

IMPORTANT POLICY NOTICE

To: Transplant Professionals

From: Brian M. Shepard
Assistant Executive Director for Contract Operations

RE: Summary of actions taken at the OPTN/UNOS Board of Directors Meeting
—November 14-15, 2011

Date: December 15, 2011

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

UNOS will implement the majority of these changes on February 1st, 2012, which is different than the usual standard. Now, you can generally expect policy and bylaw changes from:

- June Board meetings to be implemented September 1st of that year
- November Board meetings to be implemented February 1st of the following year.

UNOS is introducing this new standard to add consistency and simplicity to the implementation of policy and bylaw changes that do not require programming. In addition, members will now have more time to prepare for impending changes. Urgent actions by the Board or modifications with special circumstances will be exceptions to this standard.

This policy notice, and those notices reviewing changes from previous Board meetings, can found at optn.transplant.hrsa.gov (click on “News,” and then select “View all Policy Notices”). Thank you for your careful review. If you have any questions about a particular Board action, please contact your regional administrator at (804) 782-4800.

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Modifications to Travel Expense and Reimbursement Policy

Sponsoring Committee: Finance Committee

Policy Affected: 8.0 (Travel Expense and Reimbursement Policy)

Distributed for Public Comment: No

Effective Date: February 1, 2012

Problem Statement:
Policy 8.0, which governs how OPTN funds may be used to reimburse Board and committee members and UNOS staff travel expenses, was outdated and unclear.

Changes:
The Board of Directors adopted modifications to Policy 8.0 that updated and clarified policy language to reflect current practices in travel expense and reimbursements.

Required Action:
Members who travel on behalf of the OPTN, and who may submit reimbursement requests to the OPTN, need to familiarize themselves with the new policy language.

Encouraging Organ Procurement Organizations to Provide Non-Contrast CT Scan if Requested by Transplant Programs, and Modifications to Policies 3.7.12.3 (Essential Information for Lung Offers) and 3.7.12.4 (Desirable Information for Lung Offers) for Currency and Readability

Sponsoring Committee: Thoracic Organ Transplantation Committee

Policies Affected: 3.7.12.3 (Essential Information for Lung Offers) and 3.7.12.4 (Desirable Information for Lung Offers)

Distributed for Public Comment: March 2011

Amended After Public Comment: No

Effective Date: February 1, 2012

Problem Statement:
Deceased donor lungs may have emphysema, contusions, infiltrates, or malignant nodules, which may not be visible on a chest X-ray. Computed tomography (CT) scans are not always available from organ procurement organizations (OPO). Additionally, some policy language needed editorial modifications.

Changes:
Policy 3.7.12.4 encourages OPOs to provide CT scans of deceased donor lungs when the transplant programs request them. Additional modifications include non-substantive edits to language in policies 3.7.12.3 and 3.7.12.4.

Recommended Action:
If a transplant program asks for a CT scan of an offered deceased donor lung, then the OPO should provide the result of this test.

Requiring Updates of Certain Clinical Factors Every 14 Days for Lung Transplant Candidates with Lung Allocation Scores of at Least 50, and to Modify Policy 3.7.6.3 (Candidate Variables in UNetSM) for Currency and Readability

Sponsoring Committee: Thoracic Organ Transplantation Committee

Policy Affected: 3.7.6.3 (Candidate Variables in UNetSM)

Distributed for Public Comment: March 2011

Amended After Public Comment: No

Effective Date: February 1, 2012

Problem Statement:
Candidates with Lung Allocation Scores (LASs) of 50 or higher (high-LAS candidates) represent a sicker waiting list population whose medical management needs could require therapeutic interventions that affect their LASs. It is possible that some high-LAS candidates receive transplants due to LAS that do not reflect their true waiting list urgencies. Without requiring more frequent updates in UNet SM , changes in the candidate's medical condition/urgency are not known.
Changes:
Policy will require transplant programs to assess and report in UNet SM the date of the assessment and related clinical value of the following variables for high-LAS candidates: need for assisted ventilation; supplemental oxygen (circumstances and amount); and PCO ₂ . This assessment and reporting must occur within 14 days of a candidate's LAS becoming 50 or higher. As long as a candidate's LAS remains 50 or higher, the transplant program must repeat the assessment and reporting every 14 days from the date of the last assessment. Policy does not require transplant programs to perform a new ABG to obtain a new PCO ₂ value for high-LAS candidates during this 14-day time period; however, if a new ABG is performed, the transplant program must report the new PCO ₂ value and the test date in UNet SM in the time period specified in policy.
Required Action:
<p>For each high-LAS candidate, a transplant program must:</p> <ul style="list-style-type: none">• Monitor its candidates' LAS• Assess the need for assisted ventilation, supplemental oxygen (circumstances and amount), and PCO₂ within 14 days of a candidate's LAS becoming 50 or higher<ul style="list-style-type: none">○ Report the result and date of the blood gas test only if a new PCO₂ value is obtained during this time period• Repeat the assessment and reporting of the three variables no more than 14 days from the date of the last assessment• Resume the six-month data update schedule if the LASs become less than 50 (Policy 3.7.6.3.2 (Updating Candidate Variables)) <p>Transplant programs should review the guidance document for monitoring high-LAS candidates, which can be found at http://communication.unos.org/.</p>

Extending for One Year the Interim Policy for Outpatient Adult Heart Transplant
Candidates Implanted with Total Artificial Hearts

Sponsoring Committee: Thoracic Organ Transplantation Committee

Policy Affected: 3.7.3 (Adult Candidate Status)

Distributed for Public Comment: March 2011

Amended After Public Comment: No

Effective Date: November 15, 2011

Problem Statement:

The interim policy for outpatient candidates implanted with total artificial hearts expires on December 1, 2011. This expiration results in the classification of these candidates as Status 1B. Status 1B is an inadequate medical urgency classification for this new patient population.

Changes:

The interim policy for outpatient candidates implanted with total artificial hearts will now expire on December 1, 2012.
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Required Action:

Transplant programs may list outpatient candidates implanted with total artificial hearts as Status 1A for 30 days. Transplant programs should review the instructions to list outpatient candidates implanted with total artificial hearts as Status 1A and 1B, which can be found at http://communication.unos.org/ .
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Modifications to Policy 3.6.4.4 (Liver Transplant Candidates with Hepatocellular Carcinoma (HCC)) that more clearly define the imaging characteristics of HCC

Sponsoring Committee: Liver and Intestinal Organ Transplantation Committee

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

Distributed for Public Comment: March 2011

Amended After Public Comment: Yes

Effective Date: Pending programming in UNetSM

Problem Statement:
Patients awaiting a liver transplant who are diagnosed with hepatocellular carcinoma (HCC) are eligible for additional priority through MELD/PELD exceptions. HCC exceptions are based on diagnostic criteria that rely on imaging characteristics. The policy in place since 2002 includes limited imaging criteria, allowing the potential for inconsistent awarding of additional priority for HCC.

Changes:
HCC lesions will be classified more precisely according to newly-defined imaging criteria. Only Class 5 lesions will be potentially eligible for automatic upgrades. Please refer to the approved policy language for the specifics of the new imaging criteria.

Required Action:
Liver transplant center staff should familiarize themselves with: <ul style="list-style-type: none">• the new criteria for eligibility• criteria for the initial assessment for listing• requirements for imaging, extensions, and appeals for candidates with HCC UNOS will send a system notice when these changes have been programmed in UNet SM .

Modifications to Policy 3.6 (Adult Donor Liver Allocation Algorithm) that Provide
Broader Access to Deceased Donor Organs for Candidates Awaiting a Combined
Liver-Intestine Transplant

Sponsoring Committee: Liver and Intestinal Organ Transplantation Committee

Policy Affected: 3.6 (Adult Donor Liver Allocation Algorithm)

Distributed for Public Comment: March 2011

Amended After Public Comment: No

Effective Date: Pending programming in UNetSM

Problem Statement:
Waiting list death rates in adult candidates awaiting a combined liver-intestine transplant are nearly three times higher than those waiting for a liver alone.

Changes:
The adult donor liver algorithm will be modified so that livers would be offered to combined liver-intestine candidates <i>nationally</i> if no Regional Status 1A/1B candidates, or local candidates with a MELD/PELD score of 29 or higher, accept the liver.

Required Action:
UNOS will send a system notice when these changes have been programmed in UNet SM .

Committee-Sponsored Alternative Allocation System for Segmental Liver Allocation

Sponsoring Committee: Liver and Intestinal Organ Transplantation Committee

Policy Affected: 3.6.12 (Committee-sponsored Alternative Allocation System (CAS) for Segmental Liver Transplantation)

Distributed for Public Comment: March 2011

Amended After Public Comment: No

Effective Date: Pending receipt and the Liver and Intestinal Organ Transplantation Committee's approval of a completed CAS application

Problem Statement:
Segmental liver transplantation expands the donor pool by allowing one donor liver to be transplanted into two recipients. The current national policy for segmental liver transplantation provides little incentive for use of this procedure.

Changes:
If an adult candidate at a center participating in this CAS is primarily offered a liver (known as the index patient) and has been determined to be suitable for a segmental liver transplant, the candidate's transplant center may transplant the right lobe into the index patient. The center may then transplant the left lobe/segment into a medically suitable listed patient at that institution or an affiliated pediatric institution (if applicable), in order of the match run.

Required Action:
OPOs and Regions that wish to participate in this CAS must submit an application to UNOS. Please contact your Regional Administrator for the application and further information.

Elimination of the Requirement that Pediatric Liver Candidates Must be Located in a Hospital's Intensive Care Unit to Qualify as Status 1A or Status 1B

Sponsoring Committees: Pediatric and Liver & Intestinal Organ Transplantation Committees

Policy Affected: 3.6.4.2 (Pediatric Candidate Status)

Distributed for Public Comment: March 2011

Amended After Public Comment: No

Effective Date: February 1, 2012

Problem Statement:

The current requirement that a pediatric liver candidate must be located in the hospital's intensive care unit (ICU) to qualify for Status 1A and Status 1B uses location as a surrogate for severity of illness. Since the criteria for admission to an ICU varies from institution to institution across the country, the use of this surrogate creates inequality in pediatric Status 1A and 1B listings.
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Changes:

The requirement that a pediatric liver candidate listed as Status 1A or Status 1B must be located in the in the hospital's ICU has been eliminated. All other pediatric Status 1A and Status 1B qualifying criteria remain unchanged.

Required Action:

If a candidate meets all of the requirements of any criterion for pediatric liver Status 1A or 1B (Policy 3.6.4.2, i-vi) but is not located in the hospital's ICU, the transplant center may list that candidate as a "special case" Status 1A or 1B. In the narrative for these special cases, transplant centers will be expected to explain which Status 1A or 1B criterion the candidate meets, that the candidate is not in the ICU, and any other pertinent information about the candidate's current medical condition. The Review Subcommittee of the Liver & Intestinal Organ Transplantation Committee will consider all of these properly documented cases as appropriate.

This will be an interim solution until these changes are programmed in UNet SM . UNOS will send a system notice when these policy modifications have been programmed and this listing process will change.

Policy Modifications to List All Non-Metastatic Hepatoblastoma Pediatric Liver Candidates as Status 1B

Sponsoring Committees: Pediatric and Liver & Intestinal Organ Transplantation Committees

Policies Affected: 3.6.4.2 (Pediatric Candidate Status) and 3.6.4.4.1 (Pediatric Liver Transplant Candidates with Hepatoblastoma)

Distributed for Public Comment: March 2011

Amended After Public Comment: Yes

Effective Date: February 1, 2012

Problem Statement:
The sponsoring committees believed that current policy pertaining to non-metastatic hepatoblastoma candidates could be modified to allow for more optimal timing of related therapies in the same patients, without harming other liver candidates.

Changes:
Liver candidates with non-metastatic hepatoblastoma, proven by a biopsy, may be immediately listed as Status 1B. The current requirement that these candidates be listed at a MELD/PELD score of 30 for 30 days prior to being upgraded to Status 1B has been eliminated.

Required Action:
Transplant centers may list non-metastatic hepatoblastoma candidates as a Status 1B “special case” immediately upon listing. The clinical narrative that corresponds to this listing should clearly explain that the candidate has a non-metastatic hepatoblastoma, that there is a biopsy to prove this, and the date of the biopsy. All Status 1B special cases that are properly documented for candidates with hepatoblastoma will be considered appropriate by the Review Subcommittee of the Liver & Intestinal Organ Transplantation Committee.
This will be an interim solution until these changes are programmed in UNet SM . UNOS will send a system notice when these changes have been programmed, and when this process will change.

Modified Policies for the Packaging, Labeling, and Shipment of Living Donor
Organs, Vessels, and Tissue Typing Materials

Sponsoring Committee: Living Donor Committee

Policy Affected: 12.7 (Responsibility for Transport of Living Donor Organs.)

Distributed for Public Comment: March 2011

Amended After Public Comment: Yes

Effective Date: February 1, 2012

Problem Statement:
Requirements in OPTN policy for the packaging, labeling, and shipment of living donor organs are less stringent than those requirements for the packaging, labeling, and shipment of deceased donor organs.

Changes:
The OPTN/UNOS Board of Directors adopted policy modifications that will, to the extent possible, align the requirements for the packaging, labeling, and shipment of all organs. Changes to the packaging, labeling, and shipping requirements for living donor organs are extensive, and include the use of new labels specific to living donor organs. Please refer to the approved policy language to review the new requirements in detail.

Required Action:
Living donor transplant programs will need to develop and implement procedures to comply with new requirements for packaging, labeling, and shipping living donor organs. Members will be able to obtain the new required living donor organ labels through the UNOS website at the UNOS Store beginning in January.
Although not required, members should also be aware that UNOS will be offering a training session which will review these new policies in a session entitled "Packaging and Labeling of Organs, Vessels and Tissue Typing Materials." If interested, additional information can be found here: http://communication.unos.org/2011/11/next-live-unos-webcast-scheduled-for-january-11-2012/ .

Requirements to Perform a Second ABO Subtyping Test When a Donor is Identified as non-A₁ or non-A₁B

Sponsoring Committee: Operations and Safety Committee

Bylaw/Policies Affected: UNOS Bylaws, Appendix B, Attachment IIA, Section I (ABO Blood Group Determination) and OPTN/UNOS Policies 3.1.2 (Transplant Center), 3.1.13 (Definition of Directed Donation), 3.2.4 (Match System Access), 3.5.9.1 (Essential Information for Kidney Offers), 3.6.2 (Blood Type Similarity Stratification/Points), 3.6.9.1 (Essential Information Category), 3.7.12.1 (Essential Information), 3.8.2.2 (Essential Information for Pancreas Offers), 5.1.3 (Mechanical Preservation Machine), 5.3 (External Labeling Requirements), 5.4.1 (Solid Organ), 5.4.2 (Tissue Typing Materials), 5.4.3 (Vessels), 5.5.1 (Documentation Accompanying the Organ), 5.6.1 (Verification of Labeling and Documentation for Deceased Donor Organs or Vessels), 5.7 (Verification of Information Upon Receipt of an Organ), 5.8.2 (Blood for ABO Confirmation), 5.10.2 (Vessel Storage), 12.3.1 (ABO Identification), 12.3.2 (ABO Subtype Identification), 12.7 (Responsibility for Transport of Living Donor Organs), 12.7.2, 12.7.3, 12.7.4, and 12.8.1.1.

Distributed for Public Comment: March 2011

Amended After Public Comment: Yes

Effective Date: February 1, 2012

Problem Statement:
OPTN policy does not require a donor's ABO subtype to be confirmed by a second analysis before the donor's ABO subtype is used for allocating deceased and living donor organs.

Changes:
All deceased and living donors whose ABO subtype is determined to be non-A ₁ or non-A ₁ B must have a second ABO subtyping test. This change is to ensure the accuracy of the initial result before allocating (and transplanting) organs based on that ABO subtype.

Required Action:
OPOs (for deceased donors) and transplant centers (for living donors) are required to perform a second ABO subtype test for blood group A and AB donors when the donor is: 1) identified by the initial subtyping test to be non-A ₁ (e.g. A ₂) or non-A ₁ B (e.g. A ₂ B) <u>and</u> 2) the ABO subtype will be used for organ placement.
Blood samples for the initial and second ABO subtype determination are required to be pre-transfusion specimens and taken on two separate occasions (defined as two samples sent to two labs, or two samples from separate draws sent to the same lab). When an OPO or transplant center cannot draw samples on two separate occasions, cannot obtain pre-transfusion samples, or cannot verify or validate the ABO subtyping results with a second determination test, the deceased or living donor's organ(s) must be allocated and transplanted based on the primary ABO type without subtyping consideration.

Prohibiting the Storage of Hepatitis C Antibody Positive and Hepatitis B Surface
Antigen Positive Extra Vessels

Sponsoring Committee: Operations and Safety Committee

Policies Affected: 5.10.1 (Vessel Recovery and Transplant) and 5.10.2 (Vessel Storage)

Distributed for Public Comment: October 2010

Amended After Public Comment: No

Effective Date: February 1, 2012

Problem Statement:
The storage of hepatitis C antibody positive and hepatitis B surface antigen positive extra vessels has the potential to compromise patient safety and recipient outcomes. These serological positive vessels could be transplanted accidentally into secondary recipients that are serologically negative.

Changes:
Hepatitis C antibody positive and hepatitis B surface antigen positive extra vessels that are procured and sent to a center, but are not transplanted into the recipient for whom the donor organ and extra vessels were procured, may not be stored for subsequent use.

Required Action:
Transplant centers are required to discard hepatitis C antibody positive and hepatitis B surface antigen positive extra vessels that are not transplanted into the recipient during the original transplant procedure.

Standardized Label Requirements for Vessel Transport and Storage

Sponsoring Committee: Organ Procurement Organization (OPO) Committee

Policies Affected: 5.4.3 (Vessels), 5.10 (Vessel Recovery, Transplant, and Storage), and 5.10.2 (Vessel Storage)

Distributed for Public Comment: March 2011

Amended After Public Comment: Yes

Effective Date: February 1, 2012

Problem Statement:
Labeling requirements for vessel transport are inconsistent with those for vessel storage. Currently, only the exterior sterile barrier must be labeled for vessel storage. This could pose a significant patient safety issue if the vessel container is separated from the sterile barrier during storage.

Changes:
This policy modification will require members to label the vessel container, in addition to the outer most sterile barrier.

Required Action:
OPOs must label the vessel container with the donor's recovery date, ABO, infectious disease results, the UNOS Donor ID, and the container's contents, in addition to the OPTN contractor's standardized vessel label that must be affixed to the outermost barrier.
Transplant centers must store vessels in a rigid, sterile, sealed container that is protected by a triple sterile barrier (one of which must be the rigid container). The rigid container must be labeled with the donor's recovery date, ABO, ABO subtype when used for allocation, infectious disease results, the UNOS Donor ID, and the container's contents, in addition to the OPTN contractor's standardized vessel label which must be affixed to the outermost barrier. If the vessels are removed from the triple sterile barrier, the transplant center must re-label the vessels prior to storage.

Affected Policy Language:**Policy 8.0 Travel Expense and Reimbursement Policy**

The following policies address reimbursement for travel expenses:

8.1 - Eligibility for Reimbursement**8.1.1 – General Eligibility Requirements**

Members of the Board of Directors and committees, invited guests, and OPTN contractor employees will be reimbursed for OPTN expenses, subject to limitations of the Policy. Members are encouraged to request that their institution absorb the costs of attending meetings, where possible. OPTN contractor staff must complete a travel request form that shall be approved by management.

8.1.2 – OPTN Meetings in Conjunction with Other Meetings

If the OPTN holds a meeting in a city where the traveler will be present to attend another organization's meeting (e.g., AST, NATCO, etc.), the OPTN will pay only for the individual's additional expenses that are incurred as a direct result of attending the OPTN meeting (e.g., an extra night's lodging and/or extra meals).

8.2 – Airfare/Rail Reimbursement**8.2.1 – Airfare/Rail Costs**

OPTN members and staff are to use *UNOS Conference Planning and Travel* and its online booking tool as travel arranger for OPTN related travel. The travel department will obtain a low cost coach fare that will accommodate the traveler's needs. If the person traveling chooses not to accept those flight arrangements, the OPTN will reimburse only up to the amount the OPTN would have paid.

8.2.2 – Booking in Advance

Travelers should book airline reservations at least one month in advance of travel.

8.2.3 – Unused Ticket Credit

If the traveler has an unused airline ticket, the travel arranger will attempt to use the ticket credit on a flight that meets the needs of the traveler.

8.2.4 - Airline Ticket Changes

Additional fees resulting from airline ticket changes will be paid if the changes are related to OPTN business. Travelers who request ticket changes for reasons unrelated to OPTN business will be responsible for all fees that are incurred. Changes in airline ticketing due to emergencies will be handled on a case by case basis.

8.2.5 – Booking Earlier Flights

If a traveler requests to leave an OPTN event early, they are asked to go “standby” if it is available. If the traveler chooses to book a confirmed seat on an earlier return flight, the traveler will be responsible for all fees incurred. Leaving early due to emergencies will be handled on a case by case basis.

8.2.6 – International Air Travel

Reimbursement for all international travel expenses will be handled on a case by case basis.

8.2.7 - Miscellaneous Ticketing

Per airline policy, UNOS Conference Planning and Travel will not book back-to-back tickets and/or round-trip airfares for a one-way trip.

8.2.8 – First Class Air Travel

The OPTN will not reimburse first class airfare unless it is the same price as the low cost coach fare. If the traveler chooses to fly first class, the traveler would pay the entire cost of the first class ticket and the OPTN would only reimburse the amount of the low cost coach fare.

8.3 - Hotel Reimbursement

The OPTN will reimburse the traveler overnight accommodations for the number of nights necessary to conduct OPTN business. When making this decision, OPTN staff will take into account the distance between the departing and destination cities, time zones crossed, and the flights available to and from those cities.

8.4 - Other Transportation**8.4.1 – Mileage**

Mileage will be reimbursed at the applicable IRS rate based on date travelled.

8.4.2 – Transportation To/From Airport

The OPTN will reimburse transportation to/from the traveler’s home and home airport and to/from the airport to the meeting location. Travelers are encouraged to use the least expensive option that is convenient. The OPTN does not reimburse costs of limousines unless shared AND the total cost to OPTN is no more expensive than cab fare.

8.4.3 – Rental Cars

The OPTN will not reimburse for rental cars if less expensive modes of travel are available. The traveler must elect rental car insurance coverage and should minimize additional rental car fees. If the traveler elects to rent a car when less expensive modes of travel are available, OPTN would reimburse up to the amount of the estimated cab fare needed for the duration of the stay.

8.4.4 – OPTN Provided Ground Transportation

If ground transportation is provided between an airport and a meeting site and the person traveling could reasonably take advantage of this transportation, the OPTN will not reimburse the cost of any other ground transportation

8.5 - Meals**8.5.1 – Meal Cost**

The OPTN will reimburse individual meal costs during travel except when the traveler is present at the meeting location and a group breakfast, luncheon, or dinner is being provided at the same time as the individual meal. Individual breakfast and lunch costs must be reasonable.

8.5.2 – Evening Meal Limitations

The OPTN will reimburse evening meal costs up to the OPTN evening meal limit (currently \$45). The evening meal limit includes the cost of the meal, alcoholic beverages consumed with the meal, and tips/gratuities. The traveler will not be reimbursed costs exceeding the limit unless approved by the OPTN Assistant Executive Director level or above.

8.6 - Miscellaneous Expenses:**8.6.1 - Parking Fees/Mileage**

The OPTN will reimburse parking fees at the airport from which the traveler departs and mileage driven between the airport and the traveler's home or office.

8.6.2 – Internet / Phone Charges

The OPTN will reimburse for OPTN business and personal phone calls of a reasonable length. The OPTN will reimburse Internet connection charges if the traveler is conducting OPTN business.

8.6.3 – Other Reasonable Expenses

The OPTN will be reimburse for reasonable, out-of-pocket expenses incurred as a direct result of traveling for OPTN business.

8.7 – Non-Reimbursable Expenses

The OPTN will not reimburse costs for in-room movies, valet parking, fitness center, dry cleaning/laundry or any other personal charges. The OPTN will not reimburse charges incurred for personal travel days.

8.8 - Filing Expense Reports**8.8.1 – Expense Reimbursement Form**

To request reimbursement from the OPTN, the traveler must complete and submit an expense reimbursement form with original receipts. The person requesting reimbursement must sign the expense reimbursement form and must include the following information: dates of travel, reason for travel (including meeting location and name of event), to whom the reimbursement check shall be made payable, the address to which the reimbursement should be sent, and a contact phone number.

8.8.2 – Receipts

The expense report must have original receipts for expenses attached. If one traveler has a meal receipt which includes other OPTN travelers, the receipt must include the names of all travelers.

8.0 — TRAVEL EXPENSE AND REIMBURSEMENT POLICY

~~— The following policies address reimbursement for travel expenses.~~

~~**8.1 — REIMBURSABLE EXPENSES.** Subject to the limitations set forth in Policy 8.2 below, members of the Board of Directors and committees and OPTN contractor employees will be reimbursed for the following:~~

~~**8.1.1 — Domestic Airfare, Train and Mileage.** Airfare and/or mileage driven for the purpose of conducting business on behalf of the OPTN, will be reimbursed, provided that the person attending is a member of the Board or the Committee, or has been requested to attend the meeting by the President, the Executive Director, or a Committee chair. Members are encouraged to request that their institutions absorb their costs of attending meetings, where possible. OPTN contractor staff employees must complete a travel request form that shall be approved by management.~~

~~**8.1.2 — International Travel.** Reimbursement for all international travel expenses will be dealt with on a case by case basis.~~

~~**8.1.3 — Overnight Accommodations.** The cost of overnight accommodations and meals at the meeting site will be reimbursed, provided that the person traveling is unable to book reasonable travel arrangements on the day of the meeting and must either arrive the day before the meeting and/or leave the day after the meeting. If the meeting is scheduled to convene on two or more days, the cost of accommodations for the intervening nights, as well as meals necessitated by the stay, will be reimbursed.~~

~~**8.1.4 — Parking Fees.** Parking fees at the airport from which the traveler initially departs and mileage driven between the airport and the traveler's home or office will be reimbursed. Other reasonable costs incurred for travel between the airport and the individual's home or office (e.g.: tolls, cab fares, public transit fares, etc.) are also reimbursable.~~

~~**8.1.5 — Mileage.** Mileage at the approved IRS rate will be reimbursed, as adjusted from time to time.~~

~~**8.1.6 — Final Destination Costs.** Reasonable costs incurred for travel between the destination airport and the meeting site will be reimbursed.~~

~~**8.1.7 — Miscellaneous Expenses.** All other reasonable, out-of-pocket expenses actually incurred as a direct result of having to attend the OPTN meeting will be reimbursed.~~

~~**8.1.8 — Phone Calls.** Business and Personal phone calls of a reasonable length will be~~

reimbursed. OPTN contractor staff must use a corporate calling card to avoid the excess charges from dialing through the hotel switchboard. High speed Internet connection fee/charges will be reimbursed if the traveler is conducting OPTN business.

8.1.9 Other Meeting Expenses. At the discretion of the Executive Director, costs (as defined in Policies 8.1.1 – 8.1.5) related to attendance at meetings other than those held by the Board or its committees will be reimbursed.

8.2 LIMITATIONS. The following limitations apply to the reimbursement of travel expenses:

8.2.1 Discounts. If, for a particular trip, the OPTN contractor is able to obtain special fare discounts for travel on a particular airline or airlines, and if the person traveling chooses not to book and accept flight arrangements thus avoiding such discounts, the individual will be reimbursed for air travel only up to the amount of the discount fare. If a discount fare is available and the traveler chooses arrangements that cost more than the discount fare, the traveler will be billed for the difference between the traveler's chosen fare and the available discounted fare, when UNOS must purchase the tickets.

Exceptions:

The traveler will be reimbursed an amount greater than the discounted airfare if both of the following conditions are met:

- 1.). The cost of the preferred flight is no more than 50% greater than the available discounted fare; and
- 2.). Total travel time for the discounted ticket exceeds the preferred flight by 90 or more minutes.

8.2.1.1 Scheduling. Airline reservations should be booked at least one month in advance of any travel when possible to ensure the greatest possibility of securing the most economical ticket. Unused non-refundable tickets must be returned where they will be reissued in the name of the original ticket holder for future meetings.

Airline Ticket Changes Additional charges resulting from airline ticket changes reasonably related to OPTN business purposes will be reimbursed. Travelers who request a change to a ticket for reasons unrelated to OPTN business purposes will be financially responsible for all fees and fare price differences that are incurred. Change in airline ticketing due to emergencies will be reviewed on a case by case basis.

Saturday Night Stay over If a traveler elects to extend their travel to reduce airline ticket charges, traveler will be reimbursed for charges only to the extent that the costs do not exceed the original cost for the travel as initially scheduled. The traveler will only be reimbursed up to the Government per diem for that city for lodging and expenses during the weekend. See: <http://policyworks.gov/org/main/mt/homepage/mtt/perdiem/travel.shtml> for current per diem rates. Traveler is responsible for calculating all costs factoring in expenses such as parking, rental cars, etc. When OPTN business is not being conducted during the Saturday Night Stay over, the traveler will not be able to secure a government hotel rate, however, the amount up to the Government rate is reimbursable.

Returning Home Early If a traveler requests to leave early, they are asked to go

~~“standby”, if it is available, which does not cost additional money. If the traveler chooses to book a confirmed seat on an earlier return flight and the airline charges the traveler, this becomes a personal expense and not reimbursable, unless it is a verifiable emergency.~~

~~Booking Last Flight Home—Travelers are encouraged not to travel on the last flights of the day in event of an unforeseen circumstance.~~

~~Miscellaneous Ticketing—In accordance with airline policy, travelers may not book back to back tickets and/or round trip airfares for a one way trip.~~

~~8.2.1.2 **Meal Costs.** Reimbursement for evening meal costs incurred by meeting participants shall be limited to the federal limits designated for high cost areas (currently \$45). This limit applies to the cost of the meal, and all tips and gratuities. All meal costs exceeding this amount shall not be reimbursed.~~

~~8.2.2 **Non-Reimbursable Expenses.** The following expenses are not reimbursable.~~

~~8.2.2.1 First class airfare unless it is the same price as the lowest available price for a coach class ticket. When a traveler opts for first class airfare, the cost difference between first class and coach airfare is not reimbursable.~~

~~8.2.2.2 Rental cars, if less expensive modes of travel are available. OPTN contractor staff should minimize additional rental car fees and surcharges.~~

~~8.2.2.3 In room movies, if an extra fee is charged.~~

~~8.2.2.4 Limousines (unless shared, or no more expensive than other transportation available).~~

~~8.2.2.5 Individual meal costs if a group breakfast, luncheon, or dinner was provided at the same time as the individual meal.~~

~~8.2.2.6 Valet or other special services to include fitness center charges.~~

~~8.2.2.7 If charges for such items as those listed in 8.2.2.3–8.2.2.6 appear on hotel folios paid separately by the OPTN contractor, will be required to pay for such charges.~~

~~8.2.2.8 Travel expenses for spouses, family members, or guests of the traveler.~~

~~8.2.3 **Adjunct Committee Members.** Travel expenses for adjunct committee members will be paid or reimbursed only if the member was invited to attend the meeting for a special purpose.~~

~~8.2.4 **Meetings of Other Organizations.** If the OPTN holds a meeting in a city where the Board member, committee member, contractor staff or invited guest will be present to attend another organization's meeting (e.g., ASTS, AST, ACS, NATCO, SEOPE, etc.), only the individual's additional expenses that are incurred as a direct result of attending the OPTN meeting (e.g., an extra night's lodging and/or extra meals) are reimbursable. Those attending an OPTN function scheduled concurrently with another organization's meeting will be presumed to be attending the other meeting, if the person is a member of the other organization.~~

~~8.2.5 **Shuttle Service.** When the OPTN provides for shuttle service between an airport and a meeting site alternative ground transportation and related costs are not reimbursable.~~

~~8.2.6 **Annual Membership Meeting.** Travel and accommodation costs to attend annual membership meetings are not reimbursable.~~

8.3 FILING EXPENSE REPORTS. To request reimbursement for out of pocket expenses previously incurred, an expense report form, supplied by the OPTN contractor, must be completed and submitted to the OPTN contractor. The report must be signed by the person requesting reimbursement and must state the following:

~~_____ dates of travel~~

~~_____ reason for the travel~~

~~_____ to whom the reimbursement check should be made payable~~

~~_____ the address to which the reimbursement should be sent~~

~~_____ a daytime phone number~~

~~8.3.1 **Receipts.** Receipts for all expenses in excess of \$15.00 must be attached to the expense report. Meal receipts must show the names of all individuals present and for whom reimbursement is requested.~~

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:

3.7.12.3 Essential Information for Lung Offers. In addition to the essential information specified above for a thoracic organ offer, the Host OPO ~~or donor center~~ shall provide the following specific information with each lung offer:

- (i) Arterial blood gases on 5 cm/H₂O/PEEP including PO₂/FiO₂ ratio and preferably 100% FiO₂ within 2 hours prior to the offer;
- (ii) Bronchoscopy results. Bronchoscopy of a lung donor is recognized as an important element of donor evaluation, ~~and should be arranged by the Host OPO or donor center. If the Host OPO or donor center lacks the personnel and/or technical capabilities to comply, the bronchoscopy responsibility will be that of the recipient center. The inability of the Host OPO or donor center to perform a bronchoscopy must be documented. The Host OPO must document if it is unable to provide bronchoscopy results.~~ Confirmatory bronchoscopy may be performed by the lung retrieval team provided unreasonable delays are avoided. A lung transplant program may not insist upon performing its own bronchoscopy before being subject to the 60 minute response time limit as specified in Policy 3.4.12;
- (iii) Chest radiograph interpreted by a radiologist or qualified physician within 3 hours prior to the offer;
- (iv) Sputum gram stain with a description of the sputum character; and,
- (v) Smoking history.

3.7.12.4 Desirable Information for Lung Offers. With each lung offer, the Host OPO ~~or donor center~~ is encouraged to provide the ~~recipient center~~ transplant center with the following information:

- Mycology smear; ~~and~~
- Measurement of chest circumference in inches or centimeters at the level of the nipples and x-ray measurement vertically from the apex of the chest to the apex of the diaphragm and transverse at the level of the diaphragm, if requested; ~~and,~~
- Non-contrast computed tomography (CT) scan of the chest, if requested by the transplant center.

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:

3.7.6.3 Candidate Variables in UNetSM. Entry into UNetSM of candidate clinical data corresponding to the variables shown in Tables 1 and 2 ~~above in Policy 3.7.6.1, as they may be amended from time to time,~~ 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 ~~and whether further action is warranted~~. Estimated values will remain valid until those values are either updated with an actual value or a new estimated value is entered pursuant to ~~the procedures set forth in Policy 3.7.6.4.~~

~~**3.7.6.3.1 Candidate Variables in UNetSM upon Implementation of Lung Allocation Scores Described in Policy 3.7.6.** Candidates registered on the Lung Waiting List at the time of implementation of the Lung Allocation Score described in Policy 3.7.6 with no or incomplete clinical data will receive the Least Beneficial Value or the default pulmonary pressure value for each incomplete variable or a Lung Allocation Score of zero, as described in Policy 3.7.6 above.~~

~~**3.7.6.3.2**~~ **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 UNetSM 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. ¶

UNetSM defines a “six-month anniversary date,” which first occurs six months from the date of initial listing, then every six months thereafter. UNetSM will consider a variable to be expired if the variable’s test date is six-months older than the most recent anniversary date.¶

~~Programs must update every candidate variable, except those candidate variables that are obtainable only by heart catheterization, for each candidate at least once every six months beginning on the date of initial listing on the lung waitlist. If at any time, more than six months have elapsed since the last six-month “anniversary” date of the candidate’s initial listing, without an update, then the variable will be considered expired. (For example, if a candidate was first registered on the waitlist on January 1, 2005, and the most recent six-month “anniversary” is January 1, 2006, then any variables older than July 1, 2005, will be considered expired.)~~

If the test dates of the Functional Status or assisted ventilation variable expire, then the candidate’s will receive a Lung Allocation Score will be of 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) will be left to the discretion of the transplant center. If a transplant center repeats a heart catheterization test, it must report the results in UNetSM.

UNetSM will consider actual values or estimated values for pulmonary pressures to be valid until the transplant center they are either updateds them with a new actual values or a new estimated values is entered pursuant to Policy 3.7.6.4.

A program must update three key variables in UNetSM no more than 14 days after a candidate’s LAS becomes greater than 50: assisted ventilation, supplemental oxygen, and current PCO₂. If a program does not perform a PCO₂ test in that time, then it does not need to update this value in UNetSM. 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.

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:

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

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

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

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

NOTE: The above language (in brackets) will expire on December 1, ~~2011~~2012.

[...]

1B	<p>A candidate listed as Status 1B has at least one of the following devices or therapies in place:</p> <ul style="list-style-type: none"> (aa) left and/or right ventricular assist device implanted; or (bb) continuous infusion of intravenous inotropes.
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[A candidate with a total artificial heart who has been discharged from the listing hospital may be listed as Status 1B at any point in time after the discharge.]

NOTE: The above language (in brackets) will expire on December 1, ~~2011~~2012.

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:**3.6.4.4 Liver Transplant Candidates with Hepatocellular Carcinoma (HCC).** Candidates with stage T2 HCC that meet the staging and imaging criteria specified in sections A-E may receive extra priority on the Waiting List as specified below.

- A. **Eligible Candidates.** A candidate with an HCC tumor that is stage T2 may be registered at a MELD/PELD score equivalent to a 15% probability of candidate death within 3 months if the criteria listed in sections B-D are also met. For the purposes of this policy, stage T2 lesions are defined as

- 1 lesion \geq 2 cm and \leq 5cm; OR
- 2 or 3 lesions, \geq 1cm and \leq 3cm in size.

The largest dimension of each tumor must be reported (i.e., 1.5cm x 2.5cm must be reported as 2.5cm). Nodules $<$ 1cm are indeterminate and cannot be considered for additional priority.

- B. **Initial Assessment for Listing.** The candidate must have undergone a thorough assessment to evaluate the number and size of tumors and to rule out any extrahepatic spread (i.e. lymph node involvement) and/or macrovascular involvement (i.e., tumor thrombus in portal or hepatic vein) with dynamic contrast enhanced computed tomography (CT) or magnetic resonance imaging (MRI). The assessment of the candidate prior to transplant listing must include a CT of the chest that rules out metastatic disease. The candidate must not be eligible for resection. The alpha-fetoprotein level is required for all HCC exception applications.
- C. **Requirements for Imaging.** Any imaging examination performed for the purpose of obtaining or updating priority points on the transplant waitlist should meet minimum recommended technical and imaging protocol requirements for CT and MRI listed in Table 4 and Table 5. These must be interpreted by a radiologist at an OPTN approved transplant center. Technically inadequate or incomplete imaging examinations must be classified as OPTN Class 0 and must be repeated or completed in order to be considered for priority point allocation.
- D. **Definitions of OPTN Class 5 Nodules.** Nodules found on imaging of cirrhotic livers must be classified according to the OPTN classification shown in Table 6. OPTN class 5 nodules correspond to an imaging diagnosis of HCC and are as follows:

OPTN Class 5B nodules: The combination of the following imaging findings constitutes an OPTN class 5B nodule and qualifies for automatic MELD priority score (all 3 criteria must be met):

1. Single nodule diameter greater than or equal to 2cm and less than or equal to 5cm. Maximum diameter of lesion(s) should be measured on late arterial or portal phase images.
2. Increased contrast enhancement on late hepatic arterial images (relative to hepatic parenchyma)
3. One of the following:
 - **Washout** on portal venous/delayed phase

- **Late capsule or pseudocapsule enhancement** OR
- **Growth** (maximum diameter increase in the absence of ablative therapy) by 50% or more documented on serial MRI or CT obtained < 6 month apart. Serial imaging and measurements should be performed on corresponding contrast phases with the same modality preferred. ; OR
- **Biopsy.**

Growth criteria do not apply to previously ablated lesions. A pre-listing biopsy is not mandatory.

OPTN Class 5A nodules are defined as follows:

1. Single nodule, maximum diameter of >1 cm and <2cm. Maximum diameter of lesion(s) should be measured on late arterial or portal phase images.
2. Increased contrast enhancement on late arterial phase (relative to hepatic parenchyma)
3. Both of the following:
 - **Washout** during the later contrast phases **AND**
 - **Peripheral rim enhancement** (capsule/pseudocapsule) on delayed phase;

OR

 - Biopsy

OPTN Class 5A-g (growth) are defined as follows (all criteria must be met):

- Single nodule, maximum diameter of >1 cm and <2cm. Maximum diameter of lesion(s) should be measured on late arterial or portal phase images.
- Increased contrast enhancement on late arterial phase (relative to hepatic parenchyma)
- Growth (maximum diameter increase) by 50% or more documented on serial MRI or CT obtained < 6 months apart. Growth criteria do not apply to ablated lesions.
(i.e. a 1.2 cm hyper-enhancing nodule documented on first CT scan is found to be 1.8 cm on scan obtained 3 months later would be classified as 5A-g. This individual lesion is not eligible for MELD priority score as the tumor is still at stage T1 but if found in conjunction with a second 5A or 5A-g lesion, the patient would be eligible for an automatic MELD priority score.)

OPTN Class 5T (Treated) nodules are defined as any OPTN Class 5 or biopsy-proven HCC lesion that was automatically approved upon initial application or extension and has subsequently undergone loco-regional treatment. OPTN Class 5T nodules qualify for continued priority points predicated on the pre-treatment classification of the nodule(s) and are defined as:

1. Past loco-regional treatment for HCC (OPTN class 5 lesion or biopsy proven prior to ablation).
2. Evidence of persistent/recurrent HCC such as nodular or crescentic extra-zonal or

intra-zonal enhancing tissue on late arterial imaging (relative to hepatic parenchyma) may be present.

OPTN Class 5X: Lesions that meet radiologic criteria for HCC but are outside stage T2 as defined in section A will be considered Class 5X and are not eligible for automatic exception points. These cases may be considered by the Regional Review Board (RRB) as described in section G.

- E. **HCC Lesions Eligible for Automatic Upgrade.** Individual Class 5B and 5T are eligible for automatic priority. A single OPTN Class 5A nodule corresponds to T1 stage hepatocellular carcinoma and does not qualify for automatic priority MELD points but must be considered towards the overall staging of the patient according to criteria listed above. **Combinations of Class 5A nodules** that meet stage T2 criteria as described in section (A) are eligible for automatic priority.

For example, a candidate would be eligible for additional priority with:

- Two 1.5 cm (5A) lesions; or
- One 1.5 cm lesion (5A) and one 2.5 cm lesion (5B); or
- One 3.5cm lesion (5B); or
- Two 2.1cm lesions (5B).

- F. **Extensions of HCC Exception Applications.** Candidates will receive additional MELD/PELD points equivalent to a 10 percentage point increase in candidate mortality to be assigned every 3 months until these candidates receive a transplant or are determined to be unsuitable for transplantation based on progression of their HCC. To receive the additional points at 3-month intervals, the transplant program must re-submit an HCC MELD/PELD score exception application with an updated narrative every three months. Continued documentation of the tumor via repeat CT or MRI is required every three months for the candidate to receive the additional 10 percentage point increase in mortality points while waiting. Invasive studies such as biopsies or ablative procedures and repeated chest CTs are not required after the initial upgrade request is approved to maintain the candidate's HCC priority scores.

If the number of tumors that can be documented at the time of extension is less than upon initial application or prior extension, the type of ablative therapy must be specified on the extension application. Candidates whose tumors have been ablated after previously meeting the criteria for additional MELD/PELD points (OPTN Class 5T) will continue to receive additional MELD/PELD points (equivalent to a 10 percentage point increase in candidate mortality) every 3 months without RRB review, even if the estimated size of residual viable tumor falls below stage T2 criteria.

For candidates whose tumors have been resected since the initial HCC application or prior extension, the extension application must receive prospective review by the applicable RRB.

- G. **Candidates Not Meeting Criteria (Class 5X).** A candidate not meeting the above criteria may continue to be considered a liver transplant candidate in accordance with each center's own specific policy or philosophy, but the candidate must be listed at the calculated MELD/PELD score with no additional priority given because of the HCC diagnosis. All such candidates with HCC, including those with downsized tumors whose original/presenting tumor was

greater than a stage T2, must be referred to the applicable RRB for prospective review in order to receive additional priority.

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

- I. **Compliance Monitoring.** Documentation of the radiologic characteristics of each OPTN class 5 nodule (for an example, see Tables 7A-C) must be kept on file at the transplant center. If growth criteria are used to classify a nodule as HCC, prior and current dates of imaging, type of imaging and measurements of the nodule(s) must be documented in the radiology report.
For those candidates who receive a liver transplant while receiving additional priority under the HCC criteria, the recipient's explant pathology report must be sent to the OPTN contractor within 60 days of the transplant procedure. If the pathology report does not show evidence of HCC, the transplant center must also submit documentation and/or imaging studies confirming HCC at the time of listing. Additionally, if more than 10% of the HCC cases on an annual basis are not supported by pathologic confirmation or subsequent submission of clinical information, the center will be referred to the Liver and Intestinal Organ Transplantation Committee.

Appendices:

TABLE 4: RECOMMENDED Minimum technical requirements for CT

TABLE 5: RECOMMENDED Minimum technical requirements for MRI

TABLE 6: OPTN Classification of liver lesions (Classes 0 and 5)

TABLES 7A-C: Sample templates for centers to use when recording HCC findings for auditing purposes

Table 4: Recommended minimum technical specifications for dynamic contrast-enhanced CT of the liver

Feature	Specification	Comment
Scanner Type	<i>Multidetector row scanner</i>	
Detector Type	<i>Minimum of 8 detector rows</i>	<i>Need to be able to image entire liver during brief late arterial phase time window</i>
Reconstructed slice thickness	<i>Minimum of 5 mm reconstructed slice thickness</i>	<i>Thinner slices are preferable, especially if multiplanar reconstructions are performed</i>
Injector	<i>Power injector, preferably dual chamber injector with saline flush</i>	<i>Bolus tracking recommended</i>
Contrast injection rate	<i>3mL/sec minimum, better 4-6 mL/sec with minimum of 300 mg I/mL or higher, for dose of 1.5mL/kg body weight</i>	
Mandatory dynamic phases on contrast enhanced MDCT (comments describe typical hallmark image features)	<i>1) late arterial phase</i> <i>2) portal venous phase</i> <i>3) delayed phase</i>	<i>1) artery fully enhanced, beginning contrast enhancement of portal vein</i> <i>2) portal vein enhanced, peak liver parenchymal enhancement, beginning contrast enhancement of hepatic veins</i> <i>3) variable appearance, >120 sec after initial injection of contrast</i>
Dynamic Phases (Timing)	<i>Bolus tracking or timing bolus recommended for accurate timing</i>	

Table 5:

Recommended minimum technical specifications for dynamic contrast-enhanced MRI of the liver

Feature	Specification	Comment
Scanner Type	<i>1.5T Tesla or greater main magnetic field strength</i>	<i>low field magnets not suitable</i>
Coil Type	<i>phased array multichannel torso coil</i>	<i>unless patient-related factors precludes use (e.g. body habitus)</i>
Minimum sequences	<i>Pre-contrast and dynamic post gadolinium T1-weighted gradient echo sequence (3D preferable), T2 (with and without FAT SAT), T1w in and out of phase imaging</i>	
Injector	<i>dual chamber power injector</i>	<i>Bolus tracking recommended</i>
Contrast injection rate	<i>2-3 mL/sec of extracellular gadolinium chelate that does not have dominant biliary excretion</i>	<i>Preferably resulting in vendor-recommended total dose</i>
Mandatory dynamic phases on contrast enhanced MRI (comments describe typical hallmark image features)	<i>0)Pre-contrast T1W</i> <i>1) late arterial phase</i> <i>2) portal venous phase</i> <i>3) delayed phase</i>	<i>0) do not change scan parameters for post contrast imaging</i> <i>1) artery fully enhanced, beginning contrast enhancement of portal vein</i> <i>2) portal vein enhanced, peak liver parenchymal enhancement, beginning contrast enhancement of hepatic veins</i> <i>3) variable appearance, >120 sec after initial injection of contrast</i>
Dynamic Phases (Timing)	<i>The use of a bolus tracking method for timing contrast arrival for late arterial phase imaging is preferable. Portal venous phase (35-55 sec after initiation of late arterial phase scan), delayed phase (120-180sec after initial contrast injection)</i>	
Slice thickness	<i>5mm or less for dynamic series, 8mm or less for other imaging</i>	
Breath-holding	<i>max length of series requiring breathhold should be about 20sec. with a minimum matrix of 128 x 256</i>	<i>Compliance with breathhold instructions very important, technologists need to</i>

		<i>understand the importance of patient instruction before and during scan</i>
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Table 6: OPTN classification system for nodules seen on imaging of cirrhotic livers

Class	Description	Comment
0	<i>Incomplete or technically inadequate study</i>	<i>Repeat study required for adequate assessment; automatic priority MELD points cannot be assigned based on a OPTN 0 classified imaging study</i>
5	<p><i>Meets radiologic criteria for HCC</i></p> <p><i>5A: <u>> or equal to 1 cm and less 2 cm</u> measured on late arterial or portal phase images.</i></p> <p><i>5A-g: same size as 5A</i></p> <p><i>5B: maximum diameter > or equal to 2cm and less than or equal to 5 cm.</i></p> <p><i>5T: prior local regional treatment for HCC</i></p> <p><i>5X: maximum diameter > or equal to 5 cm.</i></p>	<p><i>May qualify for automatic exception depending on stage (see 3.6.4.4 section A.)</i></p> <p><i>Increased contrast enhancement on late hepatic arterial phase AND washout during later contrast phases AND peripheral rim enhancement (capsule/pseudocapsule).</i></p> <p><i>Increased contrast enhancement on late hepatic arterial phase AND growth by 50% or more documented on serial CT/MRI obtained <or equal to 6 months apart.</i></p> <p><i>Increased contrast enhancement on late hepatic arterial phase AND either washout during later contrast phases OR peripheral rim enhancement (capsule/pseudocapsule) OR growth by 50% or more documented on serial CT/MRI obtained <or equal to 6 months apart (5B-g).</i></p> <p><i>Describes any residual lesion or perfusion defect at site of prior UNOS class 5 lesion.</i></p> <p><i>Increased contrast enhancement on late hepatic arterial phase AND either washout during later contrast phases OR peripheral rim enhancement (capsule/pseudocapsule)</i></p>

For descriptions of Classes 1-4, which are not applicable to OPTN policy, please see

http://www.acr.org/SecondaryMainMenuCategories/quality_safety/LI-RADS.aspx.

~~3.6.4.4 Liver Transplant Candidates with Hepatocellular Carcinoma (HCC).~~ Candidates with Stage II HCC in accordance with the modified Tumor Node–Metastasis (TNM) Staging Classification set forth in Table 3 that meet all of the medical criteria specified in (i) and (ii) may receive extra priority on the Waiting List as specified below. A candidate with an HCC tumor that is greater than or equal to 2 cm and

less than or equal to 5cm or no more than 3 lesions, the largest being less than 3 cm in size (Stage T2 tumors as described in Table 3) may be registered at a MELD/PELD score equivalent to a 15% probability of candidate death within 3 months. The largest dimension of each tumor must be reported (i.e., 3.2cm x 5.1cm must be reported as 5.1cm).

- (i) The candidate has undergone a thorough assessment to evaluate the number and size of tumors and to rule out any extrahepatic spread and/or macrovascular involvement (i.e., portal or hepatic veins). A prelisting biopsy is not mandatory but the lesion must meet the following imaging criteria. The assessment of the candidate should include ultrasound of the candidate's liver, a computerized tomography (CT) or magnetic resonance imaging (MRI) scan of the abdomen that documents the tumors and a CT of the chest that rules out metastatic disease. In addition, the candidate must have at least one of the following: a vascular blush corresponding to the area of suspicion seen on the above imaging studies, an alpha-fetoprotein level of >200 ng/ml, an arteriogram confirming a tumor, a biopsy confirming HCC, chemoembolization of lesion, radio frequency, cryo, or chemical ablation of the lesion. The alpha-fetoprotein level is required for all HCC exception applications. Candidates with chronic liver disease who have a rising alpha-fetoprotein level ≥ 500 nanograms may be listed with a MELD/PELD score equivalent to an 8% mortality risk without RRB review even though there is no evidence of a tumor based on imaging studies.
- (ii) The candidate is not a resection candidate.

Candidates will receive additional MELD/PELD points equivalent to a 10% increase in candidate mortality to be assigned every 3 months until these candidates receive a transplant or are determined to be unsuitable for transplantation based on progression of their HCC. To receive the additional points at 3-month intervals, the transplant program must re-submit an HCC MELD/PELD score exception application with an updated narrative every three months. Continued documentation of the tumor via repeat CT or MRI is required every three months for the candidate to receive the additional 10% mortality points while waiting. Invasive studies such as biopsies or ablative procedures and repeated chest CTs are not required after the initial upgrade request is approved to maintain the candidate's HCC priority scores. Candidates meeting criteria based on an alpha-fetoprotein level of ≥ 500 nanograms, as specified in (i), must continue to demonstrate an ongoing rise in the alpha-fetoprotein level in order to extend the application.

If the number of tumors that can be documented at the time of extension is less than upon initial application or prior extension, the type of ablative therapy must be specified on the extension application. Candidates whose tumors have been ablated after previously meeting the criteria for additional MELD/PELD points, will continue to receive additional MELD/PELD points (equivalent to a 10% increase in candidate mortality) every 3 months without RRB review, even if the estimated size of residual viable tumor falls below Stage T2 criteria. For candidates whose tumors have been resected since the initial HCC application or prior extension, the extension application must receive prospective review by the applicable RRB.

A candidate not meeting the above criteria may continue to be considered a liver transplant candidate in accordance with each center's own specific policy or philosophy, but the candidate must be listed at the calculated MELD/PELD score with no additional priority given because of the HCC diagnosis. Candidates meeting all of the criteria in (i) and (ii) will receive a MELD/PELD score based on the tumor stage as described above without RRB review. All other candidates with HCC including those with downsized tumors whose original/presenting tumor was greater than a Stage T2), must be referred to the applicable RRB for prospective review.

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

For those candidates who receive a liver transplant while receiving additional priority under the HCC criteria, the recipient's explant pathology report must be sent to the OPTN contractor. If the pathology report does not show evidence of HCC, the transplant center must also submit documentation and/or imaging studies confirming HCC at the time of listing. Additionally, if more than 10% of the HCC cases on an annual basis are not supported by pathologic confirmation or subsequent submission of clinical information, the center will be referred to the Liver and Intestinal Organ Transplantation Committee.

Table 3

American Liver Tumor Study Group Modified Tumor-Node-Metastasis (TNM) Staging Classification

(1)

Classification-Definition

TX, NX, MX — Not assessed

TO, NO, MO — Not found

T1 — 1 nodule ≤ 1.9 cm

T2 — One nodule 2.0-5.0 cm; two or three nodules, all < 3.0 cm

T3 — One nodule > 5.0 cm; two or three nodules, at least one > 3.0 cm

T4a — Four or more nodules, any size

T4b — T2, T3, or T4a plus gross intrahepatic portal or hepatic vein involvement as indicated by CT, MRI, or ultrasound

N1 — Regional (portal hepatis) nodes, involved

M1 — Metastatic disease, including extrahepatic portal or hepatic vein involvement

Stage I — T1

Stage II — T2

Stage III — T3

Stage IVA1 — T4a

Stage IVA2 — T4b

Stage IVB — Any N1, any M1

Reference

~~1. American Liver Tumor Study Group—A Randomized Prospective Multi-Institutional Trial of Orthotopic Liver Transplantation or Partial Hepatic Resection with or without Adjuvant Chemotherapy for Hepatocellular Carcinoma. Investigators Booklet and Protocol. 1998.~~

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:**Adult Donor Liver Allocation Algorithm****Combined Local and Regional**

1. Status 1A candidates in descending point order
2. Status 1B candidates in descending point order.

Local

3. Candidates with MELD/PELD Scores ≥ 15 ~~29~~ in descending order of mortality risk scores (probability of candidate death)

National

4. Liver-Intestine Candidates in descending order of mortality risk scores (probability of candidate death)

Local

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

Regional

- ~~6.~~ 4 Candidates with MELD/PELD Scores ≥ 15 in descending order of mortality risk scores (probability of candidate death)

Local

- ~~7.~~ 5 Candidates with MELD/PELD Scores < 15 in descending order of mortality risk scores (probability of candidate death)

Regional

- ~~8.~~ 6 Candidates with MELD/PELD Scores < 15 in descending order of mortality risk scores (probability of candidate death)

National

- ~~9.~~ 7- Status 1A candidates in descending point order
- ~~10.~~ 8- Status 1B candidates in descending point order
- ~~11.~~ 9- All other candidates in descending order of mortality risk scores (probability of candidate death)

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:**3.6.12 Committee-sponsored Alternative Allocation System (CAS) for Segmental Liver Transplantation.**

Under this CAS, livers must be offered in sequence, as determined by the deceased donor liver allocation algorithm set forth in Policy 3.6 (Allocation of Livers). If a liver is accepted for a potential recipient who is medically suitable for segmental liver transplantation, the center may choose to transplant the right lobe/right trisegment into that individual. The transplant center may then transplant the left lobe/left-lateral segment into a medically suitable potential recipient listed at their center or an affiliated pediatric institution (if applicable). The potential recipient of the left lobe/left-lateral segment must be determined by following the same match run used to allocate the liver (right lobe/trisegment), documenting all refusals.

This CAS will only apply when the potential recipient receives the right lobe/right trisegment of the liver. If the potential recipient receives the left lobe/left lateral segment of the liver, then the right lobe/right trisegment of the liver must be allocated as per policy 3.6.11 (Allocation of Livers for Segmental Transplantation).

Each participating Region or DSA will meet to review the results of the first 10 segmental liver transplants performed as a result of this CAS, and each 10 thereafter. If the re-transplant rate for segmental liver transplant recipients at any liver transplant program participating in the CAS exceeds 3 of 20 grafts, an automatic hold will be placed on the procedure at that program until the results and surgical practices can be reviewed by the transplant program.

3.6.12 Transition of Currently Listed Candidates.

~~Candidates listed as Status 2A at the time the MELD system is implemented will be grandfathered into the new system for a period of 30 days following the implementation date. Candidates who are still listed as Status 2A at the end of 30 days would be converted to a MELD score based on the MELD criteria. These candidates shall be listed on the match run printout ahead of candidates who are listed by MELD scores and stratified based on the liver allocation criteria specified in Policy 3.6 in effect prior to implementation of the MELD and PELD scoring systems. At the end of the 30 days, candidates still in Status 2A will receive 30 days of waiting time towards their current MELD score. Those candidates who no longer meet the Status 2A criteria during the first 30 days will receive time accrued in Status 2A since the implementation. Candidates listed as Status 2B or 3 at the time the MELD and PELD systems are implemented will be converted to a MELD or PELD score based on the MELD or PELD criteria. All waiting time accrued by these candidates under the prior status system would apply toward their eligibility for a liver offer under the MELD and PELD system for a period of 1 year while the candidates are listed at their initial or lower mortality risk scores under the new system criteria. After 1 year, this previously accrued waiting time will not be counted and only the waiting time accrued under the MELD/PELD system from the date of its implementation would apply toward liver allocation thereafter. If the data required to calculate the MELD or PELD score (as applicable) have not been entered into the UNetSM system at the time of implementation, the candidate will automatically be assigned a MELD or PELD score of 6.~~

3.6.12.1 Transition for Currently Listed Status 2B HCC Candidates.

~~Candidates listed as Status 2B under the previous HCC criteria at the time the MELD and PELD systems are implemented will receive a MELD score equivalent to a 15% probability of candidate death within 3 months. No additional testing will be required~~

~~for these candidates unless a center wishes to apply for the T2 MELD score as described in policy 3.6.4.4. In these cases, the center must submit documentation that the candidate meets the criteria specified in 3.6.4.4(i). Previously accrued waiting time will be applied to the candidate's initial or lower MELD score, for a period of one year. These candidates must be reevaluated at 3 months, at which time the new criteria will be applied.~~

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: At its November 2011 meeting, the OPTN/UNOS Board of Directors approved two separate resolutions that modified policy 3.6.4.2 (Pediatric Candidate Status). The policy language below reflects the changes from both of these proposals: Policy Modifications to List All Non-Metastatic Hepatoblastoma Pediatric Liver Candidates as Status 1B and Elimination of the Requirement that Pediatric Liver Candidates Must be Located in a Hospital's Intensive Care Unit to Qualify as Status 1A or Status 1B (which were both sponsored by the Pediatric Transplantation Committee and Liver and Intestinal Organ Transplantation Committee).*

3.6.4.2 Pediatric Candidate Status.

Medical urgency is assigned to a pediatric liver transplant candidate (less than 18 years of age) based on either the criteria defined below for Status 1A or 1B, or the candidate's mortality risk score as determined by the prognostic factors specified in Table 2 and calculated in accordance with the Pediatric End-Stage Liver Disease Scoring System (PELD) for pediatric candidates <12 years or with the MELD System (defined above in Policy 3.6.4.1) for pediatric candidates 12-17 years. Based on the variables included in allocation score calculation in the MELD system, MELD scores may offer a more accurate picture of mortality risk and disease severity for adolescent candidates. Pediatric candidates 12-17 years will use a risk score calculated with the MELD system while maintaining other priorities assigned to pediatric candidates. A candidate who does not have a risk of candidate mortality expressed by the PELD or MELD score that, in the judgment of the candidate's transplant physician, appropriately reflects the candidate's medical urgency or was listed at less than 18 years of age and remains on or has been returned to the Waiting List upon or after reaching age 18 may nevertheless be assigned to a higher or the appropriate PELD or MELD score and pediatric classification (for candidates listed at less than age 18 who turn age 18) upon application by his/her transplant physician(s) and justification to the applicable Regional Review Board that the candidate is considered, by consensus medical judgment, using accepted medical criteria, to have an urgency and potential for benefit comparable to that of other candidates having the PELD or MELD score. The justification must include a rationale for incorporating the exceptional case as part of the PELD/MELD calculation. A report of the decision of the Regional Review Board and the basis for it shall be forwarded for review by the Liver and Intestinal Organ Transplantation and Membership and Professional Standards Committees to determine consistency in application among and within Regions and continued appropriateness of the PELD or MELD criteria.

Status	Definition
7	A pediatric candidate listed as Status 7 is temporarily inactive. Candidates who are considered to be temporarily unsuitable transplant candidates are listed as Status 7, temporarily inactive.

1A/1B

~~A pediatric candidate listed as Status 1A or 1B is located in the hospital's Intensive Care Unit (ICU).~~ For purposes of Status 1A/1B definition and classification, candidates listed at less than 18 years of age who remain on or have returned to the Waiting List upon or after reaching age 18 may be considered Status 1A/1B and shall qualify for other pediatric classifications under the following criteria. There are five allowable diagnostic groups: (i) fulminant liver failure; (ii) primary non function; (iii) hepatic artery thrombosis; (iv) acute decompensated Wilson's Disease; ~~and (v) chronic liver disease; and (vi) non-metastatic hepatoblastoma.~~ Candidates meeting criteria (i) (ii), (iii), or (iv) may be listed as a Status 1A; those meeting criteria (v) and (vi) may be listed as a Status 1B. Within each diagnostic group specific conditions must be met to allow for listing a pediatric candidate at Status 1A or 1B. Centers that list candidates not meeting these criteria for Status 1A or 1B will be referred to the Liver and Intestinal Organ Transplantation Committee for review; this review by the Liver and Intestinal Organ Transplantation Committee may result in further referral of the matter to the Membership and Professional Standards Committee for appropriate action in accordance with Appendix A of the Bylaws. Candidates meeting the criteria in (i)-(vi) will be listed in Status 1A or Status 1B without RRB review.

- (i) Fulminant hepatic failure. Fulminant liver failure is defined as the onset of hepatic encephalopathy within 8 weeks of the first symptoms of liver disease. The absence of pre-existing liver disease is critical to the diagnosis. One of three criteria below must be met to list a pediatric candidate with fulminant liver failure: (1) ventilator dependence (2) requiring dialysis or continuous veno-venous hemofiltration (CVVH) or continuous veno-venous hemodialysis (CVVD), or (3) INR > 2.0.
- (ii) Primary non-function of a transplanted liver. The diagnosis is made within 7 days of implantation. Additional criteria to be met for this indication must include 2 of the following: ALT \geq 2000, INR \geq 2.5, total bilirubin \geq 10 mg/dl, or acidosis, defined as having an arterial pH \leq 7.30 or venous pH of 7.25 and/or lactate \geq 4 mMol/L. All labs must be from the same blood draw within 24 hours to 7 days following the transplant.
- (iii) Hepatic artery thrombosis. The diagnosis must be made in a transplanted liver within 14 days of implantation.
- (iv) Acute decompensated Wilson's disease.
- (v) Chronic liver disease. Pediatric candidates with chronic liver disease ~~and in the ICU~~ can be listed at Status 1B if the candidate has a calculated PELD score of >25 or calculated MELD score of >25 for adolescent candidates (12-17 years) and one of the following criteria is met (candidates listed for a combined liver-intestine transplant may meet these criteria with their adjusted

match score as described in Policy 3.6.4.7 (Combined Liver-Intestine Candidates):

- a. On a mechanical ventilator; or
 - b. Gastrointestinal bleeding requiring at least 30 cc/kg of red blood cell replacement within the previous 24 hours; or
 candidates also on the intestine list, at least 10 cc/kg of red blood cell replacement within the previous 24 hours; or
 - c. Renal failure or renal insufficiency defined as requiring dialysis or continuous CVVH or continuous CVVD; or
 - d. Glasgow coma score <10 within 48 hours of the listing/extension.
- (vi) Non-metastatic hepatoblastoma. A pediatric candidate with a biopsy proven hepatoblastoma without evidence of metastatic disease at the time of listing may be listed as Status 1B.

Candidates who are listed as a Status 1A or 1B automatically revert back to their most recent PELD or MELD score after 7 days unless these candidates are relisted as Status 1A or 1B by an attending physician. Extensions for Status 1B candidates indicating a gastrointestinal bleed as the initial Status 1B upgrade criteria must have had another bleed in the past 7 days prior to upgrade in order to remain in Status 1B. Status 1B candidates listed with a metabolic disease (in accordance with Policy 3.6.4.3) or a hepatoblastoma (~~in accordance with Policy 3.6.4.4.1~~) will require recertification every three months with lab values no older than 14 days. Candidates must be listed with PELD/MELD laboratory values in accordance with Policy 3.6.4.2.1 (Pediatric Candidate Recertification and Reassessment Schedule) at the time of listing. A completed Liver Status 1A or 1B Justification Form must be received on UNetSM for a candidate's original listing as a Status 1A or 1B and each relisting as a Status 1A or 1B. If a completed Liver Status 1A or 1B Justification Form is not entered into UNetSM when a candidate is registered as a Status 1A or 1B, the candidate shall be reassigned to their most recent PELD or MELD score. A relisting request to continue a Status 1A or 1B listing for the same candidate waiting on that specific transplant beyond 14 days accumulated time (excluding hepatoblastoma candidates that meet criteria (vi), and candidates listed with a metabolic disease as described in Policy 3.6.4.3) will result in a review of all local Status 1A or 1B liver candidate listings.

All other pediatric liver transplant candidates on the Waiting List shall be assigned a mortality risk score calculated in accordance with the PELD (0-11 years) or MELD (12-17 years) scoring system. For each liver candidate registration, the listing transplant center shall enter data on the UNetSM for the prognostic factors specified in Table 2 for pediatric

candidates <12 years or Table 1 for pediatric candidates 12-17 years. These data must be based on the most recent clinical information (e.g., laboratory test results and diagnosis) and include the dates of the laboratory tests.

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: At its November 2011 meeting, the OPTN/UNOS Board of Directors approved two separate resolutions that modified policy 3.6.4.2 (Pediatric Candidate Status). The policy language below reflects the changes from both of these proposals: Policy Modifications to List All Non-Metastatic Hepatoblastoma Pediatric Liver Candidates as Status 1B and Elimination of the Requirement that Pediatric Liver Candidates Must be Located in a Hospital's Intensive Care Unit to Qualify as Status 1A or Status 1B (sponsored by the Pediatric Transplantation Committee and Liver and Intestinal Organ Transplantation Committee).*

3.6.4.2 Pediatric Candidate Status.

Medical urgency is assigned to a pediatric liver transplant candidate (less than 18 years of age) based on either the criteria defined below for Status 1A or 1B, or the candidate's mortality risk score as determined by the prognostic factors specified in Table 2 and calculated in accordance with the Pediatric End-Stage Liver Disease Scoring System (PELD) for pediatric candidates <12 years or with the MELD System (defined above in Policy 3.6.4.1) for pediatric candidates 12-17 years. Based on the variables included in allocation score calculation in the MELD system, MELD scores may offer a more accurate picture of mortality risk and disease severity for adolescent candidates. Pediatric candidates 12-17 years will use a risk score calculated with the MELD system while maintaining other priorities assigned to pediatric candidates. A candidate who does not have a risk of candidate mortality expressed by the PELD or MELD score that, in the judgment of the candidate's transplant physician, appropriately reflects the candidate's medical urgency or was listed at less than 18 years of age and remains on or has been returned to the Waiting List upon or after reaching age 18 may nevertheless be assigned to a higher or the appropriate PELD or MELD score and pediatric classification (for candidates listed at less than age 18 who turn age 18) upon application by his/her transplant physician(s) and justification to the applicable Regional Review Board that the candidate is considered, by consensus medical judgment, using accepted medical criteria, to have an urgency and potential for benefit comparable to that of other candidates having the PELD or MELD score. The justification must include a rationale for incorporating the exceptional case as part of the PELD/MELD calculation. A report of the decision of the Regional Review Board and the basis for it shall be forwarded for review by the Liver and Intestinal Organ Transplantation and Membership and Professional Standards Committees to determine consistency in application among and within Regions and continued appropriateness of the PELD or MELD criteria.

Status	Definition
7	A pediatric candidate listed as Status 7 is temporarily inactive. Candidates who are considered to be temporarily unsuitable transplant candidates are listed as Status 7, temporarily inactive.

1A/1B

~~A pediatric candidate listed as Status 1A or 1B is located in the hospital's Intensive Care Unit (ICU).~~ For purposes of Status 1A/1B definition and classification, candidates listed at less than 18 years of age who remain on or have returned to the Waiting List upon or after reaching age 18 may be considered Status 1A/1B and shall qualify for other pediatric classifications under the following criteria. There are five allowable diagnostic groups: (i) fulminant liver failure; (ii) primary non function; (iii) hepatic artery thrombosis; (iv) acute decompensated Wilson's Disease; ~~and (v) chronic liver disease; and (vi) non-metastatic hepatoblastoma.~~ Candidates meeting criteria (i) (ii), (iii), or (iv) may be listed as a Status 1A; those meeting criteria (v) and (vi) may be listed as a Status 1B. Within each diagnostic group specific conditions must be met to allow for listing a pediatric candidate at Status 1A or 1B. Centers that list candidates not meeting these criteria for Status 1A or 1B will be referred to the Liver and Intestinal Organ Transplantation Committee for review; this review by the Liver and Intestinal Organ Transplantation Committee may result in further referral of the matter to the Membership and Professional Standards Committee for appropriate action in accordance with Appendix A of the Bylaws. Candidates meeting the criteria in (i)-(vi) will be listed in Status 1A or Status 1B without RRB review.

- (i) Fulminant hepatic failure. Fulminant liver failure is defined as the onset of hepatic encephalopathy within 8 weeks of the first symptoms of liver disease. The absence of pre-existing liver disease is critical to the diagnosis. One of three criteria below must be met to list a pediatric candidate with fulminant liver failure: (1) ventilator dependence (2) requiring dialysis or continuous veno-venous hemofiltration (CVVH) or continuous veno-venous hemodialysis (CVVD), or (3) INR > 2.0.
- (ii) Primary non-function of a transplanted liver. The diagnosis is made within 7 days of implantation. Additional criteria to be met for this indication must include 2 of the following: ALT \geq 2000, INR \geq 2.5, total bilirubin \geq 10 mg/dl, or acidosis, defined as having an arterial pH \leq 7.30 or venous pH of 7.25 and/or lactate \geq 4 mMol/L. All labs must be from the same blood draw within 24 hours to 7 days following the transplant.
- (iii) Hepatic artery thrombosis. The diagnosis must be made in a transplanted liver within 14 days of implantation.
- (iv) Acute decompensated Wilson's disease.
- (v) Chronic liver disease. Pediatric candidates with chronic liver disease ~~and in the ICU~~ can be listed at Status 1B if the candidate has a calculated PELD score of >25 or calculated MELD score of >25 for adolescent candidates (12-17 years) and one of the following criteria is met (candidates listed for a combined liver-intestine transplant may meet these criteria with their adjusted

match score as described in Policy 3.6.4.7 (Combined Liver-Intestine Candidates):

- a. On a mechanical ventilator; or
 - b. Gastrointestinal bleeding requiring at least 30 cc/kg of red blood cell replacement within the previous 24 hours; or
 candidates also on the intestine list, at least 10 cc/kg of red blood cell replacement within the previous 24 hours; or
 - c. Renal failure or renal insufficiency defined as requiring dialysis or continuous CVVH or continuous CVVD; or
 - d. Glasgow coma score <10 within 48 hours of the listing/extension.
- (vi) Non-metastatic hepatoblastoma. A pediatric candidate with a biopsy proven hepatoblastoma without evidence of metastatic disease at the time of listing may be listed as Status 1B.

Candidates who are listed as a Status 1A or 1B automatically revert back to their most recent PELD or MELD score after 7 days unless these candidates are relisted as Status 1A or 1B by an attending physician. Extensions for Status 1B candidates indicating a gastrointestinal bleed as the initial Status 1B upgrade criteria must have had another bleed in the past 7 days prior to upgrade in order to remain in Status 1B. Status 1B candidates listed with a metabolic disease (in accordance with Policy 3.6.4.3) or a hepatoblastoma (in accordance with Policy 3.6.4.4.1) will require recertification every three months with lab values no older than 14 days. Candidates must be listed with PELD/MELD laboratory values in accordance with Policy 3.6.4.2.1 (Pediatric Candidate Recertification and Reassessment Schedule) at the time of listing. A completed Liver Status 1A or 1B Justification Form must be received on UNetSM for a candidate's original listing as a Status 1A or 1B and each relisting as a Status 1A or 1B. If a completed Liver Status 1A or 1B Justification Form is not entered into UNetSM when a candidate is registered as a Status 1A or 1B, the candidate shall be reassigned to their most recent PELD or MELD score. A relisting request to continue a Status 1A or 1B listing for the same candidate waiting on that specific transplant beyond 14 days accumulated time (excluding hepatoblastoma candidates that meet criteria (vi), and candidates listed with a metabolic disease as described in Policy 3.6.4.3) will result in a review of all local Status 1A or 1B liver candidate listings.

~~**3.6.4.4.1 Pediatric Liver Transplant Candidates with Hepatoblastoma.** A pediatric candidate with non-metastatic hepatoblastoma who is otherwise a suitable candidate for liver transplantation may be assigned a PELD (less than 12 years old) or MELD (12-17 years old) score, of 30. If the candidate does not receive a~~

~~transplant within 30 days of being listed with a MELD/PELD of 30, then the candidate may be listed as a Status 1B. Hospitalization is not a requirement for listing in Status 1B for these candidates. A biopsy is required for these candidates. Candidates meeting these criteria will be listed in as a MELD/PELD of 30 and subsequent Status 1B without RRB review.~~

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: At its November 2011 meeting, the OPTN/UNOS Board of Directors approved two separate resolutions that modified policies 12.7 (Responsibility for Transport of Living Donor Organs), 12.7.2, 12.7.3, and 12.7.4. The policy language below reflects the changes from both of these proposals: Modified Policies for the Packaging, Labeling and Shipment of Living Donor Organs, Vessels, and Tissue Typing Materials and Requirements to Perform a Second ABO Subtyping Test When a Donor is Identified as non-A₁ or non-A₁B (sponsored by the Living Donor Committee and Operations and Safety Committee, respectively).*

12.7 STANDARDIZED PACKAGING, LABELING AND TRANSPORTING OF LIVING DONOR ORGANS, VESSELS, AND TISSUE TYPING MATERIALS

The purpose of Policy 12.7 and its subsections apply only to living donor organs, tissue typing specimens and vessels which are transported outside the recovery facility and:

- state requirements for packaging and labeling living donor organs (when applicable), tissue typing specimens, and (when applicable) vessels, to prevent wastage (and/or to promote safe and efficient use);
- define terms and responsibilities related to packaging, labeling, and transporting organs of living donor organs, and if applicable living donor tissue typing specimens, and vessels; and
- state requirements for recovering, storing, and using (when applicable) living donor vessels.

The responsibility for packaging and labeling living donor organs is assigned to the donor recovery transplant center. If a living donor organ ever requires repackaging by a transplant center for transport, the transplant center will package, label and ship the organ in accordance with this policy.

12.7.1 EXTERNAL PACKAGING SPECIFICATIONS

An external transport container is defined as a: disposable shipping box, cooler or mechanical preservation machine. The transplant center must use both internal and external transport containers to package a living donor organ, which travels outside the recovery facility.

12.7.1.1 Disposable shipping box

- If living donor organs, vessels and/or tissue typing that are packaged with the organ materials are shipped commercially, a disposable shipping box must be used.
- The disposable shipping box must be labeled with the standardized label distributed by the OPTN contractor.
- Disposable boxes must not be reused.
- The outer box must be a corrugated plastic or corrugated cardboard that is coated with a water resistant substance with at least 200 pound burst strength.
- The inner container must be a 1.5 inches thick, insulated container OR have an equivalent "R" value.

- A closed colored opaque plastic bag must be placed between the outer container and the insulated container. Closed is defined as being secured in a manner to prevent leakage (i.e. watertight).
- A second closed plastic liner must also be placed inside the insulated container to encase the ice. Closed is defined as being secured in a manner to prevent leakage (i.e. water tight).

12.7.1.2 Cooler

- Coolers are permitted for non-commercial transporting of organs when the organ recovery team is transporting the donor organ with them from the donor hospital to the candidate transplant center.
- Coolers must be labeled with the standardized label distributed by the OPTN contractor.
- Coolers may be reused if properly cleaned and sanitized.
- Before re-using a cooler, all labels from the previous donor organ must be removed.

12.7.1.3 Mechanical preservation machine

- Mechanical preservation machines are permitted for transporting an organ.
- The cassette (if applicable) containing the organ must be labeled with the organ type (i.e. left kidney, right kidney), ABO and subtyping (when used to determine transplant compatibility), and UNOS ID.
- The external surface of a mechanical preservation machine must be labeled with the standardized external label distributed by the OPTN contractor.
- Before re-using a mechanical preservation machine that was used to transport an organ, all labels from the previous donor must be removed.

12.7.2 INTERNAL PACKAGING SPECIFICATIONS

All organs that have been packaged on the donor's back table must be handled using universal precautions. The packaged organs from the donor's surgical back table are to be placed directly into the wet iced shipping container. Proper insulation and temperature controlled packaging including adequate ice or refrigeration must be used to protect the organs during transport.

- Organs must be protected by a triple sterile barrier.
- Kidneys and pancreata must be placed in a rigid container, which, if sterile, can be one layer of the triple sterile barrier.
- Livers, lungs, and intestines do not require a rigid container.
- Vessels must be protected by a triple sterile barrier; if packaged separately from the organ, one barrier must be a rigid container.

12.7.3 EXTERNAL LABELING REQUIREMENTS

When a disposable shipping box or cooler is used to transport a living donor organ, the donor recovery transplant center must use the standardized external label distributed by the OPTN contractor.

The external transport container must be labeled with the: UNOS Donor I.D., Donor ABO type and subtyping (when used to determine transplant compatibility), a description of the specific contents of the box, the sender's name and telephone number, and the Organ Center telephone number. The label must be securely affixed to the external transport container. The OPTN contractor distributes a standardized external label that includes this information, which must be utilized.

12.7.4 INTERNAL LABELING REQUIREMENTS

12.7.4.1 Solid organ

The donor recovery transplant center is responsible for ensuring that a secure label identifying the specific contents (e.g., liver or right or left kidney intestines) is attached to the outer bag or rigid container housing the donor organ. The OPTN contractor distributes a standardized internal label that must be utilized for this purpose. In addition to the contents of the package, the label information must include the UNOS Donor I.D. and donor ABO type and subtyping (when used to determine transplant compatibility).

12.7.4.2 Tissue typing materials

Each separate specimen container of tissue typing material that is packaged with the organ 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.

12.7.4.3 Vessels

The vessels must be labeled with the standardized vessel label distributed by the OPTN contractor. The information must contain the: recovery date, ABO and subtyping (when used to determine transplant compatibility), all serology results, container contents, and the UNOS Donor I.D. If the donor is in a "high risk" group as defined by the U.S. Public Health Service Guidelines, the label must indicate that the vessels are from a donor who meets the CDC criteria for high risk. The appropriate packaging of vessels should be completed in the donor operating room. The label should clearly state "for use in organ transplantation only." If packaged separately from the organ, the vessels must be protected by a triple sterile barrier, one of which must be a rigid container and the standardized vessel label must be affixed to the outermost barrier.

12.7.5 DOCUMENTATION ACCOMPANYING THE ORGAN OR VESSEL

12.7.5.1 Documentation accompanying the organ

- Complete donor documentation must be sent in the container with each transported organ or vessel. This documentation must include:
 - ABO typing source documentation;
 - Consent form; and

- ⊖ Complete medical record of the living donor;
- Donor documentation must be placed in a watertight container.
- Donor documentation may be placed in either:
 - a location specifically designed for documentation, or
 - between the outer and inner containers.
- Whenever a living donor organ is transported, the donor recovery transplant center, must include the source documentation in the donor documentation.

12.7.6 VERIFICATION OF LABELING AND DOCUMENTATION INCLUDED WITH ORGANS OR VESSELS

12.7.6.1 Verification of labeling and documentation for living donor organs or vessels.

When a living donor organ or vessel(s) is procured, the donor recovery transplant center must ensure the accuracy of the donor's ABO and subtyping (when used to determine transplant compatibility) on the container label and within the donor's documentation.

Each donor recovery transplant center must establish and implement a procedure for verifying the accuracy of organ/vessel packaging labels by an individual other than the person initially performing the labeling and documentation. The donor recovery transplant center must maintain documentation that such separate verification has taken place and make such documentation available for audit.

12.7.7 VERIFICATION OF INFORMATION UPON RECEIPT OF ORGAN

Upon receipt of a living donor organ and prior to implantation, the recipient's transplant center must determine that it has received the correct organ for the correct transplant candidate by verifying the recorded donor and recipient ABO and subtyping (when used to determine transplant compatibility), and UNOS Donor ID. The recipient's transplant center must maintain documentation that this verification has taken place and make such documentation available for audit.

12.7.8 MATERIALS FOR TISSUE TYPING AND ABO CONFIRMATION

12.7.8.1 Policy for tissue typing specimen, medium, and shipping requirements

Donor recovery transplant centers must have a written policy established with an OPTN member laboratory(s). The policy shall include specific descriptions of the type of specimen(s) required, and medium, in addition to the shipping requirements of same.

12.7.8.2 Blood for ABO Confirmation

A "red top" tube of blood, specifically for confirmation of ABO must be sent to organ recipient's transplant center with each living donor organ and tissue typing material that is packaged with the organ. This tube must have a secure label with two unique identifiers, one being the UNOS Donor I.D., and one of the following three: donor date of birth, donor initial, or locally assigned unique ID (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. The donor recovery transplant center is responsible for ensuring that the tube is appropriately labeled.

12.7.8.3 Typing material for each kidney

The minimal typing material to be obtained for EACH kidney will include 2 ACD (yellow top) tubes.

12.7.8.4 Typing material for all other organs

The donor recovery transplant center will provide specimens for tissue typing if requested.

12.7.9 LIVING DONOR ORGANS THAT REMAIN IN THE SAME RECOVERY FACILITY AS THE INTENDED CANDIDATE(S)

12.7.9.1 When living donor organs are recovered and remain in the same facility as the intended candidate(s), the transplant center must develop, implement, and comply with a procedure to ensure identification of the correct donor organ for the correct recipient. A “time out” prior to leaving the donor operating room and an additional “time out” upon arrival in the candidate operating room are required. These “time outs” are for the transplant center to confirm and document that the correct organ was identified for the correct candidate prior to transplant.

12.7.10 VESSEL RECOVERY, TRANSPLANT, AND STORAGE

The intent of this policy is to permit vessel recovery and immediate use in a solid organ transplant.

12.7.10.1 Vessel recovery and 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.

12.7.10.2 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. This person must monitor the refrigerator, ensure records are up to date and available with the vessels, destroy the vessels when expired, and notify the OPTN of its use or disposal.

- The vessels must be stored in a Food and Drug Administration (FDA) approved preservation solution (ex. UW, Custodial HTK).
- The vessels must be stored in a rigid, sterile sealed container labeled with the recovery date, ABO and subtyping (when used to determine transplant compatibility), serology, container contents, and the UNOS Donor ID for tracking. The standardized vessel label distributed by the OPTN contractor must be attached to the outer sterile barrier bag and information on the label must include all of the above information and all serology testing results. The appropriate packaging of vessels should be completed in the donor operating room. The label should clearly state for use in organ transplantation only.
- The vessel(s) must be stored in a secured refrigerator with a temperature monitor and maintained within a range of 2 - 8 degrees Celsius.
- There must be daily monitoring of the vessel(s) with documented security and temperature checks by the transplant center.

- The vessel(s) can be stored up to a maximum of 14 days from the original recovery date.
- The transplant center must maintain a log of stored vessels.

12.7.11 TRANSPORTATION RESPONSIBILITY

The purpose of this policy is to define the responsibility of transportation costs for living donor organs.

12.7.11.1 Renal organs

The organ recipient's transplant center is responsible for transportation costs for living donor kidney(s) and associated tissue typing material pursuant to CMS regulations.

12.7.11.2 Non-renal organs

The member that accepted the organ is responsible for transportation costs for living donor non-renal organ(s) and associated tissue typing material to its destination. If a donor organ is first accepted by one member and subsequently forwarded to another member, payment of transportation costs for forwarding the organ is the responsibility of the member that finally accepts the organ, unless otherwise agreed upon by the parties involved. If a non-renal organ has been accepted and transported, but cannot be used for transplantation, the member that finally accepted the organ is responsible for payment of transportation costs, unless otherwise agreed upon by the parties involved. The OPTN contractor will not incur transportation costs for non-renal organs or tissue typing material.

12.7.11.3 Tissue typing material

The organ recipient's transplant center is responsible for payment of transportation costs for tissue typing material sent to crossmatch potential recipients of a living donor kidney. The organ recipient transplant center that requested the tissue typing material is responsible for the payment of transportation costs for the tissue typing material sent to crossmatch potential recipients for a non-renal organ

12.7 — Responsibility for Transport of Living Donor Organs.

The following policies address standardized packaging of living donor organs and tissue typing materials to be transported for the purposes of organ transplantation. When an organ from a living donor is procured, the Transplant Center shall be responsible for ensuring the accuracy of the donor's ABO on the container label and within the donor's documentation. The Transplant Center shall establish and implement a procedure for obtaining verification of donor ABO data by an individual other than the person initially performing the labeling and documentation requirements put forth in Policies 12.7.1 and 12.7.5. The Transplant Center shall maintain documentation that such separate verification has taken place and make such documentation available for audit.

Upon receipt of an organ from a living donor and prior to implantation, the Transplant Center shall be responsible for determining the accuracy and compatibility of the donor and recipient ABO and document this verification in compliance with Policy 3.1.2.

12.7.1 — Standard Labeling Specifications.

The Transplant Center shall be responsible for ensuring that the outermost surface of the transport box containing organs and/or tissue typing specimen containers has a

completed standardized external organ container label (provided by the OPTN contractor). Any previous labels on the transport container must be removed prior to labeling the box so that only one label exists. The Transplant Center shall label each specimen within the package in accordance with policy. The transplant center is responsible for ensuring that each tissue or donor organ container that travels outside of the recovery facility is labeled appropriately.

In the case of organs from living donors who remain in the same operating room suite as the intended candidate(s), the Transplant Center must develop, implement, and comply with a procedure to ensure identification of the correct donor organ for the correct recipient. The Transplant Center must document that the correct organ was identified for the correct candidate prior to transplant. Some type of donor organ labeling and documentation must be present in the candidate chart. A "time out" prior to leaving the donor operating room and an additional "time out" upon arrival in the candidate operating room is recommended. Exception: In the case of a single donor organ/organ

segment remaining in the same operating room suite as a single intended candidate for a simultaneous transplant, donor organ labeling and "time outs" are not necessary.

In the case of organs from living donors that travel outside of the recovery facility, the Transplant Center(s) involved shall be responsible for ensuring that packaging is consistent with the requirements of Policies 12.7.2 and 12.7.4, and that the outermost surface of the transport box containing the organ must have a completed standardized external organ container label (provided by OPTN Contractor). The recovering Transplant Center shall label each specimen within the package in accordance with these policies. The recovering Transplant Center is responsible for ensuring that each container that travels outside of the recovery facility is labeled appropriately.

12.7.2 The Transplant Center is responsible for ensuring that the Donor I.D., Donor ABO type, and a secure label identifying the specific contents (e.g., liver segment, right kidney) are attached to the outer bag or rigid container housing the donor organ prior to transport.

12.7.3 Each separate specimen container of tissue typing material must have a secure label with the Donor I.D., Donor ABO type, date and time the sample was procured and the type of tissue. The Transplant Center is responsible for labeling the materials appropriately.

12.7.4 The Transplant Center is responsible for affixing to the transport container the standardized label completed with the Donor I.D., Donor ABO type, a description of the specific contents of the box, the sender's name and telephone number, and the Organ Center telephone number. A transport container is defined as a corrugated, wax coated disposable box, cooler, or mechanical preservation cassette or machine.

12.7.5 Packaging. ABO results must be provided by the Transplant Center in all circumstances during which a donor organ is transported. Properly packaged paperwork containing complete donor information, as described in Policy 2.5.6.1, will be included with the organ transport container in all instances in which the organ is transported.

12.7.6 Packaging. In all circumstances during which a donor organ is transported outside the recovery facility, the Transplant Center is responsible for packaging,

labeling, and handling the organ in a manner which ensures arrival without compromise to the organ(s). Proper insulation and temperature controlled packaging including adequate ice or refrigeration shall be used to protect the organs during transport. All packaged organs, using disposable transport boxes, must have a red plastic bio-hazard bag that is water tight secured to allow for safe handling by medical and non-medical personnel during transport. This red bag may be placed between the waxed cardboard box and the insulated material holding the wet ice and the organ. All organs that have been packaged on the donor's back table must be handled using universal precautions. The packaged organs from the donor's surgical back table are to be placed directly into the wet iced shipping container.

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 Bylaw/Policy Language:

**Please note: At its November 2011 meeting, the OPTN/UNOS Board of Directors approved two separate resolutions that modified policies 12.7 (Responsibility for Transport of Living Donor Organs), 12.7.2, 12.7.3, and 12.7.4. Below, Policy 12.7 (Standardized Packaging, Labeling, and Transporting of Living Donor Organs, Vessels, and Tissue Typing Materials) reflects the changes from both of these proposals: Modified Policies for the Packaging, Labeling and Shipment of Living Donor Organs, Vessels, and Tissue Typing Materials and Requirements to Perform a Second ABO Subtyping Test When a Donor is Identified as non-A₁ or non-A₁B (sponsored by the Living Donor Committee and Operations and Safety Committee, respectively). Additionally, the OPTN/UNOS Board of Directors approved three separate resolutions that modified Policy 5.10.2 (Vessel Storage). Below, Policy 5.10.2 reflects the changes from all three of these proposals: Requirements to Perform a Second ABO Subtyping Test When a Donor is Identified as non-A₁ or non-A₁B, Prohibiting the Storage of Hepatitis C Antibody Positive and Hepatitis B Surface Antigen Positive Extra Vessels (both sponsored by the Operations and Safety Committee), and Standardized Label Requirements for Vessel Transport and Storage (sponsored by the OPO Committee).*

UNOS Bylaws, Appendix B, Attachment IIA, Section I**I ABO Blood Group Determination**

- I1.000 ABO blood group must be performed by techniques compliant with Federal regulations.
- I2.000 If testing for the A1 subgroup of ABO group A is performed, the extract of Dolichos biflorus must be used at a dilution and with a technique documented not to agglutinate A2-non-A₁ cells. Each assay or batch test run must include known A1 and A2 non-A₁ cells as controls.
- I3.000 If titration of anti-ABO antibodies is performed, the procedure and criteria for interpretation must be established and validated by the laboratory.
- I4.000 Laboratories using molecular techniques for ABO blood grouping must conform to all pertinent standards in Section K- Nucleic Acid Analysis.

OPTN/UNOS Policies

- 3.1.2 Transplant Center.** A transplant center is a hospital that is a Member in which transplants are performed. A transplant center may also be called a transplant hospital. It is the responsibility of the transplanting surgeon at the transplant center receiving the organ offer for the surgeon's candidate to ensure medical suitability of donor organs for transplantation into the potential recipient, including-compatibility of donor and candidate by ABO blood type and subtype (when used for allocation). Upon receipt of an organ, prior to implantation, the transplant center is responsible for verifying the recorded donor ABO and subtype (when used for allocation), with the recorded ABO and subtype (when used for allocation) of the intended recipient and UNOS Donor ID number. These actions must be documented and are subject to review upon audit.
- 3.1.13 Definition of Directed Donation** – OPOs are permitted to allocate an organ(s) to a specific transplant candidate named by the person(s) who authorized the donation unless prohibited by state law. All recipients of a deceased donor organ(s) from a directed donation must be added to the waiting list prior to transplantation.

When the candidate does not appear on at least one of the deceased donor's match runs for at least one organ type, the transplant center must document the reason why the candidate does not appear and ensure that the organ is safe and appropriate for the candidate. The transplant center must maintain all related documentation and provide written justification to the OPTN contractor upon request. The written justification must include:

- the rationale for transplanting the candidate who did not appear on the match run;
- the reason the candidate did not appear on the match run;
- the center is willing to accept an ECD or DCD organ, as applicable; and
- documentation that the transplant center verified suitability between the donor organ and recipient prior to transplant in at least, but not limited to, the following areas as applicable to each organ type:
 - ABO;
 - ABO subtype when used for allocation;
 - Serologies;
 - Donor HLA and candidate's unacceptable antigens;
 - Height; and
 - Weight.

3.2.4 Match System Access. OPOs are required to use the Match System (UNetSM) for the allocation of all deceased donor organs. The Host OPO must enter required information about the donor as required by the following Policies:

- Policy 3.5.79 (Minimum Information/Tissue for Kidney Offer),
- Policy 3.6.9 (Minimum Information for Liver Offers),
- Policy 3.7.912 (Minimum Information for Thoracic Organ Offers),
- 3.8.2.2 (Essential Information for Pancreas Offers),

and execute the Match System to determine organ allocation priorities. Such information must be entered into the Match System for all deceased donors.

- **ABO Typing.** To ensure the accuracy of the donor's ABO, ~~the~~ OPO shall be responsible for two separate determinations, either 1) two samples sent to two labs, or 2) two samples from separate draws sent to the same lab of the donor's ABO type prior to incision and for ensuring the accuracy of the donor's ABO data. The OPO shall maintain documentation that ~~such separate verification~~ the an initial and second determination tests ~~has~~ taken place and make such documentation available for audit. Each OPO shall establish and implement a procedure for utilizing ~~the~~ ABO source documents for on-line verification of donor ABO data by an individual other than the person initially entering the donor's ABO data in UNetSM.
- **ABO Subtyping.** When a blood type A (as required by policy 2.2.4.1) or AB donor is

subtyped and found to be non-A₁ (negative for A₁) or non-A₁B (negative for A₁B), the OPO must complete a second determination subtype test to assess the accuracy of the result. Blood samples for the initial and second determination subtype tests must be two separate determinations, either 1) two samples sent to two labs, or 2) two samples from separate draws sent to the same lab. Subtype testing must be performed only on pre-transfusion specimens. The two test results must indicate the same subtype before a match can be run using the subtype to allocate organs. When two pre-transfusion samples are not available, or the initial and second determination test results do not indicate the same subtype, the donor must be allocated based on the primary blood type and the subtype should not be entered into UNetSM. The OPO shall maintain documentation that the initial and second determination tests have taken place and make such documentation available for audit. Each OPO shall establish and implement a procedure for two individuals to verify the accuracy of the initial and second determination subtyping test results by utilizing both ABO subtyping source documents and document that this process has taken place.

Organs shall be allocated only to candidates who appear on a match run. In the event that an organ has not been placed after the organ has been offered for all potential recipients on the initial match run, the Host OPO may give transplant programs the opportunity to update their transplant candidates' data, and the Host OPO may re-run the match system. In any event, the organ shall be allocated only to a candidate who appears on a match run.

If the transplant center deems it necessary to transplant a candidate who does not appear on at least one of the deceased donor's match runs for at least one organ type, such as in the event of a directed donation or to prevent organ wastage, the transplant center must maintain all related documentation and provide written justification to the OPTN contractor upon request. The written justification must include:

- rationale for transplanting a candidate who did not appear on the match run;
- the reason the candidate did not appear on the match run;
- the center is willing to accept an ECD or DCD organ, as applicable; and
- documentation that the transplant center verified suitability between the donor organ and recipient prior to transplant in at least, but not limited to, the following areas as applicable to each organ type:
 - ABO;
 - ABO subtype when used for allocation;
 - Serologies;
 - Donor HLA and candidate's unacceptable antigens;
 - Height; and
 - Weight.

For all deceased donor organs, the organ must be transplanted into the original designee or be released back to the Host OPO or to the Organ Center for distribution. If an organ is accepted for a candidate who ultimately is unavailable to receive the

transplant at his/her listing transplant center in the organ allocation unit to which the organ is being distributed, then the organ shall be released back to the Host OPO or to the Organ Center for allocation to other transplant candidates in accordance with the organ-specific allocation policies. The Host OPO may delegate this responsibility to the Local OPO. Further allocation at the local OPO level must be done according to the match run. The final decision whether to use the organ will remain the prerogative of the transplant surgeon and/or physician responsible for the care of that candidate. This will allow physicians and surgeons to exercise judgment about the suitability of the organ being offered for the specific candidate. If an organ is declined for a candidate, a notation of the reason for the decision refusing the organ for that candidate must be made on the appropriate form and promptly submitted.

3.5.9.1 Essential Information for Kidney Offers. The Host OPO must provide the following information to the potential recipient center with each kidney offer:

- (i) Donor name and Donor I.D. number, age, sex, and race;
- (ii) Date of admission for the current hospitalization;
- (iii) Diagnosis;
- (i) Blood type;
- (ii) ABO subtype when used for allocation;
- (v) HLA A, B, Bw4, Bw6, C, DR and DQB antigens. When reporting DR antigens, DRB1, and DRB3/4/5 must be reported. The lab is encouraged to report splits for all loci as shown in Appendix 3A;
- (vi) Current history of abdominal injuries and operations;
- (vii) Pertinent past medical or social history;
- (viii) Current history of average blood pressure, hypotensive episodes, average urine output, and oliguria;
- (ix) Final urinalysis;
- (x) Final BUN and creatinine;
- (xi) Indications of sepsis;
- (xii) Assurance that final blood and urine cultures are pending;
- (xiii) Serologies as indicated in 2.2.4.1 qualified specimens preferred as noted in Policy 2.2.3.1);
- (xiv) Current medication and transfusion history;
- (xv) Recovery blood pressure and urine output information;
- (xvi) Recovery medications;
- (xvii) Type of recovery procedure (e.g., en bloc); flush solution and method (e.g., in situ); and flush storage solution;
- (xviii) Description of typing material available, including, as a minimum for each kidney:

- One 7 to 10ml. clot (red topped) tube for ABO Verification, plus
 - 2 ACD (yellow top) tubes
 - 3 to 5 lymph nodes
 - One 2 X 4 cm wedge of spleen in culture medium, if available
- (xix) Warm ischemia time and organ flush characteristics; and
- (xx) Anatomical description, including number of blood vessels, ureters, and approximate length of each, injuries to or abnormalities of the blood

3.6.2 Blood Type Similarity Stratification/Points. For Status 1A and 1B transplant candidates, those with the same ABO type as the liver donor shall receive 10 points. Candidates with compatible but not identical ABO types shall receive 5 points, and candidates with incompatible types shall receive 0 points. Blood type O candidates who will accept a liver from a non-A₁ (negative for A₁ subtype) blood type donor shall receive 5 points for ABO incompatible matching. Within each MELD/PELD score, donor livers shall be offered to transplant candidates who are ABO-identical with the donor first, then to candidates who are ABO-compatible, followed by candidates who are ABO-incompatible with the donor.

3.6.9.1 Essential Information Category. When the Host OPO or donor center provides the following donor information, with the exception of pending serologies, to a recipient center, the recipient center must respond to the offer within one hour pursuant to Policy 3.4.1 (Time Limit for Acceptance); however, this requirement does not preclude the Host OPO from notifying a recipient center prior to this information being available:

- (i) Donor name and Donor I.D. number, age, sex, race, height and weight;
- (ii) ABO type;
- (iii) ABO subtype when used for allocation;
- (iv) Cause of brain death/diagnosis;
- (v) History of treatment in hospital including current medications, vasopressors and hydration;
- (vi) Current history of hypotensive episodes, urine output and oliguria;
- (vii) Indications of sepsis;
- (viii) Social and drug activity histories;
- (ix) Vital signs including blood pressure, heart rate and temperature;
- (x) Other laboratory tests within the past 12 hours including:
 - (1) Total Bilirubin
 - (2) ALT

- (3) INR (PT if INR not available)
- (4) Alkaline phosphatase
- (5) WBC
- (6) HH
- (7) Creatinine;
- (xi) Arterial blood gas results;
- (xii) Serologies indicated in 2.2.4.1 (qualified specimens preferred as noted in Policy 2.2.3.1).

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

- (i) The cause of brain death;
- (ii) The details of documented cardiac arrest or hypotensive episodes;
- (iii) Vital signs including blood pressure, heart rate and temperature;
- (iv) Cardiopulmonary, social, and drug activity histories;
- (v) Serologies as indicated in 2.2.4.1(qualified specimens preferred as noted in Policy 2.2.3.1);
- (vi) Accurate height, weight, age and sex;
- (vii) ABO type;
- (viii) ABO subtype when used for allocation;
- (ix) Interpreted electrocardiogram and chest radiograph;
- (x) History of treatment in hospital including vasopressors and hydration;
- (xi) Arterial blood gas results and ventilator settings; and
- (xii) Echocardiogram, if the donor hospital has the facilities.

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

3.8.2.2 Essential Information for Pancreas Offers. The Host OPO or donor center must provide the following donor information, with the exception of pending serologies, to the recipient center with each pancreas offer:

1. Donor name and Donor I.D. number, age, sex, race and weight;
2. Date of admission for the current hospitalization;
3. Diagnosis;
4. Blood type;

5. ABO subtype when used for allocation;
6. Current history of abdominal injuries and operations including pancreatic trauma;
7. Pertinent past medical or social history including pancreatitis;
8. Current history of average blood pressure, hypotensive episodes, cardiac arrest, average urine output, and oliguria;
9. Indications of sepsis;
10. Serologies as indicated in Policies 2.2.4.1 and (qualified specimens preferred as noted in Policy 2.2.3.1):
11. Current medication and transfusion history;
12. Blood glucose;
13. Amylase;
14. Insulin protocol;
15. Alcohol use (if known);
16. Familial history of diabetes; and
17. HLA A, B, Bw4, Bw6, C, DR and DQB antigens. When reporting DR antigens, DRBI, and DRB3/4/5 must be reported. The lab is encourages to report splits for all loci as shown in Appendix 3A.

5.1.3 Mechanical preservation machine

- Mechanical preservation machines are permitted for transporting an organ.
- The cassette containing the organ must be labeled with the organ type (i.e. left kidney, right kidney), ABO, ABO subtype when used for allocation, and UNOS ID.
- The external surface of a mechanical preservation machine must be labeled with:
 - the standardized external label distributed by the OPTN contractor, or
 - an alternate label that contains all information included on the OPTN contractor standardized label.
- Before re-using a mechanical preservation machine that was used to transport an organ, all labels from the previous donor organ must be removed.

5.3 EXTERNAL LABELING REQUIREMENTS

When a disposable shipping box or cooler is used to transport a deceased donor organ, the Host OPO must use the standardized external label distributed by the OPTN contractor. When a mechanical preservation machine is used, the OPO or Transplant Center, as applicable, may use an alternative label if the label contains all of the required information.

The external transport container must be labeled with the: UNOS Donor I.D., Donor ABO type, ABO subtype when used for allocation, a description of the specific contents of the box, the sender's name and telephone number, and the Organ Center telephone number. The label must be securely affixed to the external transport container. The

OPTN contractor distributes a standardized external label that includes this information and must be utilized.

5.4.1 Solid organ

The Host OPO is responsible for ensuring that ~~the~~ a secure label identifying the specific contents (e.g., liver, right kidney, heart) is attached to the outer bag or rigid container housing the donor organ. The OPTN contractor distributes a standardized internal label that must be utilized for this purpose. In addition to the contents of the package, the label information must include the UNOS Donor I.D. ~~and~~ donor ABO type, and ABO subtype when used for allocation.

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, ABO subtype when used for allocation, 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.

5.4.3 Vessels

The vessels must be labeled with the standardized vessel label distributed by the OPTN contractor. The information must contain the: recovery date, ABO, ABO subtype when used for allocation, all serology results, container contents, and the UNOS Donor ID. If the donor is in a “high risk”¹ group as defined by the Centers for Disease Control and Prevention (CDC), the label must indicate that the vessels are from a donor who meets the CDC criteria for high risk. The appropriate packaging of vessels should be completed in the donor operating room. The label should clearly state “for use in organ transplantation only.” If packaged separately from the organ, the vessels must be protected by a triple sterile barrier, one of which must be a rigid container and the standardized vessel label must be affixed to the outermost barrier.

5.5.1 Documentation accompanying the organ

- Complete donor documentation-must be sent in the container with each transported organ. This documentation must include:
 - ABO typing source documentation;
 - ABO subtyping source documentation when subtype is used for allocation;

¹ Rogers MF, Simonds RJ, Lawton KE, et al. Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissue and Organs. CDC MMWR Recommendations and Reports. 1994;May 20/ 43(RR-8):1-17.
<http://www.cdc.gov/mmwr/preview/mmwrhtml/00031670.htm>

- Infectious disease testing results;
- Medical/Behavioral History form;
- Donor Evaluation;
- Complete record of the donor;
- Consent form; and
- Organ quality information as noted in Policy 2.5
- Donor documentation must be placed in a watertight container.
- Donor documentation may be placed in either:
 - a location specifically designed for documentation, or
 - between the outer and inner containers.
- Whenever a deceased donor organ is transported, the Host OPO or the Transplant Center, as applicable, must include in the donor documentation the source documentation.

5.6.1 Verification of labeling and documentation for deceased donor organs or vessels.

When a deceased donor organ or vessel(s) is procured, the Host OPO must ensure the accuracy of the donor's ABO, and ABO subtype when used for allocation, on the container label and within the donor's documentation. Each OPO must establish and implement a procedure for verifying the accuracy of organ/vessel packaging labels by an individual other than the person initially performing the labeling and documentation requirements stated in policy 5.3, 5.4 and 5.5. The Host OPO must maintain documentation that such separate verification has taken place and make such documentation available for audit.

5.7 Verification of Information Upon Receipt of an Organ

Upon receipt of a deceased donor organ and prior to implantation, the Transplant Center must determine that it has received the correct organ for the correct transplant candidate by verifying the recorded donor and recipient ABO, ABO subtype when used for allocation, and UNOS Donor ID, as required by Policy 3.1.2. The Transplant Center must maintain documentation that this verification has taken place and make such documentation available for audit.

5.8.2 Blood for ABO Confirmation

A "red top" tube of blood, specifically for confirmation of ABO and subtype (when used for allocation), must be sent to the receiving OPO or transplant center with each deceased organ and tissue typing material. This tube must be labeled as described in Policy 5.4.2 with the exception that the blood type may not be indicated on the label, and placed within the insulated container. The Host OPO is responsible for ensuring that the tube is appropriately labeled.

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). This person must monitor the refrigerator, ensure records are up to date and available with the conduits, destroy the vessels when expired, and notify the OPTN of its use or disposal.

- Hepatitis C antibody positive and hepatitis B surface antigen positive extra vessels may not be stored for subsequent use.
- The vessels must be stored in a Food and Drug Administration (FDA) approved preservation solution (ex. UW, Custodial HTK).
- The vessels must be stored in a rigid, sterile sealed container and must be protected by a triple sterile barrier, one of which must be the rigid container, labeled with the recovery date, ABO, ABO subtype when used for allocation, infectious disease results, container contents, and the UNOS Donor ID for tracking. The standardized vessel label distributed by the OPTN contractor must be ~~attached~~ affixed to the outer most sterile barrier bag and information on the label must include ~~all of the above information and all serology testing results~~ the: recovery date, ABO, all infectious disease results, container contents, and the UNOS Donor ID. If the donor is in a "high risk"¹ group as defined by the US Public Health Service (PHS) guidance¹, the label must indicate that the vessels are from a donor who meets the CDG(PHS) criteria for high risk. The appropriate packaging of vessels should be completed in the donor operating room. ~~The label~~ should clearly state for use in organ transplantation only. If removed from the triple sterile barrier, the transplant center must re-label the vessels prior to storage.
- The vessel(s) must be stored in a secured refrigerator with a temperature monitor and maintained within a range of 2 - 8 degrees Celsius.
- There must be daily monitoring of the vessel(s) with documented security and temperature checks by the transplant center.
- The vessel(s) can be stored up to a maximum of 14 days from the original recovery date.
- The transplant center must maintain a log of stored vessels.
- The transplant surgeon must have around the clock access to the donor information prior to using the donor vessel(s) in a recipient other than the intended recipient.

12.3.1 ABO Identification. The member transplant hospital must ABO type, ~~and subtype if appropriate,~~ each living donor on two separate occasions prior to the donation. Two separate occasions are defined as two ABO samples taken at different times, and sent to the same or different laboratories.

12.3.2 ABO Subtype Identification. The member transplant hospital subtyping a living donor whose initial subtype test indicates the donor to be non-A₁ (negative for A₁) or non-A₁B (negative for A₁B), must complete a second determination test prior to donation to assess the accuracy of the result. Blood samples for subtype testing must be taken on two separate occasions, defined as two samples taken at different times and sent to the same or different laboratories. Samples tested must not be taken after a blood transfusion. When the initial and second determination subtypings are the same result, the result can be used to determine transplant compatibility with the intended recipient or any other potential recipient (e.g., in a paired exchange program or allocation of non-directed donor). If the results do not indicate the same subtype, the donor must be allocated based on the primary blood type, A or AB.

12.7 STANDARDIZED PACKAGING, LABELING AND TRANSPORTING OF LIVING DONOR ORGANS, VESSELS, AND TISSUE TYPING MATERIALS

The purpose of Policy 12.7 and its subsections apply only to living donor organs, tissue typing specimens and vessels which are transported outside the recovery facility and:

- state requirements for packaging and labeling living donor organs (when applicable), tissue typing specimens, and (when applicable) vessels, to prevent wastage (and/or to promote safe and efficient use);
- define terms and responsibilities related to packaging, labeling, and transporting organs of living donor organs, and if applicable living donor tissue typing specimens, and vessels; and
- state requirements for recovering, storing, and using (when applicable) living donor vessels.

The responsibility for packaging and labeling living donor organs is assigned to the donor recovery transplant center. If a living donor organ ever requires repackaging by a transplant center for transport, the transplant center will package, label and ship the organ in accordance with this policy.

12.7.1 EXTERNAL PACKAGING SPECIFICATIONS

An external transport container is defined as a: disposable shipping box, cooler or mechanical preservation machine. The transplant center must use both internal and external transport containers to package a living donor organ, which travels outside the recovery facility.

12.7.1.1 Disposable shipping box

- If living donor organs, vessels and/or tissue typing that are packaged with the organ materials are shipped commercially, a disposable shipping box must be used.
- The disposable shipping box must be labeled with the standardized label distributed by the OPTN contractor.
- Disposable boxes must not be reused.

- The outer box must be a corrugated plastic or corrugated cardboard that is coated with a water resistant substance with at least 200 pound burst strength.
- The inner container must be a 1.5 inches thick, insulated container OR have an equivalent “R” value.
- A closed colored opaque plastic bag must be placed between the outer container and the insulated container. Closed is defined as being secured in a manner to prevent leakage (i.e. water tight).
- A second closed plastic liner must also be placed inside the insulated container to encase the ice. Closed is defined as being secured in a manner to prevent leakage (i.e. water tight).

12.7.1.2 Cooler

- Coolers are permitted for non-commercial transporting of organs when the organ recovery team is transporting the donor organ with them from the donor hospital to the candidate transplant center.
- Coolers must be labeled with the standardized label distributed by the OPTN contractor.
- Coolers may be reused if properly cleaned and sanitized.
- Before re-using a cooler, all labels from the previous donor organ must be removed.

12.7.1.3 Mechanical preservation machine

- Mechanical preservation machines are permitted for transporting an organ.
- The cassette (if applicable) containing the organ must be labeled with the organ type (i.e. left kidney, right kidney), ABO and subtyping (when used to determine transplant compatibility), and UNOS ID.
- The external surface of a mechanical preservation machine must be labeled with the standardized external label distributed by the OPTN contractor.
- Before re-using a mechanical preservation machine that was used to transport an organ, all labels from the previous donor must be removed.

12.7.2 INTERNAL PACKAGING SPECIFICATIONS

All organs that have been packaged on the donor’s back table must be handled using universal precautions. The packaged organs from the donor’s surgical back table are to be placed directly into the wet iced shipping container. Proper insulation and temperature controlled packaging including adequate ice or refrigeration must be used to protect the organs during transport.

- Organs must be protected by a triple sterile barrier.

- Kidneys and pancreata must be placed in a rigid container, which, if sterile, can be one layer of the triple sterile barrier.
- Livers, lungs, and intestines do not require a rigid container.
- Vessels must be protected by a triple sterile barrier; if packaged separately from the organ, one barrier must be a rigid container.

12.7.3 EXTERNAL LABELING REQUIREMENTS

When a disposable shipping box or cooler is used to transport a living donor organ, the donor recovery transplant center must use the standardized external label distributed by the OPTN contractor.

The external transport container must be labeled with the: UNOS Donor I.D., Donor ABO type and subtyping (when used to determine transplant compatibility), a description of the specific contents of the box, the sender's name and telephone number, and the Organ Center telephone number. The label must be securely affixed to the external transport container. The OPTN contractor distributes a standardized external label that includes this information, which must be utilized.

12.7.4 INTERNAL LABELING REQUIREMENTS

12.7.4.1 Solid organ

The donor recovery transplant center is responsible for ensuring that a secure label identifying the specific contents (e.g., liver or right or left kidney intestines) is attached to the outer bag or rigid container housing the donor organ. The OPTN contractor distributes a standardized internal label that must be utilized for this purpose. In addition to the contents of the package, the label information must include the UNOS Donor I.D. and donor ABO type and subtyping (when used to determine transplant compatibility).

12.7.4.2 Tissue typing materials

Each separate specimen container of tissue typing material that is packaged with the organ 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.

12.7.4.3 Vessels

The vessels must be labeled with the standardized vessel label distributed by the OPTN contractor. The information must contain the: recovery date, ABO and subtyping (when used to determine transplant compatibility), all serology results, container contents, and the UNOS Donor I.D. If the donor is in a "high risk" group as defined by the U.S. Public Health Service Guidelines, the label must indicate that the vessels are from a donor who meets the CDC criteria for

high risk. The appropriate packaging of vessels should be completed in the donor operating room. The label should clearly state “for use in organ transplantation only.” If packaged separately from the organ, the vessels must be protected by a triple sterile barrier, one of which must be a rigid container and the standardized vessel label must be affixed to the outermost barrier.

~~12.7~~ — Responsibility for Transport of Living Donor Organs. The following policies address standardized packaging of living donor organs and tissue typing materials to be transported for the purposes of organ transplantation. When an organ from a living donor is procured, the Transplant Center shall be responsible for ensuring the accuracy of the donor’s ABO and subtype (when used to determine transplant compatibility) on the container label and within the donor’s documentation. The Transplant Center shall establish and implement a procedure for obtaining verification of donor ABO data by an individual other than the person initially performing the labeling and documentation requirements put forth in Policies 12.7.1 and 12.7.5. The Transplant Center shall maintain documentation that such separate verification has taken place and make such documentation available for audit.

Upon receipt of an organ from a living donor and prior to implantation, the Transplant Center shall be responsible for determining the accuracy and compatibility of the donor and recipient ABO and subtype (when used to determine transplant compatibility) and document this verification in compliance with Policy 3.1.2.

~~12.7.2~~ The Transplant Center is responsible for ensuring that the Donor I.D., Donor ABO type and subtype (when used to determine transplant compatibility), and a secure label identifying the specific contents (e.g., liver segment, right kidney) are attached to the outer bag or rigid container housing the donor organ prior to transport.

~~12.7.3~~ Each separate specimen container of tissue typing material must have a secure label with the Donor I.D., Donor ABO type and subtyping (when used to determine transplant compatibility), date and time the sample was procured and the type of tissue. The Transplant Center is responsible for labeling the materials appropriately.

~~12.7.4~~ The Transplant Center is responsible for affixing to the transport container the standardized label completed with the Donor I.D., Donor ABO type and subtyping (when used to determine transplant compatibility), a description of the specific contents of the box, the sender’s name and telephone number, and the Organ Center telephone number. A transport container is defined as a corrugated, wax coated disposable box, cooler, or mechanical preservation cassette or machine.

12.8.1.1 The living donor transplant program must use the source documents from both the an initial and second determination ABO typings, and subtypings (when used to determine transplant compatibility), to enter the living donor’s ABO data on the Living Donor Feedback Form. Additionally, each living donor program must develop, implement, and comply with a procedure to verify that the living donor’s ABO and subtyping was correctly entered on the Living Donor Feedback Form with both the initial and second

determination ABO typing and subtyping source documents by an individual other than the person initially entering the donor's ABO data. A transplant program must document that each ABO typing and subtyping entry was performed in adherence to the program's protocol. The program must maintain this documentation, and make it available to the OPTN Contractor, upon request.

To read the complete UNOS bylaw language visit www.unos.org and select "UNOS bylaws" in 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 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: At its November 2011 meeting, the OPTN/UNOS Board of Directors approved three separate resolutions that modified Policy 5.10.2 (Vessel Storage). Below, Policy 5.10.2 reflects the changes from all three of these proposals: Requirements to Perform a Second ABO Subtyping Test When a Donor is Identified as non-A₁ or non-A₁B, Prohibiting the Storage of Hepatitis C Antibody Positive and Hepatitis B Surface Antigen Positive Extra Vessels (both sponsored by the Operations and Safety Committee), and Standardized Label Requirements for Vessel Transport and Storage (sponsored by the OPO Committee).*

5.10.1 Vessel recovery and transplant

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

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). This person must monitor the refrigerator, ensure records are up to date and available with the conduits, destroy the vessels when expired, and notify the OPTN of its use or disposal.

- Hepatitis C antibody positive and hepatitis B surface antigen positive extra vessels may not be stored for subsequent use.

- The vessels must be stored in a Food and Drug Administration (FDA) approved preservation solution (ex. UW, Custodial HTK).
- The vessels must be stored in a rigid, sterile sealed container and must be protected by a triple sterile barrier, one of which must be the rigid container, labeled with the recovery date, ABO, ABO subtype when used for allocation, infectious disease results, container contents, and the UNOS Donor ID for tracking. The standardized vessel label distributed by the OPTN contractor must be ~~attached~~ affixed to the outer most sterile barrier bag and information on the label must include ~~all of the above information and all serology testing results~~ the: recovery date, ABO, all infectious disease results, container contents, and the UNOS Donor ID. If the donor is in a “high risk”¹ group as defined by the US Public Health Service (PHS) guidance¹, the label must indicate that the vessels are from a donor who meets the CDC(PHS) criteria for high risk. The appropriate packaging of vessels should be completed in the donor operating room. The label should clearly state for use in organ transplantation only. If removed from the triple sterile barrier, the transplant center must re-label the vessels prior to storage.
- The vessel(s) must be stored in a secured refrigerator with a temperature monitor and maintained within a range of 2 - 8 degrees Celsius.
- There must be daily monitoring of the vessel(s) with documented security and temperature checks by the transplant center.
- The vessel(s) can be stored up to a maximum of 14 days from the original recovery date.
- The transplant center must maintain a log of stored vessels.
- The transplant surgeon must have around the clock access to the donor information prior to using the donor vessel(s) in a recipient other than the intended recipient.

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Affected Policy Language:

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5.4.3 Vessels

~~Both the~~ The vessels container and outer sterile barrier must be labeled with the standardized vessel labels distributed by the OPTN contractor. The information must contain the: recovery date, ABO, all ~~serology~~ infectious disease testing results, container contents, and the UNOS Donor ID. If the donor is in a “high risk” group as defined by the ~~Centers for Disease Control and Prevention (CDC), US~~ Public Health Service (PHS) guidance¹, the label must indicate that the vessels are from a donor who meets the ~~CDC~~ (PHS) criteria for high risk. The appropriate packaging of vessels should be completed in the donor operating room. The label should clearly state “for use in organ transplantation only.” If packaged separately from the organ, the vessels must be protected by a triple sterile barrier, one of which must be a rigid container and the standardized vessel label must be affixed to the outermost barrier and container.

5.10 VESSEL RECOVERY, TRANSPLANT, AND STORAGE

The intent of this policy is to permit:

- vessel recovery and immediate use in a solid organ transplant (for example either a current liver or pancreas transplant); and
- vessel recovery and storage for use in a subsequent solid organ transplant from a donor with a different UNOS Donor ID (for example, when the vessel(s) and the liver or pancreas allograft are being transplanted from different donors with different numbers).

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). This person must monitor the refrigerator, ensure records are up to date and available with the conduits, destroy the vessels when expired, and notify the OPTN of its use or disposal.

- Hepatitis C antibody positive and hepatitis B surface antigen positive extra vessels may not be stored for subsequent use.

- The vessels must be stored in a Food and Drug Administration (FDA) approved preservation solution (ex. UW, Custodial HTK).
- The vessels must be stored in a rigid, sterile sealed container and must be protected by a triple sterile barrier, one of which must be the rigid container, labeled with the recovery date, ABO, ABO subtype when used for allocation, infectious disease results, container contents, and the UNOS Donor ID for tracking. The standardized vessel label distributed by the OPTN contractor must be ~~attached~~ affixed to the outer most sterile barrier bag and information on the label must include ~~all of the above information and all serology testing results~~ the: recovery date, ABO, all infectious disease results, container contents, and the UNOS Donor ID. If the donor is in a “high risk”¹ group as defined by the US Public Health Service (PHS) guidance¹, the label must indicate that the vessels are from a donor who meets the CDC(PHS) criteria for high risk. The appropriate packaging of vessels should be completed in the donor operating room. The label should clearly state for use in organ transplantation only. If removed from the triple sterile barrier, the transplant center must re-label the vessels prior to storage.
- The vessel(s) must be stored in a secured refrigerator with a temperature monitor and maintained within a range of 2 - 8 degrees Celsius.
- There must be daily monitoring of the vessel(s) with documented security and temperature checks by the transplant center.
- The vessel(s) can be stored up to a maximum of 14 days from the original recovery date.
- The transplant center must maintain a log of stored vessels.
- The transplant surgeon must have around the clock access to the donor information prior to using the donor vessel(s) in a recipient other than the intended recipient.

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