be 15% *higher* than the lowest value in the threshold change calculation.

If a center enters a new current PCO_2 value for a candidate who has lost the impact from threshold change, UNet[SM] 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 threshold change calculation, UNet[SM] will *reapply* the impact from threshold change to the candidate's lung allocation score.

f.~~(vi)~~ *Impact of PCO_2 Threshold Change in the Lung Allocation Score*

A change in PCO_2 that is 15% or higher, or threshold change, will impact a candidate's lung allocation score. The candidate will not lose the lung allocation score impact from threshold change provided that the current PCO_2 is at least 15% higher than the lowest value used in the threshold change calculation.

Figure 1
Use of Current PCO_2 in the Lung Allocation Score

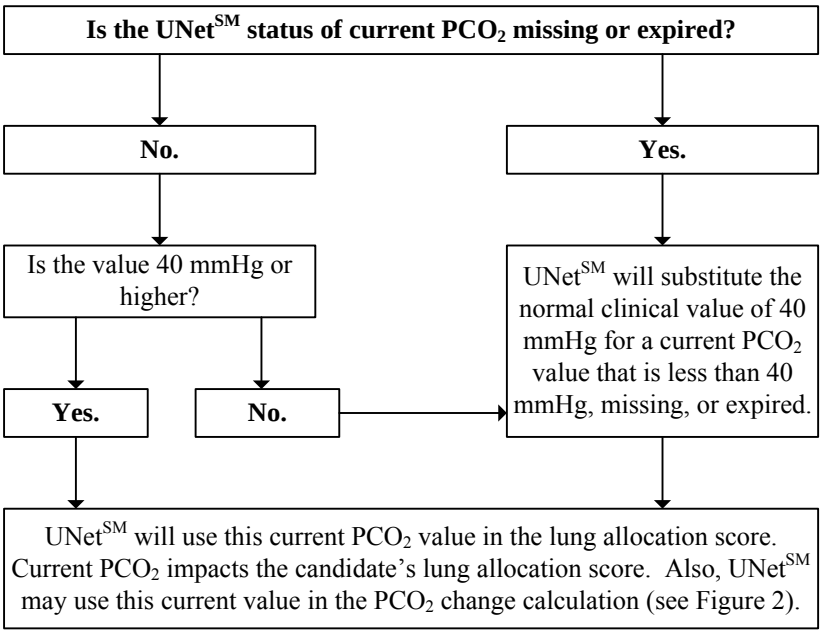


Figure 2
PCO2 Threshold Change Calculation

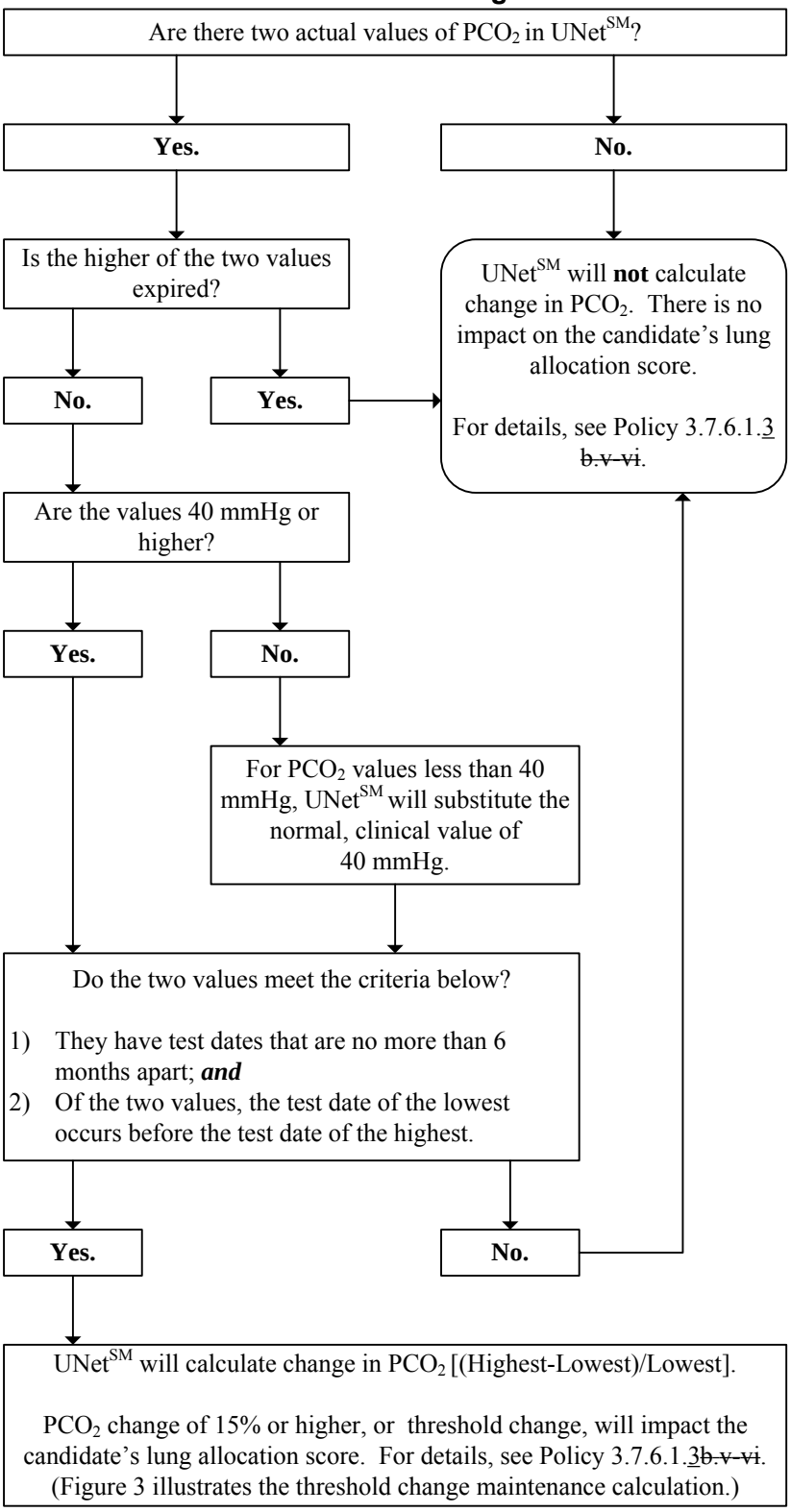
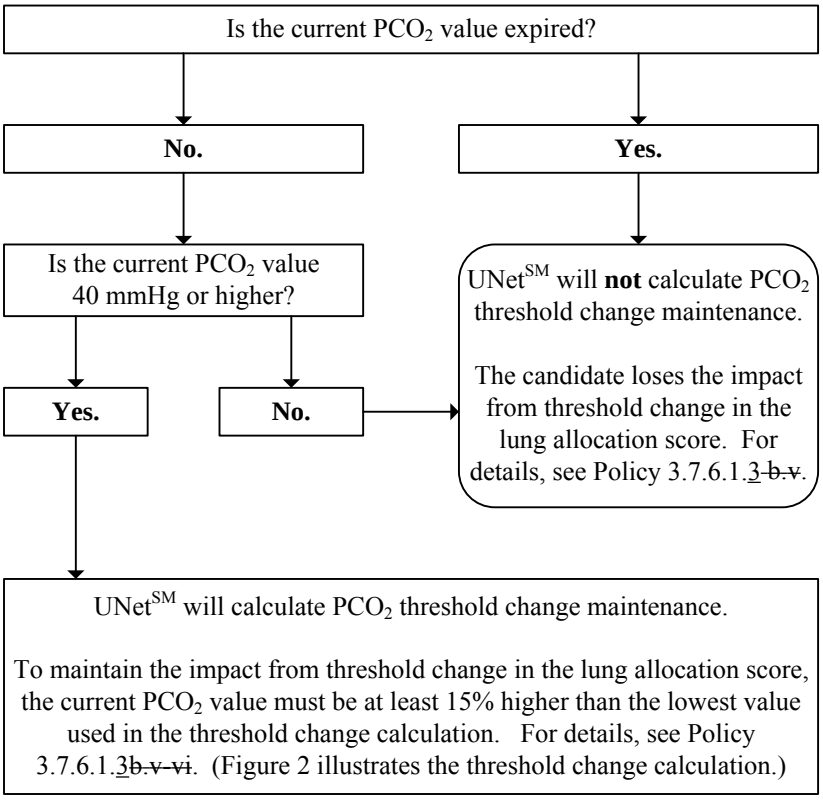


Figure 3
PCO_2 Threshold Change Maintenance Calculation



3.7.6.1.4 Bilirubin in the Lung Allocation Score (LAS)

~~*c. Bilirubin in the Lung Allocation Score*~~

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

a. ~~*(i)*~~ *Definition of Current Bilirubin*
Current bilirubin is the total bilirubin value with the most recent test date and time entered in UNet^{SM}. UNet^{SM} will include in the lung allocation score calculation a current bilirubin value that is at least 1.0 mg/dL.

b. ~~*(ii)*~~*Expiration of Current Bilirubin Value*
UNet^{SM} will evaluate a current bilirubin value as expired according to Policy 3.7.6.3~~.2.~~

c. ~~*(iii)*~~*Use of Normal Clinical Value for Current Bilirubin*
The normal clinical value of current bilirubin is 0.7 mg/dL.

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

d. ~~(iv)~~*Bilirubin Values Used in the Change Calculations (Group B Only)*
There are two types of bilirubin change calculations: threshold change and threshold change maintenance.

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

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

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UNet^{SM} will perform the threshold change maintenance calculation either when the current bilirubin value expires (Policy 3.7.6.3~~.2~~) or a new current bilirubin value is entered. For this calculation, the lowest and highest values that were used in the threshold change calculation can be expired. The current bilirubin value can be the highest one that was used in the threshold change calculation. If a current bilirubin value expires, the candidate's lung allocation score will lose the impact from threshold change. The reason for this loss is that when a current bilirubin value expires, UNet^{SM} will substitute that expired value with the normal clinical value of 0.7 mg/dL.

This normal value, therefore, cannot be 50% higher than the lowest value in the threshold change calculation.

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

e. ~~(v)~~*Impact of Bilirubin Threshold Change in the Lung Allocation Score (Group B only)*
A change in bilirubin that is 50% or higher, or threshold change, will impact a candidate's lung allocation score. The candidate will not lose the lung allocation score impact from threshold change provided that the current bilirubin is at least 50% higher than the lowest value used in the threshold change calculation.

3.7.6.1.5 Creatinine in the Lung Allocation Score (LAS)

The LAS calculation uses two measures of creatinine: current creatinine and increase in creatinine.

a. Current Creatinine
Current creatinine is the serum creatinine value from the most recent test date and time reported to the OPTN Contractor. The LAS calculation only uses current creatinine for candidates who are at least 18 years of age.

b. Increase in Creatinine
An increase in creatinine will influence a candidate's LAS only if it is at least 150%. The Increase-In-Creatinine calculation uses the highest and lowest values of creatinine. For this variable to impact a candidate's LAS, the test date of the lowest value must be earlier than the test date of the highest value. The highest value must be at least 1.0 mg/dL. Test dates of the highest and lowest values cannot be more than 6 months apart. The Increase-In-Creatinine calculation can use an expired lowest value, but not an expired highest value. The equation for this Increase-In-Creatinine calculation is:

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If a candidate's LAS is influenced by an increase in creatinine, then the LAS calculation will assess whether to maintain that influence. To maintain the influence of the increase in creatinine, the candidate's current creatinine value must be at least 150% higher than the lowest value used in the Increase-

In-Creatinine calculation. The equation for this maintenance calculation is:

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

3.7.6.3 Reporting Data for Candidates Who Receive Lung Allocation Scores (LAS)

When registering a candidate who is at least 12 years of age for lung transplantation, transplant programs must report to the OPTN Contractor clinical data corresponding to the covariates shown in Tables 1 and 2 in Policy 3.7.6.1.1. Data reported upon registering the candidate must be no more than six months older than the registration date. The transplant program must maintain source documentation for the reported data in the candidate's chart.

Except as noted in Policy 3.7.6.3.1, transplant programs must report to the OPTN Contractor each element of a candidate's clinical data at every six-month anniversary date. A six-month anniversary date first occurs six months after the date of initial registration, then every six months after. A covariate's value expires if the covariate's test date is six-months older than the most recent six-month anniversary date. Actual values or estimated values for pulmonary pressures are valid until the transplant program submits new actual values or new estimated values to the OPTN Contractor according to Policy 3.7.6.4.

Transplant programs may determine how often to update clinical data that must be obtained through heart catheterization. However, if a transplant program performs a heart catheterization on the candidate during any six month interval, then it must report the relevant results to the OPTN Contractor. The transplant program must maintain source documentation of all heart catheterization test results in the candidate's chart.

If values for certain covariates are missing, expired, or below a threshold as defined by Table 5, 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 5 lists the normal and least beneficial values that will be substituted.

Table 5
Data Substituted for Missing, Expired, or Below Threshold Actual Values in Calculating the LAS

If h s c v r e 's v lue s missing, expired, or below the threshold value:	Then the LAS calculation will use this substituted value:
Bilirubin: current	1.0 mg/dL if the actual value is missing, expired, or less than 1.0 mg/dL
Body mass index (BMI)	100 kg/m^2 if the actual value is missing or expired
Cardiac index	3.0 L/min/m^2 if the actual value is missing
Central venous pressure (CVP)	5 mm Hg if the actual value is missing or less than 5 mm Hg
Continuous mechanical ventilation	No mechanical ventilation in the waiting list model if the actual value is missing or expired Continuous mechanical ventilation in the post-transplant model if the actual value is missing or expired
Creatinine: serum	0.1 mg/dL in the waiting list model if the actual value is missing or expired 40 mg/dL in the post-transplant model for candidates at least 18 years of age if the actual value is missing or expired 0 mg/dL in the post-transplant model for candidates less than 18 years of age if the actual value is missing or expired
Diabetes	No diabetes if the actual value is missing or expired
Forced vital capacity (FVC)	150% for Group D if the actual value is missing or expired
Functional status	No assistance needed in the waiting list model if the actual value is missing or expired Some or total assistance needed in the post-transplant model if the actual value is missing or expired

If h s c v r e 's v lue s missing, expired, or below the threshold value:	**Then the LAS calculation will use this substituted value:**
Oxygen needed at rest	No supplemental oxygen needed in the waiting list model if the actual value is missing or expired 26.33 L/min in the post-transplant model if the actual value is missing or expired
PCO_2: current	40 mm Hg if the actual value is missing, expired, or less than 40 mm Hg
Pulmonary artery (PA) systolic pressure	20 mm Hg if the actual value is missing or less than 20 mm Hg
Six minute walk distance	4000 feet in the waiting list urgency model if the actual value is missing or expired 0 feet in the post-transplant survival model if the actual value is missing or expired

Programs are permitted to enter a medically reasonable estimated value if a test needed to obtain an actual value for a variable cannot be performed due to the medical condition of a candidate. Before entering such estimated values, programs must receive approval from the Lung Review Board, which will determine whether the estimated values are appropriate. Estimated values will remain valid until those values are either updated with an actual value, or a new estimated value is entered according to Policy 3.7.6.4.

~~**3.7.6.3 Candidate Variables in UNet℠**. Entry into UNet℠ of candidate clinical data corresponding to the variables shown in Tables 1 and 2 in Policy 3.7.6.1 is required when listing a candidate for lung transplantation. Diagnosis, birth date (used to calculate age), height and weight (used to calculate BMI) must be entered for a candidate to be added to the waitlist. Candidates will receive a Lung Allocation Score of zero if the Functional Status class or assisted ventilation variable is missing a value at any time.~~

~~If values for pulmonary artery systolic pressure, pulmonary capillary wedge pressure, or pulmonary artery mean pressure are missing, then a default value will be assigned that represents a normal clinical value for these missing pulmonary pressure variables. A default value of 20 mm Hg will be assigned for missing pulmonary artery systolic pressure, a default value of 5 mm Hg will be assigned for missing pulmonary capillary wedge pressure, and a default value of 15 mm Hg will be assigned for~~

~~missing pulmonary artery mean pressure. The default values for pulmonary pressures will also be used in the calculation of Lung Allocation Scores for those candidates whose actual values are provided, but are lower than the default value. If any other candidate variables are missing, then a default value, which will be the value that results in the lowest contribution to the Lung Allocation Score for that variable field ("Least Beneficial Value"), will be selected for the candidate.~~

~~Programs are permitted to enter a value deemed medically reasonable in the event a test needed to obtain an actual value for a variable cannot be performed due to the medical condition of a specific candidate. Prior to entering such estimated values, programs must request review and approval from the Lung Review Board to determine whether the estimated values are appropriate. Estimated values will remain valid until those values are either updated with an actual value or a new estimated value is entered pursuant to Policy 3.7.6.4.~~

3.7.6.3.1 Reporting Data for Candidates with LASs of 50 or Greater

A program must report three key variables to the OPTN Contractor no more than 14 days after a candidate's LAS becomes 50 or greater:

a. Assisted ventilation,
b. Supplemental oxygen
c. Current PCO_2.

If a program does not perform a PCO_2 test in that time, then it does not need to report this updated value to the OPTN Contractor. While the candidate's LAS remains 50 or greater, the program must continue to assess and report any observed change in the three clinical variables every 14 days.

The transplant program must maintain source documentation for each assessment in the candidate's chart.

~~**3.7.6.3.1 Updating Candidate Variables.** Programs may update their candidates' clinical data at any time they believe a change in candidate medical condition warrants such modification. Programs must update each element of a candidate's clinical data in UNet℠ every six months, except those data obtainable only by heart catheterization. Also, as described further below, programs must update three clinical variables more frequently than six months for candidates with LAS of 50 or higher.~~

~~UNet℠ defines a "six-month anniversary date," which first occurs six months from the date of initial listing, then every six months thereafter. UNet℠ will consider a variable to~~

~~be expired if the variable's test date is six -months older than the most recent anniversary date.~~

~~If the test dates of the Functional Status or assisted ventilation variable expire, then the candidate's Lung Allocation Score will be zero. If any other candidate variable expires - excluding pulmonary artery systolic pressure, pulmonary capillary wedge pressure, or pulmonary artery mean pressure - then the candidate will receive the Least Beneficial Value for that variable. The transplant center determines the frequency of updating those candidate variables that are required to be obtained by heart catheterization (pulmonary artery pressures and pulmonary capillary wedge pressure) If a transplant center repeats a heart catheterization test, it must report the results in UNet℠.~~

~~UNet℠ will consider actual values or estimated values for pulmonary pressures to be valid until the transplant center updates them with new actual values or new estimated values pursuant to Policy 3.7.6.4.~~

~~A program must update three key variables in UNet℠ no more than 14 days after a candidate's LAS becomes greater than 50: assisted ventilation, supplemental oxygen, and current PCO_2. If a program does not perform a PCO_2 test in that time, then it does not need to update this value in UNet℠. While the candidate's score remains 50 or higher, a program must continue to assess and report any observed change in the three clinical variables no less frequently than 14 days from the date of the previous assessment.~~

3.7.9.2 Waiting Time Accrual for Lung Candidates at Least 12 Years of Age Following Implementation of Lung Allocation Score (LAS) System
~~Waiting time accrued by lung candidates age 12 and older at the time of implementation of the Lung Allocation Score described in Policy 3.7.6 and thereafter will be used to determine priority in lung allocation among candidates with Lung Allocation Scores of zero. In the event that multiple candidates receive identical Lung Allocation Scores greater than zero, whether computed Lung Allocation Scores or assigned Lung Allocation Scores that have been approved by the Lung Review Board pursuant to an exceptional case request, and have identical priority for a lung offer considering all other allocation factors, then priority among those candidates will be determined by their total active waiting time accrued.~~

In the event that multiple candidates receive identical computed Lung Allocation Scores greater than zero, and have identical priority for a lung offer considering all other allocation factors, then priority among those candidates will be determined by the earliest date and time of each

candidate's most recent update in UNet^{SM} by the member, of variables used in calculation of the Lung Allocation Score. (For example, if Candidate A and Candidate B have an identical Lung Allocation Score and identical priority for a lung offer, and Candidate A's data variables were most recently updated by the transplant center on May 1, 2005, and Candidate B's data variables were most recently updated by the transplant center on June 1, 2005, then Candidate A would receive higher priority for the lung offer because his most recent data update by the transplant center occurred first and the same set of data variables has been used to calculate Candidate A's Lung Allocation Score for the longest amount of time.)

In the event that multiple candidates receive identical assigned Lung Allocation Scores pursuant to an exceptional case request, and have identical priority for a lung offer considering all other allocation factors, then priority among those candidates will be determined by the earliest date and time that each candidate's most recent approval of that Lung Allocation Score by the Lung Review Board was entered in UNet^{SM} (For example, if Candidate X and Candidate Y have identical Lung Allocation Scores assigned to them by the Lung Review Board and identical priority for a lung offer, and the approval for Candidate X's score was entered in UNet^{SM} on June 1, 2005, and the approval for Candidate Y's score was entered in UNet^{SM} on July 1, 2005, then Candidate X would receive higher priority for the lung offer because his most recent Lung Allocation Score was approved and entered in UNet^{SM} first.)

~~Candidates that receive a Lung Allocation Score of zero due to missing or expired candidate variables as described in Policy 3.7.6.3 will be screened from the lung match following notification of the listing center, and will not receive isolated lung offers. Upon the entry or update of previously missing or expired candidate variables as described in Policy 3.7.6.3, those candidates will appear on the lung match.~~

Candidates awaiting a lung transplant on the Waiting List at inactive status will be subject to the same requirements for updating candidates' clinical data as indicated in Policy 3.7.6.3 and Policy 3.7.6.4 and will not accrue any waiting time while at inactive status.

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