Changes are denoted by blue highlight, and can be found in the Change Log.

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Monitoring Compliance

This section is organized by policy or bylaw reference, and provides guidance on how to comply and how members will be evaluated.

Policy 2.1: Host OPO

Purpose

The purpose of the policy is to:

- Identify and define the role of the Host OPO within the organ transplant process. Host OPOs identify the donor, evaluate and maintain the donor, obtain authorization for the removal of organs, and allocate organs.
- Outline the Host OPO's responsibilities for registering each donor in UNet^{SM}, executing match runs, obtaining the donor's social history, and preserving and shipping donor organs. This policy also specifies what documentation should accompany the organ.

How to comply

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Comply with all the specific provisions related to minimum procurement standards for procuring and allocating an organ
- Make reasonable attempts to obtain a medical/behavioral history from individual(s) familiar with the donor

How OPTN/UNOS will evaluate member compliance

During the site review, staff selects a random sample of donor records, based on the number of donors the OPO had in the previous year and reviews the donor file documentation to verify that the OPO has complied with all policies related to the evaluation of potential donors.

DEQ staff forward potential violations of these policies to the Membership and Professional Standards Committee (MPSC) for review.

Policy 2.2.1: Evaluation of Potential Donors

Purpose of policy

The purpose of the policy is to

- Ensure that the donor has been declared dead prior to organ procurement

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Develop policies and procedures regarding how OPO staff is to verify that the donor has been declared legally dead

How OPTN/UNOS will evaluate member compliance with this policy

During the site review, staff selects a random sample of donor records and staff reviews for documentation, including:

- Donor monitoring during withdrawal of card for DCD donors
- That the donor has been declared dead in accordance with applicable laws.

DEQ staff forward potential violations of these policies to the Membership and Professional Standards Committee (MPSC) for review.

Detailed guidance on policy compliance

- Retain all documentation related to the determination of brain death in the donor file
- Retain all declaration of death progress notes for all Donation after Cardiac Death (DCD) donors in the donor file
- Educate clinical coordinators in these requirements
- Maintain of copy of the brain death law for every state in which it provides services
- Educate staff in pertinent brain death law(s)
- Include compliance with document retention policies in OPO's routine quality assurance process

Policy 2.2.2: Evaluation of Potential Donors

Purpose of policy

The purpose of the policy is to

- Make the OPO responsible for ensuring that all required testing related to the presence of transmissible diseases and/or malignancies and any other known condition is performed and that the results are communicated to transplant centers with organ offers
- Ensure that the OPO has thoroughly evaluated the donor (obtaining the donor's medical/behavioral history) and that the results of the evaluation are communicated to transplant centers with organ offers

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Host OPOs are expected to:

- Ensure that all required evaluations are performed, documented, and communicated to the OPO or transplant centers with organ offers
- Thoroughly evaluate the donor, document the evaluation, and make the results of the evaluation available to transplant centers with organ offers
- Document in the donor record the circumstances when such information is not available

How OPTN/UNOS will evaluate member compliance with this policy

During the site review, staff selects a random sample of donor records and staff reviews donor file documentation to verify

- That the donor has been properly evaluated. The Host OPO must:
    - Obtain the donor's medical/behavioral history
    - Review the donor's medical record
    - Perform a physical examination of the donor
    - Obtain the donor's vital signs
- That all required evaluations are performed as specified by this policy and its subsections

DEQ staff forward potential violations of these policies to the Membership and Professional Standards Committee (MPSC) for review.

Detailed guidance on policy compliance

- Evaluate all donors in accordance with established policies
- Educate clinical coordinators in these requirements
- Obtain history from persons familiar with the donor by conducting interviews in

person or by telephone

- Interview more than one person when necessary to clarify or obtain additional information about the donor
- Maintain clear documentation of interviews in the donor file, including the relationship of the person(s) interviewed to the donor
- Maintain the following records in the donor file: a completed donor history form, evidence that the OPO has reviewed the donor's medical record, written evidence that the OPO has performed a physical examination, records of the donor's vital signs
- Document circumstances when such information is not available
- Include compliance with document retention policies in OPO's routine quality assurance process
- Policy 2.2.2.1—For additional information related to prion diseases, refer to the following: http://www.cdc.gov/ncidod/dvrd/prions/
    - Prion diseases or transmissible spongiform encephalopathies (TSEs) are a family of rare, progressive neurodegenerative disorders that affect both humans and animals.
    - Creutzfeldt-Jakob Disease (CJD) is a human prion disease.

Policy 2.2.3.1: Screening Potential Organ Donors

Purpose of policy

The purpose of the policy is to:

- Require the Host OPO to determine if donor blood used for required screening tests is hemodiluted and provide any screening result information to the accepting transplant program(s)

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Host OPOs are expected to:

- Assess all blood samples obtained and used for screening tests for hemodilution utilizing an FDA-approved hemodilution calculation
- Maintain in the donor record a complete history of all transfusions received by the donor since admission
- Perform all specified tests as required and maintain hard copies of the results of all tests performed in the donor file
- Document when such information is not available in the donor record

How OPTN/UNOS will evaluate member compliance with this policy

During the site review, staff reviews a sample of donor records based on the number of donors the OPO had in the previous year. Staff verifies that the OPO has performed the required clinical tests by reviewing documentation maintained in the donor file, specifically:

- Donor's medical history
- Hemodilution worksheets
- Documentation of communication of hemodiluted samples to transplant centers
- Types of serology tests used by the Host OPO

DEQ staff forward potential violations of these policies to the Membership and Professional Standards Committee (MPSC) for review.

Detailed guidance on policy compliance

- OPO policies and procedures should include requirements to conduct all required tests. The OPO should monitor compliance with this policy as part of its own quality assurance process.
- The OPO must maintain documentation that required tests were performed and document unavailability of pertinent testing in progress notes in donor file.
- Hemodilution is defined as a sample with plasma dilution sufficient to affect the

results of communicable disease testing. An FDA- approved hemodilution calculation should be utilized to make this determination. The FDA's terminology (from Code of Federal Regulations Title 21." *U.S. Department of Health and Human Services*. April 1, 2009. U.S. Food and Drug Administration, Web. 22 Jan 2010 at: http://www.accessdata.fda.gov/scrIpts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=1271.80) includes the definition of hemodiluted and qualified specimens.

- Hemodilution occurs when an increase in plasma volume (due to blood products, colloids and/or crystalloids administered to bring a person's blood volume back up to a normal level after suffering trauma, etc.) and can result in a reduced concentration of red blood cells (RBCs) in the blood. Hemodilution can result in false negative serology testing because not enough of the donor's own serum is present to test for viruses and other pathogens.
- A qualified specimen is a specimen that has not been hemodiluted.
- A hemodilution calculation can be completed to assess whether a sample has an acceptable level of hemodilution to be used in serologic screening tests. FDA-approved hemodilution calculations are the standard.
- For more information on hemodilution and qualified samples, including an example of a FDA-approved hemodilution calculation, please review the FDA's current guidance regarding hemodilution. See the appendices for an example of a hemodilution calculation.

Policies 2.2.3.2-2.2.3.5: Screening Potential Organ Donors

Purpose of policy

The purpose of the policy is to:

- Specify the testing required of all potential donors for Human Immune Deficiency Virus (HIV-1 and HIV-2)
- Specify requirements for communication of additional HIV test results
- Require that OPTN Members shall not knowingly participate in the transplantation or sharing of organs from donors who are identified as HIV positive unless subsequent confirmatory testing indicates the original results were false positive for HIV
- Outline exceptions to the policy related to cases involving non-renal organs when an extreme medical emergency warrants the transplantation of an organ that has not been tested for HIV
    - Specify informed authorization requirements related to non-renal organs not tested for HIV
- Specify requirements for informing personnel caring for potential donors for donors who test positive for HIV to be informed only when necessary for medical decision-making purposes

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Host OPOs are expected to:

- Test all potential deceased donors for HIV-1 and HIV-2 using a serological antibody screening test licensed by the FDA
- Maintain documentation of the results of all tests performed in the donor record
- Document when such information is not available in the donor record

How OPTN/UNOS will evaluate member compliance with this policy

During the site review, staff reviews a sample of donor records based on the number of donors the OPO had in the previous year. Staff verifies that the OPO has performed the required clinical tests by reviewing documentation maintained in the donor record.

Additionally, staff will verify that:

- Communication to transplant program(s) regarding results of all positive post-recovery donor screening tests

DEQ staff forward potential violations of these policies to the Membership and Professional Standards Committee (MPSC) for review.

Detailed guidance on policy compliance

- Effective August 27, 2011, nucleic acid testing (NAT) may be completed in addition to antibody screening, **but by itself is not an acceptable alternative to meet this policy requirement**
- OPO policies and procedures should include requirements to conduct all required tests
- The OPO should monitor compliance with this policy as part of its own quality assurance process
- The OPO must maintain documentation that required tests were performed and document unavailability of pertinent testing in progress notes in donor record

Policies 2.2.4.2-2.2.4.6: Donor Evaluation

Purpose of policy

The purpose of the policy is to:

- Outline requirements for the Host OPOs to perform or coordinate evaluation of the donor
- Outline requirements that all donor laboratory testing must be performed by an appropriately accredited laboratory
- Outline additional organ specific information that may be required in addition to standard testing for all potential donors, based upon what organs are offered for allocation and transplant.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Host OPOs are expected to:

- Utilize FDA-licensed, approved or cleared serological screening tests
- With the exception of HIV screening, utilize a FDA-approved diagnostic test in the event a required screening test is not commercially available prior to transplant.
- Document in the donor record occurrences when a donor was assessed using an FDA-approved diagnostic test instead of a screening test.
- Provide the above information to the transplant program(s)

How OPTN/UNOS will evaluate member compliance with this policy

During the site review, staff reviews policies and procedures related to screening, including requirements for documentation of test results.

DEQ staff forward potential violations of these policies to the Membership and Professional Standards Committee (MPSC) for review.

Detailed guidance on policy compliance

- The Host OPO must communicate immediately to all recipient institutions the results of an additional testing for a potential donor beyond testing required by policy
- Diagnostic testing is ***NOT*** acceptable for HIV testing
- For assistance in determining what donor testing is considered screening vs. diagnostic, refer to:

http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/ucm073964.htm

- The Host OPO is should retain copies of ***source documents*** for the following required tests. DEQ will review this documentation during on-site and desk reviews.
- **2.2.4.1 (for all potential deceased donors)**
  - ABO typing (and confirmation as outlined in Policy 3.2.4) with sub-typing for ABO-A donors
  - FDA-licensed Anti-HIV I, II (diagnostic testing not acceptable)
  - Hepatitis screen serological testing, including HBsAG, HBcAb, and Anti-HCV
  - VDRL or RPR (FDA-approved diagnostic tests are acceptable)
  - Anti-CMV
  - EBV serologic testing
  - Blood and urine cultures
  - Chest x-ray
- **2.2.4.4 (for potential heart donors)**
  - 12-Lead ECG
  - Cardiology consult and/or echocardiogram
- **2.2.4.6 (for potential lung donors)**
  - Sputum gram stain

Policy 2.2.5: Follow-up on Donor Testing

Purpose

The purpose of the policy is to:

- Specify requirements related to timely follow-up and reporting to the transplant program(s) of any new or changed clinically relevant information regarding the donor

How to comply

Compliance strategies may include, but are not limited to, the expectations stated below.

Host OPOs are expected to:

- Establish a procedure for obtaining post-recovery donor testing results from the hospital where the donor recovery took place
- Report within 24 hours all positive screening or diagnostic tests results to the transplant center's Patient Safety Contact (as defined in Policy 4.4), including, but not limited to updates of organism and sensitivity

How OPTN/UNOS will evaluate member compliance

During the site review, staff reviews a sample of donor records based on the number of donors in the previous year. Staff will verify that the OPO has notified transplant center(s) of post-recovery positive culture results.

DEQ staff forward potential violations of these policies to the Membership and Professional Standards Committee (MPSC) for review.

Detailed guidance on policy compliance

- For information regarding the Patient Safety Contact, refer to the January 17, 2011 UNOS Communications e-newsletter at:
- http://transplantpro.org/reminder-for-opos-and-transplant-centers-to-submit-patient-safety-contact-plans/
- NOTE: OPOs are encouraged to discuss whether or not a new donor finding should be considered a potential donor-derived disease transmission event (PDDTE) with their medical director or contact the OPTN Patient Safety Staff regarding questions about when to report, and to document that contact in the donor records.

Policy 2.2.6: Reporting Disease

Purpose of policy

The purpose of the policy is to:

- Outline requirements for the Host OPO to make historical and laboratory assessments to identify malignant and infectious conditions.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Host OPOs are expected to:

- Perform historical and laboratory assessments to identify malignant and infections conditions that may adversely affect a potential organ recipient.
- Communicate any known or suspected infectious or neoplastic conditions that may be transmitted by the donor organ(s) to the transplant program(s).

How OPTN/UNOS will evaluate member compliance with this policy

During the site review, staff reviews a sample of donor records based on the number of donors in the previous year. Staff will:

- Verify that the OPO has notified transplant center(s) all of -pre-recovery positive testing and laboratory results and any information learned during the medical-social history collection that may adversely affect a potential organ recipient.

DEQ staff forward potential violations of these policies to the Membership and Professional Standards Committee (MPSC) for review.

Detailed guidance on policy compliance

- OPOs are encouraged to make efforts to follow-up on information received during the medical/social history if there are questions regarding possible malignancies and other infectious diseases.

Policy 2.3: Donor Maintenance

Purpose of policy

The purpose of the policy is to:

- Specify the OPO's responsibility for donor maintenance and for the documentation of donor maintenance.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Make reasonable efforts to maintain the deceased donor, document these efforts, and communicate this information to the OPO or transplant center
- Develop policies and procedures specific to donor maintenance
- Monitor compliance with these policies as part of quality assurance process

How OPTN/UNOS will evaluate member compliance with this policy

During the site review, staff reviews a sample of donor records based on the number of donors in the previous year. Staff verifies that the OPO has documented a donor's vital signs and fluid intake and output. Staff also verifies that the OPO has documented any donor management medications.

DEQ staff forward potential violations of these policies to the Membership and Professional Standards Committee (MPSC) for review.

Detailed guidance on policy compliance

- Ensure that all procurement staff are competent in donor management and documenting all aspects of donor maintenance
- Ensure staff are familiar with the OPO's donor management regimes and medication administration protocols
- Document any medications given to the donor in the donor file
- Include the date, time, and duration a medication was administered in the documentation
- Include documentation of the donor's vital signs and the donor's fluid intake and output in the donor record

Policy 2.4: Obtaining Authorization

Purpose of policy

The purpose of the policy is to:

- Specify that the OPO must properly document the authorization for organ donation

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Ensure that the donor files contain evidence of authorization for donation and that there is evidence of authorization with states that have first person authorization laws
- Maintain documentation in the donor file to reflect the donor's wishes if authorization for donation was based on documentation of the donor's wishes

How OPTN/UNOS will evaluate member compliance with this policy

During the site review, staff reviews a sample of donor records based on the number of donors the OPO had in the previous year. Staff verifies that all donor files include documentation of authorization for organ donation.

DEQ staff forward potential violations of these policies to the Membership and Professional Standards Committee (MPSC) for review.

Detailed guidance on policy compliance

OPOs are encouraged to:

- Include copies of documentation in the donor file such as a copy of the driver's license, donor card, donor registry information
- Include compliance with document retention policies in the OPO's routine quality assurance process

Policy 2.5: Organ Procurement Quality

Purpose of policy

The purpose of the policy is to:

- Verify that the donor file includes documentation of all items in section 2.2, the use of standard surgical techniques in a sterile operating environment, maintaining preservation media at appropriate temperature, and the use of flush solutions and additives.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Maintain flush solutions and preservation media at appropriate temperatures and maintain specified data in the record (2.5.3)
- Ensure donor medications are given at appropriate times and that medication administration, including flush solutions and additives, is recorded during the retrieval process
- Ensure that procurement staff is aware that these factors maintaining donor quality are to be documented in the donor file
- Reflect donor quality factors as outlined in OPTN Policy in the OPO's policies and procedures

How OPTN/UNOS will evaluate member compliance with this policy

During the site review staff reviews a sample of donor records based on the number of donors the OPO had in the previous year. Staff verifies that all donor files include documentation of donor quality factors.

DEQ staff forward potential violations of these policies to the Membership and Professional Standards Committee (MPSC) for review.

Policy 2.5.4: Organ Procurement Quality

Purpose of policy

The purpose of the policy is to:

- Ensure that OPOs and their respective histocompatibility laboratories define and document the minimum tissue typing material required to generate match runs for local or regional placement of all organs.
- Since kidneys and pancreata are frequently shipped outside of the OPO's service area, this policy outlines the minimal amount of tissue typing material that must be sent with each kidney and pancreas.
- For all other organs, the OPO will provide lymph nodes if requested and available.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Ensure that they, along with the histocompatibility laboratories in their service area, have written requirements for tissue typing materials
- Ensure that their policies and procedures for shipping kidneys and pancreata meet the minimum requirements for tissue typing materials
- Ensure that their policies and procedures for all other organs address providing lymph nodes if requested and available.
- Ensure that procurement staff is familiar with these requirements and that the amount of tissue typing materials sent with each kidney or pancreas and, for all other organs, the provision of lymph nodes is documented in the donor file

How OPTN/UNOS will evaluate member compliance with this policy

During the site review, staff reviews the OPO's policies and procedures to determine if the OPO's policies for tissue typing materials meet this requirement.

DEQ staff forward potential violations of these policies to the Membership and Professional Standards Committee (MPSC) for review.

Detailed guidance on policy compliance

- Best practice suggestion: Some OPO's include a quality assurance feedback form with the tissue typing materials to obtain feedback regarding the adequacy of materials sent
- Link to "Specimens for Histocompatibility Testing Guidelines for OPOs"
- Review the OPTN's Recommended Histocompatibility Guidelines
- As of December 18, 2007, policy was modified to clarify that one red topped tube needs to be sent with each kidney or pancreas for ABO verification.

Policies 2.5.5-2.5.6: Organ Procurement Quality

Purpose of policy

The purpose of the policy is to:

- Require proper packaging for organs (see Policy 5.0)
- Require that information must be maintained by the Host OPO for seven years per the Final Rule

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Host OPOs are expected to:

- Ensure that their policies and procedures meet these requirements and that their coordinators are familiar with the requirements

How OPTN/UNOS will evaluate member compliance with this policy

During the site review, staff will observe how a procurement coordinator would pack a kidney for shipping. Staff inspects the shipping supplies and labels, and asks a coordinator what documentation accompanies the organ for shipping. Staff also reviews the Host OPO's policies and procedures for compliance with these requirements.

Additionally, staff will verify that the host OPO has policies/procedures to maintain donor records for seven years.

DEQ staff forward potential violations of these policies to the Membership and Professional Standards Committee (MPSC) for review.

Detailed guidance on policy compliance

- Refer to Policy 5.0 for information about proper packaging of organs for transplant http://optn.transplant.hrsa.gov/PoliciesandBylaws2/policies/pdfs/policy_17.pdf

Policies 2.5.7-2.5.8: Organ Procurement Quality

Purpose of policy

The purpose of the policy is to:

- Require the Host OPO to maintain a serum sample for each donor from whom organs were transplanted for at least ten years after the date of recovery.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Maintain a serum sample for each donor from whom organs were transplanted
- Ensure that the retained serum sample is available for retrospective testing if needed
- Maintain documentation in the donor record of the type of specimen that has been archived
- Maintain, if possible, a specimen that is qualified and not hemodiluted
- Arrange transportation to and from the local airport for non-local procurement teams

How OPTN/UNOS will evaluate member compliance with this policy

During the site review, staff reviews a sample of donor files based on the number of donors the OPO had in the previous year. Staff will verify that the OPO archived a serum sample for each donor for ten years.

DEQ staff forward potential violations of these policies to the Membership and Professional Standards Committee (MPSC) for review.

Policy 2.6: Initiating Organ Procurement and Placement

Purpose of policy

The purpose of the policy is to:

- Specify when OPOs should initiate tissue typing

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Ensure that, if possible, pre-procurement tissue typing is performed

How OPTN/UNOS will evaluate member compliance with this policy

UNOS monitors all allocations and investigates instances in which an OPO offers an organ prior to performing tissue typing.

DEQ staff forward potential violations of these policies to the Membership and Professional Standards Committee (MPSC) for review.

Detailed guidance on policy compliance

- Link to "Specimens for Histocompatibility Testing Guidelines for OPOs" http://optn.transplant.hrsa.gov/SharedContentDocuments/Histo_Brochure_2006.pdf
- Review the OPTN's Recommended Histocompatibility Guidelines: http://optn.transplant.hrsa.gov/SharedContentDocuments/Histocompatibility_Guidelines.pdf
- Review the Specimens for Histocompatibility Testing Guidelines for OPOs: http://transplantpro.org/wp-content/uploads/Histo_Brochure.pdf

Policy 2.7: Removal of Non-Renal Organs

Purpose of policy

The purpose of the policy is to:

- Give the extra-renal transplant team the option to procure extra-renal organs

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Allow for extra-renal procurement teams to procure extra-renal organs in their policies and procedures

How OPTN/UNOS will evaluate member compliance with this policy

During the site review, staff reviews and verifies that the OPO's policies and procedures allow for the procurement of extra-renal organs.

DEQ staff forward potential violations of these policies to the Membership and Professional Standards Committee (MPSC) for review.

Policy 2.7.1: Multiple Abdominal Organ Procurement

Purpose of policy

The purpose of the policy is to:

- Ensure that both the liver and pancreas are procured, if transplantable, and to maximize the number of recovered organs. If both cannot be procured, the surgeon(s) should document in writing on the donor form the specific reason(s) for failure to procure both organs.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Require procurement teams to work together in order to procure the optimal number of donor organs
- Document the specific reason for non-recovery of an authorized organ
- Complete the related questions on the DDR

How OPTN/UNOS will evaluate member compliance with this policy

During the site review, staff reviews a sample of donor files based on the number of donors the OPO had in the previous year. If all authorized organs are not recovered, UNOS site surveyors verify that this documentation is in the donor record.

Detailed guidance on policy compliance

- As of April 21, 2008, the OPO should document in the donor workbook the clinical findings that do not allow pancreas recovery for organ transplant.
- Include compliance with documentation requirements in the OPO's routine quality assurance process

Policy 2.8: Organ Recovery from a DCD Donor

Purpose of policy

The purpose of the policy is to:

- Set standards for organ recovery from a DCD donor

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Develop, implement and follow protocols that contain the standards of the DCD Model Elements as adopted in the OPTN Bylaws, Appendix B, Attachment III.

How OPTN/UNOS will evaluate member compliance with this policy

DEQ staff monitors complaints received through the Patient Services Line, the confidential Member Reporting Line, and any other UNOS employees. Any complaints received through these mechanisms that have the potential for policy or bylaw violation are forwarded to the Membership and Professional Standards Committee (MPSC) for review.

Policy 2.9: Multi-Cultural and Diversity Issues

Purpose of policy

The purpose of the policy is to:

- Ensure that the OPO develops and implements a plan to address multi-cultural issues related to organ donation

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Develop and implement plans addressing and educating the public about cultural issues that serve as barriers to organ donation.

How OPTN/UNOS will evaluate member compliance with this policy

No monitoring efforts are required.

Policy 3.1.1: OPO
Purpose of policy The purpose of the policy is to: • Define an Organ Procurement Organization (OPO) • State the purpose of OPOs and explain OPOs work within geographic territories
How to comply with this policy No specific action is required of members.
How OPTN/UNOS will evaluate member compliance with this policy No monitoring efforts are required.

Policy 3.1.2: Transplant Center

Purpose of policy

The purpose of the policy is to:

- Define a transplant center as a Member of OPTN/UNOS.
- Outline the responsibility of the transplanting surgeon at the transplant center receiving an organ.
- Ensure that transplant centers establish, document and perform a verification of the recorded ABO and subtype (when used for allocation) of the donor, UNOS Donor ID, and recorded ABO and subtype (when used for allocation) of the recipient upon receipt of an organ and prior to implantation.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Require that transplant surgeons ensure medical suitability between donor and recipient.
- Verify and document the accuracy of the UNOS Donor ID number, donor ABO and subtype (when used for allocation), and recipient ABO and subtype (when used for allocation) after receipt of a live or deceased donor organ and prior to its implantation.

How OPTN/UNOS will evaluate member compliance with this policy

During surveys of transplant centers, Department of Evaluation and Quality (DEQ) staff will verify that the following information is verified and documented after receipt of an organ and prior to its implantation:

- Donor ABO and subtype (when used for allocation)
- Recipient ABO and subtype (when used for allocation)
- UNOS Donor ID

Department of Evaluation and Quality (DEQ) staff will also verify that the following information is documented:

- Organ arrival time/date
- Verification time/date
- Implantation/anastomosis time/date

DEQ staff will request a corrective action plan if the center's documentation does not comply with the requirements of this policy and forward the survey results to the

OPTN/UNOS Membership and Professional Standards Committee (MPSC) for review.

6. Detailed guidance on policy compliance

- As of September 1, 2007, this policy requires that the Donor ID be included in the verification performed after receipt of a live or deceased donor organ and prior to its implantation.
- As of February 1, 2004, the policy:
    a. places the responsibility to ensure medical suitability between donor and recipient, including ABO compatibility, on the transplanting surgeon; and
    b. requires the transplant center to verify and document verification of recorded donor ABO and recipient ABO after receipt of an organ and prior to implantation.
- Documentation should contain date- and time-stamps to ensure that verification occurred **after receipt in the transplanting hospital** and prior to implantation.
- Refer to OPTN Policy 5.0 for deceased donor organ verification and packaging requirements and to OPTN Policy 12.7 for live donor organ verification and packaging requirements.

Policy 3.1.4: Waiting List

Purpose of policy

The purpose of the policy is to:

- Define the OPTN waiting list
- Ensure the accuracy of ABO data for transplant candidates listed within UNet[SM]
- Ensure that only transplant candidates whose ABO has been verified in UNet[sm] by two different users appear on organ match runs

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Ensure that each candidate is ABO typed on two separate occasions prior to listing (see Detailed Guidance for definition of "two separate occasions").
- Ensure that the individual who **adds a candidate to the waiting list** reviews the **source documents** from each of the two ABO typings prior to **entering the candidate's ABO** on the waiting list
- Ensure that the individual who **reviews the candidate's ABO** after the candidate has been added to the waiting list also reviews the source document from each of the two ABO typings to **verify the candidate's ABO** on the waiting list
- Maintain written documentation that the candidate's ABO was entered and verified by two separate individuals reviewing **both of the source documents** from each ABO typing

How OPTN/UNOS will evaluate member compliance with this policy

During surveys of transplant centers, UNOS staff will verify the following:

- Accuracy of ABO
- Two separate typings prior to listing
- Procedures to ensure that entry and verification occurs by two separate individuals reviewing source documentation.

DEQ staff will request a corrective action plan if the center's documentation does not comply with the requirements of this policy and forward the survey results to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for its review.

Detailed guidance on policy compliance

- As of April 21, 2008, "two separate occasions" is defined as two samples, taken at different times, sent to the same or different labs.
- Transplant centers are expected to develop, implement, and comply with a procedure(s) that ensures:

  - Each candidate is ABO typed on two separate occasions prior to listing
  - Both source documents are used to enter and verify a candidate's ABO in UNet[sm]
  - That adherence to this process is adequately documented for each candidate who is added to the waiting list
- Policy 3.1.4 was implemented on October 4, 2004.
- It is the transplant center's responsibility to ensure that each candidate's ABO is accurate and that the source documents are reviewed by the users who enter and verify a candidate's ABO in UNet[sm]. **Delegation of this duty to another institution such as a histocompatibility laboratory does not negate the transplant center's membership responsibility to ensure the accuracy of candidate ABO data on the waiting list**.
- For help with performing the initial ABO entry when adding a candidate to the waiting list, follow these steps in UNet[SM]:
  - Select Waitlist[SM] Help, select Index, and then search for "Adding a Candidate to the WaitList[SM]."
- For help with verifying a candidate's ABO after the candidate has been added to the waiting list, follow these steps in UNet[SM]:
  - Select Waitlist[SM] Help, select Index, and then search for "Verifying a Candidate's ABO."
- UNOS staff monitors newly listed candidates to ensure that transplant centers are performing the ABO verification in a timely manner because a candidate is not eligible to appear on a match run until the candidate's ABO has been verified. When a candidate's ABO remains unverified for more than 24 hours, UNOS staff will contact the listing transplant center.
- UNOS staff also monitors the waiting list for any changes made to a candidate's ABO. A change may occur when:
  - A candidate is listed for multiple organs
  - A candidate is listed at multiple transplant centers
  - The user changes the ABO before the ABO has been verified by a second user
  - A candidate is removed from the waiting list and relisted with a different ABO
- When a change is detected, UNOS staff contacts the transplant center to request source documentation of the candidate's ABO and an explanation of the event. If an error has occurred, a corrective action plan may be requested.

Policy 3.1.5: Match System
Purpose of policy The purpose of the policy is to: • Define the Match System
How to comply with this policy *Compliance strategies may include, but are not limited to, the expectations stated below.* No specific action is required of members.
How OPTN/UNOS will evaluate member compliance with this policy No monitoring efforts are required.

Policy 3.1.6: Host OPO
Purpose of policy The purpose of the policy is to: • Define Host OPO
How to comply with this policy *Compliance strategies may include, but are not limited to, the expectations stated below.* No specific action is required of members.
How OPTN/UNOS will evaluate member compliance with this policy No monitoring efforts are required.

Policy 3.1.13: Directed Donation

Purpose of policy

The purpose of the policy is to:

- Permit OPOs to allocate an organ (s) to a specific transplant candidate named by the person who authorized the donation, unless prohibited by state law
- Require that all recipients of a deceased donor organ(s) from a directed donation be added to the waiting list prior to transplantation

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Allocate directed donation organs to a specific transplant candidate named by the person authorizing the donation

Transplant centers are expected to:

- Add recipients of a deceased donor organ from a directed donation to the waiting list prior to transplantation
- Maintain documentation if the 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 and provide written justification to the OPTN upon request

How OPTN/UNOS will evaluate member compliance with this policy

UNOS conducts on-site reviews and desk reviews to verify that:

- Directed donation organs are offered to the transplant candidate named by the person who authorized the donation

UNOS staff conducts inquiries of all potential policy violations and forwards the results of the inquiry to the OPTN/UNOS Membership and Professional Standards Committee for its review and potential action.

Detailed guidance on policy compliance

- Members should be familiar with how to determine why a candidate does not appear on a match run and the reasons why a candidate may not appear on a match run.
    - To find out why a specific candidate does not appear on a match run, follow these steps: In DonorNet℠, select online Help, select Index, and then search for "Finding a Specific Candidate on the Match Results List."

- To view the list of reasons why a candidate may not appear on a match run, follow these steps: In DonorNet[SM], select online Help, select Index, and then search for "Reason not on the match code."

- If a candidate does not appear on a match run and the transplant center deems it necessary to transplant this candidate, the following documentation should be maintained and provided to the OPTN upon request:
  - Rationale for transplanting a candidate who did not appear on a match run
  - Reason that the candidate did not appear on the match run
  - The center is willing to accept an expanded criteria donor organ or a DCD donor organ as applicable
  - Documentation that the center verified suitability between donor organ and recipient prior to transplant

Policy 3.2.1.2: Permissible Access to UNet[SM]

Purpose of policy

The purpose of the policy is to:

- Provide explicit requirements to protect the confidentiality and security of data when any Institutional Member gives a third party access to UNet[SM]

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers, OPOs, and histocompatibility laboratories are expected to:

- See that the third party agent adheres to all applicable policies and bylaws
- Have in place a data use agreement with the third party agent that thoroughly addresses issues of confidentiality and security

How OPTN/UNOS will evaluate member compliance with this policy

UNOS conducts on-site and off-site reviews of OPTN members. During the review process, UNOS will request copies of data use agreements and review them to verify the member fulfilled the requirements.

Detailed guidance on policy compliance

- Agents acting on behalf of OPTN Institutional Members (transplant centers, OPOs, and histocompatibility laboratories) may require access to UNet[SM] to match transplant candidates with donor organs and collect information on candidates, recipients, and donors.
- Review Policy 3.2.1.2 for a list of elements to include in data use agreements
- Policy modifications effective September 19, 2008

Policy 3.2.1.4: Prohibition for Organ Offers to Non-Members

Purpose of policy

The purpose of the policy is to:

- Outline requirements for providing organs to non-members

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers and OPOs are expected to:

- Exhaust the match run before exporting any organ
- Never provide organs to non-member transplant centers in the US

How OPTN/UNOS will evaluate member compliance with this policy

UNOS staff reviews the match runs of organs that were exported outside the US, and verifies that the match run was exhausted for each. Policy violations are referred to the MPSC.

Detailed guidance on policy compliance

Transplant Programs and OPOs who export organs are encouraged to submit obtain an Organ Export Verification Form from the Organ Center to submit to UNOS as documentation that the match run was exhausted.

Policy 3.2.3: Waiting Time Transferal and Multiple Listing

Purpose of policy

The purpose of the policy is to:

- Ensure that every transplant program provides each candidate with written material on the options of listing at multiple transplant centers, transferring primary waiting time from one transplant center to another, and transferring their care to a different transplant center without loss of time accumulated while on the waiting list

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- During the evaluation process, provide each candidate with written material on the options of listing at multiple transplant centers and the option to transfer their care to another transplant center without losing accumulated time on the waiting list
- Maintain documentation that this requirement was fulfilled

How OPTN/UNOS will evaluate member compliance with this policy

UNOS conducts on-site and off-site reviews of transplant centers. During the review process, UNOS will request any documentation showing that written materials were provided to the patient prior to listing.

DEQ staff will request a corrective action plan if the center's documentation does not comply with the requirements of this policy and forward the survey results to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for review.

Detailed guidance on policy compliance

- Review the OPTN's brochure entitled, "Questions and Answers for Transplant Candidates and Families about Multiple Listing and Waiting Time Transfers": http://optn.transplant.hrsa.gov/SharedContentDocuments/multiple_listing(2).pdf (English) http://optn.transplant.hrsa.gov/SharedContentDocuments/span_multiple_listing(2).pdf (Spanish)
- Options for providing written materials to patients:
    - Distribute OPTN brochure and keep signed and dated back sheet in patient chart;
    - Distribute center-specific handouts during education and prior to listing. Maintain sign-in sheet with names and dates.

Policy 3.2.4: Match System Access

Purpose of policy

The purpose of the policy is to:

- Promote safe and fair distribution of organs by requiring that all applicable donor information be entered in UNet^{SM} correctly, and that distribution of organs be made through the UNOS Match System
- Promote candidate safety by requiring that an individual other than the person initially entering the donor's blood type verify donor's blood type and subtype (when used for allocation)

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Enter all required donor information into UNet^{SM} and assist in distribution of all organs through the UNOS Match System using UNet^{SM}
- Provide and carry out their own procedure for providing online verification of donor blood type, and subtype (when used for allocation) by an individual other than the person initially entering the data
- Document the double verification of a donor's blood type and subtype (when used for allocation) and have the documentation available for review by UNOS
- Use the source document(s) to enter and verify the donor's blood type and subtype (when used for allocation) in UNet^{sm}. A source document is documentation of the donor's blood type from the laboratory that performed the blood type testing.
- Obtain two separate determinations of the donor's blood type and subtype (when used for allocation) prior to incision
- Allocate organs according to the match run sequence and to candidates who appear on the match run

Transplant centers are expected to:

- Release the organ back to the Host OPO or the Organ Center for distribution in instances where the organ is accepted but cannot be used for the original candidate
- Maintain documentation if the 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 and provide written justification to the OPTN upon request

How OPTN/UNOS will evaluate member compliance with this policy

UNOS conducts on-site reviews and desk reviews to verify that:

- OPOs document and use protocols to ensure that an individual other than the person who initially entered a donor's blood type verifies the donor's blood type

and subtype (when used for allocation) online prior to the execution of a match run;
- Organs are offered according to the match run sequence and to candidates who appear on the match run;
- OPOs obtain two determinations of donor ABO and ABO subtype (when used for allocation) prior to incision; and
- OPOs document the double verification of donor ABO and subtype (when used for allocation).

UNOS staff conducts inquiries of all potential policy violations and forward the results of the inquiry to the OPTN/UNOS Membership and Professional Standards Committee for its review and potential action.

Detailed guidance on policy compliance

- Subtype can only be entered into UNet[SM] if:
  - Subtyping was only performed on pre-transfusion specimens, AND
  - The two test results indicate the same subtype
- The OPO should ensure that staff uses ABO source documents when entering and verifying the donor's ABO, and subtype (when used for allocation) in UNet[SM]
- Retain source documents from two ABO tests and subtype tests (when used for allocation) in donor file
- Ensure OPO policies and procedures require that both source documents are referenced when confirming the ABO and subtype (when used for allocation) of a potential donor in UNet[SM]
- Include compliance with document retention requirements in OPO's routine quality assurance process
- Two separate determinations of donor ABO and subtype (when used for allocation) is defined as: two samples sent to two labs, or two samples from separate draws sent to the same lab
- Members should be familiar with how to determine why a candidate does not appear on a match run and the reasons why a candidate may not appear on a match run.
  - To find out why a specific candidate does not appear on the match run, follow these steps: In DonorNet®, select online Help, select Index, and then search for "Finding a Specific Candidate on the Match Results List."
  - To view the list of reasons why a candidate may not appear on a match run, follow these steps: In DonorNet®, select online Help, select Index, and then search for "Reason not on the match code."
- If a candidate does not appear on a match run and the transplant center deems it necessary to transplant this candidate, the following documentation should be maintained and provided to the OPTN upon request:
  - Rationale for transplanting a candidate who did not appear on a match run

- Reason that the candidate did not appear on the match run
- The center is willing to accept an expanded criteria donor organ or a DCD donor organ as applicable
- Documentation that the center verified suitability between donor organ and recipient prior to transplant

Policy 3.2.4.1: Removal of Kidney Transplant Candidates from Kidney Waiting Lists when Transplanted or Deceased

Purpose of policy

The purpose of the policy is to:

- Maximize the efficiency of the organ allocation system by requiring that candidates who receive a transplant or die be immediately removed from the waiting list
- Describe waiting time for kidney, kidney/pancreas, and kidney/islet candidates who receive a transplant and are re-listed

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Remove a candidate from the waiting list within 24 hours of transplantation (living or deceased donor transplant) or death

How OPTN/UNOS will evaluate member compliance with this policy

During routine site surveys, UNOS staff reviews a sample of records to verify that candidates were removed from the waiting list by midnight (Eastern Standard Time) the day after transplant or death.

Detailed guidance on policy compliance

- If you learn of a candidate's death more than 24 hours after the death, document in the candidate's record the date you become aware of the death. Remove the candidate from the waiting list within 24 hours of learning of the candidate's death. Include documentation in the candidate's record to support the date of death, if available.

Policy 3.2.10: Waiting Time Adjustment for Candidates Needing a Life Saving Organ Transplant when the Need for a Second Organ Transplant Arises

Purpose of policy

The purpose of the policy is to:

- Clarify waiting time accumulated for a candidate who is initially listed for one life-saving transplant and may also be accumulated for a second organ, when it is determined at a later time that the candidate requires a multi-organ transplant

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Maintain complete and accurate documentation regarding the candidate's organ function and the need for additional transplanted organs

How OPTN/UNOS will evaluate member compliance with this policy

UNOS conducts on-site and off-site reviews to confirm the candidate's status listings when multiple organs are needed for transplant.

Policy 3.2.11: Patient Notification

Purpose of policy

The purpose of the policy is to:

- Ensure that Transplant Hospitals provide appropriate notification to patients upon being placed on or removed from the Waiting List
- Establish the information that must be included in patient notifications

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant hospitals are expected to:

- Notify patients in writing within ten business days of the patient's being placed on the Waiting List or the determination that the patient will not be placed on the Waiting List
- Notify patients in writing within ten business days of the candidate's removal from the Waiting List for reasons other than transplantation or death
- Include all the information required by the bylaw in the written notifications, including the date of listing, if applicable, and indication that they have included the UNOS Patient Information Letter
- Send a completed copy of the UNOS Patient Information Letter with these notifications in a timely manner.
- Maintain documentation of these notifications and make it available upon request for compliance monitoring purposes

How OPTN/UNOS will evaluate member compliance with this policy

During surveys of transplant centers, staff will verify the presence of appropriate notifications to candidates concerning their Waiting List status.

DEQ staff will request a corrective action plan if the center's documentation does not comply with the requirements of this bylaw and forward the survey results to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for review.

Detailed guidance on policy compliance

- As of July 1, 2009, transplant centers must **include a copy of the UNOS Patient Information letter** with all notifications and reference the inclusion of this letter.
    - Include a statement in the notification letters referencing the inclusion of the UNOS Patient Notification Letter. Centers are encouraged to use this sample language:

      "Attached is a letter from the United Network for Organ Sharing (UNOS). It

describes the services and information offered to patients by UNOS and the Organ Procurement and Transplantation Network."

- Link to the UNOS Patient Information letter: http://optn.transplant.hrsa.gov/resources/professionalresources.asp?index=15.
  - **Note**: Remove Patient Services Line number from the body of the notification letter.

- As of March 7, 2001, send written notification to patients within 10 business days of:
  - Completion of the transplant evaluation (if patient is not going to be listed)
  - Placement on the waiting list (notification must **include date of listing in body of letter**)
    - **Note**: Notification does not need to include date of removal in the body of the letter. However, if the date of removal is included, it **must be accurate**.
  - Removal from the waiting list for reasons other than transplant or death
  - Being made aware that a multiple-listed candidate has been transplanted at another transplant center, including documentation of the date center was made of aware of the transplant

- During the period February 15, 2007 through June 30, 2009, transplant hospitals were required to included the Patient Services Line telephone number in the required notifications: (888) 894-6361 (See first bullet under this section for most recent requirements.)

- If a patient is lost to follow up, send notification letter to last known address.

- If a candidate expires before the 10th business day following removal from the waiting list, the transplant center is not required to send the candidate written notification of removal from the waiting list for reasons other than transplant or death.

If a candidate is removed from the waiting list by UNOS because the candidate has transferred to a different transplant center, the transplant center where the candidate is no longer listed is required to send the candidate written notification of removal from the list for reasons other than transplant or death.

Policy 3.3.1: Donor Acceptance Criteria

Purpose of policy

The purpose of the policy is to:

- Help facilitate efficient procurement and to maximize the number of organs procured by OPOs

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Establish clear criteria for what constitutes an acceptable donor organ and to offer organs that do not meet their own criteria to OPOs with more liberal acceptance criteria

How OPTN/UNOS will evaluate member compliance with this policy

UNOS monitors OPOs' procurement and discard rates, and analyzes whether offers were made to other OPOs. The analyses are reported to the MPSC.

Policy 3.3.2: Non-renal Organ Acceptance Criteria

Purpose of policy

The purpose of the policy is to:

- Help facilitate safe and efficient allocation of organs

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Clearly define their acceptance criteria for non-renal organs and enter this information into the UNet^{sm} system

How OPTN/UNOS will evaluate member compliance with this policy

Acceptance criteria for non-renal organs are programmed into the UNet^{SM} system. UNOS reviews all allocations and checks that organs were allocated in accordance with specified criteria.

Policy 3.3.3: Renal Acceptance Criteria

Purpose of policy

The purpose of the policy is to:

- Help facilitate safe and efficient allocation of organs

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Clearly define their acceptance criteria for renal organs and enter this information into the UNet^{sm} system

How OPTN/UNOS will evaluate member compliance with this policy

Acceptance criteria for renal organs are programmed into the UNet^{SM} system. UNOS reviews all allocations and checks that organs were allocated in accordance with specified criteria.

Policy 3.3.4: Antigen Mismatch Criteria

Purpose of policy

The purpose of the policy is to:

- Help facilitate safe and efficient allocation of organs

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Enter in the maximum acceptable number of mismatched antigens for their candidates

How OPTN/UNOS will evaluate member compliance with this policy

UNOS reviews all allocations and checks that organs were allocated in accordance with specified antigen mismatch criteria.

Policy 3.3.5: Transplant Recipient Backup for Organ Offers

Purpose of policy

The purpose of the policy is to:

- Facilitate efficient allocation of organs

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOS are expected to:

- To make back-up offers; however, this is not a requirement
- Notify the back-up transplant center of any changes in the donor status or organ disposition

Transplant centers are expected to:

- Respond to the OPO within an hour of receiving a back-up offer

How OPTN/UNOS will evaluate member compliance with this policy

Staff reviews all allocations and examines complaints related to back up offers and issues with communication related to change in donor status or organ disposition.

Policy 3.3.6.1.1: Center Acceptance of Organ Offers

Purpose of policy

The purpose of the policy is to:

- Require OPOs to re-allocate organs when a Donation after Cardiac Death (DCD) donor converts to brain death to help ensure that the most appropriate candidate receives each organ
- Ensure that each OPO allocates organs consistently when a DCD donor converts to brain death
- To increase the number of transplanted organs by encouraging OPOs to initiate the allocation of additional organs (i.e., heart, lungs, pancreas) when a DCD donor converts to brain death

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOS are expected to:

- Re-execute the match system for every organ when a donor converts from a DCD donor to a brain dead donor. Note: exceptions apply for certain circumstances; refer to policy language.
- Re-allocate organs according to the match run(s)
- Document the reason for not re-allocating organs from a donor who converts from DCD to brain death and make this documentation available upon request

How OPTN/UNOS will evaluate member compliance with this policy

Staff monitors all organ allocations and makes a written inquiry into allocations that do not occur according to policy. The OPTN/UNOS Membership and Professional Standards Committee (MPSC) reviews potential policy violations.

Detailed guidance on policy compliance

- Implementation date: August 7, 2007

Policy 3.5: Allocation of Deceased Donor Kidneys

Purpose of policy

The purpose of the policy is to:

- Ensure all deceased donor kidneys are allocated according to established policies
- Establish that the final decision to accept a particular organ will remain the prerogative of the transplant surgeon and/or physician
- Require that a notation of the reason for declining an organ is made on the appropriate form for submission to UNOS

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Allocate all kidneys in accordance with the donor match run
- Complete and submit donor PTR information in UNet[SM]

Transplant centers are expected to:

- Provide an OPO with the appropriate organ refusal code when declining an organ offer

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet[SM] system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews all deceased donor kidney match runs to determine if the organs were allocated according to the match run sequence as established by kidney allocation policy and programmed into the UNet[SM] system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. Through on-site reviews, staff selects a sample of donor records, reviews the donor file documentation and determines if the organs have been allocated in accordance with the match runs. Staff reports all instances where the match run was not followed for allocation to the appropriate OPTN/UNOS Committee.

Detailed guidance on policy compliance

- Retain all documentation used for allocation
- Document all allocation attempts including telephone calls

Policy 3.5.1: Definition of Expanded Criteria Donor and Standard Donor

Purpose of policy

The purpose of the policy is to:

- Distinguish between an expanded criteria donor and a standard donor. The policy provides a detailed list of what variables are considered to qualify a donor as an expanded criteria donor. Transplant centers may elect to list candidates who agree to receive expanded criteria donor kidneys.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Accurately list deceased donors as expanded or standard

Transplant centers are expected to:

- Obtain consent from candidates prior to their being listed for expanded criteria donor kidney transplantation

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews all deceased donor kidney match runs to determine if the organs were allocated according to the match run sequence as established by kidney allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. Through on-site reviews, staff selects a sample of donor records, reviews the donor file documentation and determines if the organs have been allocated in accordance with the match runs. Staff reports all instances where the match run was not followed for allocation to the appropriate OPTN/UNOS Committee.

Detailed guidance on policy compliance

- Link to ECD brochure (English) http://www.unos.org/SharedContentDocuments/ExpandedCriteriaDonor_KidneysBrochure.pdf
- Link to ECD brochure (Spanish) http://optn.transplant.hrsa.gov/SharedContentDocuments/Answers_to_Questions-Spanish.pdf

Policy 3.5.2: ABO "O" Kidneys into ABO "O" Recipients and ABO "B" Kidneys into ABO "B" Recipients

Purpose of policy

The purpose of the policy is to:

- Address waiting time disparities among candidates with different blood types. The policy allows ABO "O" kidneys to be allocated only to ABO "O" recipients and ABO "B" kidneys to be allocated only to ABO "B" recipients. Exceptions to this policy are for zero antigen mismatch recipients.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- List donors with accurate ABO type
- Maintain donor record documentation of ABO typing and provide, upon request, such documentation for review
- Allocate deceased donor kidneys according to the match run generated by UNet^{SM}

Transplant centers are expected to:

- List transplant candidates with the accurate ABO typing
- Maintain medical record documentation of ABO typing and provide, upon request, such documentation for review

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews all deceased donor kidney match runs to determine if the organs were allocated according to the match run sequence as established by kidney allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. Through on-site reviews, staff selects a sample of donor records, reviews the donor file documentation and determines if the organs have been allocated in accordance with the match runs. Staff reports all instances where the match run was not followed for allocation to the appropriate OPTN/UNOS Committee.

Policy 3.5.3: Mandatory Sharing of Zero Antigen Mismatched Kidneys

Purpose of policy

The purpose of the policy is to:

- Ensure optimal kidney match and survival. The policy for isolated kidney allocation was developed based on data showing that deceased renal transplants with zero antigen mismatches have the highest graft survival rates. Additionally, opportunities for transplanting highly sensitized (i.e., relatively high panel reactive antibody levels) candidates are increased based upon HLA match and low probability of a positive crossmatch match.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Allocate all kidneys according to the system match run
- Make zero antigen mismatch kidney offers according to the requirements stated in Policy 3.5.3.5

Transplant centers are expected to:

- List transplant candidates with the accurate HLA typing and any current unacceptable antigens as defined by the center.

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews all deceased donor kidney match runs to determine if the organs were allocated according to the match run sequence as established by kidney allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. Through on-site reviews, staff selects a sample of donor records, reviews the donor file documentation and determines if the organs have been allocated in accordance with the match runs. Staff reports all instances where the match run was not followed for allocation to the appropriate OPTN/UNOS Committee.

Policy 3.5.3.1: Definition of Zero Antigen Mismatch

Purpose of policy

The purpose of the policy is to:

- Define a zero antigen mismatch

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- List candidates with accurate HLA typing
- List candidates with the accurate ABO type

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to the system through the use of system notices and documentation updates.

Policy 3.5.3.2: Computer Entry

Purpose of policy

The purpose of the policy is to:

- Ensure that every deceased kidney donor is registered on the UNOS computer system prior to kidney allocation

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Register all deceased kidney donors into the UNOS computer system prior to kidney allocation
- Obtain pre-procurement tissue typing
- Submit a written explanation if pre-procurement tissue typing is not initiated

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs of modifications to system through the use of system notices and documentation updates. UNOS reviews all deceased donor kidney match runs to determine if the organs were allocated according to the match run sequence as established by kidney allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. Through on-site reviews, staff selects a sample of donor records, reviews the donor file documentation and determines whether donors were registered appropriately and whether pre-procurement tissue typing occurred prior to kidney allocation. Staff forwards potential policy violations to the appropriate OPTN/UNOS Committee.

Policy 3.5.3.3: Sharing

Purpose of policy

The purpose of the policy is to:

- Define the mandatory sharing requirements for kidney allocation

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs centers are expected to:

- OPOs are expected to allocate all kidneys according to the match run

Transplant centers are expected to:

- List all kidney candidates with accurate HLA, ABO and any current unacceptable antigens as defined by the center. and with accurate expanded donor acceptance information

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates.

UNOS reviews all deceased donor kidney match runs to determine if the organs were allocated according to the match run sequence as established by kidney allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy.

Through on-site reviews, staff selects a sample of donor records, reviews the donor file documentation and determines if the organs have been allocated in accordance with the match runs. Staff reports all instances where the match run was not followed for allocation to the appropriate OPTN/UNOS Committee.

Policy 3.5.3.4: Kidney/Non-Renal Exception

Purpose of policy

The purpose of the policy is to:

- Outline the process for when kidneys are procured for the purpose of combined kidney/non-renal organ transplantation. Only one of the kidneys must be shared as a zero antigen mismatch. In the event, however, that the combined kidney/non-renal transplant is not performed, the kidney retained for that transplantation must be immediately offered for other zero antigen mismatch candidates.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Place zero antigen mismatch kidneys according to the requirements stated in Policy 3.5.3.5

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs of modifications to system through the use of system notices and documentation updates. UNOS reviews all deceased donor kidney match runs to determine if the organs were allocated according to the match run sequence as established by kidney allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. Through on-site reviews, staff selects a sample of donor records, reviews the donor file documentation and determines if the organs have been allocated in accordance with the match runs. Staff reports all instances where the match run was not followed for allocation to the appropriate OPTN/UNOS Committee.

Detailed guidance on policy compliance

- Organ Center telephone: (800) 292-9537

Policy 3.5.3.5: Organ Offer Limit

Purpose of policy

The purpose of the policy is to:

- Promote efficiency in placement of zero antigen mismatch kidneys. The policy's offer limit for placement of these organs is intended to help address concerns with prolonged cold ischemic time during the offer and acceptance process. This policy defines specific offer limits for zero antigen mismatch kidney placement.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Share all zero mismatch kidneys, either through DonorNet® or through the UNOS Organ Center, according to policy:
    a. Standard Criteria Donor (SCD) – within 8 hours of cross clamp to the first 10 zero mismatch potential recipients on the match run, in sequential order
    b. Expanded Criteria Donor (ECD) – within 4 hours of cross clamp to the first 5 zero mismatch potential recipients on the match run, in sequential order
- Submit a completed Kidney Payback Accounting Sheet to the Organ Center for all zero mismatch kidneys that are placed by the Host OPO (it is not necessary to complete this sheet for zero mismatch kidneys placed by the Organ Center on behalf of the Host OPO)

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet℠ system according to current approved policies and notifies OPOs of modifications to system through the use of system notices and documentation updates. UNOS staff monitors all deceased donor kidney match runs to ensure:

- organs were allocated according to the match run sequence, and
- mandatory shares were offered according to policy.

When insufficient information is provided by the OPO, UNOS staff makes a written inquiry into any allocations that do not follow the match run sequence. During on-site surveys of organ procurement organizations, staff reviews a sample of kidney allocations and validates data entered into DonorNet® and Tiedi® for donors in the review sample. UNOS staff forwards potential policy violations to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for review.

Detailed guidance on policy compliance

- Organ Center telephone: (800) 292-9537

- The Host OPO will **not** be entitled to a payback if the kidney is accepted for a zero antigen mismatched potential recipient beyond the 10th potential recipient for a SCD or the 5th potential recipient for an ECD
- To receive a payback credit, OPOs must:
    - Fax a completed Kidney Payback Sheet to the Organ Center within 5 business days of organ recovery
    - Enter the final acceptance in DonorNet®
    - Enter the cross-clamp date/time in DonorNet®

Policy 3.5.4: Sharing of Zero Antigen Mismatched Kidneys to Combined Kidney-Pancreas Candidates

Purpose of policy

The purpose of the policy is to:

- Ensure that an offer of a zero antigen mismatch donor kidney to a candidate who is registered for a combined kidney-pancreas transplant is accompanied by an offer of the pancreas from the same donor

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Offer the pancreas with a kidney if there is a zero antigen mismatch candidate on the waiting list who requires both organs for transplant

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs of modifications to system through the use of system notices and documentation updates. UNOS reviews all deceased donor kidney match runs to determine if the organs were allocated according to the match run sequence as established by kidney allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. Through on-site reviews, staff selects a sample of donor records, reviews the donor file documentation and determines if the organs have been allocated in accordance with the match runs. Staff reports all instances where the match run was not followed for allocation to the appropriate OPTN/UNOS Committee.

Policy 3.5.4.1: Mandatory Sharing

Purpose of policy

The purpose of the policy is to:

- Define the requirements for mandatory sharing of combined kidney/pancreas to highly sensitized zero antigen mismatch candidates on the waiting list
- Further define that allocation of these organs shall be first locally, then regionally and then nationally, based upon length of time waiting

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Allocate all zero antigen mismatch kidney/pancreas according to the match run
- Make zero antigen mismatch kidney/pancreas offers according to the requirements stated in Policy 3.5.3.5 and Policy 3.8.1.6.1

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs of modifications to system through the use of system notices and documentation updates. UNOS reviews all deceased donor kidney match runs to determine if the organs were allocated according to the match run sequence as established by kidney allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. Through on-site reviews, staff selects a sample of donor records, reviews the donor file documentation and determines if the organs have been allocated in accordance with the match runs. Staff reports all instances where the match run was not followed for allocation to the appropriate OPTN/UNOS Committee.

Policy 3.5.5: Payback Requirements

Purpose of policy

The purpose of the policy is to:

- Ensure that no area of the country or candidate population would be disadvantaged by disproportionate sharing of zero antigen mismatched kidneys from the pool of locally available organs, in light of the number of imported zero antigen mismatched organs. For example, localities with relatively high candidate populations having uncommon antigens could be required to export many more of these organs out of the area than they might be expected to receive due to lower likelihood of finding zero antigen mismatches in these populations. The payback system promotes justice in the system, while the mandatory sharing rules for zero antigen-mismatched kidneys promote organ utility.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Allocate all organs according to the match run
- Contact the UNOS Organ Center for placement of all payback kidneys

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs of modifications to system through the use of system notices and documentation updates. UNOS reviews all deceased donor kidney match runs to determine if the organs were allocated according to the match run sequence as established by kidney allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. Through on-site reviews, staff selects a sample of donor records, reviews the donor file documentation and determines if the organs have been allocated in accordance with the match runs. Staff reports all instances where the match run was not followed for allocation to the appropriate OPTN/UNOS Committee.

Policy 3.5.5.1.1: Deferment of Kidney/Non-Renal Exception

Purpose of policy

The purpose of the policy is to:

- Limit the number of payback obligations an OPO can accrue within each blood type and still be allowed to keep a kidney locally for a combined kidney/non-renal transplant

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Allocate all organs according to the match run
- Offer both kidneys in satisfaction of payback debts if they have accumulated six or more obligations within the donor blood type
- Contact the Organ Center for placement of all payback kidneys

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs of modifications to system through the use of system notices and documentation updates. UNOS reviews all deceased donor kidney match runs to determine if the organs were allocated according to the match run sequence as established by kidney allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. Through on-site reviews, staff selects a sample of donor records, reviews the donor file documentation and determines if the organs have been allocated in accordance with the match runs. Staff reports all instances where the match run was not followed for allocation to the appropriate OPTN/UNOS Committee.

Policy 3.5.5.1.2: Deferment of Voluntary Arrangements

Purpose of policy

The purpose of the policy is to:

- Prohibit an OPO that has accumulated six or more paybacks within a blood type from voluntarily accepting a kidney/pancreas from the same blood type until the OPO has reduced its payback obligations to less than six. This policy does not include voluntarily shared zero antigen mismatch kidney/pancreas.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Allocate organs according to the match run
- Refuse voluntary kidney/pancreas offers, other than zero antigen mismatch, if they have six or more debts in the same blood type of the donor

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs of modifications to system through the use of system notices and documentation updates. UNOS reviews all deceased donor kidney match runs to determine if the organs were allocated according to the match run sequence as established by kidney allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. Through on-site reviews, staff selects a sample of donor records, reviews the donor file documentation and determines if the organs have been allocated in accordance with the match runs. Staff reports all instances where the match run was not followed for allocation to the appropriate OPTN/UNOS Committee.

Policy 3.5.5.2: Exceptions for Prior Living Organ Donors

Purpose of policy

The purpose of the policy is to:

- Establish priorities for previous living organ donors for the allocation of kidneys. Locally, prior living organ donors shall be allocated kidneys before they are offered in satisfaction of payback obligations.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Allocate kidneys according to the match run

Transplant centers are expected to:

- List kidney candidates accurately and at the appropriate status
- Maintain medical record documentation of patient's donation status and provide, upon request, such documentation for review

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews all deceased donor kidney match runs to determine if the organs were allocated according to the match run sequence as established by kidney allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. Through on-site reviews, staff selects a sample of donor records, reviews the donor file documentation and determines if the organs have been allocated in accordance with the match runs. Staff reports all instances where the match run was not followed for allocation to the appropriate OPTN/UNOS Committee.

Policy 3.5.5.3: Kidney Payback Debt Limit

Purpose of policy

The purpose of the policy is to:

- Limit the number of kidney payback debts that an OPO can incur. Violations of this policy will result in referral to the MPSC. Additionally, priority for zero antigen mismatch kidney offers will be adjusted.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Pay back kidney debt obligations in a timely manner
- Adhere to the kidney payback debt limit of nine

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs of modifications to system through the use of system notices and documentation updates. UNOS monitors payback debt balances for each OPO monthly. Instances of violation of this policy are referred to the appropriate OPTN/UNOS Committee.

Policy 3.5.6: Geographic Sequence of Deceased Kidney Allocation

Purpose of policy

The purpose of the policy is to:

- Establish that kidneys are to be allocated locally first, then regionally and then nationally

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Allocate kidneys according to the match run

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs of modifications to system through the use of system notices and documentation updates. UNOS reviews all deceased donor kidney match runs to determine if the organs were allocated according to the match run sequence as established by kidney allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. Through on-site reviews, staff selects a sample of donor records, reviews the donor file documentation and determines if the organs have been allocated in accordance with the match runs. Staff reports all instances where the match run was not followed for allocation to the appropriate OPTN/UNOS Committee.

Policy 3.5.6.1: Local Allocation

Purpose of policy

The purpose of the policy is to:

- Specify that except for kidneys that are 1) shared as a result of a zero antigen mismatch, 2) offered as payback as defined in Policy 3.5.5, or 3) allocated according to voluntary organ sharing arrangement as provided in Policy 3.4.7, all kidneys will be allocated locally first to candidates within the DSA.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Allocate kidneys according to the match run
- Maintain a complete record of all organ offers

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs of modifications to system through the use of system notices and documentation updates. UNOS reviews all deceased donor kidney match runs to determine if the organs were allocated according to the match run sequence as established by kidney allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. With on-site reviews, staff selects a sample of donor records, reviews the donor file documentation and determines if the organs have been allocated in accordance with the match runs. Staff reports all instances where the match run was not followed for allocation to the appropriate OPTN/UNOS Committee.

Policy 3.5.6.2: Regional Allocation

Purpose of policy

The purpose of the policy is to:

- Specify that if a donor kidney is not accepted by any local transplant center the kidney is to be allocated next via the regional list
- Provide instruction for allocating Expanded Criteria Donor (ECD) kidneys regionally if a local recipient is not identified within a certain period of time

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Allocate kidneys according to the match run
- Maintain a complete record of all organ offers

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs of modifications to system through the use of system notices and documentation updates. UNOS reviews all deceased donor kidney match runs to determine if the organs were allocated according to the match run sequence as established by kidney allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. With on-site reviews, staff selects a sample of donor records, reviews the donor file documentation and determines if the organs have been allocated in accordance with the match runs. Staff reports all instances where the match run was not followed for allocation to the appropriate OPTN/UNOS Committee.

Policy 3.5.6.3: National Allocation

Purpose of policy

The purpose of the policy is to:

- Outline how kidneys are to be allocated nationally

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Allocate kidneys according to the match run
- Maintain a complete record of all organ offers

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet℠ system according to current approved policies and notifies OPOs of modifications to system through the use of system notices and documentation updates. UNOS staff monitors all deceased donor kidney match runs to ensure:

- organs were allocated according to the match run sequence, and
- national organ offers were made according to policy.

When insufficient information is provided by the OPO, UNOS staff makes a written inquiry into any allocations that do not follow the match run sequence. During on-site surveys of organ procurement organizations, staff reviews a sample of kidney allocations and validates data entered into DonorNet® and Tiedi® for donors in the review sample. UNOS staff forwards potential policy violations to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for review.

Detailed guidance on policy compliance

- Organ Center telephone: (800) 292-9537
- The OPTN/UNOS Executive Committee approved a decision to require the UNOS Organ Center to make all national kidney, kidney-pancreas, and pancreas offers; this change was effective on May 23, 2007. Until further notice, all OPOs will turn over kidney, kidney-pancreas, and pancreas placement to the Organ Center upon reaching national-level potential recipients on the match run.
    - System notice sent May 21, 2007 to announce and describe the changes
    - System notice sent on May 29, 2007 that includes additional information

Policy 3.5.6.4: Regions
Purpose of policy The purpose of the policy is to: • Name the states in each of the 11 regions
How to comply with this policy *Compliance strategies may include, but are not limited to, the expectations stated below.* No specific action is required of members.
How OPTN/UNOS will evaluate member compliance with this policy No monitoring efforts are required.

Policy 3.5.7: Double Kidney Allocation

Purpose of policy

The purpose of the policy is to:

- Define the conditions that an adult donor must meet for double kidney allocation

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Allocate kidneys according to the match run
- Clearly document in the donor record if a donor meets the conditions for double kidney allocation
- Maintain a complete record of all organ offers

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs of modifications to system through the use of system notices and documentation updates. UNOS reviews all deceased donor kidney match runs to determine if the organs were allocated according to the match run sequence as established by kidney allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. With on-site reviews, staff selects a sample of donor records, reviews the donor file documentation and determines if the organs have been allocated in accordance with the match runs. Staff reports all instances where the match run was not followed for allocation to the appropriate OPTN/UNOS Committee.

Policy 3.5.8: Expanded Criteria Donor Kidney Allocation

Purpose of policy

The purpose of the policy is to:

- Establish that kidneys from expanded criteria donors must be offered locally first, then regionally and then nationally

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Allocate kidneys according to the match run
- Maintain a complete record of all organ offers

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs of modifications to system through the use of system notices and documentation updates. UNOS reviews all deceased donor kidney match runs to determine if the organs were allocated according to the match run sequence as established by kidney allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. With on-site reviews, staff selects a sample of donor records, reviews the donor file documentation and determines if the organs have been allocated in accordance with the match runs. Staff reports all instances where the match run was not followed for allocation to the appropriate OPTN/UNOS Committee.

Policy 3.5.9: Minimum Information/Tissue for Kidney Offer

Purpose of policy

The purpose of the policy is to:

- Specify the minimum information the OPOs must provide to recipient centers with each kidney offer

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Educate organ recovery and placement staff with the requirements for kidney offers
- Provide transplant program personnel with the minimum information required when making kidney offers
- Maintain documentation of the minimum information required and provide such documentation, upon request, for review
- Maintain a complete record of all organ offers

How OPTN/UNOS will evaluate member compliance with this policy

With on-site reviews, staff selects a sample of donor records, reviews the donor file documentation and determines if the organs have been allocated in accordance with the match runs. Staff reports all instances where the match run was not followed for allocation to the appropriate OPTN/UNOS Committee.

Detailed guidance on policy compliance

- As of May 10, 2007, policy includes standardized renal biopsy procedures. Please refer to Policy 3.5.9.2 for detailed recommendations.
- As of December 18, 2007, policy was modified to clarify that one red topped tube needs to be sent with each kidney for ABO verification.

Policy 3.5.11: The Point System for Kidney Allocation

Purpose of policy

The purpose of the policy is to:

- Specify that all candidates who are active on the waiting list will be assigned points and priority for kidney allocation

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Allocate each organ according to the match run

Transplant centers are expected to:

- List all transplant candidates with accurate information (e.g., ABO, HLA) on the waiting list

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews all deceased donor kidney match runs to determine if the organs were allocated according to the match run sequence as established by kidney allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. For on-site OPO reviews, staff selects a sample of donor records, reviews the donor file documentation and determines if the organs have been allocated in accordance with the match runs. Staff reports all instances where the match run was not followed for allocation to the appropriate OPTN/UNOS Committee.

Policy 3.5.11.1: Time of Waiting

Purpose of policy

The purpose of the policy is to:

- Define precisely what criteria kidney transplant candidates must meet prior to accruing waiting time on the waiting list

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- List kidney transplant candidates with accurate dialysis and lab data
- Maintain medical record documentation of:
    - The date a candidate started chronic maintenance dialysis
    - The date a candidate's creatinine clearance or GFR was less than or equal to 20 ml/min
- Maintain documentation to support all candidate data entered into UNet^{SM,} and provide such documentation upon request

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to the system through the use of system notices and documentation updates. UNOS staff monitors changes made to candidate data, and makes an inquiry to ensure policy compliance and data accuracy as appropriate.

- Site surveyors will request a copy of the candidate's Medicare 2728 Form to verify dialysis start date.

UNOS staff forwards potential policy violations to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for review and potential action.

Detailed guidance on policy compliance

Transplant centers must retain medical record documentation to support candidate data entered into UNet^{SM}. It is not acceptable to enter clinical data, such as a dialysis date or creatinine clearance / GFR value or test date, based on verbal information alone, because documentation must be presented upon request.

UNOS staff will look for the **chronic** dialysis start date on the Medicare 2728 Form, if available, to verify dialysis start date. Otherwise, UNOS staff will verify the dialysis start date on another form from the physician or dialysis center.

Policy 3.5.11.1.1: Time of Waiting Points

Purpose of policy

The purpose of the policy is to:

- Define specifically how waiting time points are accrued by candidates on the waiting list

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

No specific action is required of members.

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to the system through the use of system notices and documentation updates.

Policy 3.5.11.2: Quality of Antigen Mismatch

Purpose of policy

The purpose of the policy is to:

- Assign points to kidney transplant candidates on the basis of antigen mismatch with the donor

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- List kidney transplant candidates with accurate HLA information
- Maintain medical record documentation of candidate HLA and provide, upon request, such documentation for review

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews all deceased donor kidney match runs to determine if the organs were allocated according to the match run sequence as established by kidney allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy.

Policy 3.5.11.3: Panel Reactive Antibody

Purpose of policy

The purpose of the policy is to:

- Assign 4 additional points to kidney transplant candidates who have a CPRA level of 80 percent or greater

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- List kidney transplant candidates with any current unacceptable antigens as defined by the center.
- Maintain medical record documentation of candidate's CPRAand provide, upon request, such documentation for review

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews all deceased donor kidney match runs to determine if the organs were allocated according to the match run sequence as established by kidney allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy.

Detailed guidance on policy compliance

- Review the LiveMeeting training recording on CPRA. Log onto UNet^{SM}, select Waitlist^{SM}, select Resources, then Reference Docs. Look for the section on CPRA.
- A waiting list candidate with a CPRA of 80% or greater will receive 4 additional points if at least one unacceptable HLA antigen is identified in UNet^{SM}.

Policy 3.5.11.4: Medical Urgency

Purpose of policy

The purpose of the policy is to:

- Allow a candidate's physician to use medical judgment in assignment of points for medical urgency to candidates awaiting a kidney transplant. If there is more than one local renal center, a cooperative medical decision is required prior to assignment of medical urgency points.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Allocate kidneys according to the match run

Transplant centers are expected to:

- Maintain documentation of a candidate's medical urgency and provide it, upon request, for review
- Reach a cooperative agreement between other local transplant centers prior to assigning medical urgency points and maintain documentation of this agreement

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews all deceased donor kidney match runs to determine if the organs were allocated according to the match run sequence as established by kidney allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. With on-site reviews, staff selects a sample of donor records, reviews the donor file documentation and determines if the organs have been allocated in accordance with the match runs. Staff reports all instances where the match run was not followed for allocation to the appropriate OPTN/UNOS Committee.

Policy 3.5.11.5: Pediatric Kidney Transplant Candidates

Purpose of policy

The purpose of the policy is to:

- Assign additional points to zero antigen mismatch pediatric (<18 years) kidney transplant candidates on the basis of age

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:
List kidney transplant candidates with accurate date of birth, HLA typing and any current unacceptable antigens as defined by the center.

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to system through the use of system notices and documentation updates. UNOS examines any reported instances for a potential policy violation and will refer any instances of potential policy violations to the appropriate committee.

Detailed guidance on policy compliance

- UNOS site surveyors verify date of birth

Policy 3.5.11.5.1: Pediatric Kidney Transplant Candidates Priority for Kidneys from Donors Aged Less than 35 Years

Purpose of policy

The purpose of the policy is to:

- Give priority in kidney allocation to pediatric kidney transplant candidates who have surpassed the pediatric kidney transplant goals

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Allocate kidneys according to the match run

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs of modifications to system through the use of system notices and documentation updates. UNOS reviews all deceased donor kidney match runs to determine if the organs were allocated according to the match run sequence as established by kidney allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy.

Policy 3.5.11.6: Donation Status

Purpose of policy

The purpose of the policy is to:

- Increase awareness of and focus upon the need for organ donation, while acknowledging the donation made by those persons who have served as actual living donors

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Submit the required documentation of previous living donation to UNOS for review

How OPTN/UNOS will evaluate member compliance with this policy

UNOS reviews requests for additional donation status points and verifies that the candidate is a living donor before donation status points are assigned to the candidate.

Detailed guidance on policy compliance

To request donation status points for a kidney candidate who is a prior living donor, the candidate's physician must submit a request to the UNOS Organ Center via fax at (804) 697-4372, Attn: Data Operations Specialist, or via email to theorgancenter@unos.org.

Be sure to include the following information in your request:

- Name of kidney candidate (the prior living donor)
- Name of recipient who received living donation
- Name of transplant facility where transplant occurred
- Date of transplant
- Any name changes of candidate (prior living donor) or recipient
- Signature of the candidate's physician

Policy 3.5.12: The Point System for Expanded Criteria Donor Kidney Allocation

Purpose of policy

The purpose of the policy is to:

- Define that when information about expanded criteria donors is entered into the match system, all candidates who have agreed to receive expanded criteria donor kidneys will be assigned points and priority for allocation

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Accurately register expanded criteria donors

Transplant centers are expected to:

- Obtain consent from candidates prior to their being listed for expanded criteria donor kidney transplantation
- List candidates with the accurate HLA typing, ABO and any current unacceptable antigens as defined by the center. and indicate each candidate's willingness to accept an ECD kidne

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews all deceased donor kidney match runs to determine if the organs were allocated according to the match run sequence as established by kidney allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. With on-site reviews, staff selects a sample of donor records, reviews the donor file documentation and determines if the organs have been allocated in accordance with the match runs. Staff reports all instances where the match run was not followed for allocation to the appropriate OPTN/UNOS Committee.

Policy 3.5.12.1: Time of Waiting

Purpose of policy

The purpose of the policy is to:

- Define precisely what criteria kidney transplant candidates, who have agreed to accept organs from expanded criteria donors, must meet prior to accruing waiting time on the waiting list

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- List kidney transplant candidates with accurate dialysis and lab data
- Maintain medical record documentation of candidate dialysis start date and/or GFR scores and provide, upon request, such documentation for review

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to system through the use of system notices and documentation updates.

Policy 3.5.12.1.1: Time of Waiting Points

Purpose of policy

The purpose of the policy is to:

- Define specifically how waiting time points are accrued by candidates on the waiting list who have agreed to accept organs from expanded criteria donors

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

No specific action is required of members.

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates.

Policy 3.5.13: Choice of Right Versus Left Donor Kidney

Purpose of policy

The purpose of the policy is to:

- Allow the recipient center of the candidate with the greater priority on the waiting list to select which kidney the candidate will receive. This policy does not apply to those kidneys that are shared for zero antigen mismatch candidates or kidney non-renal transplant.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Give the recipient transplant center of the candidate with the greater priority on the waiting list the choice of which kidney the transplant center wants to receive

How OPTN/UNOS will evaluate member compliance with this policy

UNOS examines any reported conflicts to determine if a policy violation has occurred and facilitates review by the appropriate OPTN/UNOS Committee.

Policy 3.5.14: Broad and Split Antigen Specificities

Purpose of policy

The purpose of the policy is to:

- Define how broad and split antigens are considered for listing and matching purposes

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

No specific action is required of members.

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies Members of modifications to system through the use of system notices and documentation updates. UNOS annually updates the A, B, and DR antigens listed in Appendix 3A based on the recommendations of the OPTN/UNOS Histocompatibility Committee.

Policy 3.5.15: Local Conflicts

Purpose of policy

The purpose of the policy is to:

- Provide a platform where local conflicts may be submitted for review and resolution

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs and transplant centers are expected to:

- Report any conflicts or irresolvable inequities to the appropriate OPTN/UNOS Committee for review

How OPTN/UNOS will evaluate member compliance with this policy

UNOS examines any reported conflicts to determine if a policy violation has occurred and facilitates review by the appropriate OPTN/UNOS Committee and the OPTN/UNOS Board of Directors. The facilitation includes the use of the alternate dispute resolution, which encourages both parties to discuss their issues with each other or an impartial subcommittee of the MPSC.

Policy 3.5.16: Allocation of Deceased Kidneys with Discrepant HLA Typing

Purpose of policy

The purpose of the policy is to:

- Define a process in case there are discrepant HLA typings between the Host OPO and the recipient center

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

In a case where a discrepancy in HLA typing exists, the transplant center that received the kidney is expected to:

- Allocate the organ either with the original HLA typing or according to the new HLA typing. However, new allocation must be in accordance with existing kidney allocation policies.

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS also examines allocations with discrepant HLA typing for potential policy violations and forwards potential policy violations to the appropriate OPTN/UNOS Committee.

Detailed guidance on policy compliance

- See policy Appendix 3C, "Resolving Discrepant Donor and Recipient HLA Typing Results in the OPTN Database" http://optn.transplant.hrsa.gov/PoliciesandBylaws2/policies/pdfs/policy_104.pdf

Policy 3.5.17: Prospective Crossmatching

Purpose of policy

The purpose of the policy is to:

- Provide an exception for omission of prospective crossmatching warranted by clinical circumstances

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers and histocompatibility laboratories are required to:

- Develop a joint written policy concerning clinical circumstances which substantiate the omission of prospective crossmatching

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs of modifications to system through the use of system notices and documentation updates. UNOS reviews all deceased donor kidney match runs to determine if the organs were allocated according to the match run sequence as established by kidney allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. With on-site reviews, staff selects a sample of donor records, reviews the donor file documentation and determines if the organs have been allocated in accordance with the match runs. Staff reports all instances where the match run was not followed for allocation to the appropriate OPTN/UNOS Committee.

Detailed guidance on policy compliance

- See policy Appendix 3D, "Guidelines for the Development of Joint Written Agreements Between Histocompatibility Laboratories and Transplant Programs" http://optn.transplant.hrsa.gov/PoliciesandBylaws2/policies/pdfs/policy_109.pdf

Policy 3.6: Allocation of Livers

Purpose of policy

The purpose of the policy is to:

- Equitably allocate livers and reduce mortality for those candidates awaiting transplant. Candidates are categorized based on the severity of their illness, using objective, verifiable medical criteria. The MELD/PELD score is an estimate of a candidate's risk of mortality while on the transplant waiting list. Candidates are prioritized for liver allocation according to an assigned point score based on the probability of dying on the waiting list.
- Define the status priority and geographic sequence of liver allocation
- Specify that a liver recovered from a pediatric organ donor shall be allocated to a pediatric liver candidate before the liver is allocated to an adult candidate
- Define that livers must be transplanted into the original designee or be released back to the Host OPO or to UNOS Organ Center for distribution
- Establish that the final decision to use the liver will remain the prerogative of the transplant surgeon and/or physician
- Define the sequence for allocating a liver segment

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Allocate all livers in accordance with the donor match run
- Document accurate refusal reasons

Transplant centers are expected to:

- Transplant the original designee for whom the liver was accepted
- Contact the Host OPO or UNOS Organ Center for further distribution if the original designee is not available for transplant
- Document accurate refusal reasons
- Allocate the remaining portion of a liver according to the sequence in policy if a

transplant center wishes to split the liver

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews all deceased donor liver match runs to determine if the organs were allocated according to the match run sequence as established by liver allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy.

Policy 3.6.1: Preliminary Stratification

Purpose of policy

The purpose of the policy is to:

- Match only potential donors who are an acceptable size for a particular candidate and to eliminate those candidates who do not match with a specific donor

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Allocate all livers in accordance with the donor match run

Transplant centers are expected to:

- List candidates with a realistic donor weight range

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews all deceased donor liver match runs to determine if the organs were allocated according to the match run sequence as established by liver allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. With on-site reviews, staff selects a sample of donor records, reviews the donor file documentation and determines if livers have been allocated in accordance with the match runs. Staff also verifies the donor weight with the donor's documentation and analyzes instances where a donor organ was turned down for size despite falling within the ranges stated by the center.

Policy 3.6.2: Blood Type Similarity Stratification/Points

Purpose of policy

The purpose of the policy is to:

- Assign a specific point value on the basis of donor blood type similarity for Status 1A and 1B liver transplant candidates. (Identical ABO =10pts, Compatible ABO =5pts, Incompatible ABO =0pts.)
- Specify that within each MELD/PELD score, livers shall be offered to candidates who are ABO-identical with the donor first, then to ABO-compatible candidates, and finally to ABO-incompatible candidates

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- List donors with accurate ABO type
- Allocate all livers in accordance with the donor match run

Transplant centers are expected to:

- List transplant candidates with the accurate ABO typing
- Maintain medical record documentation of ABO typing and provide, upon request, such documentation for review

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews all deceased donor liver match runs to determine if the organs were allocated according to the match run sequence as established by liver allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. During on-site reviews, staff verifies donor and transplant candidate's ABO. Staff refers any instances of potential policy violations to the appropriate OPTN/UNOS Committee.

Policy 3.6.2.1: Allocation of Blood Type O Donors

Purpose of policy

The purpose of the policy is to:

- Define how blood type O donor livers will be allocated to candidates within each status category
- Address waiting time disparities among candidates with different blood types

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- List donors with accurate ABO type
- Maintain donor record documentation of ABO typing and provide, upon request, such documentation for review
- Allocate all livers in accordance with the donor match run

Transplant centers are expected to:

- List transplant candidates with the accurate ABO typing
- Maintain medical record documentation of ABO typing and provide, upon request, such documentation for review

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews all deceased donor liver match runs to determine if the organs were allocated according to the match run sequence as established by liver allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. During on-site reviews, staff verifies donor and transplant candidate's ABO. Staff refers any instances of potential policy violations to the appropriate OPTN/UNOS Committee.

Policy 3.6.2.2: Liver Allocation to Candidates Willing to Accept an Incompatible Blood Type

Purpose of policy

The purpose of the policy is to:

- Allow Status 1A or 1B liver candidates and MELD/PELD candidates with a score of 30 (as of April 11, 2007) or greater to accept a liver from a donor of any blood type and indicate that designation on the waiting list

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Allocate all liver organs in accordance with the donor match run

Transplant centers are expected to:

- List candidates with accurate ABO typing
- List all candidates at the appropriate liver status
- Maintain medical record documentation of ABO typing and liver status
- Comply with all OPTN policies relating to listing candidates for transplant and allocating organs including, but not limited to, Policies 3.1.4 (Waiting List), 3.6.2 (Blood Type Similarity Stratification/Points) and 3.6.4 (Degree of Medical Urgency)
- Specify in UNet^{SM} any candidates for whom they are willing to accept a liver from a donor of any blood type
- Provide, upon request, such documentation for review

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews all deceased donor liver match runs to determine if the organs were allocated according to the match run sequence as established by liver allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy and makes a written inquiry into any allocations that do not follow the match run sequence.

During on-site reviews, staff verifies that the laboratory data entered into UNet^{SM} and used to calculate a candidate's MELD/PELD score are accurate, and that candidates are listed with their correct blood type.

Staff refers any instances of potential policy violations to the appropriate OPTN/UNOS

Committee.

Policy 3.6.3: Time Waiting

Purpose of policy

The purpose of the policy is to:

- Specify how waiting time will be accrued within each liver status. Transplant candidates will accrue waiting time within Status 1A or 1B or any assigned MELD/PELD score. Waiting time accrued at a lower MELD/PELD score will not be counted toward liver allocation if the candidate is upgraded to a higher MELD/PELD score. Stratification of candidates within a particular MELD/PELD score will be based on total waiting time currently and previously accrued at that (higher) score. Waiting time will not be accrued by candidates awaiting a liver transplant while they are registered on the OPTN waiting list as inactive.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

No specific action is required of members.

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies Members of modifications to system through the use of system notices and documentation updates.

Policy 3.6.4: Degree of Medical Urgency

Purpose of policy

The purpose of the policy is to:

- Assign a status code or mortality risk score that corresponds to the candidate's medical condition

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- List all candidates at the appropriate liver status or mortality risk score and to maintain medical record documentation in support of each status listing
- Provide, upon request, medical record documentation in support of listing criteria for review

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. Through on-site reviews, staff verifies the status or score information submitted to UNet^{SM} with the medical documentation.

Detailed guidance on policy compliance

UNet^{SM} allows laboratory values supporting MELD/PELD scores to be entered with two decimal places (hundredths). When the system calculates MELD/PELD scores, it rounds the laboratory value to one decimal place (tenths) using the following rules:

- If the hundredths value is 5 or greater, round up to the next tenth (i.e., 1.05 rounds to 1.1)
- If the hundredths value is 4 or less, the tenths value stays the same (i.e., 1.04 rounds to 1.0)

System users are expected to use the same rounding rules if rounding is necessary during data entry.

Policy 3.6.4.1: Adult Candidate Status

Purpose of policy

The purpose of the policy is to:

- Define the medical urgency statuses for adult (18 years and older) liver transplant candidates. An adult liver transplant candidate can be listed at Status 1A, a specified MELD score or Status 7.
- Define Status 1A as being a candidate who has fulminant liver failure with a life expectancy without a liver transplant of less than seven days
- Define the variables used to calculate the MELD score and the formula used in the calculation
- Define terms for Status 1A candidates

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- List all candidates at the appropriate liver status and to maintain medical record documentation in support of each status listing
- Accurately complete the appropriate information, Status Justification Form or application in UNet^{SM} at the time of candidate listing or status extension
- Adjust a candidate's status if the medical criterion for listing changes
- Provide, upon request, medical record documentation in support of listing for review

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to system through the use of system notices and documentation updates. UNOS staff facilitates and monitors liver listings with the RRB process by communicating with transplant centers and appropriate OPTN/UNOS Committees regarding RRB decisions. Members may access downgrade information through UNet^{SM}.

During surveys of transplant centers, UNOS staff will verify the following:

- MELD/PELD
  - Lab values and dates indicated in UNet^{SM} at the time of listing
- Status 1A
  - Medical record documentation of listing criteria indicated in UNet^{SM} on the status justification forms

DEQ staff will request a corrective action plan if the center's documentation does not

comply with the requirements of this policy and forward the survey results to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for review.

Detailed guidance on policy compliance

- Review the MELD Calculator: http://optn.transplant.hrsa.gov/resources/MeldPeldCalculator.asp?index=98
- Review brochures entitled "Q & A about MELD and PELD" and "MELD/PELD Calculator Q & A": http://www.unos.org/donation/index.php?topic=patient_brochures
- Review the Liver Justification Form Quick Reference Guide: Log onto UNet^{SM}, search for the document "Liver Justification Form Quick Reference Guide."
- The data entered into UNet^{sm} to calculate a candidate's MELD score must be based on the most recent clinical information.
- For Status 1 patients, the section in Policy reading "*For (ii) and (iii), all labs must be from the same blood draw within 24 hours to 7 days following the transplant*" means that laboratory values used for qualification should be drawn no earlier than 24 hours post transplant.
- The transplant center must enter laboratory data into UNet^{sm} using the same number of decimal places in the value as provided by the laboratory whenever possible.
  Review System Notice sent June 14, 2006.
- If a candidate's laboratory value is above or below the range UNet^{SM} will accept for that laboratory value, the transplant center should:
  - Enter in UNet^{SM} the value that is acceptable to UNet^{SM} and numerically closest to the value reported by the laboratory for that candidate.
  - Document in the candidate's record why you are entering into UNet^{SM} a value that is different than the value reported by the laboratory for that candidate.
  - Submit to UNOS a work order request that includes the candidate's name, the value you tried to enter, and the error message you received. This information is necessary so UNOS staff can:
    - Verify the system is working appropriately;
    - Track the incidence of actual laboratory values that fall outside the range UNet^{SM} will accept; and
    - Evaluate the need to change the range of laboratory values UNet^{SM} will accept.
  - Maintain all of this documentation and present it to UNOS staff upon request. If this candidate's record is reviewed during a site survey, UNOS staff will need to review this documentation in addition to medical record documentation of the candidate's laboratory values.
- Continuous dialysis (CVVHD) for at least 24 hours in the week prior to the laboratory draw meets the policy definition of dialysis (at least twice in the week prior) for calculating the MELD score, as approved by the OPTN/UNOS Board of Directors in

June 2008

Policy 3.6.4.1.1: Adult Candidate Reassessment and Recertification

Purpose of policy

The purpose of the policy is to:

- Define a specific reassessment and recertification schedule for an assigned MELD score. The appropriateness of an assigned MELD score shall be reassessed and recertified by the listing transplant center.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Reassess and recertify transplant candidates' MELD scores in accordance with the schedule outlined in policy
- List all candidates at the appropriate liver status and to maintain medical record documentation in support of each status listing
- Accurately complete the appropriate information in UNet^{SM} at the time of candidate listing or status extension
- Provide, upon request, medical record documentation in support of listing for review

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to system through the use of system notices and documentation updates. UNOS staff facilitates and monitors liver listings with the RRB process by communicating with transplant centers and appropriate OPTN/UNOS Committees regarding RRB decisions. Members may access downgrade information through UNet^{SM}.

During surveys of transplant centers, UNOS staff will verify the following:

- MELD/PELD
    - Lab values and dates indicated in UNet^{SM} at the time of listing
- Status 1A
    - Medical record documentation of listing criteria indicated in UNet^{SM} on the status justification forms

DEQ staff will request a corrective action plan if the center's documentation does not comply with the requirements of this policy and forward the survey results to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for review.

Detailed guidance on policy compliance

- Review the MELD Calculator: http://optn.transplant.hrsa.gov/resources/MeldPeldCalculator.asp?index=98
- Review brochures entitled "Q & A about MELD and PELD" and "MELD/PELD Calculator Q & A": http://www.unos.org/donation/index.php?topic=patient_brochures
- Review the Liver Justification Form Quick Reference Guide: Log onto UNet^{SM}, select Waitlist^{SM}, select Resources, then Reference Docs. Look for the section entitled "Liver Justification Form and MELD/PELD Documents."
- Review policy Appendix 3B, "Indications for liver transplantation in children" http://optn.transplant.hrsa.gov/PoliciesandBylaws2/policies/pdfs/policy_15.pdf

Policy 3.6.4.2: Pediatric Candidate Status

Purpose of policy

The purpose of the policy is to:

- Define the medical urgency statuses for pediatric (<18 years) liver transplant candidates. A pediatric liver transplant candidate can be listed at Status 1A or 1B, PELD score (<12 years), MELD score (12-17 years), or Status 7.
- Define Statuses 1A and 1B.
- Define the variables used and how to calculate a PELD score
- Define specific listing terms for Status 1A and 1B candidates

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- List all candidates at the appropriate liver status and maintain medical record documentation in support of each status listing
- Accurately complete the appropriate information, Status Justification Form or application in UNet^{SM} at the time of candidate listing or status extension
- Adjust a candidate's status if the medical criterion for listing changes
- Provide, upon request, medical record documentation in support of listing for review
- Comply with all OPTN policies related to listing candidates for transplant, including, but not limited to, 3.6.4.2 (Pediatric Candidate Status), 3.6.4.3 (Pediatric Candidates with Metabolic Diseases), and 3.6.4.7 (Combined Liver-Intestine Candidates)

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to system through the use of system notices and documentation updates. UNOS staff facilitates and monitors liver listings with the RRB process by communicating with transplant centers and appropriate OPTN/UNOS Committees regarding RRB decisions. Members may access downgrade information through UNet^{SM}.

During surveys of transplant centers, UNOS staff will verify the following:

- MELD/PELD
  - Lab values and dates indicated in UNet^{SM} at the time of listing
- Status 1A and 1B
  - Medical record documentation of listing criteria indicated in UNet^{SM} on the status justification forms

DEQ staff will request a corrective action plan if the center's documentation does not comply with the requirements of this policy and forward the survey results to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for review.

Detailed guidance on policy compliance

- Review information on interim listing procedures for pediatric patients not in the ICU: http://transplantpro.org/upcoming-changes-to-listing-procedures-for-pediatric-liver-candidates/
- Growth failure is a prognostic factor in the PELD calculation. The candidate's height, weight, and age are used to calculate growth failure. The height and weight must be measured in accordance with the Pediatric Candidate Reassessment and Recertification Schedule outlined in Policy 3.6.4.2.1. The height and weight are considered laboratory values for the purposes of the PELD calculation, and the date the height and weight were measured are subject to the same requirements as other laboratory values used in the PELD calculation; these requirements are outlined in Policy 3.6.4.2.1.
- Review the MELD/PELD Calculator: http://optn.transplant.hrsa.gov/resources/MeldPeldCalculator.asp?index=99
- Review brochures entitled "Q & A about MELD and PELD" and "MELD/PELD Calculator Q & A": http://www.unos.org/donation/index.php?topic=patient_brochures
- Review the Liver Justification Form Quick Reference Guide: Log onto UNet^{SM}, select Waitlist^{SM}, select Resources, and then select Reference Docs. Look for the section entitled "Liver Justification Form and MELD/PELD Documents."
- The data entered into UNet^{sm} to calculate a candidate's MELD/PELD score must be based on the most recent clinical information
- The transplant center must enter laboratory data into UNet^{SM} using the same number of decimal places in the value as provided by the laboratory whenever possible. Review System Notice sent June 14, 2006.
- If a candidate's laboratory value is above or below the range UNet^{SM} will accept for that laboratory value, the transplant center should:
    - Enter in UNet^{SM} the value that is acceptable to UNet^{SM} and numerically closest to the value reported by the laboratory for that candidate.
    - Document in the candidate's record why you are entering into UNet^{SM} a value that is different than the value reported by the laboratory for that candidate.
    - Submit to UNOS a work order request that includes the candidate's name, the value you tried to enter, and the error message you received. This information is necessary so UNOS staff can:
        - verify the system is working appropriately;
        - track the incidence of actual laboratory values that fall outside the range UNet^{SM} will accept; and
        - evaluate the need to change the range of laboratory values UNet^{SM}

will accept.

- Maintain all of this documentation and present it to UNOS staff upon request. If this candidate's record is reviewed during a site survey, UNOS staff will need to review this documentation in addition to medical record documentation of the candidate's laboratory values.

Policy 3.6.4.2.1: Pediatric Candidate Reassessment and Recertification Schedule

Purpose of policy

The purpose of the policy is to:

- Define a specific reassessment and recertification schedule of an assigned MELD/PELD score. The appropriateness of an assigned MELD/PELD score shall be reassessed and recertified by the listing transplant center.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Reassess and recertify transplant candidates' MELD/PELD score in accordance to the schedule outlined in policy
- List all candidates at the appropriate liver status and to maintain medical record documentation in support of each status listing
- Accurately complete the appropriate information in UNet^{SM} at the time of candidate listing or status extension
- Provide, upon request, medical record documentation in support of listing for review

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to system through the use of system notices and documentation updates. UNOS staff facilitates and monitors liver listings with the RRB process by communicating with transplant centers and appropriate OPTN/UNOS Committees regarding RRB decisions. UNOS also informs transplant centers of pending downgrades in status due to the expiration of a listing term.

During surveys of transplant centers, UNOS staff will verify the following:

- MELD/PELD
  - Lab values and dates indicated in UNet^{SM} at the time of listing
- Status 1A and 1B
  - Medical record documentation of listing criteria indicated in UNet^{SM} on the status justification forms

DEQ staff will request a corrective action plan if the center's documentation does not comply with the requirements of this policy and forward the survey results to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for review.

Detailed guidance on policy compliance

- Review UNet^{SM} System Notice – Implementation of Change for Listing Pediatric Liver

Candidates with Hepatoblastoma for instructions on how to enter Heptoblastoma beginning February 1, 2012, until programming changes are completed.

- Growth failure is a prognostic factor in the PELD calculation. The candidate's height, weight, and age are used to calculate growth failure. The height and weight must be measured in accordance with the Pediatric Candidate Reassessment and Recertification Schedule outlined in Policy 3.6.4.2.1. The height and weight are considered laboratory values for the purposes of the PELD calculation, and the date the height and weight were measured are subject to the same requirements as other laboratory values used in the PELD calculation; these requirements are outlined in Policy 3.6.4.2.1.

Policy 3.6.4.3: Pediatric Liver Transplant Candidates with Metabolic Diseases

Purpose of policy

The purpose of the policy is to:

- Define at what status pediatric candidates with metabolic disease can be listed
- Define the regional review process for metabolic disease candidates listed at Status 1B and elevated MELD/PELD scores

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- List all candidates at the appropriate liver status and to maintain medical record documentation in support of each status listing
- Accurately complete the appropriate information in UNet^{SM} at the time of candidate listing, status extension or status upgrade
- Provide, upon request, medical record documentation in support of listing for review

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to system through the use of system notices and documentation updates. UNOS staff facilitates and monitors liver listings with the RRB process by communicating with transplant centers and appropriate OPTN/UNOS Committees regarding RRB decisions. Members may access downgrade information through UNet^{SM}.

During surveys of transplant centers, UNOS staff will verify the following:

- MELD/PELD
    - Lab values and dates indicated in UNet^{SM} at the time of listing
- Status 1A and 1B
    - Medical record documentation of listing criteria indicated in UNet^{SM} on the status justification forms

DEQ staff will request a corrective action plan if the center's documentation does not comply with the requirements of this policy and forward the survey results to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for review.

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

Purpose of policy

The purpose of the policy is to:

- Define requirements for listing transplant candidates with Hepatocellular Carcinoma to receive additional priority
- Outline acceptable tumor stages for listing
- Define the specific assessment tools that must be completed prior to listing
- Outline the schedule for an increase in MELD/PELD points every three months
- Require that the explant pathology form be submitted to UNOS for every candidate who receives a liver transplant while listed with additional priority for HCC
- Require the submission of the imaging studies used to support the exception application if the pathology report does not show HCC

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- List all candidates at the appropriate liver status/score and to maintain medical record documentation in support of each status listing
- Accurately complete the exception application in UNet^{SM} at the time of candidate listing or status extension using current clinical information
- Adjust a candidate's status if the medical criterion for listing changes
- Provide, upon request, medical record documentation in support of listing for review
- Submit the explant pathology TIEDI form to UNOS within 60 days of transplant for every candidate with an approved HCC exception who receives a liver transplant
    a. Submit documentation (imaging studies used to support the exception application) to UNOS for every candidate transplanted with an approved HCC exception where there is no evidence of HCC on the explant pathology report. This supplemental documentation should be faxed to (804) 782-4680, Attention: RRB Administrative Supervisor.

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to system through the use of system notices and documentation updates. UNOS staff facilitates and monitors liver listings with the RRB process by communicating with transplant centers and appropriate OPTN/UNOS Committees regarding RRB decisions. Members may access downgrade information through UNet^{SM}.

Staff will verify that explant pathology forms are submitted within 60 days of transplant.

Through site surveys, staff verifies that the information submitted on the exception application and the explant pathology form is supported by the medical record documentation.

- Staff will verify the following information submitted on HCC exception applications:
  - Chest CT to rule out metastasis performed prior to the initial HCC exception application
  - AFP level
  - Laboratory values
  - Tumor sizes
  - Ablative therapy
  - Narrative information as applicable
- Staff will verify that evidence or absence of HCC on the explant pathology report is accurately reported on the explant pathology form

Detailed guidance on policy compliance

- If an imaging study is reviewed during an interdisciplinary conference, and it is decided that a tumor(s) size(s) is/are different from those documented by the radiologist on the imaging study report, this review and determination must be documented.
- When a member's explant pathology forms show that the HCC exception was not supported by the explant pathology report in more than 10% of cases over a 12 month period, the member will be referred for review by the Liver and Intestinal Organ Transplantation Committee.

Policy 3.6.4.5: Liver Candidates with Exceptional Cases

Purpose of policy

The purpose of the policy is to:

- Identify the process required for a candidate to receive additional MELD/PELD points on the basis of a submitted exceptional case application and narrative
- Outline how the candidate may receive an increase in MELD/PELD score equivalent to a ten percent increase in candidate mortality every three months if the candidate continues to meet the original criteria
- Define the Regional Review Board process for the aforementioned cases

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- List all candidates at the appropriate liver status/score and to maintain medical record documentation in support of each status listing
- Accurately complete the exception application in UNet^{SM} at the time of candidate listing or status extension
- Adjust a candidate's status if the medical criterion for listing changes
- Provide, upon request, medical record documentation in support of listing for review

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to system through the use of system notices and documentation updates. UNOS staff facilitates and monitors liver listings with the RRB process by communicating with transplant centers and appropriate OPTN/UNOS Committees regarding RRB decisions. Members may access downgrade information through UNet^{SM}.

Through on-site reviews, staff verifies the information submitted to UNet^{SM} to justify a candidate's score with the medical record documentation. To verify an exceptional case application, UNOS staff will review medical record documentation to support the laboratory data and narrative information submitted on the exception application.

Detailed Guidance on Policy Compliance

UNet users initiate a 21-day countdown when they initially submit MELD exception applications to the liver review boards. The Review Boards are asked to vote at their earliest convenience, but the voting may last for the entire 21-day period. If a MELD exception application is denied and appealed, the appealed MELD exception must be

evaluated within the remaining days of the 21-day period that began when the initial application was submitted.

A MELD score represents a candidate's mortality risk during the next 3 months. When a user chooses to extend a candidate's MELD exception score, UNet auto-populates the requested score field with the MELD score that is equivalent to a 10% mortality increase. UNet converts the candidate's expiring MELD exception score to the 3-month mortality risk that it represents, adds 10% to the mortality risk, and then converts the increased mortality risk to its equivalent MELD score. The tables listed below display the entire MELD and PELD scoring range along with the scores that correspond with a 10% mortality risk increase.

MELD/PELD Scores for Liver/Intestine Candidates

This section shows examples of the increase in MELD/PELD score equivalent to a 10% risk of pre-transplant mortality. There are two tables. The first is based upon the revised mortality curve presented at the July 2003 Liver/Intestine meeting and implemented in UNet on March 16, 2005, and is used for adult candidates; the second is based upon the original mortality curve that was implemented on February 27, 2002 and is used for pediatric candidates.

MELD Scores and Associated 10% Increase in Mortality Risk

MELD Score	With 10% Increase in Mortality Risk
6	20
7	20
8	20
9	20
10	21
11	21
12	21
13	21
14	22
15	22
16	22
17	23
18	23
19	24
20	24
21	25
22	25
23	26

24	27
25	27
26	28
27	29
28	30
29	31
30	32
31	33
32	34
33	35
34	36
35	37
36	39
37	40
38	40
39	40
40	40

How calculated: A MELD score of 15 represents a 4.6% risk of 3 month waiting list mortality. A 10% increase in this risk equates to a risk of 14.6% (4.6+10). A 14.6% mortality risk is represented by a MELD score of 22.

PELD Scores and Associated 10% Increase in Mortality Risk

PELD Score	With 10% Increase in Mortality Risk
-10	28
-9	28
-8	28
-7	28
-6	28
-5	28
-4	28
-3	28
-2	28
-1	28
0	28
1	28
2	28
3	28
4	28
5	28
6	29

	7	29	
	8	29	
	9	29	
	10	29	
	11	29	
	12	30	
	13	30	
	14	30	
	15	30	
	16	30	
	17	31	
	18	31	
	19	31	
	20	32	
	21	32	
	22	32	
	23	33	
	24	33	
	25	34	
	26	34	
	27	35	
	28	35	
	29	36	
	30	36	
	31	37	
	32	38	
	33	38	

Policy 3.6.4.5.1: Liver Candidates with Hepatopulmonary Syndrome (HPS)

Purpose of policy

The purpose of the policy is to:

- Allow candidates with a clinical evidence of portal hypertension, evidence of a shunt, and a $PaO_2 < 60$ on room air to apply to the Regional Review Board for consideration of a MELD score that would provide them a reasonable probability of being transplanted within three months

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- List all candidates at the appropriate liver status/score and to maintain medical record documentation in support of each status listing
- Accurately complete the exception application in UNet^{SM} at the time of candidate listing or status extension
- Adjust a candidate's status if the medical criterion for listing changes
- Provide, upon request, medical record documentation in support of listing for review

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to system through the use of system notices and documentation updates. UNOS staff facilitates and monitors liver listings with the RRB process by communicating with transplant centers and appropriate OPTN/UNOS Committees regarding RRB decisions. Members may access downgrade information through UNet^{SM}.

Through on-site reviews, staff verifies the information submitted to UNet^{SM} to justify a candidate's score. UNOS staff will review the candidate's medical record documentation to verify the laboratory data and narrative information submitted on the exception application.

Detailed Guidance on Policy Compliance

- In June 2009, the OPTN/UNOS Board of Directors approved standardized criteria and MELD/PELD exception scores for patients with certain diagnoses (See OPTN/UNOS Policy 3.6.4.5). Clinical personnel at transplant centers can now enter these scores for their patients into UNet^{SM}.
- However, the software application in UNet^{SM} cannot automatically review and approve these exceptions and some level of human review is still necessary.

- The liver committee developed templates for each diagnoses to allow for easier submission. The templates should be used when entering the required information into the MELD/PELD exception application. The link may be found at: http://transplantpro.org/submitting-standardized-meldpeld-exception-scores/ or refer to the UNet^{SM} System Notice dated 02/15/10: Submitting Standardized MELD/PELD Exception Scores.
- To avoid the possible 21-day lag time, the liver committee modified the RRB Guidelines to allow the RRB chairs to determine if the standardized cases meet the criteria in the policy without forwarding to the entire review board.
- If the criteria are met based on the RRB chair's review, the chair will mark it as approved and the candidate will receive the automatic 22 points.
- If the criteria are not met based on the RRB chair's review, then the information will be forwarded for consideration by the entire review board.

Contact the Review Board staff assigned to your region if there are questions.

Policy 3.6.4.5.2: Liver Candidates with Cholangiocarcinoma

Purpose of policy

The purpose of the policy is to:

- Allow candidates with cholangiocarcinoma to apply to the Regional Review Board for consideration of a MELD score that would provide them a reasonable probability of being transplanted within three months.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- List all candidates at the appropriate liver status/score and to maintain medical record documentation in support of each status listing
- Accurately complete the exception application in UNet^{SM} at the time of candidate listing or status extension
- Adjust a candidate's status if the medical criterion for listing changes
- Provide, upon request, medical record documentation in support of listing for review

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to system through the use of system notices and documentation updates. UNOS staff facilitates and monitors liver listings with the RRB process by communicating with transplant centers and appropriate OPTN/UNOS Committees regarding RRB decisions. Members may access downgrade information through UNet^{SM}.

Through on-site reviews, staff verifies the information submitted to UNet^{SM} to justify a candidate's score. UNOS staff will review the candidate's medical record documentation to verify the laboratory data and narrative information submitted on the exception application.

Detailed guidance on Policy Compliance

- In June 2009, the OPTN/UNOS Board of Directors approved standardized criteria and MELD/PELD exception scores for patients with certain diagnoses (See OPTN/UNOS Policy 3.6.4.5). Clinical personnel at transplant centers can now enter these scores for their patients into UNet^{SM}.
- However, the software application in UNet^{SM} cannot automatically review and approve these exceptions and some level of human review is still necessary.
- The liver committee developed templates for each diagnosis to allow for easier

submission. The templates should be used when entering the required information into the MELD/PELD exception application. The link may be found at: http://transplantpro.org/submitting-standardized-meldpeld-exception-scores/ or refer to the UNet[SM] System Notice dated 02/15/10: Submitting Standardized MELD/PELD Exception Scores.

- To avoid the possible 21-day lag time, the liver committee modified the RRB Guidelines to allow the RRB chairs to determine if the standardized cases meet the criteria in the policy without forwarding to the entire review board.
- If the criteria are met based on the RRB chair's review, the chair will mark it as approved and the candidate will receive the automatic 22 points.
- If the criteria are not met based on the RRB chair's review, then the information will be forwarded for consideration by the entire review board.

Contact the Review Board staff assigned to your region if there are questions.

Policy 3.6.4.5.3: Liver Candidates with Cystic Fibrosis

Purpose of policy

The purpose of the policy is to:

- Allow candidates with cystic fibrosis to apply to the Regional Review Board for consideration of a MELD score that would provide them a reasonable probability of being transplanted within three months.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- List all candidates at the appropriate liver status/score and to maintain medical record documentation in support of each status listing
- Accurately complete the exception application in UNet^{SM} at the time of candidate listing or status extension
- Adjust a candidate's status if the medical criterion for listing changes
- Provide, upon request, medical record documentation in support of listing for review

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to the system through the use of system notices and documentation updates. UNOS staff facilitates and monitors liver listings with the RRB process by communicating with transplant centers and appropriate OPTN/UNOS Committees regarding RRB decisions. Members may access downgrade information through UNet^{SM}.

Through on-site reviews, staff verifies the information submitted to UNet^{SM} to justify a candidate's score. UNOS staff will review the candidate's medical record documentation to verify the laboratory data and narrative information submitted on the exception application.

Detailed guidance on Policy Compliance

- In June 2009, the OPTN/UNOS Board of Directors approved standardized criteria and MELD/PELD exception scores for patients with certain diagnoses (See OPTN/UNOS Policy 3.6.4.5). Clinical personnel at transplant centers can now enter these scores for their patients into UNet^{SM}.
- However, the software application in UNet^{SM} cannot automatically review and approve these exceptions and some level of human review is still necessary.
- The liver committee developed templates for each diagnoses to allow for easier

submission. The templates should be used when entering the required information into the MELD/PELD exception application. The link may be found at: http://transplantpro.org/submitting-standardized-meldpeld-exception-scores/ or refer to the UNet[SM] System Notice dated 02/15/10: Submitting Standardized MELD/PELD Exception Scores.

- To avoid the possible 21-day lag time, the liver committee modified the RRB Guidelines to allow the RRB chairs to determine if the standardized cases meet the criteria in the policy without forwarding to the entire review board.
- If the criteria are met based on the RRB chair's review, the chair will mark it as approved and the candidate will receive the automatic 22 points.
- If the criteria are not met based on the RRB chair's review, then the information will be forwarded for consideration by the entire review board.

Contact the Review Board staff assigned to your region if there are questions.

Policy 3.6.4.5.4: Liver Candidates with Familial Amyloid Polyneuropathy (FAP)

Purpose of policy

The purpose of the policy is to:

- Allow candidates with familial amyloid polyneuropathy to apply to the Regional Review Board for consideration of a MELD score that would provide them a reasonable probability of being transplanted within three months.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- List all candidates at the appropriate liver status/score and to maintain medical record documentation in support of each status listing
- Accurately complete the exception application in UNet^{SM} at the time of candidate listing or status extension
- Adjust a candidate's status if the medical criterion for listing changes
- Provide, upon request, medical record documentation in support of listing for review

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to the system through the use of system notices and documentation updates. UNOS staff facilitates and monitors liver listings with the RRB process by communicating with transplant centers and appropriate OPTN/UNOS Committees regarding RRB decisions. Members may access downgrade information through UNet^{SM}.

Through on-site reviews, staff verifies the information submitted to UNet^{SM} to justify a candidate's score. UNOS staff will review the candidate's medical record documentation to verify the laboratory data and narrative information submitted on the exception application.

Detailed guidance on Policy Compliance

- In June 2009, the OPTN/UNOS Board of Directors approved standardized criteria and MELD/PELD exception scores for patients with certain diagnoses (See OPTN/UNOS Policy 3.6.4.5). Clinical personnel at transplant centers can now enter these scores for their patients into UNet^{SM}.
- However, the software application in UNet^{SM} cannot automatically review and approve these exceptions and some level of human review is still necessary.
- The liver committee developed templates for each diagnoses to allow for easier

submission. The templates should be used when entering the required information into the MELD/PELD exception application. The link may be found at: http://transplantpro.org/submitting-standardized-meldpeld-exception-scores/ or refer to the UNet[SM] System Notice dated 02/15/10: Submitting Standardized MELD/PELD Exception Scores.

- To avoid the possible 21-day lag time, the liver committee modified the RRB Guidelines to allow the RRB chairs to determine if the standardized cases meet the criteria in the policy without forwarding to the entire review board.
- If the criteria are met based on the RRB chair's review, the chair will mark it as approved and the candidate will receive the automatic 22 points.
- If the criteria are not met based on the RRB chair's review, then the information will be forwarded for consideration by the entire review board.

Contact the Review Board staff assigned to your region if there are questions.

Policy 3.6.4.5.5: Liver Candidates with Primary Hyperoxaluria

Purpose of policy

The purpose of the policy is to:

- Allow candidates with primary oxaluria to apply to the Regional Review Board for consideration of a MELD score that would provide them a reasonable probability of being transplanted within three months.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- List all candidates at the appropriate liver status/score and to maintain medical record documentation in support of each status listing
- Accurately complete the exception application in UNet^{SM} at the time of candidate listing or status extension
- Adjust a candidate's status if the medical criterion for listing changes
- Provide, upon request, medical record documentation in support of listing for review

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to the system through the use of system notices and documentation updates. UNOS staff facilitates and monitors liver listings with the RRB process by communicating with transplant centers and appropriate OPTN/UNOS Committees regarding RRB decisions. Members may access downgrade information through UNet^{SM}.

Through on-site reviews, staff verifies the information submitted to UNet^{SM} to justify a candidate's score. UNOS staff will review the candidate's medical record documentation to verify the laboratory data and narrative information submitted on the exception application.

Detailed guidance on Policy Compliance

- In June 2009, the OPTN/UNOS Board of Directors approved standardized criteria and MELD/PELD exception scores for patients with certain diagnoses (See OPTN/UNOS Policy 3.6.4.5). Clinical personnel at transplant centers can now enter these scores for their patients into UNet^{SM}.
- However, the software application in UNet^{SM} cannot automatically review and approve these exceptions and some level of human review is still necessary.
- The liver committee developed templates for each diagnosis to allow for easier

submission. The templates should be used when entering the required information into the MELD/PELD exception application. The link may be found at: http://transplantpro.org/submitting-standardized-meldpeld-exception-scores/ or refer to the UNet[SM] System Notice dated 02/15/10: Submitting Standardized MELD/PELD Exception Scores.

- To avoid the possible 21-day lag time, the liver committee modified the RRB Guidelines to allow the RRB chairs to determine if the standardized cases meet the criteria in the policy without forwarding to the entire review board.
- If the criteria are met based on the RRB chair's review, the chair will mark it as approved and the candidate will receive the automatic 22 points.
- If the criteria are not met based on the RRB chair's review, then the information will be forwarded for consideration by the entire review board.

Contact the Review Board staff assigned to your region if there are questions.

Policy 3.6.4.5.6: Liver Candidates with Portopulmonary Syndrome

Purpose of policy

The purpose of the policy is to:

- Allow candidates with portopulmonary syndrome to apply to the Regional Review Board for consideration of a MELD score that would provide them a reasonable probability of being transplanted within three months

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- List all candidates at the appropriate liver status/score and to maintain medical record documentation in support of each status listing
- Accurately complete the exception application in UNet^{SM} at the time of candidate listing or status extension
- Adjust a candidate's status if the medical criterion for listing changes
- Provide, upon request, medical record documentation in support of listing for review

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to the system through the use of system notices and documentation updates. UNOS staff facilitates and monitors liver listings with the RRB process by communicating with transplant centers and appropriate OPTN/UNOS Committees regarding RRB decisions. Members may access downgrade information through UNet^{SM}.

Through on-site reviews, staff verifies the information submitted to UNet^{SM} to justify a candidate's score. UNOS staff will review the candidate's medical record documentation to verify the laboratory data and narrative information submitted on the exception application.

Detailed guidance on Policy Compliance

- In June 2009, the OPTN/UNOS Board of Directors approved standardized criteria and MELD/PELD exception scores for patients with certain diagnoses (See OPTN/UNOS Policy 3.6.4.5). Clinical personnel at transplant centers can now enter these scores for their patients into UNet^{SM}.
- However, the software application in UNet^{SM} cannot automatically review and approve these exceptions and some level of human review is still necessary.
- The liver committee developed templates for each diagnoses to allow for easier

submission. The templates should be used when entering the required information into the MELD/PELD exception application. The link may be found at: http://transplantpro.org/submitting-standardized-meldpeld-exception-scores/ or refer to the UNet[SM] System Notice dated 02/15/10: Submitting Standardized MELD/PELD Exception Scores.

- To avoid the possible 21-day lag time, the liver committee modified the RRB Guidelines to allow the RRB chairs to determine if the standardized cases meet the criteria in the policy without forwarding to the entire review board.
- If the criteria are met based on the RRB chair's review, the chair will mark it as approved and the candidate will receive the automatic 22 points.
- If the criteria are not met based on the RRB chair's review, then the information will be forwarded for consideration by the entire review board.

Contact the Review Board staff assigned to your region if there are questions.

Policy 3.6.4.6: On-Site Review of Status 1A and 1B Candidate Listings

Purpose of policy

The purpose of the policy is to:

- Trigger an on-site review for a program that transplants a candidate whom the RRB has disapproved Status 1A or 1B listing on three occasions

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- List all candidates at the appropriate liver status/score and to maintain medical record documentation in support of each status listing
- Complete the appropriate information in UNet^{SM} at the time of candidate listing or status extension
- Adjust a candidate's status if the medical criterion for listing changes
- Provide, upon request, medical record documentation in support of listing criteria for review

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to system through the use of system notices and documentation updates. UNOS staff facilitates and monitors liver listings with the RRB process by communicating with transplant centers and appropriate OPTN/UNOS Committees regarding RRB decisions. UNOS also informs transplant centers of pending downgrades in status due to the expiration of a listing term.

Through on-site reviews, staff verifies a recipient's status indicated in UNet^{SM} and on Status Justification Forms with actual candidate medical record documentation.

Policy 3.6.4.7: Combined Liver-Intestine Candidates

Purpose of policy

The purpose of the policy is to:

- Allow those adult candidates awaiting a combined liver-intestine transplant who are registered on both waiting lists to automatically receive an increase in their MELD/PELD score equivalent to a 10 percent risk of three-month mortality
- Provide an increased opportunity for pediatric liver/intestine candidates (age 0-17) to receive a multivisceral transplant in a more timely manner by awarding these candidates an additional 23 point increase in their calculated MELD/PELD score (implementation date June 20, 2007)
- Require the transplant center to verify that an intestinal transplant is required and took place

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Register each candidate who needs a liver/intestine transplant on the liver waiting list and on the intestine waiting list
- List all candidates at the appropriate liver status/score and to maintain medical record documentation in support of each status listing
- Complete the appropriate information in UNet^{SM} at the time of candidate listing or status extension
- Adjust a candidate's status if the medical criterion for listing changes
- Provide, upon request, medical record documentation in support of listing criteria for review

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews all deceased donor liver match runs to determine if the organs were allocated according to the match run sequence as established by liver allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy.

Through on-site reviews, staff verifies a recipient's status indicated in UNet^{SM} and on Status Justification Forms with actual candidate medical record documentation.

Staff will request a written explanation from the listing transplant center if it appears an intestinal transplant was not required. Staff will forward any potential policy violations to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for

review.

Policy 3.6.4.8: Combined Liver-Intestine Allocation

Purpose of policy

The purpose of the policy is to:

- Define the allocation sequence for combined liver-intestine grafts

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Make liver offers sequentially according to the liver match run (including all MELD/PELD potential recipients) through national Status 1A and 1B potential recipients **before** making offers to combined liver-intestine potential recipients sequentially according to the intestine match run

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to the system through the use of system notices and documentation updates. UNOS reviews all liver and intestine match runs to verify that the organs were allocated according to the match run sequence as established by policy and programmed into the UNet^{SM} system.

When insufficient information is provided by the OPO, UNOS staff makes a written inquiry into any allocations that do not follow the match run sequence. During on-site surveys of organ procurement organizations, staff reviews a sample of allocations and validates data entered into DonorNet® and Tiedi® for donors in the review sample. UNOS staff forwards potential policy violations to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for confidential medical peer review.

Detailed guidance on policy compliance

This policy language was approved by the OPTN/UNOS Board of Directors in June 2008, to clarify existing policy requirements for allocating liver-intestine grafts.

Policy 3.6.5: Center Contact and Acceptance

Purpose of policy

The purpose of the policy is to:

- Streamline the organ offer process. A transplant center is allowed one hour from the time of offer to accept or decline. If a transplant center fails to respond to an organ offer within the permitted timeframe, the Host OPO may rescind the offer.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Allocate all livers in accordance with the donor match run
- Maintain complete documentation of all organ offers
- Document the complete first and last name, and title of the person to whom the offer was made
- Document the time the offer was made and the time the center responded
- Document the appropriate refusal code

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews all deceased donor liver match runs to determine if the organs were allocated according to the match run sequence as established by liver allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. Staff also reviews the time elapsed between the offer of the organ and acceptance by the center to ensure that the center communicated their acceptance or decline in a timely manner.

Through on-site review, staff verifies a recipient's status as reflected by the data submitted in UNet^{SM} with the candidate's medical record documentation.

Policy 3.6.5.1: Execution of the Liver Match System

Purpose of policy

The purpose of the policy is to:

- Prevent multiple matches being run with different information about recipients, which may be attempts to circumvent the allocation algorithm. The match system for liver allocation shall be executed within eight hours prior to the initial liver offer. The liver match system may be re-executed if a previously accepted liver is subsequently turned down because there is a change in donor related information.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Educate organ recovery and placement staff with this policy
- Maintain documentation pertaining to the reasons for match system re-execution
- Allocate all livers in accordance with the donor match run
- Maintain complete documentation of all organ offers and provide such documentation, upon request, for review

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs of modifications to system through the use of system notices and documentation updates. UNOS reviews all deceased donor liver match runs to determine if the organs were allocated according to the match run sequence as established by liver allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy.

Through on-site reviews, staff verifies donor information submitted in UNet^{SM} with the on-site documentation.

Policy 3.6.6: Removal of Liver Transplant Candidates from Liver Waiting Lists when Transplanted or Deceased

Purpose of policy

The purpose of the policy is to:

- Maximize efficiency of allocating organs to all potential recipients on the waiting list. Candidates on the waiting list who receive a transplant or who die while awaiting a transplant should immediately be removed.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Remove all candidates who have died, and all recipients of deceased or living donor organs, from the waiting list within 24 hours of the event

How OPTN/UNOS will evaluate member compliance with this policy

During routine site surveys, UNOS staff reviews a sample of records to verify that candidates were removed from the waiting list by midnight (Eastern Standard Time) the day after transplant or death.

Detailed guidance on policy compliance

Transplant centers should document when they learn of a patient's death and remove them from the waiting list within 24 hours. Also include a copy of the death certificate in the medical record, if available.

Policy 3.6.7: Organ Center Assistance with Liver Allocation

Purpose of policy

The purpose of the policy is to:

- Recommend that the UNOS Organ Center be notified when a liver donor is identified and be provided all clinical information that is necessary to offer the liver to potential recipients on the waiting list. Upon request by the OPO, staff shall attempt to locate a liver recipient on the waiting list or identify backup recipients for the liver.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Employ the assistance of UNOS for placement of livers when necessary

How OPTN/UNOS will evaluate member compliance with this policy

The Organ Center facilitates in the allocation of livers only upon the request of transplant centers and reports any potential policy violations to the appropriate department.

Detailed guidance on policy compliance

- Organ Center telephone number: (800) 292-9537

Policy 3.6.8: Local Conflicts

Purpose of policy

The purpose of the policy is to:

- Provide a platform where local conflicts may be submitted for review and resolution

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs and transplant centers are expected to:

- Report any conflicts or irresolvable inequities to the appropriate OPTN/UNOS Committee for review

How OPTN/UNOS will evaluate member compliance with this policy

UNOS examines any reported conflicts to determine if a policy violation has occurred and facilitates review by the appropriate OPTN/UNOS Committee and the OPTN/UNOS Board of Directors. The facilitation includes the use of the alternate dispute resolution, which encourages both parties to discuss their issues with each other or an impartial subcommittee of the MPSC.

Policy 3.6.9.1: Minimum Information for Liver Offers, Essential Information Category

Purpose of policy

The purpose of the policy is to:

- Specify the minimum information that OPOs must provide to recipient centers with each liver offer

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Educate organ recovery and placement staff with the requirements for liver offers
- Provide transplant program personnel with the minimum information required when making liver offers
- Maintain documentation of the minimum information required and provide such documentation, upon request, for review
- Maintain a complete record of all organ offers

How OPTN/UNOS will evaluate member compliance with this policy

During on-site reviews, UNOS staff reviews a sample of donor records based on the number of donors the OPO had in the previous year and determines whether the OPO documented the minimum information for liver offers. UNOS also examines any complaints or potential policy violations and refers them to the appropriate OPTN/UNOS Committee.

Policy 3.6.9.2: Listing Accuracy and Appropriateness

Purpose of policy

The purpose of the policy is to:

- Assure that organs are being allocated to appropriately listed candidates on the waiting list

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Report any suspicious listing inaccuracies or inappropriateness to the UNOS Regional Review Board staff

Transplant centers are expected to:

- List all candidates at the appropriate liver status and to maintain medical record documentation in support of each status listing
- Accurately complete the appropriate information, Status Justification Form or application in UNet^{SM} at the time of candidate listing or status extension
- Adjust a candidate's status if the medical criterion for listing changes
- Provide, upon request, medical record documentation in support of listing for review

How OPTN/UNOS will evaluate member compliance with this policy

UNOS also examines any complaints or potential policy violations and refers them to the appropriate OPTN/UNOS Committee.

Policy 3.6.10: Allocation of Livers for Other Methods of Hepatic Support

Purpose of policy

The purpose of the policy is to:

- Prohibit use of a liver for other methods of hepatic support prior to being offered first for transplantation

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Educate organ recovery and placement staff with this policy
- Allocate all livers in accordance with the donor match run
- Maintain complete documentation of all organ offers and provide such documentation, upon request, for review

Transplant centers are expected to:

- Accurately list whether or not a candidate would accept a liver for other methods of hepatic support

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews all deceased donor liver match runs to determine if the organs were allocated according to the match run sequence as established by liver allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. With on-site reviews, staff selects a sample of donor records, reviews the donor file documentation and determines if livers have been allocated in accordance with the match runs.

Policy 3.6.11: Allocation of Livers for Segmental Transplantation

Purpose of policy

The purpose of the policy is to:

- Define the sequence in which livers for segmental transplantation shall be allocated
- Initiate and facilitate discussions between organ procurement organizations (OPOs) and transplant centers concerning the feasibility of splitting donor livers
    - As of November 28, 2007, identify donors under the age of 40 and with a BMI less than or equal to 28 on every liver match run as a donor with a liver that could potentially be split.
    - As of November 28, 2007, clarify that the center getting the primary whole organ offer will determine the method of splitting and use of vessels.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Educate staff regarding this policy
- Continue placement efforts for the remaining segment until the time of procurement
- Allocate all livers, and liver segments, in accordance with the donor match run
- Maintain complete documentation of all organ offers and provide such documentation, upon request, for review

Transplant centers are expected to:

- Educate staff regarding this policy

How OPTN/UNOS will evaluate member compliance with this policy

UNOS staff monitors all liver organ allocations and makes a written inquiry into any allocations that do not follow the match run sequence. During on-site surveys of organ procurement organizations, staff reviews a sample of liver organ allocations and validates data entered into DonorNet® and Tiedi® for donors in the review sample. The OPTN/UNOS Membership and Professional Standards Committee (MPSC) reviews instances of allocations that do not follow the match run sequence.

Detailed guidance on policy compliance

If the transplant center anticipates splitting the liver, and makes this decision prior to donor procurement, the transplant center must notify the OPO so that the OPO has the opportunity to attempt to place the remaining liver segment according to the match run sequence. After the decision has been made to split the liver, the remaining liver segment must be allocated according to the match run sequence until the donor

procurement starts. If the remaining liver segment has not been placed by the time donor procurement starts, the remaining liver segment may be allocated to any medically appropriate candidate on the waiting list.

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

Purpose of policy

The purpose of the policy is to:

- Provide for an alternative allocation system for segmental livers

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Offer livers in sequence according to Policy 3.6
- Document all refusals

Transplant Centers and OPOs are expected to:

- Determine the recipient of the left lobe/left-lateral segment by following the same match run used to allocate the right lobe/trisegment of the liver under the CAS.

How OPTN/UNOS will evaluate member compliance with this policy

UNOS staff monitors all liver organ allocations and makes a written inquiry into any allocations that do not follow the match run sequence.

An automatic hold will be placed on the CAS program at any transplant program whose re-transplant rate exceeds 3/20 grafts, until the results and surgical practices are reviewed by the transplant program.

Policy 3.6.13: Histocompatibility Testing for Liver Transplantation

Purpose of policy

The purpose of the policy is to:

- Ensure that all liver transplant programs and their histocompatibility laboratories have a joint written policy on HLA typing, antibody screening, and crossmatching

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Collaborate with histocompatibility labs to create a joint policy on HLA typing, antibody screening, and crossmatching
- Provide, upon request, documentation of this policy

How OPTN/UNOS will evaluate member compliance with this policy

During on-site reviews, UNOS staff verifies the existence of a written policy on histocompatibility testing.

6. Detailed guidance on policy compliance

- Review policy Appendix 3D, "Guidelines for the Development of Joint Written Agreements Between Histocompatibility Laboratories and Transplant Programs" http://optn.transplant.hrsa.gov/PoliciesandBylaws2/policies/pdfs/policy_109.pdf

Policy 3.7.1: Exceptions

Purpose of policy

The purpose of the policy is to:

- Reiterate the need to allocate organs in accordance with 3.7, unless a formalized exception has been approved and fully programmed on the UNet^{SM} system

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Apply for and obtain approval before deviating from OPTN thoracic allocation policy, if an alternative allocation system is desired
- Understand that approved variances are implemented pending programming in UNet^{SM}. If a variance, due to complexity issues, cannot be programmed in UNet^{SM}, the OPO or transplant center will be notified.
- Ensure that the variance is fully understood by their staff and followed

Transplant centers are expected to:

- Understand that approved variances are implemented pending programming in UNet^{SM}. If a variance, due to complexity issues, cannot be programmed in UNet^{SM}, the OPO or transplant center will be notified.
- Ensure that the variance is fully understood by their staff and followed

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews all deceased donor thoracic match runs to determine if the organs were allocated according to the match run sequence as established by thoracic allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy.

During on-site reviews, staff selects a sample of donor records and reviews the donor file documentation to determine whether thoracic organs were allocated in accordance with the match runs.

Policy 3.7.1.1: Exception for Sensitized Candidates

Purpose of policy

The purpose of the policy is to:

- Allow an OPO to forgo the policies set forth in Policy 3.7 for allocation of a thoracic organ to a sensitized candidate when the results of a crossmatch between the blood serum of that candidate and cells of the thoracic organ donor are negative. All thoracic organ transplant centers within an OPO must agree prior to this type of allocation.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Obtain permission from all local thoracic transplant programs to allow their sensitized candidate to receive an organ ahead of other potential recipients if the results of a crossmatch between a specific donor and the candidate are negative

How OPTN/UNOS will evaluate member compliance with this policy

UNOS reviews all deceased donor thoracic match runs to determine if the organs were allocated according to the match run sequence as established by thoracic allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy.

In allocations where this exception is utilized, staff verifies that all the thoracic transplant centers within the Host OPO's service area agreed to bypass their own potential recipients in order to transplant the sensitized potential recipient.

Policy 3.7.2: Geographic Sequence of Thoracic Organ Allocation

Purpose of policy

The purpose of the policy is to:

- Define the geographic sequence of thoracic organ allocation. As of May 16, 2007, organs are allocated locally first and then within five concentric circles or zones:
  - Zone A: 0 – 500 miles
  - Zone B: > 500 miles – 1,000 miles
  - Zone C: > 1,000 – 1,500 miles
  - Zone D: > 1,500 – 2,500 miles
  - Zone E: > 2,500 miles
- The purpose of this geographic allocation sequence is to prevent lengthy cold ischemic time related to thoracic organs.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Allocate all thoracic organs in accordance with the donor match run

How OPTN/UNOS will evaluate member compliance with this policy

UNOS reviews all deceased donor thoracic match runs to determine if the organs were allocated according to the match run sequence as established by thoracic allocation policy and programmed into the UNet^{SM} system. Staff makes written inquiry regarding any allocations that do not follow the match run sequence. The OPTN/UNOS Membership and Professional Standards Committee (MPSC) reviews responses to written inquiries.

Detailed guidance on policy compliance

- The miles in the five concentric geographic zones are **nautical miles**. Click here for an explanation and conversion table for nautical miles versus statute miles.

Policy 3.7.3: Adult Candidate Status

Purpose of policy

The purpose of the policy is to:

- Outline the adult candidate (18 years of age and older) statuses and the medical criteria required to be listed at each specific status. Each candidate awaiting a heart transplant is assigned a status code that ranks the candidate on the waiting list based on clinical acuity as determined by the medical criteria described in policy.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- List all candidates at the appropriate heart status and to maintain medical record documentation in support of each status listing
- Complete the appropriate Status Justification Forms in UNet^{SM} at the time of candidate listing or status extension
- Adjust a candidate's status within 24 hours if the medical condition used to justify listing changes
- Provide, upon request, medical record documentation in support of listing criteria for review.

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to system through the use of system notices and documentation updates. UNOS staff facilitates and monitors thoracic listings with the RRB process by communicating with transplant centers and appropriate OPTN/UNOS Committees regarding RRB decisions.

Through on-site reviews, staff verifies candidate status listings as submitted in UNet^{SM} and on Status Justification Forms with the actual medical record documentation. UNOS staff also monitors the percentage of Status 1A listings by criterion on a monthly basis through in-house analyses.

Detailed guidance on policy compliance

- VAD time at Status 1A
    - Candidates with a VAD may only use their 30 days at 1A while that VAD is in place. If it is removed, and the candidate has only used a portion of the 30 days, they lose the remaining time.
    - If a candidate receives another VAD, they can use up to 30 days of 1A time while they have the new VAD in place, regardless of previous time with other

VADs.
    - If the candidate is listed at more than one transplant hospital, they can be listed as 1A at any or all hospitals simultaneously for up to 30 days. However, the candidate may not be listed as 1A for 30 days at one hospital, and for a different 30 days at another hospital.
    - If a candidate changes hospitals, the 30 days does not restart.
- The following was effective August 27, 2011:
    - The Status 1A Justification form will not allow transplant centers to list a candidate as Status 1A by exception unless the patient is admitted to the transplant center hospital or affiliated VA hospital.
    - Status 1A criterion (b) complication listed as "other" will result in a review by the respective heart regional review board.
    - Status 1A criterion (d) is now programmed to include the additional intravenous inotropes listed in the System Notice dated October 20, 2010.
- Based on interim policy changes effective November 10, 2010, a new patient population will now receive thirty (30) days of Status 1A time. Outpatient adult heart transplant candidates implanted with Total Artificial Hearts (TAH) may now be listed as Status 1A for 30 days.
    - At the end of the 30 days, if these TAH candidates are no longer eligible to be listed as Status 1A, they must be listed as Status 1B.
    - This policy expires on December 1, 2012.
    - Candidates with TAHs that are hospitalized still qualify to be listed under Status 1A for 14 days under 1A criteria a-ii, renewable every 14 days as long as they remain hospitalized.
- UNet^{SM} allows only one decimal place for inotrope dosages (i.e. Dobutamine, Dopamine, and Milrinone). If the transplant center enters more than one decimal place in a dosage field, the system drops all of the numbers past the first decimal instead of rounding the value. If your candidate's dosage includes more than one decimal, round to the nearest tenth by rounding up if the hundredths value is 5 or greater, and enter that value into UNet^{SM}. If the value exceeds the upper limit of the allowable range, enter the upper limit of the range and maintain documentation in the file.

    - Maintain all of this documentation and present it to UNOS staff upon request. If this candidate's record is reviewed during a site survey, UNOS staff will need to review this documentation in addition to medical record documentation of the candidate's laboratory values.

Policy 3.7.4: Pediatric Candidate Status

Purpose of policy

The purpose of the policy is to:

- Detail the pediatric candidate statuses and the medical criteria required to list at each specific status. Each candidate awaiting a heart transplant is assigned a status code that ranks the candidate on the waiting list based on clinical acuity as determined by the medical criteria described in policy. (Note that pediatric heart candidates are not required by OPTN policy to be admitted to the listing transplant center hospital to be listed as Status 1A as is the case with adult heart candidates. Compare to Policy 3.7.3.)
- Define a pediatric heart transplant candidate as less than 18 years of age at the time of listing
- Establish that pediatric heart transplant candidates, who remain on the waiting list at the time of their 18th birthday without receiving a transplant, shall continue to qualify for medical urgency status based upon the criteria set forth in Policy 3.7.4

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- List all candidates at the appropriate heart status and to maintain medical record documentation in support of each status listing
- Complete the appropriate Status Justification Forms in UNet℠ at the time of candidate listing or status extension
- Adjust a candidate's status within 24 hours if the medical condition used to justify listing changes
- Provide, upon request, medical record documentation in support of listing criteria for review

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet℠ system according to current approved policies and notifies transplant centers of modifications to system through the use of system notices and documentation updates. UNOS staff facilitates and monitors thoracic listings with the RRB process by communicating with transplant centers and appropriate OPTN/UNOS Committees regarding RRB decisions.

Through on-site reviews, staff verifies candidate status listings as submitted in UNet℠ with the actual candidate medical record documentation. UNOS staff also monitors the percentage of Status 1A listings by criterion on a monthly basis through in-house analyses.

Detailed guidance on policy compliance

UNet[SM] allows only one decimal place for inotrope dosages (i.e. Dobutamine, Dopamine, and Milrinone). If the transplant center enters more than one decimal place in a dosage field, the system drops all of the numbers past the first decimal instead of rounding the value. If your candidate's dosage includes more than one decimal, round to the nearest tenth by rounding up if the hundredths value is 5 or greater, and enter that value into UNet[SM]. If the value exceeds the upper limit of the allowable range, enter the upper limit of the range and maintain documentation in the file.

Maintain all of this documentation and present it to UNOS staff upon request. If this candidate's record is reviewed during a site survey, UNOS staff will need to review this documentation in addition to medical record documentation of the candidate's laboratory values.

Policy 3.7.5: Allocation of Adolescent Donor Hearts to Pediatric Heart Candidates

Purpose of policy

The purpose of the policy is to:

- Allow hearts retrieved from an adolescent donor to be allocated to a pediatric heart candidate before the heart is allocated to an adult candidate
- Define an adolescent organ donor as an individual who is 11 years of age or older, but less than 18 years of age

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Allocate all thoracic organs in accordance with the donor match run

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews all deceased donor thoracic match runs to determine if the organs were allocated according to the match run sequence as established by thoracic allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. During on-site reviews, staff verifies donor and transplant candidate's ABO. Staff refers any instances of potential policy violations to the appropriate OPTN/UNOS Committee.

Policy 3.7.6.1: Status of Candidates Awaiting Lung Transplantation

Purpose of policy

The purpose of the policy is to:

- Establish that all candidates age 12 and older awaiting isolated lung transplantation are assigned priority for lung offers based on a Lung Allocation Score (LAS) which reflects the estimated transplant benefit measure. The transplant benefit measure equals waitlist urgency measure minus post-transplant survival measure.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Maintain medical record documentation to support each clinical variable entered into UNet^{SM} and utilized to calculate a candidate's LAS
- Update a candidate's clinical values every six months from the date of initially listing the candidate
- Provide, upon request, medical record documentation in support of listing criteria for review
- Enter accurate data into UNet^{SM} for each candidate

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to system through the use of system notices and documentation updates. UNOS staff facilitates and monitors lung listings with the Lung Review Board (LRB) process by communicating with transplant centers and appropriate OPTN/UNOS Committees regarding LRB decisions.

Through on-site reviews, staff verifies the clinical variables entered into UNet^{SM} and utilized to calculate the LAS with the actual medical record documentation. Staff also verifies all information submitted to the Lung Review Board with the actual medical record documentation.

Detailed guidance on policy compliance

- Web address for Lung Allocation Score information: http://optn.transplant.hrsa.gov/resources/allocationcalculators.asp?index=88
- Review: A Guide to Calculating Lung Allocation Score: http://www.unos.org/docs/lung_allocation_score.pdf
- As of January 9, 2008, UNet^{SM} was modified to allow the transplant center to enter a candidate's supplemental oxygen as a percentage. This means the transplant center can enter a candidate's F_iO_2 in liters per minute or as percentage. The transplant

center is expected to enter a candidate's supplemental oxygen usage as it is being delivered by the oxygen delivery device.

- As of October 9, 2008, PCO_2 is included in the LAS. Transplant centers must enter PCO_2 values into UNet^{SM} as reported by the laboratory. For example, a venous value of 50 mmHg must be entered into UNet^{SM} as 50 mmHg; the user must **not** subtract 6 mmHg from the value before entering the value into UNet^{SM}. UNet^{SM} will convert venous values to approximate arterial values as described in policy.
- Only PCO_2 values obtained from blood gas sampling may be entered into UNet^{SM} as PCO_2 values. The total CO_2 obtained from venous sampling, such as from a chemistry or metabolic panel, is not acceptable.
- When the Central Venous Pressure (CVP) is not available for entry in UNet^{SM}, it is permissible to enter the Right Atrial Pressure (RAP) into the CVP Field for lung candidates. When the RAP is available (and the CVP is not available), it is preferable to enter the RAP in the CVP field than to not report any values. The transplant center should maintain documentation in the candidate's record of: which value was entered into UNet^{SM}, and why the value was entered in place of the requested value.

Policy 3.7.6.2: Candidates Age 0-11

Purpose of policy

The purpose of the policy is to:

- Detail policy modifications (effective September 12, 2010) that creates simple priority system that ranks pediatric candidates younger than 12 years of age based on medical urgency
- Define how UNet[SM] will now rank Priority 1 and Priority 2 candidates (effective September 12, 2010)

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- List all candidates with the appropriate clinical values requested
- Provide, upon request, medical record documentation in support of listing criteria for review

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet[SM] system according to current approved policies and notifies transplant centers of modifications to UNet[SM] through the use of system notices and documentation updates.

During on-site interviews, site surveyors will review a sample of Priority 1 applications and verify that information submitted matches information contained in the patients' medical records.

DEQ staff will request a corrective action plan if the center's documentation does not comply with the requirements of this policy and forward the survey results to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for its review.

Detailed guidance on policy compliance

- A patient will not become a Priority 1 candidate until a center makes a request even when the patient meets all the necessary requirements.
    - If the request is granted, lab value information should be updated every 6 months, with the exception of the cardiac catheterization information. Information regarding the catheterization may be used indefinitely.
    - If a Priority 1 categorization is denied, a center may apply for an exception. That information will be review **prospectively** by the Region Review Board.
- Otherwise, a patient is categorized a Priority 2 when added to the waitlist.

Policy 3.7.6.3: Candidate Variables in UNet[SM]

Purpose of policy

The purpose of the policy is to:

- Specify required candidate variables when listing a candidate for lung transplantation and to explain the use of default and least beneficial values. Missing variables may not allow a candidate to be listed, or may result in a Lung Allocation Score of zero. If a test to obtain a value cannot be performed due to the medical condition of the candidate, the transplant program can petition the Lung Review Board to determine whether estimated values are appropriate.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- List all candidates with the appropriate clinical values requested and to maintain medical record documentation to support each listing
- Update all of each candidate's clinical values every six months from the date of initially listing the candidate
- For candidates with an LAS over 50, update the following clinical values in UNet[SM] every 14 days:
    - assisted ventilation,
    - supplemental oxygen, and
    - current PCO2 (if performed)
- Provide, upon request, medical record documentation in support of listing criteria for review.

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet[SM] system according to current approved policies and notifies transplant centers of modifications to UNet[SM] through the use of system notices and documentation updates. UNOS staff facilitates and monitors lung listings with the LRB process by communicating with transplant centers and appropriate OPTN/UNOS Committees regarding LRB decisions.

Through on-site reviews, staff verifies candidate listings and clinical values as submitted in UNet[SM] and on Exception Scores, Special Diagnosis, or Estimated Values Justification Forms with the actual medical record documentation.

Policy 3.7.6.3.1: Candidate Variables in UNet[SM] upon Implementation of Lung Allocation Scores Described in Policy 3.7.6

Purpose of policy

The purpose of the policy is to:

- Specify that candidates already registered on the lung Waiting List at the time of implementation of the Lung Allocation Score with no or incomplete data will receive the least beneficial value or the default pulmonary pressure value as appropriate

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

No specific action is required of members.

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet[SM] system according to current approved policies and notifies transplant centers of modifications to UNet[SM] through the use of system notices and documentation updates.

Detailed guidance on policy compliance

- Web address for Lung Allocation Score information: http://optn.transplant.hrsa.gov/resources/allocationcalculators.asp?index=88
- Review: A Guide to Calculating Lung Allocation Score: http://www.unos.org/docs/lung_allocation_score.pdf

Policy 3.7.6.3.2: Updating Candidate Variables

Purpose of policy

The purpose of the policy is to:

- Describe when a transplant program can update a candidate's clinical data and when they must update this data. Other than heart catheterization data, all data must be updated at least once every six months. If the New York Heart Association class or assisted ventilation variable is expired, the candidate will receive a zero Lung Allocation Score and be screened off potential lung donor match runs. If any other variable is expired, the candidate will receive the least beneficial value for that variable.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- List all candidates with the appropriate clinical values requested and to maintain medical record documentation to support each listing
- Update a candidate's clinical values every six months from the date of initially listing the candidate
- Provide, upon request, medical record documentation in support of listing criteria for review

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to UNet^{SM} through the use of system notices and documentation updates. UNOS staff facilitates and monitors lung listings with the LRB process by communicating with transplant centers and appropriate OPTN/UNOS Committees regarding LRB decisions

Through on-site reviews, staff verifies candidate listings as submitted in UNet^{SM} and on Exception Scores, Special Diagnosis, or Estimated Values Justification Forms with the actual medical record documentation.

Detailed guidance on policy compliance

- Web address for Lung Allocation Score information: http://optn.transplant.hrsa.gov/resources/allocationcalculators.asp?index=88
- Review: A Guide to Calculating Lung Allocation Score: http://www.unos.org/docs/lung_allocation_score.pdf
- There are four options when entering diabetes information into the LAS calculator. If the candidate is not diabetic, select Not diabetic. If the candidate is diabetic, select

one of the following:
- (Insulin) Dependency unknown
- Insulin dependent
- Not insulin dependent

Policy 3.7.6.4: Lung Candidates with Exceptional Cases

Purpose of policy

The purpose of the policy is to:

- Establish the function and duties of the Lung Review Board (LRB). Transplant programs may request approval of estimated values, diagnosis, or a specific Lung Allocation Score (LAS). The LRB will have seven days to review each request. If the LRB does not complete voting within seven days, the candidate will receive the requested score or value. If a request is denied, the center may request a conference call with the LRB. After each denial during this process, the transplant center also has the option to override the decision of the LRB. Any requests overridden or not voted on within seven days and granted will be referred to the Thoracic committee.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- List all candidates with the appropriate clinical values requested and to maintain medical record documentation to support each listing
- Accurately complete the appropriate information, Status Justification Form, or application in UNet^{SM} at the time of candidate listing or status extension
- Update a candidate's clinical values every six months from the date of initially listing the candidate
- Provide, upon request, medical record documentation in support of listing criteria for review

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to UNet^{SM} through the use of system notices and documentation updates. UNOS staff facilitates and monitors lung listings with the LRB process by communicating with transplant centers and appropriate OPTN/UNOS Committees regarding LRB decisions.

Through on-site reviews, staff verifies candidate listings as submitted in UNet^{SM} and on Exception Scores, Special Diagnosis, or Estimated Values Justification Forms with the actual medical record documentation.

Detailed guidance on policy compliance

- Web address for Lung Allocation Score information: http://optn.transplant.hrsa.gov/resources/allocationcalculators.asp?index=88
- Review: A Guide to Calculating Lung Allocation Score:

http://www.unos.org/docs/lung_allocation_score.pdf

- Candidates with an approved exception score will appear on lung matches according to the approved exception score. If the candidate's actual Lung Allocation Score (LAS) exceeds the approved exception score, the transplant center must withdraw the LAS exception to use the actual score on lung matches.
- The OPTN/UNOS Thoracic Organ Transplantation Committee on November 21, 2006, approved an increased LAS score for candidates who meet additional criteria under the Primary Pulmonary Hypertension guidelines in order to address candidates with pulmonary hypertension whose scores were affected by system changes. Those additional criteria are:
    - Patient deteriorating on optimal therapy and
    - Right atrial pressure greater than 15mmHG and
    - Cardiac Index less than 1.8 L/min/m^2
- When appealing for a modification in LAS for a lung candidate with pulmonary hypertension, the criteria should be provided to the LRB to receive an increase in the patient's LAS to the 90^{th} percentile of all the lung allocation scores nationally at the time of the request.
- Monthly national scores are distributed through UNet^{SM} System Notices and reflect the candidate scores at the time of transplant and the where candidates' LAS scores fall within certain percentiles.
- Each request requires a narrative to explain the rationale for an exception.
- Members may contact the UNet^{SM} Help Desk at 1-800-978-4334 or at unethelpdesk@unos.org. Members may also contact the review board staff assigned to their region.

Policy 3.7.7: Allocation of Thoracic Organs to Heart-Lung Candidates

Purpose of policy

The purpose of the policy is to:

- Outline how thoracic organs should be allocated to candidates listed for a combined heart/lung transplant. Candidates for heart/lung transplant must be registered on the individual candidate waiting list for each organ. If a candidate is eligible to receive a heart, the lung should be allocated to the candidate from the same donor. If a transplant candidate is eligible to receive a lung, the heart should be allocated to the candidate from the same donor, provided there are no suitable Status 1A isolated heart candidates eligible to receive the heart.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Allocate all thoracic organs in accordance with the donor match run
- Educate organ placement staff on this policy and should allocate heart/lung combinations accordingly

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews all deceased donor thoracic match runs to determine if the organs were allocated according to the match run sequence as established by thoracic allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. During on-site reviews, staff verifies donor and transplant candidate's ABO. Staff refers any instances of potential policy violations to the appropriate OPTN/UNOS Committee.

Policy 3.7.8: ABO Typing for Heart Allocation

Purpose of policy

The purpose of the policy is to:

- Define how hearts will be allocated to candidates within each heart status category according to ABO matching requirements. This policy was developed to address waiting time disparities among candidates with different blood types.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- List donors with accurate ABO type
- Maintain donor record documentation of ABO typing and provide, upon request, such documentation for review
- Allocate all thoracic organs in accordance with the donor match run

Transplant centers are expected to:

- List transplant candidates with the accurate ABO type
- Maintain medical record documentation of ABO typing and provide, upon request, such documentation for review

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews all deceased donor thoracic match runs to determine if the organs were allocated according to the match run sequence as established by thoracic allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. During on-site reviews, staff verifies donor and transplant candidate's ABO. Staff refers any instances of potential policy violations to the appropriate OPTN/UNOS Committee.

Detailed guidance on policy compliance

- The following was effective November 22, 2010:
    - Isohemagglutinin titer (titer) data are required for all born candidates eligible to receive an ABO-incompatible heart offer.
    - Titer level and related treatment restriction now apply to candidates older than one year of age who are eligible to receive an ABO-incompatible heart offer.
    - System Notice dated November 22, 2010, provides additional guidance

related to:
  - Listing eligibility
  - Titer data requirements
  - Eligibility based on titer level and titer-related treatment
  - Allocation changes
  - Critical data
  - Waitlist reports
  - Data submission requirements
  - TIEDI®
- Two source documents for ABO verification need to be present in the medical record.

Policy 3.7.8.1: Heart Allocation to Pediatric Candidates Registered under Blood Type "Z"

Purpose of policy

The purpose of the policy is to:

- Allow a transplant program to accept a heart from a donor of any blood type for pediatric candidates less than two years of age. This policy also allows this "Z" designation to be used in the case of in-utero candidates where the actual blood type is not known.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Allocate all thoracic organs in accordance with the donor match run

Transplant centers are expected to:

- List candidates with the accurate ABO type and date of birth
- Maintain medical record documentation of ABO typing/date of birth and provide, upon request, such documentation for review

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews all deceased donor thoracic match runs to determine if the organs were allocated according to the match run sequence as established by thoracic allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. During on-site reviews, staff verifies donor and transplant candidate's ABO. Staff refers any instances of potential policy violations to the appropriate OPTN/UNOS Committee.

Policy 3.7.8.2: ABO Typing for Lung Allocation

Purpose of policy

The purpose of the policy is to:

- Set priorities for lung allocation on the basis of ABO compatibility between the donor and the transplant candidate. Lungs are first allocated to potential recipients who have the same blood type as the donor. Lungs are then allocated to potential recipients with compatible blood types.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Allocate all thoracic organs in accordance with the donor match run

Transplant centers are expected to:

- List candidates with accurate ABO typing
- Maintain medical record documentation of ABO typing and provide, upon request, such documentation for review

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews all deceased donor thoracic match runs to determine if the organs were allocated according to the match run sequence as established by thoracic allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy.
During on-site reviews, staff verifies donor and transplant candidate's ABO.

Detailed guidance on policy compliance

- Two source documents for ABO verification need to be present in the medical record.

Policy 3.7.9: Time Waiting for Thoracic Organ Candidates

Purpose of policy

The purpose of the policy is to:

- Specify exactly how waiting time is accrued for thoracic organs. Waiting time is not accrued while a transplant candidate is inactive on the waiting list. Waiting time accrued by a candidate for a single thoracic organ (heart or single lung) while waiting on the waiting list may be transferred to the waiting list for a multiple thoracic organ transplant. Conversely, waiting time accrued by a candidate for a multiple thoracic organ (heart-lung or double lung) transplant while waiting on the waiting list may be transferred to the waiting list for a single thoracic organ transplant.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

No specific action is required of members.

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies Members of modifications to system through the use of system notices and documentation updates. UNOS staff also monitors and analyzes the total accumulated time at Status 1A on a monthly basis.

Policy 3.7.9.1: Waiting Time Accrual for Heart Candidates

Purpose of policy

The purpose of the policy is to:

- Specify how waiting time will be accrued within each heart status. Waiting time accrued at a Status 1A, 1B or 2 is counted within each status separately. Waiting time accrued at a lower status will not be applied toward heart allocation if the candidate is upgraded to a higher status.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

No specific action is required of members.

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies Members of modifications to system through the use of system notices and documentation updates. UNOS staff also monitors and analyzes the total accumulated time at Status 1A on a monthly basis.

Policy 3.7.9.2: Waiting Time Accrual for Lung Candidates Age 12 and Older
Purpose of policy The purpose of the policy is to: • Establish how waiting time will be utilized in determining priority in lung allocation among lung candidates with a Lung Allocation Score
How to comply with this policy *Compliance strategies may include, but are not limited to, the expectations stated below.* No specific action is required of members.
How OPTN/UNOS will evaluate member compliance with this policy UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates.

Policy 3.7.10: Sequence of Adult Heart Allocation

Purpose of policy

The purpose of the policy is to:

- Specify the sequence by which hearts recovered from donors 18 years of age and older are allocated

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOS are expected to:

- Allocate all thoracic organs in accordance with the donor match run

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews all deceased donor thoracic match runs to determine if the organs were allocated according to the match run sequence as established by thoracic allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy.

Policy 3.7.11: Sequence of Adult Donor Lung Allocation

Purpose of policy

The purpose of the policy is to:

- Specify the sequence by which lungs from adult donors (age 18 years and older) are allocated. For allocation purposes, a candidate awaiting a single lung transplant is grouped with those awaiting a double lung transplant. Candidates age 12 and over will be grouped together for adult donor lung allocation, and lungs from adult donors will first be offered to candidates aged 12 and older.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOS are expected to:

- Allocate all thoracic organs in accordance with the donor match run

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to the system through the use of system notices and documentation updates. UNOS reviews all deceased donor thoracic match runs to determine if the organs were allocated according to the match run sequence as established by thoracic allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy.

Policy 3.7.11.1: Sequence of Pediatric Donor Lung Allocation

Purpose of policy

The purpose of the policy is to:

- Detail policy modifications (effective September 12, 2010) that improves the sickest candidates' access to lungs by more broadly sharing lungs from deceased donors ages 0-11

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOS are expected to:

- Allocate all thoracic organs in accordance with the donor match run

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to the system through the use of system notices and documentation updates. UNOS reviews all deceased donor thoracic match runs to determine if the organs were allocated according to the match run sequence as established by thoracic allocation policy and programmed into the UNet^{SM} system.

Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy and forward the information to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for its review.

Detailed guidance on policy compliance

- Lung offers from young pediatric donors will be extended to a combined group of local, Zone A and Zone B pediatric candidates, then to a combined group of local and Zone A adolescents before local offers are made to adults.

Policy 3.7.12.1: Minimum Information for Thoracic Organ Offers, Essential Information

Purpose of policy

The purpose of the policy is to:

- Specify the minimum information that OPOs must provide to recipient centers with each thoracic offer

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOS are expected to:

- Educate organ recovery and placement staff with the requirements for heart offers
- Provide transplant center personnel with the minimum information required when making heart offers
- Maintain documentation of the minimum information required and provide such documentation, upon request, for review
- Maintain a complete record of all organ offers

How OPTN/UNOS will evaluate member compliance with this policy

During on-site reviews, UNOS staff reviews a sample of donor records based on the number of donors the OPO had in the previous year and determines whether the OPO documented the minimum information for thoracic offers. UNOS also examines any complaints or potential policy violations and refers them to the appropriate OPTN/UNOS Committee.

Policy 3.7.12.2: Desirable Information for Heart Offers

Purpose of policy

The purpose of the policy is to:

- Identify information that the OPO is encouraged to provide the recipient center with each heart offer

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOS are expected to:

- Educate organ recovery and placement staff with the requirements for heart offers
- Provide transplant center personnel with the desired information for heart offers whenever possible
- Maintain documentation of this information and provide such documentation, upon request, for review
- Maintain a complete record of all organ offers

How OPTN/UNOS will evaluate member compliance with this policy

During on-site reviews, UNOS staff reviews a sample of donor records based on the number of donors the OPO had in the previous year and determines whether the OPO documented the minimum information for thoracic offers. UNOS also examines any complaints or potential policy violations and refers them to the appropriate OPTN/UNOS Committee.

Policy 3.7.12.3: Essential Information for Lung Offers

Purpose of policy

The purpose of the policy is to:

- Specify the minimum information that OPOs must provide to recipient centers with each lung organ offer, in addition to the essential information required for thoracic offers defined by Policy 3.7.12.1

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOS are expected to:

- Educate organ recovery and placement staff with the requirements for lung offers
- Provide transplant center personnel with the minimum information required when making lung offers
- Maintain documentation of the minimum information required and provide such documentation, upon request, for review
- Maintain a complete record of all organ offers

How OPTN/UNOS will evaluate member compliance with this policy

During on-site reviews, UNOS staff reviews a sample of donor records based on the number of donors the OPO had in the previous year and determines whether the OPO documented the minimum information for lung offers. UNOS also examines any complaints or potential policy violations and refers them to the appropriate OPTN/UNOS Committee.

Policy 3.7.12.4: Desirable Information for Lung Offers

Purpose of policy

The purpose of the policy is to:

- Identify information that the OPO is encouraged to provide to the recipient center with each lung offer

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOS are expected to:

- Educate organ recovery and placement staff with the requirements for lung offers
- Provide transplant program personnel with the desired information for lung offers whenever possible
- Maintain documentation of this information and provide such documentation, upon request, for review
- Maintain a complete record of all organ offers

How OPTN/UNOS will evaluate member compliance with this policy

During on-site reviews, UNOS staff reviews a sample of donor records based on the number of donors the OPO had in the previous year and determines whether the OPO documented the minimum information for lung offers. UNOS also examines any complaints or potential policy violations and refers them to the appropriate OPTN/UNOS Committee.

Policy 3.7.13: Removal of Thoracic Organ Transplant Candidates from Thoracic Waiting Lists when Transplanted or Deceased

Purpose of policy

The purpose of the policy is to:

- Maximize the efficiency of the organ allocation system by requiring that candidates who receive a transplant or die be immediately removed from the waiting list

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Remove candidates from the waiting list within 24 hours of transplant or death

How OPTN/UNOS will evaluate member compliance with this policy

During routine site surveys, UNOS staff reviews a sample of records to verify that candidates were removed from the waiting list by midnight (Eastern Standard Time) the day after transplant or death.

Detailed guidance on policy compliance

- If you learn of a candidate's death more than 24 hours after the death, document in the candidate's record the date you become aware of the death. Remove the candidate from the waiting list within 24 hours of learning of the candidate's death. Include documentation in the candidate's record to support the date of death, if available.

Policy 3.7.14: Local Conflicts Involving Thoracic Organ Allocation

Purpose of policy

The purpose of the policy is to:

- Provide a platform where local conflicts may be submitted for review and resolution

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs and transplant centers are expected to:

- Report any conflicts or irresolvable inequities to the appropriate OPTN/UNOS Committee for review

How OPTN/UNOS will evaluate member compliance with this policy

UNOS examines any reported conflicts to determine if a policy violation has occurred and facilitates review by the appropriate OPTN/UNOS Committee and the OPTN/UNOS Board of Directors. The facilitation includes the use of the alternate dispute resolution, which encourages both parties to discuss their issues with each other or an impartial subcommittee of the MPSC.

Policy 3.7.15: Allocation of Domino Donor Hearts

Purpose of policy

The purpose of the policy is to:

- Define a domino heart transplant
- Specify how domino donor hearts should be allocated

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Allocate all thoracic organs in accordance with the donor match run

Transplant centers are expected to:

- Allocate organs in accordance with current policy

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews all deceased donor thoracic match runs to determine if the organs were allocated according to the match run sequence as established by thoracic allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. Staff refers any instances of potential policy violations to the appropriate OPTN/UNOS Committee.

Policy 3.7.16: Crossmatching for Thoracic Organs

Purpose of policy

The purpose of the policy is to:

- Ensure that all thoracic transplant programs and their histocompatibility laboratories have a joint written policy on when a crossmatch is necessary

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Collaborate with histocompatibility labs to create a joint policy on crossmatching
- Provide, upon request, documentation of this policy

How OPTN/UNOS will evaluate member compliance with this policy

During on-site reviews, UNOS staff verifies the existence of a written policy on crossmatching.

Detailed guidance on policy compliance

- Review policy Appendix 3D, "Guidelines for the Development of Joint Written Agreements Between Histocompatibility Laboratories and Transplant Programs" http://optn.transplant.hrsa.gov/PoliciesandBylaws2/policies/pdfs/policy_109.pdf

Policy 3.8: Pancreas Organ Allocation

Purpose of policy

The purpose of the policy is to:

- Establish specific requirements, allocation sequence, etc. for pancreas allocation

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs and transplant centers are expected to:

- Comply with these policies for pancreas allocation

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to the system through the use of system notices and documentation updates. UNOS reviews all deceased donor match runs to determine if the organs were allocated according to the match run sequence as established by organ allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy.

During on-site reviews, staff selects a sample of donor records and reviews the donor file documentation to determine whether pancreata were allocated in accordance with the match runs.

Policy 3.8.1: Pancreas Organ Allocation

Purpose of policy

The purpose of the policy is to:

- Specifically define how isolated pancreas, combined kidney-pancreas or combined solid organ-islet transplants are to be allocated
- Define how zero antigen mismatch pancreas organs are to be allocated

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Allocate organs according to the match run
- Maintain documentation of all organ offers and provide such documentation upon request for review

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs of modifications to the system through the use of system notices and documentation updates. UNOS reviews all deceased donor match runs to determine if the organs were allocated according to the match run sequence as established by organ allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy.

During on-site reviews, staff selects a sample of donor records and reviews the donor file documentation to determine whether pancreata were allocated in accordance with the match runs.

Policies 3.8.1.1-3.8.1.3: Whole Pancreas Allocation

Purpose of policy

The purpose of these policies is to:

- Define the specific geographic allocation of pancreata

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Allocate organs according to the match run
- Maintain documentation of all organ offers and provide such documentation upon request for review

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs of modifications to the system through the use of system notices and documentation updates. UNOS reviews all deceased donor match runs to determine if the organs were allocated according to the match run sequence as established by organ allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy.

During on-site reviews, staff selects a sample of donor records and reviews the donor file documentation to determine whether pancreata were allocated in accordance with the match runs.

Policy 3.8.1.4: Facilitated Pancreas Allocation

Purpose of policy

The purpose of the policy is to:

- Expedite the placement of pancreata and therefore minimize ischemia time

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Use the Organ Center for expedited placement of pancreata

Transplant centers are expected to:

- Notify UNOS in writing if they are willing to participate in this system

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to the system through the use of system notices and documentation updates. UNOS reviews all deceased donor match runs to determine if the organs were allocated according to the match run sequence as established by organ allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy.

During on-site reviews, staff selects a sample of donor records and reviews the donor file documentation to determine whether pancreata were allocated in accordance with the match runs.

Policy 3.8.1.5: Islet Transplantation

Purpose of policy

The purpose of the policy is to:

- Define the allocation sequence for pancreatic islet cell transplantation

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Allocate all organs according to the match run
- Maintain documentation of all organ offers and provide such documentation upon request for review

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs of modifications to the system through the use of system notices and documentation updates. UNOS reviews all deceased donor match runs to determine if the organs were allocated according to the match run sequence as established by organ allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy.

Policy 3.8.1.6: Islet Allocation Protocol

Purpose of policy

The purpose of the policy is to:

- Establish a protocol for the allocation and reallocation of pancreata for islet cell transplantation
- Define how waiting time is accrued for islet cell transplant candidates
- Define medical suitability of an islet preparation
- Define active and inactive candidate status
- Establish a protocol for updating candidate status and removal from the waiting list

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Allocate islet cells according to this policy
- Maintain documentation of all organ offers and provide such documentation upon request for review

Transplant centers are expected to:

- Allocate islet cells according to this policy
- Document whether the islet preparation is medically suitable or medically unsuitable for the candidate for whom the center accepted the islets, and the reasons why the islets are medically unsuitable
- Update candidate status in UNet^{SM} within 72 hours of a transplant center's knowledge of a clinical change and provide such documentation upon request for review
- Remove a candidate from the waiting list within 24 hours of the candidate receiving his/her third islet infusion
- Maintain and submit documentation upon request

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to the system through the use of system notices and documentation updates. UNOS reviews all deceased donor match runs to determine if the organs were allocated according to the match run sequence as established by organ allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy.

Policy 3.8.1.7: Mandatory Sharing of Zero Antigen Mismatch Pancreata

Purpose of policy

The purpose of the policy is to:

- Define the mandatory sharing requirements for pancreas allocation

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Allocate all pancreata according to the match run
- Maintain documentation of all organ offers and provide such documentation upon request for review

Transplant centers are expected to:

- List all pancreas candidates with accurate information

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to the system through the use of system notices and documentation updates. UNOS reviews all deceased donor match runs to determine if the organs were allocated according to the match run sequence as established by organ allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy.

During on-site reviews, staff selects a sample of donor records and reviews the donor file documentation to determine whether pancreata were allocated in accordance with the match runs.

Policy 3.8.1.7.1: Organ Offer Limit

Purpose of policy

The purpose of the policy is to:

- Define requirements for offering zero antigen mismatch pancreata
- Promote efficiency in placement of zero antigen mismatch pancreata

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Offer zero antigen mismatched pancreata according to the match run sequence, either through the Organ Center or through DonorNet®
- Make offers for at least the first 10 zero antigen mismatched potential recipients on the match run. If fewer than 10 zero mismatched potential recipients appear on the match run, offers must be made for all potential recipients on the match run.
- Make offers within eight hours after organ procurement
- Maintain documentation of all organ offers and provide such documentation upon request for review

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet℠ system according to current approved policies and notifies OPOs of modifications to system through the use of system notices and documentation updates. UNOS staff monitors all deceased donor pancreas and kidney/pancreas match runs to ensure:

- Organs were allocated according to the match run sequence, and
- Mandatory shares were offered according to policy.

When insufficient information is provided by the OPO, UNOS staff makes a written inquiry into any allocations that do not follow the match run sequence. During on-site surveys of organ procurement organizations, staff reviews a sample of kidney allocations and validates data entered into DonorNet® and Tiedi® for donors in the review sample. UNOS staff forwards potential policy violations to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for review.

Detailed guidance on policy compliance

- Organ Center telephone: (800) 292-9537
- The Host OPO **will** be entitled to a kidney payback if the kidney/pancreas combination is accepted for any potential recipient who is located outside the host OPO's local service area. This includes potential recipients who are beyond the 10th potential recipient on the match run.
- To receive a payback credit, OPOs must:
    - Fax a completed Kidney Payback Sheet to the Organ Center within 5 business days of organ recovery

- Enter the final acceptance in DonorNet®
- Enter the cross-clamp date/time in DonorNet®

Policy 3.8.2: Waiting Time Adjustment

Purpose of policy

The purpose of the policy is to:

- Specify when waiting time accrued by a transplant candidate for one or more organs shall be transferred if it is determined that the candidate requires another organ or organ combination

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Comply with this policy for waiting time accrual

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to the system through the use of system notices and documentation updates. The Organ Center manages any requests for waiting time transfers and adjustments and refers any potential policy violations to the appropriate department.

Policy 3.8.3: Inclusion of HLA Data

Purpose of policy

The purpose of the policy is to:

- Require recipient HLA information at the time of listing for a pancreas or combined kidney-pancreas transplant

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- To provide recipient HLA information at the time of listing for a pancreas or combined kidney-pancreas transplant

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to the system through the use of system notices and documentation updates.

Policy 3.8.5: Regional or National Allocation to Alternate Recipients

Purpose of policy

The purpose of the policy is to:

- Require that for pancreata shared regionally or nationally, the Organ Center will advise the OPO for the recipient transplant center to seek alternate backup candidates on the OPO local waiting list

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Facilitate local backup for all imported organs
- Maintain documentation of all organ offers and provide such documentation upon request for review

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs of modifications to the system through the use of system notices and documentation updates. UNOS reviews all deceased donor match runs to determine if the organs were allocated according to the match run sequence as established by organ allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy.

During on-site reviews, staff selects a sample of donor records and reviews the donor file documentation to determine whether pancreata were allocated in accordance with the match runs.

Policy 3.8.6: Minimum Information for Pancreas Offers, Essential Information Category

Purpose of policy

The purpose of the policy is to:

- Specify the essential information that OPOs must provide to potential recipient centers with each pancreas offer

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Educate organ recovery and placement staff with the requirements for pancreas offers
- Provide transplant center personnel with the minimum information required when making pancreas offers
- Maintain documentation of the essential information required and provide such documentation, upon request, for review
- Maintain a complete record of all organ offers

How OPTN/UNOS will evaluate member compliance with this policy

During on-site reviews, UNOS staff reviews a sample of donor records based on the number of donors the OPO had in the previous year and determines whether the OPO documented the minimum information for thoracic offers. UNOS also examines any complaints or potential policy violations and refers them to the appropriate OPTN/UNOS Committee.

Policy 3.8.7: Removal of Pancreas Transplant Candidates from Pancreas Waiting Lists when Transplanted or Deceased

Purpose of policy

The purpose of the policy is to:

- Maximize the efficiency of the organ allocation system by requiring that candidates who receive a pancreas transplant or who die while awaiting a transplant be immediately removed from the waiting list

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Remove all candidates from the waiting list within 24 hours of transplant or death

How OPTN/UNOS will evaluate member compliance with this policy

During routine site surveys, UNOS staff reviews a sample of records to verify that candidates were removed from the waiting list by midnight (Eastern Standard Time) the day after transplant or death.

Detailed guidance on policy compliance

- If you learn of a candidate's death more than 24 hours after the death, document in the candidate's record the date you become aware of the death. Remove the candidate from the waiting list within 24 hours of learning of the candidate's death. Include documentation in the candidate's record to support the date of death, if available.

Policy 3.8.8: Waiting Time Reinstatement for Pancreas Recipients

Purpose of policy

The purpose of the policy is to:

- Define the requirements and procedures for reinstating previously accrued waiting time to pancreas transplant candidates following graft failure

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Submit a completed Pancreas Waiting Time Reinstatement Form to the Organ Center
- Maintain documentation to support the information submitted on the Pancreas Waiting Time Reinstatement Form, including documentation of radiographic evidence indicating that the transplanted pancreas has failed
- Submit supporting medical record documentation to UNOS upon request

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to the system through the use of system notices and documentation updates. The Organ Center manages any requests for waiting time transfers and adjustments and refers any potential policy violations to the appropriate department.

Detailed guidance on policy compliance

- A partial pancreatectomy performed in the first two weeks of transplant should be treated as a "removal of the organ" for the purposes of Policy 3.8.7.
- The Pancreas Waiting Time Reinstatement Form can be found in Waitlist^{SM} under Forms and Tools.

Policy 3.8.9: Prospective Crossmatching

Purpose of policy

The purpose of the policy is to:

- Provide an exception for omission of prospective crossmatching warranted by clinical circumstances

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers and histocompatibility laboratories are required to:

- Develop a joint written policy concerning clinical circumstances which substantiate the omission of prospective crossmatching

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs of modifications to the system through the use of system notices and documentation updates. Documentation of joint policy is subject to review by UNOS staff.

Detailed guidance on policy compliance

- Review policy Appendix 3D, "Guidelines for the Development of Joint Written Agreements Between Histocompatibility Laboratories and Transplant Programs" http://optn.transplant.hrsa.gov/PoliciesandBylaws2/policies/pdfs/policy_109.pdf

Policy 3.9: Allocation System for Organs Not Specifically Addressed

Purpose of policy

The purpose of the policy is to:

- Assign a point system for allocation of organs not specifically addressed in other organ specific policies

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- List all candidates at the appropriate status and to maintain medical record documentation in support of each status listing
- Provide, upon request, medical record documentation in support of listing criteria for review

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies transplant centers of modifications to system through the use of system notices and documentation updates.

Policy 3.9.1: Degree of Medical Urgency

Purpose of policy

The purpose of the policy is to:

- Assign a status code or mortality risk score that corresponds to the medical urgency of the candidate

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- List all candidates at the appropriate status and to maintain medical record documentation in support of each status listing
- Provide, upon request, medical record documentation in support of listing criteria for review

How OPTN/UNOS will evaluate member compliance with this policy

During an on-site or desk audit, UNOS reviews the assigned status code or mortality risk score and verifies it with the medical documentation.

Policy 3.9.2: Distance Criteria

Purpose of policy

The purpose of the policy is to:

- Define the geographic sequence of allocation for organs not specifically addressed in policy

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Allocate all organs in accordance with this policy

How OPTN/UNOS will evaluate member compliance with this policy

UNOS programs the UNet^{SM} system and notifies OPOs of system modifications through the use of system notices and documentation updates.

Policy 3.9.3: Organ Allocation to Multiple Organ Transplant Candidates

Purpose of policy

The purpose of the policy is to:

- Specify that candidates needing multiple organs must be registered on each organ list for the organ that they need
- Specify that allocation of additional organs for those listed for a heart and/or lung and/or liver is mandatory when the donor is located within the same local organ distribution unit as the candidate. If the multiple organ candidate is on a waiting list outside the local organ distribution unit where the donor is located, voluntary sharing of the second organ is recommended.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- OPOs are expected to allocate organs according to the match run

Transplant centers are expected to:

- List all candidates at the appropriate status and to maintain medical record documentation in support of each status listing
- Provide, upon request, medical record documentation in support of listing criteria for review

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews all deceased donor organ match runs to determine if the organs were allocated according to the match run sequence as established by organ allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy. During on-site reviews, staff verifies donor organ allocation.

Detailed guidance on policy compliance

- To receive a payback credit for sharing a kidney with a non-renal organ to a multiple organ candidate located outside the local organ distribution unit, OPOs must fax a completed Kidney Payback Sheet to the Organ Center
- Organ Center telephone: (800) 292-9537
- For instruction on heart-lung allocation, review Policy 3.7.7

- For instruction on liver-intestine allocation, review Policy 3.11.4 and Policy 3.6.4.8

Policy 3.9.4: Local Conflicts

Purpose of policy

The purpose of the policy is to:

- Provide a platform where local conflicts may be submitted for review and resolution

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs and transplant centers are expected to:

- Report any conflicts or irresolvable inequities to the appropriate OPTN/UNOS Committee for review

How OPTN/UNOS will evaluate member compliance with this policy

UNOS examines any reported conflicts to determine if a policy violation has occurred and facilitates review by the appropriate OPTN/UNOS Committee and the OPTN/UNOS Board of Directors. The facilitation includes the use of the alternate dispute resolution, which encourages both parties to discuss their issues with each other or an impartial subcommittee of the MPSC.

Policy 3.11: Intestinal Organ Allocation

Purpose of policy

The purpose of the policy is to:

- Define how intestinal organs will be allocated. Intestinal organs may include the stomach, small and/or large intestine and any portion of the gastro-intestinal tract.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Follow this policy when listing candidates or allocating intestinal organs and to maintain medical records in support of both

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS reviews all deceased donor match runs to determine if the organs were allocated according to the match run sequence as established by organ allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy.

Policy 3.11.1: Degree of Medical Urgency

Purpose of policy

The purpose of the policy is to:

- Outline the Status candidates may be assigned according to the medical condition of the candidate

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- List all candidates at the appropriate intestinal organ status and maintain medical record documentation in support of each status listing
- Accurately complete the appropriate information and Justification Form in UNet^{SM} at the time of candidate listing
- Adjust a candidate's status if the medical criterion for listing changes

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates.

Policy 3.11.2: Geographic Sequence for Intestinal Organ Allocation

Purpose of policy

The purpose of the policy is to:

- Define the way in which intestinal organs will be allocated. Intestinal organs are allocated first to size compatible and blood type identical candidates and followed by candidates who have a blood type that is compatible to the organ donor. Allocation is based upon length of time waiting and in accordance with the sequence: To local Status 1 first then Local Status 2; Status 1 candidates in the Host OPO's region; Status 2 candidates in the Host OPO's region; Status 1 candidates in all other regions; and Status 2 candidates in all other regions.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Comply with this policy when executing a match run and contacting possible recipients

Transplant centers are expected to:

- List all candidates at the appropriate intestinal organ status and to maintain medical record documentation in support of each status listing
- Accurately complete the appropriate information and justification form in UNet^{SM} at the time of candidate listing. Transplant centers are also expected to adjust a candidate's status if the medical criterion for listing changes

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to the system through the use of system notices and documentation updates. UNOS reviews all deceased donor match runs to determine if the organs were allocated according to the match run sequence as established by organ allocation policy and programmed into the UNet^{SM} system.

When insufficient information is provided by the OPO, UNOS staff makes a written inquiry into any allocations that do not follow the match run sequence. During on-site surveys of organ procurement organizations, staff reviews a sample of allocations and validates data entered into DonorNet® and Tiedi® for donors in the review sample. UNOS staff forwards potential policy violations to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for confidential medical peer review.

Policy 3.11.3: Justification Form

Purpose of policy

The purpose of the policy is to:

- Inform the transplant center of the requirement to complete a Justification Form in order to list a candidate on the intestinal organ waiting list. This requirement is for any Status 1 listing or renewal.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- List Status 1 candidates in the UNet^{SM} system utilizing the Justification Form provided in an electronic format
- List candidates appropriately according to policy and medical urgency and maintain medical records supporting the listing

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates.

Policy 3.11.4: Combined Intestine-Liver Organ Candidates

Purpose of policy

The purpose of the policy is to:

- Define the allocation sequence for combined intestine-liver grafts

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Make liver offers sequentially according to the liver match run (including all MELD/PELD potential recipients) through national Status 1A and 1B potential recipients **before** making offers to combined liver-intestine potential recipients sequentially according to the intestine match run

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to the system through the use of system notices and documentation updates. UNOS reviews all liver and intestine match runs to verify that the organs were allocated according to the match run sequence as established by policy and programmed into the UNet^{SM} system.

When insufficient information is provided by the OPO, UNOS staff makes a written inquiry into any allocations that do not follow the match run sequence. During on-site surveys of organ procurement organizations, staff reviews a sample of allocations and validates data entered into DonorNet® and Tiedi® for donors in the review sample. UNOS staff forwards potential policy violations to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for confidential medical peer review.

Policy 3.11.4.1: Waiting Time Accrual for Combined Liver-Intestinal Organ Candidates

Purpose of policy

The purpose of the policy is to:

- Define how waiting time accrued by a candidate for an isolated intestinal organ transplant while waiting on the waiting list also may be accrued for a combined liver-intestinal organ transplant when it has been determined that the candidate requires multiple organs

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- List candidates appropriately according to policy and medical urgency and maintain medical records supporting the listing

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS, through the Organ Center, facilitates waiting time transfers and adjustments and reports any potential policy violations to the appropriate department.

Policy 3.11.4.2: Combined Liver-Intestinal Organs from Donors 0-10 years of age

Purpose of policy

The purpose of the policy is to:

- Increase the availability of liver/intestine grafts for pediatric candidates awaiting liver/intestine transplant by changing the allocation priority that displays on the liver match run for liver/intestine donors between the ages of 0 and 10

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Allocate combined liver-intestine organs from donors aged 0-10 according to the liver match runs generated by DonorNet® and according to Policies 3.11.4 and 3.11.4.2

How OPTN/UNOS will evaluate member compliance with this policy

Staff monitors all liver and intestinal organ allocations and makes a written inquiry into any allocations that do not follow the match run sequence. During on-site surveys of organ procurement organizations, staff reviews a sample of liver and intestinal organ allocations. The OPTN/UNOS Membership and Professional Standards Committee (MPSC) reviews instances of allocations that do not follow the match run sequence and the responses to the written inquiries.

Detailed guidance on policy compliance

- Implementation date June 20, 2007

Policy 3.11.5: Removal of Intestinal Transplant Candidates from Intestine Waiting Lists when Transplanted or Deceased

Purpose of policy

The purpose of the policy is to:

- Maximize the efficiency of the organ allocation system by requiring that candidates who receive an intestinal transplant or who die while awaiting a transplant be immediately removed from the waiting list.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Remove candidates from the waiting list within 24 hours of transplant or death

How OPTN/UNOS will evaluate member compliance with this policy

During routine site surveys, UNOS staff reviews a sample of records to verify that candidates were removed from the waiting list within 24 hours of transplant or death.

Detailed guidance on policy compliance

If you learn of a candidate's death more than 24 hours after the death, document in the candidate's record the date you become aware of the death. Remove the candidate from the waiting list within 24 hours of learning of the candidate's death. Include documentation in the candidate's record to support the date of death, if available.

Policy 3.11.5.1: Waiting Time Reinstatement for Intestinal Organ Transplant Recipients

Purpose of policy

The purpose of the policy is to:

- Define the circumstances that would allow a candidate to continue to accrue additional time and maintain their previously accrued time on the waiting list when they may need to be re-listed after transplant for immediate and permanent non-function
- Further define for the transplant centers that immediate and permanent non-function means an intestinal organ graft failure resulting in the removal of the organ within the first seven days following transplantation

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Re-list candidates only under the circumstances defined in this policy for the purpose of requesting reinstatement of previously accrued time
- Complete and submit all reinstatement requests to the Organ Center on the proper form with documentation including, but not limited to, the operative report

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. UNOS, through the Organ Center may facilitate waiting time reinstatement upon a center's request and reports any instances of potential policy violations to the appropriate department.

Policy 3.11.6: Waiting Time for Intestinal Organ Transplant Candidates in an Inactive Status

Purpose of policy

The purpose of the policy is to:

- Define the parameters in which a candidate who has been made inactive on the waiting list may still continue to accrue an aggregate of 30 days inactive status waiting time. The waiting time is calculated on a cumulative basis.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Ensure that a candidate's status on the waiting list accurately reflects the current medical urgency or condition

How OPTN/UNOS will evaluate member compliance with this policy

UNOS continuously programs the UNet^{SM} system according to current approved policies and notifies OPOs and transplant centers of modifications to system through the use of system notices and documentation updates. The system counts the total number of days at inactive time and is programmed according to policy.

Policy 4.1: Screening Potential Transplant Recipients for Blood-Borne Pathogens

Purpose of policy

The purpose of the policy is to:

- Specify the testing requirements for HIV, Hepatitis B and Hepatitis C screening of all potential candidates
- Specify that a potential candidates who test positive for HIV should not be excluded from candidacy unless there is documented contraindication to transplantation based on local policy
- Outline requirements related to informing personnel

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Comply with the HIV, Hepatitis B and Hepatitis C testing and reporting requirement for all donors
- Maintain documentation of donor/recipient screening and provide such documentation upon request for review
- Specify requirements for informing personnel caring for potential donors for donors who test positive for HIV to be informed only when necessary for medical decision-making purposes

How OPTN/UNOS will evaluate member compliance with this policy

During on-site reviews, staff selects a sample of donor records and reviews the on-site documentation to determine whether the OPO was compliant with this policy.

DEQ staff forward potential violations of these policies to the Membership and Professional Standards Committee (MPSC) for review.

Policy 4.2: Requirements for Informed Consent Regarding Risk of Transmissible Disease

Purpose of policy

The purpose of the policy is to:

- Specify requirements of transplant centers to obtain informed consent prior to transplant of an organ when in the transplant program's medical judgment there are all of the following:
    - Known medical conditions (with the exception of HIV, see Policy 2.2.3.3) that may be transmittable to the recipient
    - Increased risk for blood borne viruses (including those instances when a hemodiluted specimen is used for donor HIV, HBV, and/or HCV screening, see Policy 2.2.3.1)
    - General risks of potential infection and/or tumor acquisition outside of the standard donor screening requirements (defined in Policy 2.2.4.1).

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Develop policies and procedures to address the requirements set forth in this policy
- Explain the risks and obtain informed consent from the recipient or next of kin, the legal next of kin, designated health care representative or appropriate surrogate prior to transplant
- Maintain documentation of informed consent in the donor record and make available to the OPTN contractor
- Offer the recipient additional testing, monitoring and/or therapy to treat or provide prophylaxis as appropriate to minimize the risk of infection
    - Maintain documentation related to the offer

How OPTN/UNOS will evaluate member compliance with this policy

During on-site reviews, staff selects a sample of donor records and reviews informed consent and testing/monitoring/treatment as accepted for recipients regarding risks of transmissible diseases.

DEQ staff forward potential violations of these policies to the Membership and Professional Standards Committee (MPSC) for review.

Detailed guidance on policy compliance

Additional post-transplant testing should be offered in addition to routine post-transplant follow-up care.

Policy 4.3: Disclosure of Post-Transplant Discovery of Donor Disease or Malignancy and Notification of Recipients

Purpose of policy

The purpose of the policy is to:

- Specify requirements for notification to recipients when donor disease or malignancy is discovered post-transplant

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Notify recipient or next of kin, the legal next of kin, designated health care representative or appropriate surrogate of a risk of transmissible disease when noted as clinically relevant by the recipient's care team
- Maintain documentation of new donor information and potential risk for disease/malignancy in the recipient medical record and make available to the OPTN contractor
- Offer the recipient additional testing, monitoring and/or therapy as appropriate to minimize the risk of infection
    - Maintain documentation related to the offer

How OPTN/UNOS will evaluate member compliance with this policy

UNOS examines any reported instances for a potential policy violation and will refer any instances of potential policy violations to the appropriate OPTN/UNOS Committee.

Policy 4.4: Patient Safety Contact

Purpose of policy

The purpose of the policy is to:

- Define the process for identification of the Patient Safety Contact for each OPO and transplant program
- Define the responsibilities of the Patient Safety Contact

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers and OPOs are expected to:

- Develop a process and identify a Patient Safety Contact
- Develop a process for communicating and receiving potential disease transmission notifications and other related communication between Host OPO and transplant programs as well as the OPTN

How OPTN/UNOS will evaluate member compliance with this policy

During on site reviews, staff will review policies and procedures related to the Patient Safety Contact regarding the Contact's role and responsibilities.

DEQ staff forward potential violations of these policies to the Membership and Professional Standards Committee (MPSC) for review.

Detailed guidance on policy compliance

Patient safety contact plans should be submitted to patientsafetycontact@unos.org and kept up to date. This information is accessible to DEQ, Organ Center, Patient Safety and Regional Administration staff at UNOS and will be used as needed for potential donor-derived disease transmission events (PDDTE) and other patient safety matters. The policy language was written in a manner to allow OPOs and transplant programs the flexibility to develop a plan that best suits their specific needs and staffing:

- Plans can be as simple as a specific name(s) or a specific title (Program Director, Quality Assurance Coordinator, etc). A phone number is required and email is also recommended.
- Many transplant centers have opted to create program specific patient safety contact plans.
- If the patient safety contact role is a specific person at an OPO or transplant program, a back-up contact (such as on call coordinator or call center staff) is recommended.
- Many members have opted to use their on-call staff as the point of contact for patient safety contact plans, and have created and submitted internal policy to

direct how and to whom information that is received should be shared. While this information is helpful, it is not required to meet the new OPTN policy requirement.

- Medical personnel are not required to fulfill this role. The key is that whoever receives this information understands the importance of facilitating communication to the recipient's care team.

Policy 4.5: Post-Transplant Reporting of Potential Transmission of Disease or Medical Conditions, Including Malignancies

Purpose of policy

The purpose of the policy is to:

- Require reporting to the OPTN Improving Patient Safety Portal℠ as soon as possible, within 24 hours of unexpected potential or proven transmissions of medical conditions, infections and malignancies, discovered after procurement of a deceased donor organ, or after transplant of a living donor organ

How to comply with this policy

Compliance strategies include, but are not limited to:

Transplant hospitals are expected to:

- Notify the living donor recovery hospital or Host OPO within 24 hours of knowledge of the event when an organ recipient is suspected to have, is confirmed positive for or has died from a potential transmissible disease or medical condition
- Not wait for all medical documentation before informing the living donor recovery hospital, Host OPO, and/or the OPTN Improving Patient Safety Portal℠

Living donor recovery hospitals that learn new information regarding possible transmission of disease or malignancy from a living donor are expected to:

- Inform the living donor of the required reporting
- Notify the recipient hospital
- Report through the OPTN Improving Patient Safety Portal℠

How OPTN/UNOS will evaluate member compliance with this policy

- Upon notification by the Host OPO or living donor recovery hospital of the potential or confirmed transmission of a disease or medical condition by an organ donor, UNOS will assist in identifying all recipients of those organs. UNOS will monitor the notification process by the procuring OPO to the affected transplant hospitals.
-

Detailed guidance on policy compliance

- For additional information on nationally notifiable diseases per the CDC, please see http://wwwn.cdc.gov/nndss/document/2012_Case%20Definitions.pdf
- For additional guidance on the types of events to report, review the Guidance for Reporting Potential Deceased and Living Donor-Derived Disease Transmission Events
- Transplant hospitals that learn new information regarding possible transmission of disease or malignancy from a living donor may also need to report the information to health authorities.

Policy 4.5.1: Host OPO Responsibilities

Purpose of policy

The purpose of the policy is to:

- Outline living donor recovery hospital and Host OPO Responsibilities for post-transplant reporting of potential transmission of disease or medical conditions, including malignancies

How to comply with this policy

Compliance strategies include, but are not limited to:

Host OPOs and living donor recovery hospitals are expected to:

- Communicate the test results and diagnosis of a potentially transmissible disease in an organ donor, to any transplant hospitals' Patient Safety Contact (defined in Policy 4.4) and tissue bank(s) that received an organ or tissue from that donor, as soon as possible, and within 24 hours
  - Information communicated should include results of all test that were not available at the time of procurement or recovery, or were performed after procurement or recovery
  - Maintain documentation that the above information was communicated to all recipient centers and tissue banks
- Notify the OPTN of the event through the Improving Patient Safety Portal in Secure Enterprise℠ as soon as possible, but not to exceed 24 hours when this new information is relevant to acute patient care (i.e. requiring clinical observation, diagnostic testing or therapeutic intervention to diagnose, prevent or treat a potentially transmitted disease) and could result in unexpected PDDTE.
- If requested by Patient Safety Staff, complete and submit the *Potential Disease Transmission DONOR Follow-up Report* (which may be sent by the OPTN staff) 45 days after the initial reporting date.
- Manage the review in partnership with the OPTN Patient Safety Staff

In addition, Host OPOs are expected to:

- Complete and submit the *Potential Disease Transmission Report Form* (which will be sent to the Host OPO after the OPTN receives notification through UNet℠) within 24 hours of reporting the event

How OPTN/UNOS will evaluate member compliance with this policy

Upon notification of the potential or confirmed transmission of a disease or medical condition by an organ donor, UNOS will assist the reporting member in identifying all recipients of those organs. UNOS will monitor the notification process by to the affected

transplant hospitals.

UNOS will also review the *Potential Disease Transmission Report Form* to make sure it was completed within 24 hours.

Detailed guidance on policy compliance

- For additional guidance on the types of events to report, review the Guidance for Reporting Potential Deceased and Living Donor-Derived Disease Transmission Events
- OPTN staff may request additional Potential Disease Transmission long-term follow-up depending on the disease or condition potentially transmitted if any additional donor testing results related to the potential donor-derived disease transmission are still pending at 45 days after reporting.

Policy 4.5.2: Transplant Program Responsibilities

Purpose of policy

The purpose of the policy is to:

- Outline Transplant Program responsibilities for any transplant program treating recipient(s) that receive organ(s) from a donor who is the subject of a potential disease transmission report

How to comply with this policy

Compliance strategies include, but are not limited to:

Transplant hospitals are expected to:

- Respond in a timely fashion to Host OPO, living donor recovery hospital, and OPTN Patient Safety Staff requests for information regarding recipients and communicate updated information regarding recipients, including condition, test results, diagnosis, treatment plans and follow-up plans
- Submit copies of test results to OPTN Patient Safety Staff
- Notify recipients in cases of possible or confirmed transmissions per Policy 4.3 if determined as clinically relevant by the recipient's care team.
  - Maintain documentation related to recipient notification
- Provide UNOS Patient Safety Staff with documentation and other information to complete the *Potential Disease Transmission RECIPIENT Follow-up Report*
- Provide the OPTN Patient Safety Staff with any requested available data to complete extended follow-up depending on the disease or condition potentially transmitted (i.e. malignancy).

How OPTN/UNOS will evaluate member compliance with this policy

Upon notification by the procuring OPO or transplant hospital of the potential or confirmed transmission of a disease or medical condition by an organ donor, UNOS will assist in identifying all recipients of those organs. UNOS will monitor the notification to the affected transplant hospitals.

Detailed guidance on policy compliance

- For additional guidance on the types of events to report, review the Guidance for Reporting Potential Deceased and Living Donor-Derived Disease Transmission Events
- The OPTN Patient Safety Staff may also contact the recipient center(s) for follow-up information on a recipient beyond the 45 day review period to determine the probability of donor-derived transmission. This may involve collect of recipient test results not complete or received at 45 days, or ongoing updates regarding recipient monitoring in certain circumstances (i.e. potential malignancy transmissions).

Policy 5.0: Standardized Packaging and Transporting of Organs, Vessels and Tissue Typing Materials

Purpose of policy

The purpose of the policy is to:

- Outline requirements for standardized packaging and transporting of organs, tissue typing specimens, and vessels in order to improve patient safety and reduce the number of wasted organs by reducing the number of labeling errors
- Define new responsibilities for the Host OPO and Transplant Center when the packaging and labeling of an organ takes place
- Remove all references to Living Donors due to the creation of Policy 12.0 regarding living donation
- Effective January 10, 2011, all OPOs and transplant centers who package and label organs for transport must use the new internal label and vessel label distributed by the OPTN contractor

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Both OPOs and Transplant centers are expected to:

- Determine if current policies, procedures and/or protocols are consistent with the updated OPTN policy
- If no OPO policies, procedures and/or protocols exist, develop and implement such to reflect OPTN policy requirements

Host OPOs are responsible for :

- Labeling and packaging deceased donor organs
- Making all reasonable efforts to package and label the organ in a timely manner
- Submitting a report through the Patient Safety System when a Transplant center fails to remain in the operating room while the OPO is packaging and labeling an organ

Transplant centers are expected to:

- Package, label and ship an organ in accordance with this policy if an organ is

repackaged by a transplant center for transport
How OPTN/UNOS will evaluate member compliance with this policy UNOS reviews and verifies transplant center and OPO policies and procedures, and verifies the presence and accuracy of the documentation for a sample of records during site surveys.
Detailed guidance on policy compliance • For training on the new organ packaging and transport labeling system visit: http://transplantpro.org/view-unos-hipaa-webcast-from-oct-5/

Policy 5.1: External Packaging Specifications

Purpose of policy

The purpose of the policy is to:

- Outline requirements for the external packaging of organs, including definitions and uses for disposable shipping boxes, coolers and mechanical preservation machines

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Host OPOs and Transplant centers are expected to:

- Use containers as specified in Policy 5.1 to package any deceased donor organ that travels outside the recovery facility
- Label the container as required by Policies 5.1.1-5.1.3.

How OPTN/UNOS will evaluate member compliance with this policy

UNOS reviews and verifies OPOs' written policies related to the required external packaging specifications. UNOS staff may request that OPOs and transplant centers demonstrate how they package organs for transport.

Detailed guidance on policy compliance

- An external transport container is defined as a disposable shipping box, cooler or mechanical preservation machine

Policy 5.1.1: Disposable shipping box

Purpose of policy

The purpose of the policy is to:

- Clarify requirements for use of a disposable shipping box related to external packaging specifications

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Host OPOs and Transplant Centers are expected to:

- Use a disposable shipping box if organs, vessels and/or tissue typing materials are shipped commercially

How OPTN/UNOS will evaluate member compliance with this policy

UNOS reviews and verifies OPOs' external packaging supplies during onsite reviews.

Policy 5.1.2: Cooler

Purpose of policy

The purpose of the policy is to:

- Clarify requirements for the use of coolers in the non-commercial transport of organs.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Host OPOs and Transplant centers are permitted to:

- Use coolers for transporting organs when the organ recovery team is transporting the donor organ with them from the donor hospital to the candidate transplant center

How OPTN/UNOS will evaluate member compliance with this policy

UNOS reviews and verifies OPOs' external packaging supplies during onsite reviews.

Detailed guidance on policy compliance

- OPOs and transplant centers must label a cooler with the standardized label provided by UNOS, the OPTN contractor.
    - Members can purchase organ shipping container labels from UNOS by calling (800) 292-9548 during normal business hours, or by visiting the UNOS online store at: http://store.unos.org/index.php
    - Members may download PDF versions of 2×5 inch and 2×4 inch formats of extra vessels container labels (to print and sterilize as needed)
    - New UNOS organ container shipping labels contain all required information on one external label. **As of October 1, 2008, all Members must use the revised organ container shipping labels.**
    - Revised shipping labels – available for use as of 7/1/08, **required for use as of 10/1/08**
    - If labels from UNOS are not available when the OPO requests them, the OPO should maintain documentation of efforts to obtain labels and present this documentation upon request.
    - If reused, coolers must be properly cleaned and sanitized and all previous labels must be removed

Policy 5.1.3: Mechanical preservation machine

Purpose of policy

The purpose of the policy is to:

- Clarify the requirements for the use of mechanical preservation machine related to external packaging specifications.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs and Transplant centers are expected to:

- Comply with updated requirements related to the use of a mechanical preservation machine.

How OPTN/UNOS will evaluate member compliance with this policy

UNOS reviews and verifies OPOs' external packaging supplies during onsite reviews.

Detailed guidance on policy compliance

- The external surface of the mechanical preservation machine must include the standardized label provided by the OPTN contractor.
    - Members can purchase labels from UNOS by calling (800) 292-9548 during normal business hours, or by visiting the UNOS online store at: http://store.unos.org/index.php.
- The cassette containing the organ must be labeled with the organ type (e.g. left kidney, right kidney), ABO, ABO subtype (when used for allocation) and UNOS ID.

Policy 5.2: Internal Packaging Specifications

Purpose of policy

The purpose of the policy is to:

- Clarify internal packaging specifications related to procurement of an organ on the donor's back table.
- Outline requirements related to the protection required for internal packaging.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Host OPOs and Transplant centers are expected to:

- Package organs on the donor OR's back table using universal precautions.
    - In order to ensure a water tight seal, bags must be tied – twisting and tucking is not sufficient.

How OPTN/UNOS will evaluate member compliance with this policy

During site surveys of OPOs, Department of Evaluation and Quality (DEQ) staff reviews packaging requirements with each OPO and requests a corrective action plan if the OPO's policies and procedures do not comply with the requirements of Policy 5.2.

DEQ staff also investigates reports of noncompliance.

DEQ staff forwards potential violations of policy to the Membership and Professional Standards Committee (MPSC) for review.

Detailed guidance on policy compliance

- New policy requirements were effective January 17, 2010.
- 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 required triple sterile barrier.
- Hearts, lungs, livers and intestines do not require a rigid barrier.
- Vessels must be protected by a triple sterile barrier. If packaged separately from the organ, one barrier must be a rigid container.

Policy 5.3: External Labeling Requirements

Purpose of policy

The purpose of the policy is to:

- Outline requirements for labeling a disposable shipping box or cooler used to transport a deceased donor organ.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Host OPOs and Transplant centers are expected to:

- Use the standardized external label distributed by UNOS, the OPTN contractor, when a disposable shipping box or cooler is used to transport a deceased donor organ.

How OPTN/UNOS will evaluate member compliance with this policy

During site surveys of OPOs, Department of Evaluation and Quality (DEQ) staff reviews packaging requirements with each OPO and requests a corrective action plan if the OPO's policies and procedures do not comply with the requirements of Policy 5.3.

Detailed guidance on policy compliance

- New policy requirements were effective January 17, 2010.
- The external transport container must be labeled with:
    - The UNOS Donor ID;
    - The Donor ABO type (and 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—all of which are included in the standardized external label.
- Additional information for the standardized labels:
    - Members may download PDF versions of 2×5 inch and 2×4 inch formats of extra vessels container labels (to print and sterilize as needed)
    - Members can purchase organ shipping container labels from UNOS by calling (800) 292-9548 during normal business hours, or by visiting the UNOS online store at: http://store.unos.org/index.php.
    - New UNOS organ container shipping labels contain all required information on one external label. **As of October 1, 2008, all Members must use the revised organ container shipping labels.**
    - If labels from UNOS are not available when the OPO requests them, the OPO should maintain documentation of efforts to obtain labels and present this

documentation upon request.

Policy 5.4: Internal Labeling Requirements

Purpose of policy

The purpose of the policy is to:

- Outline requirements for internal labeling requirements for solid organs, tissue typing materials and vessels.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs and Transplant centers are expected to:

- Incorporate new requirements related to the internal labeling of solid organs, tissue typing materials and vessels.
- Effective January 10, 2011, label vessels with the standardized vessel label distributed by the OPTN contractor.

How OPTN/UNOS will evaluate member compliance with this policy

At transplant centers, UNOS may verify that the center has a documented solid organ, tissue typing material and vessel internal labeling procedure that is consistent with policy requirements.

Detailed guidance on policy compliance

- New policy requirements were effective January 17, 2010.
- UNOS recommends that OPOs and transplant centers label the inner vessel container as well as the outer rigid, sterile sealed container when vessels are packaged separately from the organ. Labeling the inner vessel container is not required by policy, however, in the interest of patient safety, the above guidance is recommended.
- For training on the new organ packaging and transport labeling system visit: http://transplantpro.org/view-unos-hipaa-webcast-from-oct-5/

Policy 5.4.2: Tissue Typing Materials

Purpose of policy

The purpose of the policy is to:

- Outline labeling requirements for tissue typing materials

How to comply with this policy

Compliance strategies include, but are not limited to:

Transplant hospitals are expected to:

- When a UNOS ID and ABO are available:
  - Label each separate specimen container of tissue typing material with
    - UNOS Donor I.D., and
    - **One** of the following three:
      - donor date of birth
      - donor initials
      - locally assigned unique ID
    - Donor ABO
    - Date and time the sample was procured
    - Type of tissue
- In the preliminary evaluation of a donor, if the UNOS ID and ABO are unavailable, label initial screen specimens with both:
  - locally assigned unique ID
  - one other identifier
- Document in the donor record any unique identifiers used to label tissue typing specimens

How OPTN/UNOS will evaluate member compliance with this policy

During on-site reviews, the Department of Evaluation and Quality (DEQ) staff reviews and verifies transplant hospitals' and OPOs' policies and procedures, and conducts interviews with staff to ensure compliance with this policy.

DEQ staff will request a corrective action plan if the center's documentation does not comply with the requirements of this policy and forward the survey results to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for its review.

Detailed guidance on policy compliance

- ABO is not considered a unique identifier

Policy 5.5: Documentation Accompanying the Organ or Vessel

Purpose of policy

The purpose of the policy is to:

- Clarify the requirements related to the documentation that must accompany an organ or vessel

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs and Transplant centers are expected to:

- Include necessary documentation in the container with all transported organs, including new requirements effective January 10, 2011.

How OPTN/UNOS will evaluate member compliance with this policy

At OPO onsite review, UNOS staff reviews and verifies the completion of documentation related to a donor organ and inclusion with packaged organ or vessel

Detailed guidance on policy compliance

- Documentation accompanying a donor organ must be placed in a watertight container and placed in either a location specifically designed for documentation or between the outer and inner liners. This documentation must include:
    - ABO typing source documentation
    - ABO subtyping source documentation when subtype is used for allocation
    - Infectious disease testing results
    - Medical/behavioral history form
    - Donor evaluation
    - Complete donor record
    - Deceased donor authorization form
    - Organ quality information as defined in Policy 2.5
- If vessels are not packaged with the donor organ, the same documentation must be included with the vessels as is included with the organ.

Policy 5.6: Verification of Labeling and Documentation Included with Organs or Vessels

Purpose of policy

The purpose of the policy is to:

- Outline requirements for the verification of package internal and external labeling and documentation included with organs or vessels.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Host OPOs are expected to:

- Have a second person verify the accuracy of the information on the package labels and the documentation included with organs or vessels prepared for transport.
- 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 Policies 5.3, 5.4 and 5.5.
- Retain specific documentation that this verification occurred.

How OPTN/UNOS will evaluate member compliance with this policy

UNOS reviews and verifies OPOs' written policies related to the verification of internal and external packaging labels and documentation that accompanies organs or vessels. UNOS staff also reviews documentation that a second person verified the accuracy of organ labels and contents. UNOS investigates all reports of improper labeling reported and refers instances of non-compliance to the Membership and Professional Standards Committee (MPSC).

Detailed guidance on policy compliance

- OPOs may use the verification form to document verification.
- New policy requirements were effective January 17, 2010.
- The Host OPO is responsible for ensuring the accuracy of the donor's ABO on the container label and on the donor's documentation when a donor organ or vessel is procured.
- The Host OPO must maintain documentation that such separate verification has taken place and make such documentation available for audit.

Policy 5.7: Verification of Information Upon Receipt of Organ

Purpose of policy

The purpose of the policy is to:

- Outline requirements for verification of information once an organ is received by a Transplant center.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Maintain documentation that verification of information upon receipt of an organ has taken place.

How OPTN/UNOS will evaluate member compliance with this policy

UNOS reviews documentation verifying the donor and recipient ABO, ABO subtype (when used for allocation), and the Donor ID upon the receipt of an organ.

Detailed guidance on policy compliance

- New policy requirements were effective January 17, 2010.
- The Transplant center must verify and document that it has received the correct organ for the correct candidate by verifying the donor and recipient ABO and UNOS Donor ID per Policy 3.1.2.

Policy 5.8: Materials for Tissue Typing and ABO Confirmation

Purpose of policy

The purpose of the policy is to:

- Outline requirements for tissue typing specimen, medium and shipping requirements; blood for ABO confirmation; typing material for each kidney and pancreas; and typing material for all other organs.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Host OPOs are expected to:

- For 5.8.1, have a written policy established with an OPTN member laboratory(s) which includes specific descriptions of the type of specimen and medium, in addition to the shipping requirements of the same.
- For 5.8.2, send a "red top" tube of blood, specifically for confirmation of ABO and ABO subtype (when used for allocation), to the receiving OPO or transplant center with each deceased donor organ and tissue typing material.
    - The host OPO is responsible for ensuring the tube is appropriately labeled per Policy 5.4.2.
    - The blood type **may not** be indicated on the label.
    - The tube must be placed within the insulated container.
- For 5.8.3, include the following typing material to be obtained for EACH kidney and pancreas at a minimum:
    - 2 ACD (yellow top) tubes
    - 3 to 5 lymph nodes
    - One 2x4 cm. wedge of spleen in culture medium, if available
- For 5.8.4, provide specimens for tissue typing if requested.

How OPTN/UNOS will evaluate member compliance with this policy

UNOS investigates all reports of failure to include required materials related to tissue typing and ABO confirmation reported by members and refers instances of non-compliance to the Membership and Professional Standards Committee (MPSC).

Detailed guidance on policy compliance

- New policy requirements were effective January 17, 2010.

Policy 5.9: Deceased Donor Organs that Remain in the Same Operating Room Suite as the Intended Candidate(s)

Purpose of policy

The purpose of the policy is to:

- Clarify the requirements for Transplant Centers when donor organs are recovered and remain in the same operating room suite as the intended candidate(s), specifically, "time outs."

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers and OPOs (if applicable) are expected to:

- Develop, implement and comply with a procedure to ensure identification of the correct donor organ for the correct recipient.
- Confirm and document that the correct organ was identified for the correct candidate prior to transplant per Policy 3.1.2.

How OPTN/UNOS will evaluate member compliance with this policy

During onsite reviews at OPOs and transplant centers, UNOS may verify the OPO's and transplant center's procedures for verifying the correct organ for the correct recipient.

Detailed guidance on policy compliance

A "time out" prior to leaving the donor operating room and an additional "time out" upon arrival in the candidate operating room are required.

Policy 5.10: Vessel Recovery, Storage, and Transplant

Purpose of policy

The purpose of the policy is to:

- Outline the requirements for vessel recovery and immediate use in a solid organ transplant
- Outline the requirements for vessel recovery and storage for use in a subsequent solid organ transplant

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs and transplant centers are expected to:

- Recover and store vessels only to be used for implanting or modifying a solid organ transplant
- Handle recovered vessels that are not immediately used according to policies governing packaging, labeling, storage, storage medium and temperature, location, and duration of storage
    - In order to ensure a water tight seal, bags must be tied – twisting and tucking is not sufficient.
- Destroy any hepatitis C antibody positive or hepatitis B surface antigen positive extra vessels. OPOs and transplant centers may not store these vessels for subsequent use.

Transplant centers are expected to:

- Only use recovered vessels for the implantation or modification of a solid organ transplant
- Verify the vessel recipient's ABO and serologies with the donor ID, vessel container contents, vessel expiration date, donor ABO and all donor serologies before transplanting the extra vessels
- Document sharing of vessels with other transplant centers and provide notice about the sharing of vessels to UNOS
- Notify UNOS when vessels are stored and then subsequently used for the intended recipient or for another transplant recipient
- Maintain all documentation of vessel storage, usage, and destruction
- Re-label vessels which have been removed from the triple sterile barrier before storing the vessels.

OPOs are expected to:

- Include language in authorization forms to indicate that vessels will be used for transplant

How OPTN/UNOS will evaluate member compliance with this policy

During on-site reviews at OPOs, site surveyors will evaluate compliance with this policy through interviews, observations, and obtaining copies of the following:

- The authorization form used by the OPO, which must include language indicating that vessels will be used for transplant
- The rigid container packaging label, which must contain:
  - recovery date
  - ABO and subtype
  - Infectious disease results
  - container contents
  - UNOS Donor ID
- The outermost sterile bag packaging label, which must contain:
  - recovery date
  - ABO
  - All infectious disease results
  - container contents
  - UNOS Donor ID
  - Indicate if the donor is PHS high risk
  - "for use in organ transplant only"

At transplant centers, site surveyors will interview the designated staff who monitor and maintain the extra vessels and obtain a copy of the center's policy and procedure for handing vessels. The vessel monitoring log will be reviewed to verify the following:

- Vessels are stored for no more than 14 days from their original recovery date
- Vessels are destroyed were destroyed by the end of the 14th day
- Daily monitoring of vessels includes: documented security checks, and recorded daily temperature checks (note: policy requires vessels to be stored between 2 and 8 degrees Celsius)

Detailed guidance on policy compliance

- Effective January 10, 2011, OPOs and transplant centers must label the inner vessel container as well as the outer rigid, sterile sealed container when vessels are packaged separately from the organ.
- To report the use of stored vessels transplanted into an intended or different recipient or to report discarded vessels to the OPTN, complete the Vessel Transplantation/Destruction Information Sheet and fax it to the UNOS Research Department/Data Quality at (804) 782-4809. Alternatively, you may submit vessel data to the UNOS Research Department/Data Quality via email at dataquality@unos.org.
  - All discarded vessels should be reported in this manner, even if they were never stored (such as hepatitis C antibody positive or hepatitis B surface antigen positive vessels).
- Transplant centers must designate a person to monitor all aspects of vessel usage

and storage.

- Transplant centers must provide the transplant surgeon with 24 hour access to donor information so that he/she can review this information before using the vessels in a recipient other than the recipient who received an organ from the same donor.
- If transplant programs share vessels, the implanting transplant program must provide a justification to the OPTN/UNOS Membership and Professional Standards Committee (MPSC). You should submit this justification in writing to the UNOS Department of Evaluation and Quality via fax to (804) 782- 4660, Attention: Allocation Analysis.
- If a transplant program uses vessels from a donor with positive hepatitis serologies in a recipient who did not also receive an organ(s) from that donor, the transplant program must provide a justification to the MPSC. You should submit this justification in writing to the UNOS Department of Evaluation and Quality via fax to (804) 782- 4660, Attention: Allocation Analysis.
- Document ***all*** donor serology results on the vessel container label. This includes all negative results. Include if the donor is CDC high risk

Policy 5.11: Transportation Responsibility

Purpose of policy

The purpose of the policy is to:

- Define the responsibility of transportation costs for deceased donor organs.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

- For 5.11.1, the Host OPO assumes responsibility for transportation costs for deceased donor kidney(s) and associated tissue typing material pursuant to CMS regulations.
- For 5.11.2, the member that accepted the organ is responsible for transportation costs to its destination for deceased donor non-renal organs and associated tissue typing material.
- For 5.11.3, the Host OPO is responsible for payment of transportation costs for tissue typing material sent to crossmatch potential recipients of a deceased donor kidney. The member 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.

Policy 6.2.1: Nondiscrimination/Organ Allocation

Purpose of policy

The purpose of the policy is to:

- Outline how transplant centers should operate and manage when allocating an organ to a non-resident alien transplant candidate

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Abide by the guidelines set forth in Policy 6.2 if they agree to list non-US residents/non-US citizens

How OPTN/UNOS will evaluate member compliance with this policy

UNOS verifies that candidates are listed appropriately, including non-US residents/non-US citizens, during surveys of transplant centers. UNOS staff reviews organ allocations and makes an inquiry if an organ was not allocated according to the match run sequence. UNOS forwards potential policy violation to the Membership and Professional Standards Committee (MPSC) for review.

Policy 6.2.2: Referrals

Purpose of policy

The purpose of the policy is to:

- Prohibit OPTN Members from entering into formal contractual agreements for the transplantation of non-US residents/non-US citizens

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected **NOT** to:

- Enter any type of formal contractual agreement with foreign agencies or governments to list and transplant non-US residents/non-US citizens

How OPTN/UNOS will evaluate member compliance with this policy

UNOS examines any reported instances for a potential policy violation and will refer any instances of potential policy violations to the MPSC.

Detailed guidance on policy compliance

This policy does not prohibit a transplant center from receiving insurance reimbursements from a foreign entity, as long as the transplant candidate was evaluated on an individual basis.

Policy 6.4.1: Formal Deceased Donor Organ Import Agreement

Purpose of policy

The purpose of the policy is to:

- Outline the process for OPTN members to enter into formal organ exchange arrangements with a foreign transplant program

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs and transplant centers are expected to:

- Only enter into formal deceased donor organ import agreements with foreign entities
    - That do not exceed two years
    - After receiving approval from the OPTN
- When importing a deceased donor organ pursuant to an approved, formal importation agreement:
    - Report the import within 72 hours to the Organ Center
    - Comply with OPTN/UNOS requirements, including:
        - Allocation according to the organ-specific policy
        - Minimum information for the organ (see Policies 2, 3.5.9, 3.7.12, and 3.8.2)
        - ABO verification (see Policies 2 and 3.2.4)
        - Transmissible disease screening (see Policy 4)
    - Verify that the foreign entity is authorized by its government as an OPO or transplant center
    - Obtain documentation that the foreign entity is authorized to export organs for transplantation

How OPTN/UNOS will evaluate member compliance with this policy

UNOS reviews all deceased donor match runs to determine if the organs were allocated according to the match run sequence as established by allocation policy and programmed into the UNet^{SM} system. Staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy.

Detailed guidance on policy compliance

Proposal:

To request approval of a formal deceased donor import agreement, members must submit a proposal to the Ad Hoc International Relations Committee. The proposal must contain:

- Basis for the agreement
- Expected benefits to the foreign entity
- Expected benefits to the member
- Credentials of the foreign entity
- Number and type of organs anticipated for import
- Plan for reporting results of the agreement
- Requirements that the foreign entity submit:
    - Donor authorization
    - Brain death and DCD documentation (in compliance with US standards)
    - Donor ABO documentation

- Organ Center telephone (800) 292-9537

Policy 6.4.2: Deceased Donor Organs Imported from Outside of the United States

Purpose of policy

The purpose of the policy is to:

- Set forth minimum standards for organs imported for transplantation without a formal agreement

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs and transplant hospitals who import a deceased donor organ recovered outside the US without a formal organ import agreement are expected to:

- Meet requirements of 6.4.1.1:
  - Report the import within 72 hours to the Organ Center
  - Comply with OPTN/UNOS requirements, including:
    - Allocation according to the organ-specific policy
    - Minimum information for the organ (see Policies 2, 3.5.9, 3.7.12, and 3.8.2)
    - ABO verification (see Policies 2 and 3.2.4)
    - Transmissible disease screening (see Policy 4)
  - Verify that the foreign entity is authorized by its government as an OPO or transplant center
  - Obtain documentation that the foreign entity is authorized to export organs for transplantation
- Notify the Organ Center immediately so that the Organ Center can allocate the organ
- Provide documentation of the following to UNOS:
  a. The donor met recognized US standards for brain death or DCD protocols
  b. Certification from the donor organization certifying the donor authorization
  c. Verification from the donor organization of the donor ABO

How OPTN/UNOS will evaluate member compliance with this policy

UNOS reviews all deceased donor match runs to determine if the organs were allocated according to the match run sequence as established by allocation policy and programmed into the UNet^{SM} system. UNOS staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy.

During on-site reviews, UNOS staff also reviews and verifies a sample of donor medical records and verifies that each chart contains documentation which certifies death, informed authorization of the donor or legal representative and verifies the donor's ABO.

The Ad Hoc International Relations Committee reviews the circumstances of each deceased -donor organ imported without a formal agreement.
Detailed guidance on policy compliance • Organ Center telephone (800) 292-9537

Policy 7.0: Data Submission Requirements

Purpose of policy

The purpose of the policy is to:

- Require all OPOs, transplant centers and histocompatibility labs to submit data to the OPTN through standardized data collection screens in UNet^{SM}
- Require online submission of data as of January 1, 2003
- Require OPOs to submit patient-level data for all authorized donors, authorized, but not recovered potential donors, imminent neurological and eligible deaths in its DSA.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs, transplant centers, and histocompatibility laboratories are expected to:

- Submit their respective online forms in a timely fashion according to data submission policies established within Policy 7.0 (i.e. complete 95% of forms with a quarter; complete 100% of forms within 6 months of their expected date).

How OPTN/UNOS will evaluate member compliance with this policy

UNOS Department of Evaluation and Quality (DEQ) staff monitors data submission compliance rates on a quarterly basis and contacts members who have outstanding forms that are more than six months overdue. If a member fails to submit the overdue forms in a timely manner, DEQ staff refers the member to the OPTN/UNOS Membership and Professional Standards Committee. DEQ staff also reviews each member's data submission compliance rates with the member during the site survey process.

Detailed guidance on policy compliance

- Related to living donation:
  - Effective August 29, 2011, if a transplant program operates on living donors, that transplant center is responsible for all elements of the living donation process, which includes, but is not limited to:
    - Informed consent
    - Medical and psychosocial evaluations
    - Perioperative care
    - Required follow-up reporting
- UNet^{SM} was modified on January 9th, 2008 to allow OPOs to submit patient-level data for all imminent or eligible deaths; however, the requirement for reporting this information applies to all deaths referred or identified on January 1, 2008 and beyond to ensure complete data collection.
- To access the Imminent and Eligible Data Collection Training Presentation
  Access the DonorNet^{SM} online help. Click **E-learning Modules**, and then click **Imminent and Eligible Death Data Collection**.
  (https://portal.unos.org/DonorNet/help/donornet/Imminent_and_Eligible_Death_Data_Collection.htm)
- To access the Importing and Exporting Death Notification Registration Records Training

Presentation
Access the DonorNet℠ online help. Click **E-learning Modules**, and then click **Death Notification Registration Import-Export**.
(https://portal.unos.org/DonorNet/help/donornet/DNR_Import-Export.htm)

- To access the Donation Data Report Changes Presentation
  Access the DonorNet℠ online help. Click **E-learning Modules**, and then click **Donation Data Report**. (https://portal.unos.org/DonorNet/help/donornet/Donation_Data_Report.htm)

Policy 7.1.3: Follow-up Period for Transplant Recipients

Purpose of policy

The purpose of the policy is to:

- Define expectations that a transplant center will follow up with transplant recipients until the recipient's death or re-transplantation.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Meet the requirement to report follow-up information on transplant recipients until graft failure

How OPTN/UNOS will evaluate member compliance with this policy

UNOS programs the UNet^{SM} system and notifies transplant centers of system modifications through the use of system notices and documentation updates. UNOS staff monitors and evaluates transplant centers' data submission compliance on a routine basis and assists them with submitting forms by consistent contact regarding overdue online forms. Staff could refer non-compliant transplant centers to the OPTN/UNOS Membership and Professional Standards Committee for further review and action. UNOS staff also reviews data submission standards with transplant centers during on-site reviews.

Detailed guidance on policy compliance

If a multi-organ recipient experiences graft failure, each organ must be followed until failure. For example, if a liver-kidney recipient begins dialysis, liver follow-up forms must be submitted until the liver fails.

Policy 7.1.5: Definition of the Length of the Follow-up Period for Living Donors

Purpose of policy

The purpose of the policy is to:

- Require transplant centers to submit to Tiedi® follow-up information about living donors for two years after donation

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are required to:

- Submit follow-up information about living donors to Tiedi® at six months, one year, and two years following donation on the appropriate Living Donor Follow-up (LDF) form
- Accurately enter all data required on the LDF forms
- Maintain documentation to support all data entered on the LDF forms, including documentation of the attempts to contact the living donor for follow-up information
- Submit all forms within the timeframes required by Policy 12.8.

How OPTN/UNOS will evaluate member compliance with this policy

UNOS Department of Evaluation and Quality (DEQ) staff monitors data submission compliance rates on a quarterly basis and contacts members who have outstanding forms that are more than six months overdue. If a member fails to submit the overdue forms in a timely manner, DEQ staff refers the member to the OPTN/UNOS Membership and Professional Standards Committee. DEQ staff also reviews each member's data submission compliance rates with the member during the site survey process.

Detailed guidance on policy compliance

The policy change to require living donor follow-up information for two years post donation was implemented on March 1, 2008. The two year follow-up requirement applies to all living donation transplant events that occur on March 1, 2008 and beyond.

Policy 7.1.6: Definition of Timely Data

Purpose of policy

The purpose of the policy is to:

- Define and provide examples of how timely data should be when reporting follow-up information on transplant recipients or living donors

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are required to:

- Collect follow-up data for transplant recipients and living donors for reporting purposes to UNOS as close as possible to the specified transplant event anniversary

How OPTN/UNOS will evaluate member compliance with this policy

UNOS programs the UNet^{SM} system and notifies transplant centers of system modifications through the use of system notices and documentation updates. UNOS staff monitors and evaluates transplant centers' data submission compliance on a monthly basis and assists them with submitting forms by consistent contact regarding overdue online forms. UNOS staff also reviews data submission standards with transplant centers during on-site reviews.

Policy 7.1.7: Definition of Imminent Neurological Death

Purpose of policy

The purpose of the policy is to:

- Define imminent neurological death
- Provide direction for reporting purposes:
  - state **when** the OPO should apply the definition to the referral to determine if the referral should be reported as an imminent neurological death
  - state what conditions would **exclude** the referral from meeting the definition of an imminent neurological death

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are required to:

- Report patient level data for all imminent neurological deaths referred each month
- Apply the policy definition to the referral at the time of OPO disposition
- Be familiar with the list of conditions in Policy 7.1.8 and not report any persons with those conditions, who would otherwise meet the definition, as an imminent neurological death

How OPTN/UNOS will evaluate member compliance with this policy

UNOS Department of Evaluation and Quality (DEQ) staff reviews death referral information reported to the OPTN during OPO site surveys. DEQ staff verifies that OPO staff use the definitions in policy to report death referral information to the OPTN.

Policy 7.2: General Submission of OPTN Forms

Purpose of policy

The purpose of the policy is to:

- Establish deadlines for all OPOs, transplant hospitals and histocompatibility labs submission of Transplant Candidate Registration, Deceased Donor Registration, Recipient Histocompatibility, Donor Histocompatibility, Recipient Malignancy, and Living Donor Follow-up online forms to UNOS

How to comply with this policy

Compliance strategies include, but are not limited to:

Transplant hospitals are expected to submit Transplant Candidate Registration and Recipient Malignancy online forms to UNOS within 30 days of the form generation date.

Living donor recovery hospitals are expected to submit Living Donor Follow-up forms to UNOS within 60 days of the form generation date.

OPOs are expected to submit Deceased Donor Registration online forms to UNOS within 30 days of the form generation date.

Histocompatibility laboratories are expected to submit Recipient Histocompatibility and Donor Histocompatibility online forms to UNOS within 30 days of the form generation date.

How OPTN/UNOS will evaluate member compliance with this policy

UNOS programs the UNet^{SM} system and notifies OPOs, transplant hospitals, living donor recovery hospitals, and histocompatibility labs of system modifications through the use of system notices and documentation updates. UNOS staff monitors and evaluates OPOs', transplant hospitals', living donor recovery hospitals' and histocompatibility labs' data submission compliance on a routine basis and assists them with submitting forms by consistent contact regarding overdue online forms.

Detailed guidance on policy compliance

For purposes of calculating form submission deadlines, the first day counted is the day after the form is generated. Days end at midnight EST.

Policy 7.3.1: Submission of Organ-Specific Transplant Recipient Registration Forms

Purpose of policy

The purpose of the policy is to:

- Establish the requirement of all transplant centers to submit organ-specific Transplant Recipient Registration online forms within 60 days of the generation date
- Establish the time frame for data reported on the Transplant Recipient Registration online form

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Submit organ-specific Transplant Recipient Registration online forms within 60 days of the generation date

How OPTN/UNOS will evaluate member compliance with this policy

UNOS programs the UNet^{SM} system and notifies transplant centers of system modifications through the use of system notices and documentation updates. UNOS staff monitors and evaluates transplant centers' data submission compliance on a routine basis and assists them with submitting forms by consistent contact regarding overdue online forms.

Policy 7.4: Submission of Organ-Specific Transplant Recipient Follow-up Forms

Purpose of policy

The purpose of the policy is to:

- Establish the requirement of all transplant centers to submit organ-specific Transplant Recipient Follow-up online forms within 14 days of the recipient's death or graft failure

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Submit organ-specific Transplant Recipient Follow-up online forms reporting death or graft failure within 14 days of the event

How OPTN/UNOS will evaluate member compliance with this policy

UNOS programs the UNet^{SM} system and notifies transplant centers of system modifications through the use of system notices and documentation updates. UNOS staff monitors and evaluates transplant centers' data submission compliance on a routine basis and assists them with submitting forms by consistent contact regarding overdue online forms.

Policy 7.5: Submission of Donor Information

Purpose of policy

The purpose of the policy is to:

- Require OPOs to submit information for Deceased Donor Feedback within five working days of the procurement date

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Submit Deceased Donor Feedback information within five working days of the procurement date

How OPTN/UNOS will evaluate member compliance with this policy

UNOS programs the UNet^{SM} system and notifies OPOs and transplant centers of system modifications through the use of system notices and documentation updates. UNOS staff monitors and evaluates OPOs' and transplant centers' data submission compliance on a routine basis and assists them with submitting forms by consistent contact regarding overdue online forms. Staff could refer non-compliant OPOs and transplant centers to the OPTN/UNOS Membership and Professional Standards Committee for further review and action. UNOS staff also reviews data submission standards with OPOs and transplant centers during on-site reviews.

Policy 7.6: Submission of Potential Transplant Recipient Forms

Purpose of policy

The purpose of the policy is to:

- Require OPOs to submit Potential Transplant Recipient (PTR) data to the OPTN within 30 days of the match run date for each deceased donor organ that is offered to a potential recipient
- Establish the requirement that PTR refusal codes must be obtained directly from the physician, surgeon or designee involved with the potential recipient

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Submit Potential Transplant Recipient information within 30 days of the match run date
- Obtain this information directly from the physician, surgeon or designee involved with the potential recipient

How OPTN/UNOS will evaluate member compliance with this policy

UNOS programs the UNet℠ system and notifies OPOs of system modifications through the use of system notices and documentation updates. UNOS staff monitors and evaluates OPOs' data submission compliance on a monthly basis and assists them with submitting forms by consistent contact regarding overdue online forms. Staff could refer non-compliant OPOs to the OPTN/UNOS Membership and Professional Standards Committee for further review and action. UNOS staff also reviews data submission standards with OPOs during on-site reviews.

Detailed guidance on policy compliance

- To access a tutorial on how to enter PTR information into DonorNet®
  Access the DonorNet℠ online help. Click **E-learning Modules**, and then click **Completing PTR and Closing the Match**.
  (https://portal.unos.org/DonorNet/help/donornet/Complete_PTR_Close_Match.htm)

Policy 7.6.1.1: Entry and Validation of Offers

Purpose of policy

The purpose of the policy is to:

- Establish that the donor OPO and transplant center considering an offer have a shared responsibility to enter patient-specific refusal reasons for all organ offers
- Require the donor OPO to ensure acceptance or refusal reasons are documented for each organ offer
- Require all transplant centers to validate candidate-specific potential recipient refusal reasons for all offers using the online procedure available in UNet[SM]

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Enter candidate-specific refusal reasons for all offers within 30 days of the match run date using the online procedure available in UNet[SM]

Transplant centers are expected to:

- Validate the refusal reasons using the online procedure available in UNet[SM] within 15 days of the OPO entering the refusal code. The system will automatically validate the OPOs' entered refusal code after 15 days if the transplant center has failed to validate the code.

How OPTN/UNOS will evaluate member compliance with this policy

UNOS programs the UNet[SM] system and notifies OPOs and transplant centers of system modifications through the use of system notices and documentation updates.

Policy 7.6.2: Recording and Reporting of the Outcomes of Organ Offers

Purpose of policy

The purpose of the policy is to:

- Require OPOs and transplant centers to cooperate when recording and reporting refusal reasons

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs and transplant centers are expected to:

- Cooperate when recording and reporting refusal reasons

How OPTN/UNOS will evaluate member compliance with this policy

UNOS monitors and reviews PTR code usage on a daily basis. UNOS staff refers any disparities in PTR code use to the OPTN/UNOS Membership and Professional Standards Committee for further review and action.

Policy 7.6.2.1: PTR Validation and Dispute Resolution

Purpose of policy

The purpose of the policy is to:

- Require OPOs and transplant centers to be familiar with the current refusal reasons and use the correct reasons during the offer/refusal transaction
- Require transplant centers to validate PTRs within 15 days following the recording of the offer by the OPO. If the transplant center does not verify the refusal reasons, the reason entered by the OPO will be considered accurate and validated.
- Establish that if there is a dispute between the OPO and the transplant center, the transplant center's record will take precedence and will be reported to UNOS

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Be familiar with the current refusal reasons and refer to them explicitly during the offer/refusal transaction
- Submit PTRs within 30 days of the match run

Transplant centers are expected to:

- Be familiar with the current refusal reasons and refer to them explicitly during the offer/refusal transaction.
- Validate PTRs within 15 days following the recording of the offer by the OPO

How OPTN/UNOS will evaluate member compliance with this policy

UNOS programs the UNet^{SM} system and notifies OPOs and transplant centers of system modifications through the use of system notices and documentation updates. UNOS staff monitors and evaluates OPOs' and transplant centers' data submission compliance on a routine basis and assists them with submitting forms by consistent contact regarding overdue online forms. Staff could refer non-compliant OPOs and transplant centers to the OPTN/UNOS Membership and Professional Standards Committee for further review and action. UNOS staff also reviews data submission standards with OPOs during on-site reviews.

Detailed guidance on policy compliance

To review PTR refusal codes:

- Go to Secure Enterprise
- Click on Waitlist^{SM}
- On the top toolbar, click on Resources
- On the left sidebar, click on File Layouts

- Under Exports/Imports, click PTR offer
- Click Primary Refusal Code

Policy 7.6.2.2: Cooperation in Reviewing and Verifying Organ Offer Data

Purpose of policy

The purpose of the policy is to:

- Require transplant centers to cooperate with OPOs in the review and verification of the data on all offers of organs for transplantation

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Cooperate with OPOs when reviewing and verifying data on all organ offers for transplantation

How OPTN/UNOS will evaluate member compliance with this policy

UNOS reviews all match runs and conducts analysis on disparities in data or reported conflicts between OPOs and transplant centers. UNOS staff could refer any potential policy violations to the appropriate OPTN/UNOS Committee.

Policy 7.7: Submission of Death Notification Information

Purpose of policy

The purpose of the policy is to:

- Establish the timeframe requirements for OPOs to submit death notification information to the OPTN

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs are expected to:

- Submit patient level data for each authorized donor, authorized, but not recovered potential donor, imminent neurological death, and eligible death in its DSA by completing a Death Notification Registration in DonorNet®
- Submit the total number of deaths reported by each hospital, or identified during death record review, monthly using the Donation Data Report in DonorNet®
- Submit the information identified during the current month by the end of the next calendar month

How OPTN/UNOS will evaluate member compliance with this policy

UNOS Department of Evaluation and Quality (DEQ) staff monitors data submission compliance rates on a quarterly basis and contacts members who have outstanding forms that are more than six months overdue. If a member fails to submit the overdue forms in a timely manner, DEQ staff refers the member to the OPTN/UNOS Membership and Professional Standards Committee. DEQ staff also reviews each member's data submission compliance rates with the member during the site survey process.

Detailed guidance on policy compliance

Link to Donation Data Report Changes Presentation

Access the DonorNet℠ online help. Click **E-learning Modules**, and then click **Donation Data Report**.
(https://portal.unos.org/DonorNet/help/donornet/Donation_Data_Report.htm)

Policy 7.8.1: Deadlines and Thresholds for Submitting Data

Purpose of policy

The purpose of the policy is to:

- Require all OPOs, transplant centers and histocompatibility labs to meet data submission deadlines and submission thresholds

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs, transplant centers, and histocompatibility laboratories are expected to:

- Submit their respective online forms in a timely fashion according to the data submission standards established in Policy 7.8.1
- Ensure that data submission standards are met: 95 percent of data collected on online forms must be complete within three months of the due date and 100 percent complete within six months of the due date
- Ensure that recipient refusal code standards are met: Potential recipient refusal codes must be 100 percent complete within 30 days of the match run date

How OPTN/UNOS will evaluate member compliance with this policy

UNOS programs the UNet℠ system and notifies OPOs, transplant centers and histocompatibility labs of system modifications through the use of system notices and documentation updates. UNOS staff monitors and evaluates OPOs', transplant centers' and histocompatibility labs' data submission compliance on a routine basis and assists them with submitting forms by consistent contact regarding overdue online forms. Staff could refer non-compliant Members to the OPTN/UNOS Membership and Professional Standards Committee for further review and action. UNOS staff also reviews data submission standards with these Members during on-site reviews.

Detailed guidance on policy compliance

As of October 29, 2008, a new data submission compliance report is available to members. This report uses the same methodology that UNOS uses when providing this information to the Centers for Medicare and Medicaid Services (CMS). This new report is based on the completion of 95% of expected records within 90 days of the due date.

- To access this report, select **CMS Compliance Report** from the **Reports** menu in Tiedi®.

Policy 7.8.2: Feedback Submission Standards

Purpose of policy

The purpose of the policy is to:

- Establish deadlines for OPOs and transplant centers when submitting feedback information

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs and transplant centers are expected to:

- Submit feedback information within 30 days of the transplant date

How OPTN/UNOS will evaluate member compliance with this policy

UNOS programs the UNet^{SM} system and notifies OPOs and transplant centers of system modifications through the use of system notices and documentation updates. UNOS staff monitors and evaluates OPOs' and transplant centers' data submission compliance on a routine basis and assists them with submitting forms by consistent contact regarding overdue online forms. Staff could refer non-compliant OPOs and transplant centers to the OPTN/UNOS Membership and Professional Standards Committee for further review and action. UNOS staff also reviews data submission standards with OPOs and transplant centers during on-site reviews.

Policy 7.9: Data Submission Non-compliance

Purpose of policy

The purpose of the policy is to:

- Require OPOs, transplant centers and histocompatibility labs to comply with the data submission standards established in Policy 7.8.1 by submitting their data in a timely fashion according to those standards. Members that fail to submit their data after repeated attempts by UNOS to assist the Member in submitting all overdue data and after a hearing by the Membership and Professional Standards Committee resulting in a determination of Member non-compliance, the MPSC can recommend an on-site audit to retrieve the missing data at the Member's expense.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs, transplant centers, and histocompatibility laboratories are expected to:

- Comply with the data submission standards established in Policy 7.8.1 by submitting their data in a timely fashion according to those standards

How OPTN/UNOS will evaluate member compliance with this policy

UNOS programs the UNet^{SM} system and notifies OPOs, transplant centers and histocompatibility labs of system modifications through the use of system notices and documentation updates. UNOS staff monitors and evaluates OPOs', transplant centers' and histocompatibility labs' data submission compliance on a routine basis and assists them with submitting forms by consistent contact regarding overdue online forms. Staff could refer non-compliant Members to the OPTN/UNOS Membership and Professional Standards Committee for further review and action. UNOS staff also reviews data submission standards with these Members during on-site reviews.

Policy 11.0: Registration Fee

Purpose of policy

The purpose of the policy is to:

- Establish the registration fee (provided for in Article I, Section 1.2(D) of the OPTN Bylaws) for the mandatory listing of all candidates who are potential recipients on the waiting list, as required by Policy 3.2.1. The fee structure is two-fold comprising a Candidate Registration Fee and the UNOS Computer Registration Fee.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Pay all registration fees within 30 days of invoice from UNOS

How OPTN/UNOS will evaluate member compliance with this policy

For billing purposes, a center's listing activity is reviewed in 30-day increments. The invoice UNOS sends to centers includes all candidates added to the waiting list during a 30-day period. The invoices are detailed and include each candidate's name and the organ(s) for which each candidate was listed. Staff monitors accounts receivables on a monthly basis and attempts to collect payment on delinquent accounts.

Detailed guidance on policy compliance

Members should receive a letter from UNOS listing the fees for each year.

Policy 12.2: Informed Consent of Living Donors

Purpose of policy

The purpose of the policy is to:

- Establish requirements for the informed consent of potential living kidney donors

How to comply with this policy

Compliance strategies include, but are not limited to:

Living donor recovery hospitals are expected to document in the donor chart that each of the required elements listed for living donor informed consent have been completed.

How OPTN/UNOS will evaluate member compliance with this policy

During site reviews of living donor recovery hospitals, the Department of Evaluation and Quality (DEQ) staff reviews living donor recovery hospitals' policies and procedures. DEQ staff also verifies the presence and accuracy of the documentation of required elements for a sample of potential living donor records.

DEQ staff will interview staff and request to review any internal policies that specify how the hospital provides information in a language in which the donor is able to engage in a meaningful dialogue with the transplant program staff.

DEQ staff will review donor records to verify that the hospital:

- Attained written assurance from the donor of the following elements:
  - That he/she is willing to donate
  - That he/she is free from inducement or coercion
  - That he/she has been informed that he/she may decline to donate at any time
- Documented that:
  - The potential donor was offered an opportunity to discontinue the donor consent or evaluation process and to do so in a way that is protected and confidential
  - The IDA was available to assist the potential donor during the process
- Provided instruction to the donor regarding all phases of the living donation process listed in Policy 12.2
- Provided all disclosures and information required by Policy 12.2 to the donor

DEQ staff will also investigate any reports of noncompliance.

DEQ staff will request a corrective action plan if they are unable to verify compliance

with the requirements of Policy 12.2. Results of the review and any corrective action plans submitted will be forwarded to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for review.
Detailed guidance on policy compliance Written assurance by the donor may be demonstrated by the donor's signature on a form or by other written documentation from the donor. Living donor kidney recovery hospitals should consider viewing the webinar, offered on January 15, 2013, New Living Kidney Donor Program Requirements: Standardizing Patient Care, for more information on these changes to policy.

Policy 12.2.1: Living Kidney Donor Evaluation Consent

Purpose of policy

The purpose of the policy is to:

- Establish requirements for the informed consent for evaluation of potential living kidney donors

How to comply with this policy

Compliance strategies include, but are not limited to:

Transplant hospitals are expected to document in the donor chart that each of the required elements listed for living donor informed consent for evaluation have been completed.

How OPTN/UNOS will evaluate member compliance with this policy

During site reviews, the Department of Evaluation and Quality (DEQ) staff reviews living donor recovery hospitals' policies and procedures. DEQ staff also verifies the presence and accuracy of the documentation of the required policy elements for a sample of living donor records.

DEQ staff will review donor charts to verify that the hospital informed the potential living donor:

- That the potential donor must undergo a medical and psychosocial evaluation
- That the transplant hospital may refuse the potential donor, and, if refused, the potential donor must be informed that they could be evaluated by another transplant program that may have different selection criteria
- Of the inherent risks associated with evaluation for living donors as spelled out in Policy 12.2.1
- Of the surgical, medical, psychosocial and financial risks associated with living kidney donation as listed in 12.2.1, and that these risks may be transient or permanent and are not limited to those listed in 12.2.1

DEQ staff will also investigate any reports of noncompliance.

DEQ staff will request a corrective action plan if they are unable to verify compliance with the requirements of Policy 12.2.1. Results of the review and any corrective action plans submitted will be forwarded to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for review.

Detailed guidance on policy compliance

Living donor kidney recovery hospitals should consider viewing the webinar, offered on January 15, 2013, New Living Kidney Donor Program Requirements: Standardizing Patient Care, for more information on these changes to policy.

Policy 12.3: Medical Evaluation of Living Donors-ABO Identification

Purpose of policy

The purpose of the policy is to:

- Ensure the accuracy of ABO data for living donors prior to donation

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Ensure that each living donor is ABO-typed on two separate occasions prior to the donation
- Ensure that each living donor whose initial subtype test indicates the donor is non-A_1 or non-A_1B is ABO subtyped a second time
    - Blood samples for first and second test must be taken on separate occasions
    - Only allocate using subtype when both subtypings have the same result.
- Maintain written documentation that the living donor's ABO was entered and verified by two separate individuals reviewing **both of the source documents** from each ABO typing

How OPTN/UNOS will evaluate member compliance with this policy

During reviews of transplant centers, UNOS staff will verify the following:

- Accuracy of ABO and ABO subtype
- Two separate typings prior to the donation
- Two separate subtypings when used for allocation
- Procedures to ensure that entry and verification occurs by two separate individuals reviewing source documentation

DEQ staff will request a corrective action plan if the center's documentation does not comply with the requirements of this policy and forward the survey results to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for its review.

Detailed guidance on policy compliance

- Effective June 27, 2011, there are new documentation requirements, specifically system changes in TIEDI, for verifying living donor ABO.
    - If ABO verification is not completed by a second person using source documents, then the recipient information will not populate into the feedback form, preventing generation of the Living Donor Registration Forms.
    - DEQ will continue to verify that two ABOs were obtained prior to procurement and that the source documents are available for review.

- DEQ will continue to verify that the donor was registered with the OPTN prior to procurement, thus generating the Donor ID.
- The OPTN presentation on the changes outlined above may be found here: https://www117.livemeeting.com/cc/unos/view?id=WWZ5H9.

- The requirements in Policy 12.3.1 stating that each living donor is ABO-typed, **and sub-typed if appropriate** should be interpreted to mean **sub-typed if the center deems it necessary.**

Policy 12.3.3: Psychosocial Evaluation of the Living Kidney Donor

Purpose of policy

The purpose of the policy is to:

- Establish requirements for the psychosocial evaluation of potential living donors

How to comply with this policy

Compliance strategies include, but are not limited to:

Transplant hospitals are expected to have a psychosocial evaluation of each potential living donor

- Performed by a psychiatrist, psychologist, and/or clinical social worker
- Covering all required elements
- Documented in the donor record

How OPTN/UNOS will evaluate member compliance with this policy

During site reviews, the Department of Evaluation and Quality (DEQ) staff reviews living donor recovery hospitals' policies and procedures. DEQ staff also verifies the presence and accuracy of the documentation of the required policy elements for a sample of living donor records.

DEQ staff will review donor charts to verify that each potential living donor received a psychosocial evaluation, performed by a psychiatrist, psychologist, or clinical social worker. Each donor chart will be reviewed to verify that the psychosocial evaluation assessed all elements listed in Policy 12.3.3.

DEQ staff will request a corrective action plan if they are unable to verify compliance with the requirements of Policy 12.3.3. Results of the review and any corrective action plans submitted will be forwarded to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for review.

Detailed guidance on policy compliance

Living donor kidney recovery hospitals should consider viewing the webinar, offered on January 15, 2013, New Living Kidney Donor Program Requirements: Standardizing Patient Care, for more information on these changes to policy.

Policy 12.3.4: Medical Evaluation of the Living Kidney Donor

Purpose of policy

The purpose of the policy is to:

- Establish requirements for the medical evaluation of potential living donors

How to comply with this policy

Compliance strategies include, but are not limited to:

Transplant hospitals are expected to have a medical evaluation of each potential donor:

- Performed at the living donor recovery hospital and by a physician or surgeon experienced in living donation
- Covering all required elements
- Documented in the donor record

How OPTN/UNOS will evaluate member compliance with this policy

During site reviews, the Department of Evaluation and Quality (DEQ) staff reviews living donor kidney recovery hospitals' policies and procedures to verify that the recovery hospital has protocols for screening for Polycystic Kidney Disease or other inherited renal disease, and for specific cancers listed in Policy 12.3.4(K).

DEQ staff also verifies the presence and accuracy of the documentation of the required policy elements for a sample of potential living donor records. DEQ staff will review donor charts to verify that there is documentation in the medical charts that:

- Each potential living donor received a medical evaluation, performed by the living donor recovery hospital and by a physician or surgeon experienced in living donation
- Each medical evaluation assessed all components required by Policy 12.3.4
- There are results for all tests required by Policy 12.3.4
- Hospital screening protocols required by Policy 12.3.4(K) were followed
- There are results for conditional tests when required by Policy 12.3.4, including:

Test required	When
HCG quantitative pregnancy test	Potential donor is a premenopausal woman who has not been surgically sterilized
24 hour urine stone panel measuring: Calcium, Oxalate, Uric acid, Citric acid,	Potential donors has a history of nephrolithiasis, or nephrolithiasis (>3mm) is identified on radiographic imaging

Creatinine and Sodium	
Glucose tolerance test or Glycosylated Hemoglobin	Potential donor is a first degree relative of a diabetic or in a high risk group
Urine culture	Clinically indicated
Strongyloides	Living donor recovery hospital determines that the potential donor is from an endemic area
Trypanosoma cruzi	Living donor recovery hospital determines that the potential donor is from an endemic area
West Nile	Living donor recovery hospital determines that the potential donor is from an endemic area
Intradermal PPD or Interferon Gamma Release Assay (IGRA) screening for latent tuberculosis	Living donor recovery hospital determines that the potential donor is at an increased risk for the infection

No potential donors who meet exclusionary criteria should proceed to donation. During site reviews of living donor kidney recovery hospitals, DEQ staff will also review donor records for documentation of any of the exclusionary criteria listed in Policy 12.3.4(L).

DEQ staff will request a corrective action plan if they are unable to verify compliance with the requirements of Policy 12.3.4. Results of the review and any corrective action plans submitted will be forwarded to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for review.

Detailed guidance on policy compliance

Living donor kidney recovery hospitals should consider excluding all donors who meet any of the following criteria:

- Hypertension in
  - Caucasians younger than 50
  - Caucasians older than 50, on more than one anti-hypertensive medication
  - Members of racial or ethnic groups at elevated risk (regardless of age)
- Impaired fasting glucose with other features of the metabolic syndrome in a donor younger than age 50
- Significant history of thrombosis or embolism
- Bleeding disorders
- BMI greater than 35
- Clinically significant cardiovascular disease

- Clinically significant pulmonary disease
- Microalbuminuria greater than 30 mg per day
- Proteinuria (protein in the urine) greater than 300 mg/24 hours, excluding postural proteinuria
- Creatinine clearance or isotopic GFR greater than 1 standard deviation below the mean for age and gender
- History of cancer, including metastatic

Kidney recovery hospitals should consider:

- Reviewing the Guidance for Identifying Risk Factors for Mycobacterium Tuberculosis During Evaluation of Potential Living Kidney Donors
- Viewing the webinar, offered on January 15, 2013, New Living Kidney Donor Program Requirements: Standardizing Patient Care, for more information on these changes to policy.

Policy 12.4: Independent Donor Advocate

Purpose of policy

The purpose of the policy is to:

- Establish requirements for Living Donor Hospitals to provide an Independent Donor Advocates (IDA) for living kidney donors

How to comply with this policy

Compliance strategies include, but are not limited to:

Transplant hospitals are expected to:

- Provide an autonomous IDA to each potential living kidney donor

How OPTN/UNOS will evaluate member compliance with this policy

During site reviews of living donor recovery hospitals, DEQ staff will verify that an IDA was provided to each living kidney donor and that the IDA:

- Is not involved with the potential recipient evaluation
- Is independent of the decision to transplant the potential recipient

DEQ staff will also investigate any reports of noncompliance.

DEQ staff will request a corrective action plan if they are unable to verify compliance with the requirements of Policy 12.4. Results of the review and any corrective action plans submitted will be forwarded to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for review.

Detailed guidance on policy compliance

Living donor kidney recovery hospitals should consider viewing the webinar, offered on January 15, 2013, New Living Kidney Donor Program Requirements: Standardizing Patient Care, for more information on these changes to policy.

Policy 12.4.1

Purpose of policy

The purpose of the policy is to:

- Establish responsibilities of the Independent Donor Advocate (IDA) for potential living kidney donors

How to comply with this policy

Compliance strategies include, but are not limited to:

Transplant hospitals are expected to:

- Provide a knowledgeable IDA who is responsible for assisting each potential living kidney donor with the evaluation process and focusing on their needs and questions

How OPTN/UNOS will evaluate member compliance with this policy

During site reviews of living donor recovery hospitals, DEQ staff will review medical records and conduct interviews with the IDA and other members of the living donor team. They will seek to verify that an IDA was provided to each living kidney donor and that the IDA:

- Is knowledgeable about risks and benefits associated with all phases of the donation process
- Assists the potential donor with the evaluation process
- Promotes the best interests of the potential living donor
- Advocates for the rights of the potential donor
- Is not involved with the potential recipient evaluation
- Is independent of the decision to transplant the potential recipient

DEQ staff will review documentation in a sample of living donor records. They will seek to verify that potential donors were provided an IDA, and that they were assisted by the IDA in obtaining and information regarding the:

- Consent process
- Evaluation process
- Surgical procedure
- Medical and psychosocial risks
- Benefit and need for follow-up

DEQ staff will also investigate any reports of noncompliance.

DEQ staff will request a corrective action plan if they are unable to verify compliance with the requirements of Policy 12.4.1. Results of the review and any corrective action

plans submitted will be forwarded to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for review.
Detailed guidance on policy compliance Living donor kidney recovery hospitals should consider viewing the webinar, offered on January 15, 2013, New Living Kidney Donor Program Requirements: Standardizing Patient Care, for more information on these changes to policy.

Policy 12.5.6: Placement of Non-Directed Living Donor Kidneys

Purpose of policy

The purpose of the policy is to:

- Detail the requirements for allocating non-directed living donor kidneys.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Ensure that the recipient of a non-directed living donor kidney is selected using a UNet^{SM} generated match run that identifies potential recipients for transplant.

How OPTN/UNOS will evaluate member compliance with this policy

DEQ will monitor for the presence of match run documentation and documentation of justification for deviations during on-site and desk reviews.

DEQ will investigate any instance of non-compliance and forward the survey results to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for its review.

6. Detailed guidance on policy compliance

NOTE: This policy does not apply to non-directed living donor kidney donors who consent to participate in a Kidney Paired Donation system.

Policy 12.6: Center Acceptance of Living Donor Organs

Purpose of policy

The purpose of the policy is to:

- Specify the requirements that transplant centers must only accept and transplant living donor organs recovered from other OPTN member transplant hospitals

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Ensure that transplant center is accepting and transplanting organs from other OPTN member transplant hospitals.

How OPTN/UNOS will evaluate member compliance with this policy

During on-site reviews, site surveyors will review medical records to verify that living donor organs were procured at a center that is an OPTN member transplant hospital.

DEQ will investigate any instance of non-compliance and forward the survey results to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for its review.

6. Detailed guidance on policy compliance

Effective August 29, 2011, if your transplant program operates on living donors, your transplant center is responsible for all elements of the living donation process, which includes, but is not limited to:

- Informed consent
- Medical and psychosocial evaluations
- Perioperative care
- Required follow-up reporting

Policy 12.7: Standardized Packaging and Transporting of Organs, Vessels and Tissue Typing Materials

Purpose of policy

The purpose of the policy is to:

- Outline requirements for standardized packaging, labeling, verifying and transporting living donor organs, tissue typing specimens, and vessels in order to improve patient safety and reduce the number of wasted organs by reducing the number of labeling errors

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Recovery transplant centers are expected to:

- Determine if current policies, procedures and/or protocols are consistent with the updated OPTN policy
- If no transplant center policies, procedures and/or protocols exist, develop and implement such to reflect OPTN policy requirements
- Labeling and packaging living donor organs
- Making all reasonable efforts to package and label the organ in a timely manner

How OPTN/UNOS will evaluate member compliance with this policy

UNOS reviews and verifies transplant center policies and procedures, and verifies the presence and accuracy of the documentation for a sample of records during site surveys.

Detailed guidance on policy compliance

For training on the organ packaging and transport labeling system, visit https://unos.peachnewmedia.com/store/seminar/seminar.php?seminar=6516

Policy 12.7.1: External Packaging Specifications

Purpose of policy

The purpose of the policy is to:

- Outline requirements for the external packaging of living donor organs which are transported outside the recovery center, including definitions and uses for disposable shipping boxes, coolers and mechanical preservation machines

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Recovery transplant centers are expected to:

- Use containers as specified in Policy 12.7.1.1 to package any living donor organ that travels outside the recovery facility.

How OPTN/UNOS will evaluate member compliance with this policy

UNOS reviews and verifies recovery transplant centers' written policies related to the required external packaging specifications and may ask for packaging demonstrations during on-site reviews.

Policy 12.7.1.1: Disposable shipping box

Purpose of policy

The purpose of the policy is to:

- Clarify requirements for use of a disposable shipping box related to external packaging specifications

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Recovery transplant centers are expected to:

- Use a disposable shipping box if living donor organs, vessels and/or tissue typing materials are shipped commercially

How OPTN/UNOS will evaluate member compliance with this policy

UNOS reviews and verifies recovery transplant centers' external packaging supplies during onsite reviews.

1. Detailed guidance on policy compliance

The external surface of the disposable shipping box must include the standardized label provided by the OPTN contractor.

Policy 12.7.1.2: Cooler

Purpose of policy

The purpose of the policy is to:

- Clarify requirements for the use of coolers in the non-commercial transport of living donor organs.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Recovery transplant centers are permitted to:

- Use coolers for transporting organs when the organ recovery team is transporting the donor organ with them from the recovery center to the candidate transplant center

How OPTN/UNOS will evaluate member compliance with this policy

UNOS reviews and verifies Recovery transplant centers' external packaging supplies during onsite reviews.

Detailed guidance on policy compliance

- Recovery transplant centers must label a cooler with the standardized label provided by UNOS, the OPTN contractor.
    - Members can purchase organ shipping container labels from UNOS by calling (800) 292-9548 during normal business hours, or by visiting the UNOS online store at: http://store.unos.org/index.php.
    - If reused, coolers must be properly cleaned and sanitized and all previous labels must be removed

Policy 12.7.1.3: Mechanical preservation machine

Purpose of policy

The purpose of the policy is to:

- Clarify the requirements for the use of mechanical preservation machine related to external packaging specifications for living donor organs.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Recovery transplant centers are expected to:

- Comply with updated requirements related to the use of a mechanical preservation machine.

How OPTN/UNOS will evaluate member compliance with this policy

UNOS reviews and verifies recovery centers' external packaging supplies during onsite reviews.

Detailed guidance on policy compliance

- The cassette containing the organ must be labeled with the organ type (e.g. left kidney, right kidney), ABO, ABO subtype (when used to determine compatibility) and UNOS ID.
- The external surface of the mechanical preservation machine must include the standardized label provided by the OPTN contractor.
- If reused, all previous labels must be removed.

Policy 12.7.2: Internal Packaging Specifications

Purpose of policy

The purpose of the policy is to:

- Clarify internal packaging specifications related to procurement of an organ on the donor's back table.
- Outline requirements related to the protection required for internal packaging of a living donor organ that is transported outside the recovery center.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Recovery transplant centers are expected to:

- Package living donor organs (that will be transported outside the recovery center) on the donor OR's back table using universal precautions.

How OPTN/UNOS will evaluate member compliance with this policy

During site surveys of transplant centers, Department of Evaluation and Quality (DEQ) staff reviews packaging requirements with each recovery transplant center and requests a corrective action plan if the recovery transplant center's policies and procedures do not comply with the requirements of Policy 12.7.2.

Detailed guidance on policy compliance

- 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 required triple sterile barrier.
- Lungs, livers 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.

Policy 12.7.3: External Labeling Requirements

Purpose of policy

The purpose of the policy is to:

- Outline requirements for labeling a disposable shipping box, cooler or mechanical preservation device used to transport a living donor organ.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Recovery transplant centers are expected to:

- Use the standardized external label distributed by UNOS, the OPTN contractor, when a disposable shipping box or cooler is used to transport a deceased donor organ.

How OPTN/UNOS will evaluate member compliance with this policy

During site surveys of recovery transplant centers, Department of Evaluation and Quality (DEQ) staff reviews packaging requirements with each recovery transplant center and requests a corrective action plan if the recovery transplant center's policies and procedures do not comply with the requirements of Policy 12.7.3.

Detailed guidance on policy compliance

The external transport container must be labeled with the UNOS standardized label and contain the following information:

- The UNOS Donor ID
- The Donor ABO type
- The Donor ABO subtype, if used to determine compatibility
- A description of the specific contents of the box
- The sender's name and telephone number
- The Organ Center telephone number

Policy 12.7.4: Internal Labeling Requirements

Purpose of policy

The purpose of the policy is to:

- Outline requirements for internal labeling requirements for solid organs, tissue typing materials and vessels.

How to comply with this policy

Compliance strategies may include, but are not limited to:

Recovery transplant hospitals are expected to:

- Incorporate new requirements related to the internal labeling of solid organs, tissue typing materials and vessels.
- Label vessels with the standardized vessel label distributed by the OPTN contractor
- Document in the donor record any unique identifier used to label tissue typing specimens

How OPTN/UNOS will evaluate member compliance with this policy

At transplant hospitals, UNOS may verify that the hospital has a documented solid organ, tissue typing material and vessel internal labeling procedure that is consistent with policy requirements.

Detailed guidance on policy compliance

For training on the organ packaging and transport labeling system, visit https://unos.peachnewmedia.com/store/seminar/seminar.php?seminar=6516

Policy 12.7.5: Documentation Accompanying the Organ or Vessel

Purpose of policy

The purpose of the policy is to:

- Clarify the requirements related to the documentation that must accompany a living donor organ or vessel that is transported outside the recovery facility.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Recovery transplant centers are expected to:

- Include necessary documentation in the container with all transported organs.

How OPTN/UNOS will evaluate member compliance with this policy

At onsite reviews of recovery transplant centers, UNOS staff reviews and verifies the completion of documentation related to a donor organ and inclusion with packaged organ or vessel.

Detailed guidance on policy compliance

- Documentation accompanying a donor organ must be placed in a watertight container and placed in either a location specifically designed for documentation or between the outer and inner liners. This documentation must include:
    - ABO typing source documentation
    - Consent form
    - Complete medical record of the living donor
- If vessels are packaged separately from the donor organ, the same documentation must be included with the vessels as is included with the organ.

Policy 12.7.6: Verification of Labeling and Documentation Included with Organs or Vessels

Purpose of policy

The purpose of the policy is to:

- Outline requirements for the verification of package internal and external labeling and documentation included with living donor organs or vessels that are transported outside the recovery facility.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Recovery transplant centers are expected to:

- Have a second person verify the accuracy of the information on the package labels and the documentation included with organs or vessels prepared for transport.
- 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 Policies 12.7.3, 12.7.4 and 12.7.5.
- Retain specific documentation that this verification occurred.

How OPTN/UNOS will evaluate member compliance with this policy

UNOS reviews and verifies recovery transplant centers' written policies related to the verification of internal and external packaging labels and documentation that accompanies organs or vessels. UNOS staff also reviews documentation that a second person verified the accuracy of organ labels and contents. UNOS investigates all reports of improper labeling reported and refers instances of non-compliance to the Membership and Professional Standards Committee (MPSC).

Policy 12.7.7: Verification of Information Upon Receipt of Organ

Purpose of policy

The purpose of the policy is to:

- Outline requirements for verification of information once a living donor organ is received from a different transplant center.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Maintain documentation that verification of information upon receipt of an organ has taken place.

How OPTN/UNOS will evaluate member compliance with this policy

UNOS reviews documentation verifying the donor and recipient ABO and subtyping and the Donor ID upon the receipt of an organ.

Detailed guidance on policy compliance

- The Transplant center must verify and document that it has received the correct organ for the correct candidate by verifying the donor and recipient ABO and UNOS Donor ID per Policy 3.1.2.

Policy 12.7.8: Materials for Tissue Typing and ABO Confirmation

Purpose of policy

The purpose of the policy is to:

- Outline requirements for tissue typing specimen, medium and shipping requirements; blood for ABO confirmation; typing material for each kidney and pancreas; and typing material for all other living donor organs.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Recovery transplant centers are expected to:

- For 12.7.8.1, have a written policy established with an OPTN member laboratory(s) which includes specific descriptions of the type of specimen and medium, in addition to the shipping requirements of the same.
- For 12.7.8.2, send a "red top" tube of blood, specifically for confirmation of ABO, to the receiving transplant center with each transported living donor organ and tissue typing material.
    - The recovery transplant center is responsible for ensuring the tube is appropriately labeled with all of the following:
        - UNOS ID
        - Donor date of birth, donor initial, or locally assigned unique ID
        - Donor ABO (and ABO subtype, when used to determine compatibility)
        - Date and time sample was procured
        - Type of tissue
    - For 12.7.8.3, include 2 ACD (yellow top) tubes for EACH kidney at a minimum
- For 12.7.8.4, provide specimens for tissue typing if requested.

How OPTN/UNOS will evaluate member compliance with this policy

UNOS investigates all reports of failure to include required materials related to tissue typing and ABO confirmation reported by members and refers instances of non-compliance to the Membership and Professional Standards Committee (MPSC).

Policy 12.7.9: Living Donor Organs that Remain in the Recovery Facility as the Intended Candidate

Purpose of policy

The purpose of the policy is to:

- Clarify the requirements for Transplant Centers when donor organs are recovered and remain in the same hospital as the intended candidate(s), specifically, "time outs."

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Develop, implement and comply with a procedure to ensure identification of the correct donor organ for the correct recipient which includes "time outs" in the donor operating room and the recipient operating room.

How OPTN/UNOS will evaluate member compliance with this policy

UNOS reviews and verifies recovery transplant centers' written policies to ensure that they have a written policy for identifying the correct donor and correct recipient in both operating rooms.

UNOS staff will verify that the policy provides for:

1. Verifying:
    - A unique identifier for the donor, and
    - A unique identifier for the recipient
2. At two times:
    - While still in the donor operating room, and
    - After entering the recipient operating room, but before anastamosis

UNOS staff also reviews the documentation onsite to verify that the transplant center complies with its own policies. Incidents of noncompliance will be forwarded to the MPSC.

Policy 12.7.10: Vessel Recovery, Storage, and Transplant

Purpose of policy

The purpose of the policy is to:

- Outline the requirements for living donor vessel recovery, and immediate use in a solid organ transplant

How to comply with this policy

Compliance strategies include, but are not limited to:

Recovery transplant hospitals are expected to:

- Only recover vessels from living donor after receiving consent from the living donor to remove extra vessels
- Only use living donor vessels for implantation or modification of a solid organ transplant for the original recipient
- Designate a person to monitor and maintain information on all donor vessels
- Follow requirements of Policy 12.7.10.2 for any stored vessels
- Notify the OPTN of extra vessel use or disposal

How OPTN/UNOS will evaluate member compliance with this policy

During site reviews at transplant hospitals, site surveyors will evaluate compliance with this policy through interviews, observations, and obtaining copies of the following:

- The packaging labels to verify that they contain:
  - The recovery date,
  - ABO and subtype of used to determine compatibility,
  - All serology results,
  - Container contents,
  - Donor ID
  - Indicate if the donor is CDC high risk
  - The language, “for use in organ transplant only.”

Site surveyors will interview the designated staff who monitor and maintain the extra vessels and obtain a copy of the center’s policy and procedure for handing vessels. The vessel monitoring log will be reviewed to verify the following:

- Vessels are stored for a maximum of 14 days from their original recovery date
- Vessels that are destroyed were destroyed at the end of the 14th day
- Daily monitoring of vessels includes:
  - documented security checks
  - recorded daily temperature checks (policy requires vessels to be stored between 2 and 8 degrees Celsius)

Policy 12.7.11: Transportation Responsibility

Purpose of policy

The purpose of the policy is to:

- Define the responsibility of transportation costs for living donor organs.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

- For 12.7.11.1, the recovery transplant center assumes responsibility for transportation costs for living donor kidney(s) and associated tissue typing material pursuant to CMS regulations.
- For 12.7.11.2, the member that accepted the organ is responsible for transportation costs to its destination for living donor non-renal organs and associated tissue typing material.
- For 12.7.11.3, 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.

Policy 12.8.1: Reporting Requirements

Purpose of policy

The purpose of the policy is to:

- Clarify requirements for living donor registration with the OPTN contractor via the Living
  Donor Feedback Form prior to surgery
- Ensure the accuracy of ABO data for living donor candidates using the Living Donor Feedback Form

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Host OPOs and Transplant centers are expected to:

- Develop, implement and comply with a procedure to verify the accuracy of ABO information entered on the Living Donor Feedback Form
- Maintain written documentation that the living donor candidate's ABO was entered and verified by two separate individuals reviewing **both of the source documents** from each ABO typing and subtyping (when used to determine compatibility)

How OPTN/UNOS will evaluate member compliance with this policy

During on-site reviews, site surveyors will verify the following:

- Accuracy of ABO and ABO subtype
- Two separate typings entered on the Living Donor Feedback Form
- Procedures to ensure that two separate individuals reviewing source documentation perform the entry and verification of ABO and subtyping

DEQ staff will request a corrective action plan if the center's documentation does not comply with the requirements of this policy and forward the survey results to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for review.

Detailed guidance on policy compliance

- Effective June 27, 2011, there are new documentation requirements, specifically system changes in TIEDI, for verifying living donor ABO.
  - If ABO verification is not completed by a second person using source documents, then the recipient information will not populate into the feedback form, preventing generation of the Living Donor Registration Forms.
  - DEQ will continue to verify that two ABOs were obtained prior to procurement and that the source documents are available for review.
  - DEQ will continue to verify that the donor was registered with the OPTN prior to procurement, thus generating the Donor ID.

- The OPTN presentation on the changes outlined above may be found at: https://www117.livemeeting.com/cc/unos/view?id=WWZ5H9.
- As of April 21, 2008, “two separate occasions” is defined as two samples, taken at different times, sent to the same or different labs.

Policy 12.8.2: Reporting Requirements— Living Donor Follow-up

Purpose of policy

The purpose of the policy is to:

- Define requirements for living donor follow-up

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

OPOs and Transplant centers are expected to:

- Maintain documentation of information entered onto the forms

How OPTN/UNOS will evaluate member compliance with this policy

During on-site reviews, site surveyors will verify follow-up forms for 6 months, 1 year and 2 years. Site surveyors will verify information submitted on the form with medical record documentation.

DEQ staff will request a corrective action plan if the center's documentation does not comply with the requirements of this policy and forward the survey results to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for review.

Policy 12.8.3: Reporting Requirements

Purpose of policy

The purpose of the policy is to:

- Require transplant centers to submit to Tiedi® follow-up information about living donors for two years after donation

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers that recover living donor organs are required to:

- Submit the Living Donor Registration Form to UNOS
  - Within 60 days of the form generation date
  - The data on the form should be from the date the donor is discharged from the hospital, or 6 weeks after transplant, if the donor has not yet been discharged
- Submit the Living Donor Follow-up (LDF) form at the following times:
  - six months after donation
  - one year after donation
  - two years after donation
- Accurately enter all data required on the LDF forms
- Maintain documentation to support all data entered on the LDF forms, including documentation of the attempts to contact the living donor for follow-up information

How OPTN/UNOS will evaluate member compliance with this policy

UNOS Department of Evaluation and Quality (DEQ) staff monitors data submission compliance rates on a quarterly basis and contacts members who have outstanding forms that are more than six months overdue. If a member fails to submit the overdue forms in a timely manner, DEQ staff refers the member to the OPTN/UNOS Membership and Professional Standards Committee.

During on-site reviews, site surveyors will verify follow-up forms for 6 months, 1 year and 2 years. Site surveyors will verify information submitted on the form with medical record documentation.

DEQ staff will request a corrective action plan if the center's documentation does not comply with the requirements of this policy and forward the survey results to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for review.

Detailed guidance on policy compliance

- The policy change to require living donor follow-up information for two years post donation was implemented on March 1, 2008. The two year follow-up requirement

applies to all living donation transplant events that occur on March 1, 2008 and beyond.

Policy 12.8.3.1: Reporting Requirements

Purpose of policy

The purpose of the policy is to:

- Require transplant hospitals to submit to Tiedi® follow-up information about living donors for two years after donation

How to comply with this policy

Compliance strategies include, but are not limited to:

Transplant hospitals that recover living donor organs are expected to:

- Submit the Living Donor Follow-up (LDF) form at the following times:
  - six months after donation
  - one year after donation
  - two years after donation
- Accurately enter all data required on the LDF forms
- Maintain documentation to support all data entered on the LDF forms, including documentation of the attempts to contact the living donor for follow-up information

How OPTN/UNOS will evaluate member compliance with this policy

UNOS staff monitors form submission and contacts members who fall below thresholds for completeness listed in the policy.

During site reviews, site surveyors will verify follow-up forms for 6 months, 1 year and 2 years. Site surveyors will verify information submitted on the form with medical record documentation.

DEQ staff will request a corrective action plan if the center's documentation does not comply with the requirements of this policy and forward the survey results to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for review.

Detailed guidance on policy compliance

The policy change to require living donor follow-up information for two years post donation was implemented on March 1, 2008. The two year follow-up requirement applies to all living donation transplant events that occur on March 1, 2008 and beyond.

Living donor kidney recovery hospitals should consider

- Reviewing the Guidance for Developing and Implementing Procedures to Collect Post-Donation Follow-up Data from Living Donors for follow-up recommendations

from the Living Donor Committee

- Viewing the webinar, offered on January 15, 2013, New Living Kidney Donor Program Requirements: Standardizing Patient Care, for more information on these changes to policy.

Policy 12.8.4: Reporting Requirements— Submission of Living Donor Death and Organ Failure Data

Purpose of policy

The purpose of the policy is to:

- Detail requirements for transplant programs to report all instances of living donor deaths and failure of the living donor's native organ function within 72 hours of knowledge of such event
- For kidney donors, this includes the initiation of dialysis

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Transplant centers are expected to:

- Report living donor deaths and organ failure through the UNet^{SM} Patient Safety System for a period of two years from the date of donation.

How OPTN/UNOS will evaluate member compliance with this policy

During on-site reviews, site surveyors will review program :

- Policies for data submission of living donor death and/or organ failure; and
- Records of living donor adverse events.

DEQ staff will request a corrective action plan if the center's documentation does not comply with the requirements of this policy and forward the survey results to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for review.

6. Detailed guidance on policy compliance

- Any instance of living donor death (even if unrelated the original organ donation, e.g. car accident) must be reported through the UNet^{SM} Patient Safety System for up to two years post-donation. **NOTE:** Do not use Tiedi forms to report living donor adverse events.
- For kidney donors, dialysis includes **acute** and/or **chronic** dialysis.

Policy 12.8.5: Reporting of Non-Utilized Living Donor Organs

Purpose of policy

The purpose of the policy is to:

- Detail requirements for reporting all instances of living donor organs recovered but not transplanted into the intended recipient.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Organ recovery centers are expected to:

- Report all instances defined above through the Patient Safety System or by providing a written description of the event to UNOS Patient Safety.

How OPTN/UNOS will evaluate member compliance with this policy

DEQ will monitor for any reports of non-utilized living donor organs submitted through the UNet^{SM} Living Donor Adverse Event Portal. Membership will forward all non-utilized and redirected living donor organ cases received in the Living Donor Adverse Event Portal to the allocation analyst staff. Upon receipt of the report, the allocation analyst staff will request additional information from the member to gather data for consideration by the MPSC.

Policy 12.8.6: Reporting of Redirected Living Donor Organs

Purpose of policy

The purpose of the policy is to:

- Detail requirements for reporting all instances of living donor organs recovered but redirected and not transplanted into the intended recipient.

How to comply with this policy

Compliance strategies may include, but are not limited to, the expectations stated below.

Organ recovery centers are expected to:

- Report all instances defined above through the Patient Safety System or by providing a written description of the event to UNOS Patient Safety.

How OPTN/UNOS will evaluate member compliance with this policy

DEQ will monitor for any reports of redirected living donor organs submitted through the UNet℠ Living Donor Adverse Event Portal. Membership will forward all non-utilized and redirected living donor organ cases received in the Living Donor Adverse Event Portal to the allocation analyst staff. Upon receipt of the report, the allocation analyst staff will request additional information from the member to gather data for consideration by the MPSC.

Policy 12.10: Required Protocols for Kidney Recovery Hospitals

Purpose of policy

The purpose of the policy is to:

- Require living donor kidney recovery hospitals to have and follow a process for all parts of living donation

How to comply with this policy

Compliance strategies include, but are not limited to:

Living donor kidney recovery hospitals are expected to:

- Develop written protocols for all phases of the living donation process
- Follow their written protocols
- Maintain documentation that they followed their protocols

How OPTN/UNOS will evaluate member compliance with this policy

During site reviews, site surveyors will verify that living donor kidney recovery hospitals have written living donation protocols in place. Site surveyors will review medical records and conduct staff interviews to verify compliance with center-specific policies.

DEQ staff will request a corrective action plan if the center's documentation does not comply with the requirements of this policy and forward the survey results to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for review.

Detailed guidance on policy compliance

Living donor kidney recovery hospitals should consider viewing the webinar, offered on January 15, 2013, New Living Kidney Donor Program Requirements: Standardizing Patient Care, for more information on these changes to policy.

Policy 13.2.2 Potential Donors

Purpose of policy

The purpose of the policy is to:

- Outline requirements for potential donor participation in the kidney paired donation (KPD) program

How to comply with this policy

Compliance strategies include, but are not limited to:

Participating OPTN KPD transplant hospitals are expected to:

- Only list potential OPTN KPD donors who are 18 or older;
- Only list potential donors one time in the OPTN KPD Program (not list one donor for multiple candidates)

How OPTN/UNOS will evaluate member compliance with this policy

During site reviews, the UNOS Department of Evaluation and Quality (DEQ) staff reviews and verifies participating OPTN KPD transplant programs' policies and procedures. DEQ staff also verifies the presence and accuracy of the documentation for a sample of records during site surveys.

DEQ staff will verify the following:

- Donors are at least 18 years old

DEQ staff will also investigate any reports of noncompliance.

DEQ staff will request a corrective action plan if the center does not comply with the requirements of Policy 13.2.2 and forward the survey results to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for review.

Detailed guidance on policy compliance

Participation in the OPTN KPD pilot program also requires compliance with the KPD Operational Guidelines.

Policy 13.8: Transportation of Kidneys

Purpose of policy

The purpose of the policy is to:

- Outline packaging, labeling and transportation requirements that are specific to kidney paired donation (KPD)

How to comply with this policy

Compliance strategies include, but are not limited to:

Recovery transplant hospitals are expected to:

- Document who will be packaging, labeling, and transporting the kidney

How OPTN/UNOS will evaluate member compliance with this policy

During site reviews, the UNOS Department of Evaluation and Quality (DEQ) staff reviews and verifies KPD recovery hospitals' policies and procedures. DEQ staff also verifies the presence and accuracy of the documentation for a sample of records during site surveys.

During site reviews of living donor kidney recovery hospitals, DEQ staff will verify the following documentation in the KPD donor records:

- Name of person or company(s) who packaged the kidney
- Name of person or company(s) who labeled the kidney
- Name of person or company(s) who transported the kidney
- Time and date that the names were recorded

DEQ staff will verify that the recording time was before the donor entered the operating room for the kidney recovery surgery.

DEQ staff will also investigate any reports of noncompliance.

DEQ staff will request a corrective action plan if the center does not comply with the requirements of Policy 13.8 and forward the survey results to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for review.

Detailed guidance on policy compliance

Participation in the OPTN KPD pilot program also requires compliance with the KPD Operational Guidelines.

Policy 13.9: Rules for When Donors and Recipients Can Meet

Purpose of policy

The purpose of the policy is to:

- Outline requirements and restrictions on meetings facilitated by an OPTN Member between donors and matched recipients that participated in an OPTN kidney paired donation (KPD) Program exchange

How to comply with this policy

Compliance strategies include, but are not limited to:

Transplant hospitals are expected to:

- Establish and follow a protocol for when donors and recipients can meet that includes (at least):
- Timing of the meeting (must be after the transplant concludes)
- What staff must attend the meeting
- Maintain documentation of compliance with their protocol in the donor's or recipient's chart

How OPTN/UNOS will evaluate member compliance with this policy

During site reviews, the UNOS Department of Evaluation and Quality (DEQ) staff reviews and verifies living donor recovery hospitals' policies and procedures. DEQ staff also verifies the presence and accuracy of the documentation for a sample of records during site surveys.

During site reviews of transplant hospitals, DEQ staff will review the transplant hospital's protocol for when KPD participants can meet, and will verify that the protocol was followed.

DEQ staff will also investigate any reports of noncompliance.

DEQ staff will request a corrective action plan if the center does not comply with the requirements of Policy 13.9 and forward the survey results to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for review.

Detailed guidance on policy compliance

Participation in the OPTN KPD pilot program also requires compliance with the KPD Operational Guidelines.

Bylaws Appendix B: Membership Requirements for Organ Procurement Organizations (OPOs)

Purpose of bylaw

The purpose of this bylaw is to:

- Define notification responsibilities when an OPO is faced with an adverse action taken by a regulatory agency or the regulatory agency's designee.
- Explain the Membership and Professional Standards Committee's (MPSC) Performance Analysis and Improvement Subcommittee (PAIS) review of OPO performance.

How to comply with this bylaw

OPOs are expected to:

- Notify UNOS when any regulatory agency takes a final adverse action against the OPO
  - In writing
  - Within 10 business days after the OPO receives notification of the final adverse action
  - Provide all documents relating to final adverse actions to UNOS
- Cooperate with performance review process if yields meet or falls below thresholds
  - Respond to inquiries regarding performance
  - Comply with MPSC recommendations regarding performance, including participation in a peer visit to identify opportunities for improvement
  - Participate in an informal discussion regarding a performance review, if requested
  - As applicable, formulate a plan for quality improvement

How OPTN/UNOS will evaluate member compliance with this bylaw

Final Adverse Regulatory Action:
If UNOS learns of a final adverse action taken against an OPO, and the OPO did not report this action to UNOS as defined in the bylaws, matter will be referred to the MPSC for consideration and potential adverse action.

Performance Review:
Using a statistically driven method, the Scientific Registry of Transplant Recipients (SRTR) uses blinded data derived from UNet^{SM} to identify OPOs in which observed organ yield falls below the expected yield given individual OPO donor characteristics. These data are reviewed by the MPSC at each meeting. The MPSC will evaluate overall (or

aggregate) organ yield, as well as organ specific yields, for all OPOs.

When an OPO meets or falls below all of the below thresholds, for a single organ or for all organs taken together, the OPO's organ yields will be reviewed by the MPSC:

- Observed organ yield per 100 donors - expected organ yield per 100 donors < -10;
- A ratio of observed to expected yield is less than 0.90; and
- Two-sided p-value less than 0.05

The MPSC will send inquiries to OPOs identified to have experienced lower than expected yields during a specified 2.5 year cohort. The MPSC may request continued reporting until observed organ yields improve and may require the OPO to promptly adopt and implement a plan for improvement. OPOs that do not comply with MPSC requests may be considered for adverse action.

Detailed guidance on bylaw compliance

Final adverse actions by an agency include, but are not limited to:

- Decertification or threatened decertification by the Center for Medicare and Medicaid Services (CMS);
- Any action or threatened action by a state licensing authority that affects the facility's ability to function;
- Any action or threatened action by the state health department that affects the facility's ability to function; or
- Loss of accreditation or threatened loss of accreditation by the Joint Commission on Accreditation of Healthcare Organizations.

Written notification can be sent to UNOS by any of the following methods:

- By Mail: UNOS Membership Department
  Post Office Box 2484
  Richmond, VA 23218
- By Facsimile: (804) 782-4896
- By E-mail: to your regional Performance Review contact

Contact the Performance Review contact for your region for additional information and assistance in meeting these bylaw requirements, including questions relating to performance.

Bylaws Appendix C: Membership Requirements for Histocompatibility Laboratories

Purpose of bylaw

The purpose of this bylaw is to define notification responsibilities when a histocompatibility laboratory is faced with an adverse action taken by a regulatory agency or the regulatory agency's designee.

How to comply with this bylaw

Histocompatibility laboratories are expected to:

- Notify the OPTN Contractor when any regulatory agency takes a final adverse action against the histocompatibility laboratory. Notification must be:
  - in writing
  - within 10 business days after the histocompatibility laboratory receives notification of the final adverse action
- Provide all documents relating to the final adverse action to the OPTN Contractor

How OPTN/UNOS will evaluate member compliance with this bylaw

The OPTN Contractor will investigate any allegations of noncompliance.

Detailed guidance on bylaw compliance

Written notification can be sent to the OPTN Contractor by any of the following methods:

- By Mail: UNOS Membership Department
  Post Office Box 2484
  Richmond, VA 23218
- By Facsimile: (804) 782-4896
- By E-mail: your regional Performance Review contact

Final adverse actions by an agency include, but are not limited to:

- Decertification or threatened decertification by the Center for Medicare and Medicaid Services (CMS);
- Any action or threatened action by a state licensing authority that affects the facility's ability to function;
- Any action or threatened action by the state health department that affects the facility's ability to function; or
- Loss of accreditation or threatened loss of accreditation by the Joint Commission on Accreditation of Healthcare Organizations.

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

Purpose of bylaw

The purpose of this bylaw is to clarify what is expected of transplant programs regarding:

- Adverse regulatory agency action
- Physician coverage plans
- Primary physician or surgeon changes
- Loss of primary physician or surgeon coverage
- Survival rates
- Functional activity

How to comply with this bylaw

Adverse Regulatory Agency Action

- *Notice to UNOS:* Transplant programs are expected to notify UNOS when any regulatory agency takes a final adverse action against the transplant hospital
  - In writing
  - Within 10 business days after the OPO receives notification of the final adverse action
  - Provide all documents relating to final adverse actions to UNOS

Physician Coverage Plan:

- *Development of program coverage plan:* Transplant programs are expected to address each of the following requirements in their program coverage plan:
  - The program's ability to have transplant surgeons and transplant physicians available 365 days a year, 24 hours a day, 7 days a week
  - That the program provides candidates with a written summary of the program coverage plan when the candidates are listed
  - That the program provides candidates with a written summary of the program coverage plan when there are significant program or personnel changes
  - That transplant surgeons and transplant physicians on call for the program may not simultaneously be on call for another hospital's transplant program that is more than 30 miles away
  - That a transplant surgeon or transplant physician is readily available in a timely manner to:
    - Facilitate organ acceptance
    - Facilitate organ procurement
    - Facilitate organ transplantation
    - Address urgent patient issues

- That the primary transplant surgeon and primary transplant physician are not designated as the primary transplant surgeon or physician for a program at another transplant hospital unless both hospitals have additional transplant surgeons and physicians (see definitions below) for the programs in question

- *Notice to UNOS:* Transplant programs are expected to submit the program's written coverage plan to UNOS
  - With every key personnel change, new transplant program, and new transplant hospital member application
  - Upon request from UNOS staff

- *Notice to Patients:* Transplant programs are expected to:
  - Provide candidates with a written summary of the program coverage plan when the candidates are listed
  - Provide candidates with a written summary of the program coverage plan when there are significant program or personnel changes. Significant changes include:
    - Change in primary transplant surgeon or physician
    - Becoming a single-surgeon or single-physician program
    - Being able to again provide 365/24/7 coverage after previously being a single-surgeon or single-physician program
    - Any other major programmatic changes that the program feels will impact or alter patients' ability to receive transplant services
  - Inform patients if staffed by a single surgeon or physician

<u>Primary Physician or Primary Surgeon changes:</u>

- *Notice to UNOS:* Transplant programs are expected to notify UNOS in writing when designating a new primary surgeon or primary physician, or reinstating a previously designated primary surgeon or primary physician. Written notice must:
  - Be sent to your regional Application Related contact
  - Be received by UNOS within 7 business days after the program is informed of the change

- *Personnel Change Application:* Transplant programs are expected to submit a completed personnel change application any time they wish to designate a new primary physician or surgeon. The completed application must:
  - Demonstrate that the proposed surgeon/physician meets the primary surgeon/physician requirements for that organ
  - Be received by UNOS at least 30 days prior to the effective date of the change in key personnel (due date will be provided by UNOS staff)
    - However, if a program received less than 60 days advance notice of a surgeon/physician's departure or need for temporary leave,

the application must be submitted to UNOS within 30 days after the program notifies UNOS of the pending change (due date will be provided by UNOS staff)

Failure to Maintain Primary Physician or Primary Surgeon:

- *Inactivation/Withdrawal:* If a transplant program's primary surgeon or physician ends their involvement with the program on a permanent or temporary basis, and the program is unable to either submit a completed key personnel change application by the due date or demonstrate in the application that the proposed replacement meets the primary surgeon/physician requirements, the program is expected to either:
  - Voluntarily inactivate its Designated Transplant Program status , or
  - Withdraw its Designated Transplant Program status

Functional Inactivity:

- *Notice to Patients:* A transplant program is expected to provide notice to patients
  - When it has an inactive waiting list for either:
    - 15 or more consecutive days or
    - 28 or more cumulative days over any 365 consecutive day period
  - The notices must:
    - Include an explanation of reasons for the inactivity
    - Be documented
- *Cooperation with UNOS:* Upon request, transplant programs are expected to:
  - Respond to MPSC PAIS inquires regarding periods of functional inactivity.
  - Participate in an informal discussion regarding an inactivity review.

Transplant Program Survival Rates:

- *Survival Rates:* Transplant programs are expected to maintain graft survival rates above the threshold established in OPTN/UNOS Bylaws (described below)
- *Cooperation with UNOS:* Upon request, transplant programs are expected to:
  - Respond to inquiries regarding one year post-transplant outcomes.
  - Comply with MPSC recommendations regarding performance, including participation in a peer visit to identify opportunities for improvement.
  - As applicable, formulate a plan for quality improvement.
  - Participate in an informal discussion regarding a performance review.

How OPTN/UNOS will evaluate member compliance with this bylaw

Adverse Regulatory Agency Action:

UNOS staff reviews each submitted notice and investigates any allegations of noncompliance. Members that fail to inform the OPTN Contractor of an adverse regulatory agency action and provide associated documents in the time and manner required will be referred to the MPSC.

Physician Coverage Plan:
UNOS staff will verify the submission of coverage plans to the OPTN. Program coverage plans submitted in membership applications are reviewed by the ad-hoc subcommittee of the MPSC that reviews the application. Coverage plans requested by UNOS staff at other times may be requested on behalf of the full MPSC or its subcommittees and will be forwarded to the original requesting group for review.

Primary Physician or Primary Surgeon Changes
UNOS staff reviews each submitted personnel change application and investigates any allegations of noncompliance. Members that fail to inform the OPTN Contractor of a change in key personnel or submit a completed personnel change application in the time and manner required will be referred to the MPSC.

Functional Inactivity:
Members that do not respond to MPSC inquiries regarding functional inactivity, or do not provide patient notification as required for periods of waiting list inactivation, will be referred to the MPSC.

Transplant Program Survival Rates:
Programs performing 10 or more transplants during a 2.5 year cohort with one-year graft and/or patient survival rates below expected are identified for review based on three criteria:

- If a program's observed minus expected events is greater than three (i.e. the program experienced an excess of three deaths/failures over the number of expected events),
- The ratio of observed to expected events is greater than 1.5 (i.e. the program experienced 50% more deaths/failures than were expected), and,
- The p-value is less than 0.05.

Programs performing 9 or fewer transplants during the cohort are also analyzed by the SRTR using UNet^{SM} data. Programs will be identified for review if there is at least one death or graft failure during that cohort, and an event during subsequent years.

The MPSC PAIS will send inquiries to programs identified to have experienced lower than expected outcomes during a specified 2.5 year cohort.

UNOS staff will investigate any allegations of noncompliance and will facilitate review by the MPSC and/or PAIS if necessary.

Detailed guidance on bylaw compliance

Written notification can be sent to UNOS by any of the following methods:

- By Mail: UNOS Membership Department
  Post Office Box 2484
  Richmond, VA 23218
- By Facsimile: (804) 782-4896
- By E-mail: to the appropriate regional contact

Adverse Regulatory Agency Action:

Final Adverse Actions by an Agency include, but are not limited to:

- Decertification or threatened decertification by the Center for Medicare and Medicaid Services (CMS)
- Any action or threatened action by a state licensing authority that affects the facilities ability to function
- Any action or threatened action by the state health department that affects the facilities ability to function
- Loss of accreditation or threatened loss of accreditation by the Joint Commission on Accreditation of Healthcare Organizations

Contact the Performance Review contact for your region for additional information and assistance in meeting these bylaw requirements.

Physician Coverage Plan:

Succession Planning:

Transplant hospitals are strongly recommended to engage in succession planning for their transplant programs to address how the programs will handle both planned and unplanned changes to key personnel in the future. Transplant programs are expected to have qualified key personnel at all times including during the personnel change application process, regardless of the status of the application. Therefore, it is important for programs to identify which surgeons and physicians could meet the OPTN primary surgeon/physician criteria in order to seamlessly transition into the role of primary surgeon/physician if the situation arose. Some issues to consider include:

- Maintaining applicable board certifications
- Maintaining enough involvement in the transplant program to acquire sufficient transplant and procurement experience (for surgeons) or patient care experience (for physicians)
- Maintaining current working knowledge by actively participating in all aspects of transplant patient care, including performing transplants and procurements (for surgeons)

Transplant hospitals are encouraged to review the current key personnel requirements

in the Bylaws. Sample personnel change applications are available for reference on the UNOS website: http://www.unos.org/donation/index.php?topic=application.

Contact the Application Related contact for your region for additional information and assistance in meeting these bylaw requirements.

Primary Physician or Primary Surgeon Changes:

What information should the written notice of the pending key personnel change contain?

- The name of the outgoing primary surgeon/physician
- The program(s) affected by the change
- The nature of the change – for example, is the individual leaving the hospital, or is the individual going to remain involved with the program(s) as an additional surgeon/physician?
- The effective date of the change
    - In cases where the outgoing primary is leaving the hospital or otherwise ending their involvement with patient care, the effective date of the change is considered to be the last day that the doctor will be actively involved with patient care for the program(s).
- The name of the individual proposed as the new primary surgeon/physician
    - The program should be reporting the same primary surgeon and primary physician to both the OPTN Contractor and CMS.

How can I obtain the personnel change application to complete?

Your region's Application Related contact will provide the application and its due date via email upon receipt of the written notice of the pending change. The transplant hospital staff member responsible for submitting the notice and the application may contact their region's Application Related contact to discuss their specific case and receive individualized assistance.

Contact the Application Related contact for your region for additional information and assistance in meeting these bylaw requirements.

Functional Inactivity:

Definition: A transplant program that meets any of the following criteria:

- Unable to serve potential candidates, candidates, or recipients for a period of 15 consecutive days or more
- Inactive waiting list for 15 or more consecutive days
- Inactive waiting list for 28 or more cumulative days over any 365 consecutive day period
- No transplants performed for a period of time:

- 3 consecutive months for kidney, liver, and heart transplant programs
- 6 consecutive months for pancreas and lung programs
- 12 consecutive months for transplant programs located in stand-alone pediatric transplant hospitals

If a Transplant Program is unable to remain functionally active, it is recommended that the Member either:

- Voluntarily inactivate a Transplant Program's membership status for up to 12 months (see Bylaws Appendix K.1-3 for guidance on how to inactivate)
- Voluntarily withdraw (relinquish) designated Transplant Program membership status (see Bylaws Appendix K.4 for guidance on how to withdraw)

Suggestions for drafting letters to notify patients of periods of waiting list inactivity:

Content Suggestions:

- Include reasons for waiting list inactivation.
- Explain the impact of your program's inactivity to the patient.
- Disclose the expected length of time the waiting list will be inactive and if there will be periodic updates/communication with patients while inactive.
- Explain how you will notify the patient when the list is reactivated.
- Provide options and alternatives for the patient during this inactive time period.
- Explain how the transplant program/center will assist the patient.
- Provide name and phone number of coordinator serving as contact.

Format Suggestions:

- Consider writing in patient's native language.
- Consider writing in a question and answer format, such as:
  - What does this mean for me?
  - Why is the wait list inactive?
  - What are my options?
  - What do I need to do now?
  - How will I know when the wait list returns to active status?
  - Why are you telling me?

Contact the Performance Reviews contact for your region for additional information and assistance in meeting these bylaw requirements.

Transplant Program Survival Rates:

Members that do not respond to MPSC inquiries regarding lower than expected outcomes and fail to promptly adopt and implement a plan for quality improvement, will be referred to the MPSC.

Bylaws Appendix F.6(E): Conditional Approval of Living Donor Liver Transplant Programs, Conditional Program Approval Status

Purpose of bylaw

The purpose of this bylaw is to:

- Describe the reporting requirements and expectations for programs that are conditionally approved to perform living donor liver transplants.
- Describe the expectations for conditionally approved programs that are unable to become fully approved by the end of the conditional approval period.

How to comply with this bylaw

Compliance strategies may include, but are not limited to, the expectations stated below.

Conditionally approved programs are expected to:

- Comply with all applicable policies and procedures
- Demonstrate continuing progress toward full compliance with Criteria for Institutional Membership.
- Have both designated surgeons present at all living donor recoveries during the period of conditional approval
- Comply with any interim operating policies and procedures required by the MPSC, Provide a report one month prior to the conclusion of the first year of conditional approval, along with a request for an extension of a second year of conditional approval if the program is still unable to meet all requirements for full approval. The report must document:
    - The surgeon's progress towards meeting the bylaw requirements, or
    - That the program is making sufficient progress in recruiting a transplant surgeon who meets the criteria for a qualified live donor liver surgeon.
- Submit, one month prior to the conclusion of the second (final) year of conditional approval:
    - A report documenting that the surgeon can fully meet the primary living donor liver surgeon requirements, or
    - A key personnel change application proposing a replacement surgeon who can fully meet the primary living donor liver surgeon requirements and who will be on site and credentialed to perform living donor hepatectomies by the end of the conditional approval period.
- Cease performing living donor liver transplants by inactivating or relinquishing the living donor component if the program is unable to meet the requirements for full approval at the end of the conditional approval period.

How OPTN/UNOS will evaluate member compliance with this bylaw.

The progress of each program towards meeting the requirements for full approval will be monitored and reported to the Membership and Professional Standards Committee

(MPSC) on an ongoing basis.

The Committee will review a report, provided by the transplant program, prior to the conclusion of the first year of conditional approval. If the program continues to be conditionally approved for a second year, the MPSC will review a final report prior to the end of the approval period. This final report must document the Member's ability to meet the requirements for full approval.

If the program submits a key personnel change application proposing a new surgeon that fully meets the primary living donor liver surgeon criteria, the MPSC will follow its standard application review processes.

Detailed guidance on bylaw compliance

MPSC requirements:
The MPSC may require interim operating policies and procedures. These may include:

- Submission of reports describing the surgeon's progress towards meeting the requirements
- Other operating conditions to demonstrate ongoing quality and efficient patient care

Report content:
The progress report submitted one month prior to the end of the first year of conditional approval should contain at a minimum:

- A cover letter explaining the program's progress in meeting the criteria for full approval
- A request for an extension of the conditional approval status for a second year or a request for consideration of full approval of the program, depending on whether or not the surgeon has met the criteria for full approval (can be included in cover letter)
- A log of any living donor hepatectomies that the surgeon performed since the program was initially granted conditional approval. The log should include:
    - Date of surgery
    - Medical record number or other unique identifier that can be verified by UNOS staff
    - Role of the surgeon in the procedure (primary surgeon/1st assistant)
    - Recovery hospital
    - Type of procedure
    - CPT code for procedure
- Any information regarding the program's progress in recruiting a new surgeon who can fully meet the primary living donor liver surgeon criteria (if applicable; can be included in cover letter)

The progress report submitted one month prior to the end of the second (final) year of conditional approval should contain at a minimum:

- A cover letter from the program director requesting consideration of full approval of the program
- A log of any living donor hepatectomies that the surgeon performed since the program was initially granted conditional approval. The log should include:
    - Date of surgery
    - Medical record number or other unique identifier that can be verified by UNOS staff
    - Role of the surgeon in the procedure (primary surgeon/1st assistant)
    - Recovery hospital
    - Type of procedure
    - CPT code for procedure

Progress reports or key personnel changes for new living donor liver surgeons must be submitted to the Application Related contact for your region one month prior to the expiration of the conditional approval period in order to allow for processing and review of the report by the MPSC before the term expires. Programs that anticipate meeting the requirements for full approval less than one month before expiration of the conditional approval period must contact their region's Application Related contact prior to the progress report's due date to discuss the situation.

Programs submitting a request for an extension of the conditional approval status for a second year are not automatically guaranteed an extension. Extensions are granted at the MPSC's discretion based on the Committee's review of the program's progress report. If no extension is granted, it is expected that the living donor component to the liver transplant program will inactivate.

If the surgeon meets the requirements prior to the end of the conditional approval period, the program may submit a progress report and request review by the MPSC. Likewise, if the program recruits a new surgeon that can fully meet the primary living donor liver surgeon requirements prior to the end of the conditional approval period, the program may submit a key personnel change application for review by the MPSC.

If at the end of the 2-year conditional approval period the program is unable to demonstrate that it has two designated surgeons on site who can fully meet the primary living donor liver surgeon requirements, it must stop performing living donor liver transplants by either (see Bylaws F.6(F)):

- Inactivating the living donor part of the program for a period up to 12 months; or
- Relinquishing the designated transplant program status for the living donor part of

the liver transplant program until it can meet the requirements for full approval.

- Resources on living donation are available at: http://www.unos.org/donation/index.php?topic=living_donation

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

Purpose of bylaw

The purpose of this bylaw is to clarify responsibilities when one or more of a Member's transplant programs and/or living donor components:

- Experiences long-term inactivity
- Withdraws its designated transplant program status, or
- Has its designated transplant program status terminated

How to comply with this bylaw

Transplant Hospitals with a transplant program that is inactivating, withdrawing, or terminated are expected to:

Send Initial Written Notice to UNOS

- Must include:
  - The reason(s) for inactivation or withdrawal
  - The effective date for the change in status
  - A sample of each type of patient notice
  - A list of potential candidates, candidates, recipients, and living donors who received the notice.

Send Written Notice to Patients

- No later than 7 days after the effective date of the inactivation, withdrawal, or termination
  - Representative copies should be approved by UNOS membership staff before they are sent out
- Must go to the transplant program's:
  - Potential candidates
  - Candidates
  - Recipients
  - Living donors currently being followed by the program
- Must include:
  - The reason(s) for the inactivity, withdrawal, or termination of the transplant program
  - Explanation that although the candidate is still on the waiting list, the candidate cannot receive an organ offer through the program;
  - Options for potential candidates, candidates, recipients, and living donors to transfer to another transplant program
  - The phone number of the program's administrative office that can help with transferring to another transplant program

Submit a Transition Plan

- Within 7 days of the effective date (may be submitted separately from the initial notice)
- Must include:
    - A list of candidates on the transplant center's waitlist, with the following information on each candidate:
        - If the candidate chose to transfer to another transplant center:
            - To which program the candidate is transferring
        - If the candidate chose not to transfer to another transplant center:
            - Reason
            - Whether the candidate was informed of the implications before removal from the waiting list.
    - A list of the most urgent candidates, including:
        - Individualized plan for transfer
        - Potential alternative transplant programs
        - Timeline for transferring those candidates according to priorities and deadlines listed in Bylaw K.5(6).

Submit Routine Reports

- Until the program has completely cleared its waiting list of both active and inactive candidates. This process must be completed within 12 months of the inactivation, withdrawal, or termination effective date. Reports in general are due on the 1st and 15th of each month.

Manage Patient Transition

- Immediately stop organ transplantation
- Help potential candidates and candidates transfer to other programs
- Remove candidates, who do not transfer, from the waiting list
- Transfer candidates to another transplant hospital when either:
    - Requested by the candidate
    - The candidate is active and currently hospitalized at the transplant program. Then the transplant program must:
        - Initialize the transfer within 7 days of inactivation, withdrawal, or termination
        - Complete the transfer within 14 days after inactivation, withdrawal, or termination, unless any of the following:
            - Transfer would be unsafe
            - Discharge is anticipated within the 14 day time period
            - Circumstances outside the transplant center prevent transfer within 14 days
        - Document all efforts to transfer these candidates and submit that documentation to UNOS, if a program cannot meet these

deadlines

How OPTN/UNOS will evaluate member compliance with this bylaw

UNOS staff reviews all submitted materials and investigates any allegations of noncompliance. Members that fail to submit the required information in the time and manner required will be referred to the MPSC.

Detailed guidance on bylaw compliance

Definitions:

- *Short-term Inactivation:* Inactivation up to and including 14 consecutive days. (Does not require OPTN/UNOS or patient notification.)
- *Voluntary Inactivation:* Inactivation for a consecutive period between 15 days and 12 months long.
- *Voluntary Withdrawal* (Relinquishment): Inactivation expected to last more than 12 months or indefinitely.

Patient Notification Letter Suggestions:

Content Suggestions:

- Explain the impact of your program's change of status to the patient (e.g. the candidate cannot receive an organ offer, impact on scheduled appointments).
- Disclose the expected length of time the program will be inactive and if there will be periodic updates/communication with patients while inactive.
- Explain how you will notify the patient if/when the list is reactivated
- Explain how the transplant program/center will assist the patient.
- Provide a list of local transplant centers/regional alternatives

Format Suggestions:

- Write in the patient's native language.
- Write in a question and answer format, such as:
  - What does this mean for me?
  - Why is the program inactivating/closing?
  - What are my options?
  - What do I need to do now?
  - Why are you telling me?
- Send separate letters to different groups of patients, such as one type of letter for living donors, one letter for recipients, another letter for candidates

and potential candidates, etc. This is particularly relevant for transplant programs that inactivate, but intend to still provide follow up care to recipients and living donors.

Preferred Methods:

- Commercial overnight service
- Secure electronic communication
- Registered or certified mail, return receipt requested

Other Considerations:

In addition to the reports and notices described above, the Members should also

- Notify the OPO and Histocompatibility laboratory of decision to inactivate/terminate program
- Inactivate waitlist default in UNet^{SM} for the program
- Contact referring physicians
- Modify hospital website to reflect program status
- Review hospital marketing materials for potential revisions

Resources:

UNOS Staff will work with Members that voluntarily inactivate a transplant program (long term inactivation, relinquish designated program status) and assist these transplant programs with the transition procedures. Assistance includes reviewing drafts of patient notice letters, scheduling and monitoring the routine waitlist status reports, and answering questions regarding waitlist maintenance.

Contact the UNOS Application Related contact for your region at 804-782-4800 for additional information and assistance in meeting these bylaw requirements.

Bylaws Appendix L: Reviews, Actions, and Due Process

Appendix L of the OPTN/UNOS Bylaws addresses what happens when a potential policy violation is identified by UNOS staff. Appendix L outlines:

- The types of investigations UNOS may conduct
- The types of reviews that the Membership and Professional Standards Committee (MPSC) may conduct
- How and when those investigations and reviews will be conducted
- Members' rights and responsibilities after a violation has occurred.
- The determinations and adverse actions that could result
- Time frames for MPSC reviews, interviews, hearings, and other review processes

Consult the Due Process Overview chart for an outline of the review process.

Resource Materials

This section of the Evaluation Plan contains the resource materials referenced in the plan narrative.

Resource Materials	Policy / Bylaw Reference
Final Rule http://optn.transplant.hrsa.gov/policiesAndBylaws/final_rule.asp	N/A
Chart 1 – policy development process http://optn.transplant.hrsa.gov/SharedContentDocuments/Chart_1_Policy_Development_Process.pdf	N/A
Chart 2 OPTN System modification procedures http://optn.transplant.hrsa.gov/SharedContentDocuments/Visio-070331_Chart_2_IT_OPTN_System_Modification_Procedures-2004-03.pdf	N/A
NOTA http://optn.transplant.hrsa.gov/policiesAndBylaws/nota.asp	N/A
Chart 3 – Application and hearing procedures http://optn.transplant.hrsa.gov/SharedContentDocuments/Chart_3_EvaluationPlanChart.pdf	N/A
Membership Applications http://www.unos.org/donation/index.php?topic=application	N/A
New Transplant Hospital Application http://www.unos.org/docs/A_New_Transplant_Center.pdf	N/A
Designated Transplant Program Application http://www.unos.org/docs/B_New_Transplant_Program_Existing_Center.pdf	N/A
OPO Application http://www.unos.org/docs/C_OPO_application_independent.pdf	N/A
Histocompatibility Laboratory Application http://www.unos.org/docs/E_Independent_Lab_New_Member.pdf	N/A
Change of Personnel Application http://www.unos.org/docs/F_Key_Personnel_Change.pdf	N/A
Medical/Scientific Member Application http://www.unos.org/docs/G_Medical_Scientific_Org.pdf	N/A
Public Organization Member Application http://www.unos.org/docs/H_Public_Org.pdf	N/A
Business Member Application http://www.unos.org/docs/I_Business_Member.pdf	N/A
Individual Member Application http://www.unos.org/docs/J_Individual_Public_Member.pdf	N/A
UNOS Transplant Management Forum http://www.unos.org/donation/index.php?topic=transplant_management_for	N/A

Resource Materials	Policy / Bylaw Reference
um	
Information for Prion disease and transmissible spongiform encephalopathies (TSEs): http://www.cdc.gov/ncidod/dvrd/prions	2.2.2.1
Information explaining hemodilution and qualified specimens per the FDA http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=1271.80	2.2.3.1
Additional information for an example of a hemodilution calculation http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/ucm073964.htm#DONORTESTING:GENERAL1271.80	2.2.3.1
Information regarding what donor testing is screening vs. diagnostic http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/ucm073964.htm	2.2.4
Information for the Patient Safety Contact from the January 17, 2011 UNOS Communications e-newsletter http://communication.unos.org/category/patient-safety/	2.2.5
Guidelines for Histocompatibility Specimen Testing for OPOs Brochure http://optn.transplant.hrsa.gov/SharedContentDocuments/Histo_Brochure_2006.pdf	2.5.4 2.6
Recommended Histocompatibility Guidelines http://optn.transplant.hrsa.gov/SharedContentDocuments/Histocompatibility_Guidelines.pdf	2.5.4 2.6
System Notice sent June 9, 2008 regarding access to UNet℠ http://optn.transplant.hrsa.gov/SharedContentDocuments/080609_Access_to_UNet_System_Notice.pdf	3.2.1.2
Patient brochure about multiple listing in Spanish http://www.unos.org/docs/Multiple_Listing_Spanish.pdf	3.2.3
Patient brochure about multiple listing in English http://www.unos.org/docs/Multiple_Listing.pdf	3.2.3
Patient Information Letter http://optn.transplant.hrsa.gov/resources/professionalresources.asp?index=15	3.2.11
ECD brochure (English) http://optn.transplant.hrsa.gov/SharedContentDocuments/ExpandedCriteriaDonor_KidneysBrochure.pdf	3.5.1
ECD brochure (Spanish) http://optn.transplant.hrsa.gov/SharedContentDocuments/Answers_to_Questions-Spanish.pdf	3.5.1
Kidney Payback Accounting Sheet http://optn.transplant.hrsa.gov/SharedContentDocuments/Kidney_Payback_A	3.5.3.5 3.9.3

Resource Materials	Policy / Bylaw Reference
ccounting_Sheet.pdf	
System Notice sent May 21, 2007 announcing EC Change to KI-PA Placement http://optn.transplant.hrsa.gov/SharedContentDocuments/070521_System_Notice_Announcing_EC_Change_to_KI-PA_Placement.pdf	3.5.6.3
System Notice sent May 29, 2007 with additional information about EC Change to KI-PA Placement http://optn.transplant.hrsa.gov/SharedContentDocuments/070529_System_Notice_for_Executive_Committee_Change_to_National_KI-PA_Placement.pdf	3.5.6.3
LiveMeeting recording on CPRA Can be found in Waitlist[SM], under Resources, then Reference Docs.	3.5.11.3
Resolving Discrepant Donor and Recipient HLA Typing Results in the OPTN Database http://optn.transplant.hrsa.gov/PoliciesandBylaws2/policies/pdfs/policy_104.pdf	3.5.16
Guidelines for the Development of Joint Written Agreements Between Histocompatibility Laboratories and Transplant Programs http://optn.transplant.hrsa.gov/PoliciesandBylaws2/policies/pdfs/policy_109.pdf	3.5.17 3.6.13 3.7.17
System Notice sent June 14, 2006 regarding Entering Liver Lab Values as Reported by Laboratory into UNet[sm] http://optn.transplant.hrsa.gov/SharedContentDocuments/060614_SystemNotice_LiverLabsRounding.pdf	3.6.4.1 3.6.4.2
MELD Calculator http://optn.transplant.hrsa.gov/resources/MeldPeldCalculator.asp?index=98 PELD Calculator http://optn.transplant.hrsa.gov/resources/MeldPeldCalculator.asp?index=99	3.6.4.1 3.6.4.1.1 3.6.4.2
All UNOS Brochures (including MELD/PELD brochures) http://www.unos.org/resources/brochures.asp	3.6.4.1 3.6.4.1.1 3.6.4.2
System Notice sent February 1, 2012 for Implementation of Change for Listing Pediatric Liver Candidates with Hepatoblastoma http://optn.transplant.hrsa.gov//SharedContentDocuments/UNet_System_Notice_02-01-12_Hepatoblastoma.pdf	3.6.4.2
System Notice sent February 1, 2012 for Implementation of Change to Listing Procedures for Pediatric Liver Status 1A and Status 1B Candidates Not in the ICU http://optn.transplant.hrsa.gov//SharedContentDocuments/UNet_System_Notice_02-01-12_Pediatric_Liver_Status.pdf	3.6.4.2
System Notice sent February 15, 2010 for Submitting Standardized MELD/PELD Exception Scores and additional attachment http://optn.transplant.hrsa.gov/SharedContentDocuments/System_Notice_02	3.6.4.5.1

Resource Materials	Policy / Bylaw Reference
1510.pdf http://optn.transplant.hrsa.gov/SharedContentDocuments/System_Notice_021510_attachment.pdf	
MELD/PELD exception templates http://transplantpro.org/submitting-standardized-meldpeld-exception-scores/	3.6.4.5.1 3.6.4.5.2 3.6.4.5.3 3.6.4.3.4 3.6.4.5.5 3.6.4.5.6
System Notice about Distance in Nautical Miles http://optn.transplant.hrsa.gov/SharedContentDocuments/System_Notice_for_Distance_in_Nautical_Miles.doc	3.7.2
System Notice regarding Pediatric ABO incompatible blood type; titer information http://optn.transplant.hrsa.gov/SharedContentDocuments/System_Notice_102010_Liver.pdf	3.7.3
LAS calculator and brochures http://optn.transplant.hrsa.gov/resources/allocationcalculators.asp?index=88 http://www.unos.org/donation/index.php?topic=patient_brochures	3.7.6 3.7.6.3.1 3.7.6.3.2 3.7.6.4
Information regarding the Patient Safety Contact http://communication.unos.org/category/patient-safety/	4.4
System Notice regarding Adult Heart Status 1A Exception Language and changes to criteria (d) and (e) http://optn.transplant.hrsa.gov/SharedContentDocuments/System_Notice_102010_Heart.pdf	3.7.8.1
Pancreas Waiting Time Reinstatement Form Located in Waitlist under Forms and Tools	3.8.8
Kidney Payback Sheet http://optn.transplant.hrsa.gov/SharedContentDocuments/Kidney_Payback_Accounting_Sheet.pdf	3.9.3
Nationally notifiable diseases per the CDC http://www.cdc.gov/osels/ph_surveillance/nndss/phs/infdis.htm	4.5
Guidance for Reporting Potential Deceased and Living Donor-Derived Disease Transmission Events http://optn.transplant.hrsa.gov/SharedContentDocuments/PDDTE_Exhibit_B_Guidance.pdf	4.5 4.5.1 4.5.2
Training on the new organ packaging and transport labeling system: http://unos.peachnewmedia.com/store/streaming/seminar-launch.php?key=%2BYHukCtwgJMpN%2Bx6WOlYyTpufiZRe0G6kPNnBWFr9Ww%3D	5.0 5.4

Resource Materials	Policy / Bylaw Reference
Revised organ container shipping labels http://optn.transplant.hrsa.gov/SharedContentDocuments/080701_UNOS_shipping_label_system.pdf	5.1.2 5.3
Printable vessel labels 2x5 http://transplantpro.org/wp-content/uploads/Vessels-Label-2-x-5.pdf 2x4 http://transplantpro.org/wp-content/uploads/Vessel-Label-2-x-4.pdf	5.1.2 5.3
Vessel Transplantation / Destruction Sheet http://optn.transplant.hrsa.gov/SharedContentDocuments/090611_Extra_vessels_tx_destruction_fax_sheet.pdf	5.10
Donation Data Report E-learning Module (interactive tutorial) Access the DonorNet online help. Click **E-learning Modules**. Click **Donation Data Report**. (https://portal.unos.org/DonorNet/help/donornet/Donation_Data_Report.htm)	7.0 7.7
Imminent and Eligible Data Collection E-learning Module (interactive tutorial) Access the DonorNet online help. Click **E-learning Modules**. Click **Imminent and Eligible Death Data Collection**. (https://portal.unos.org/DonorNet/help/donornet/Imminent_and_Eligible_Death_Data_Collection.htm)	7.0
Importing and Exporting Death Notification Registration Records E-learning Module (interactive tutorial) Access the DonorNet online help. Click **E-learning Modules**. Click **Death Notification Registration Import-Export**. (https://portal.unos.org/DonorNet/help/donornet/DNR_Import-Export.htm)	7.0
Completing PTR E-learning Module (interactive tutorial) Access the DonorNet online help. Click **E-learning Modules**. Click **Completing PTR and Closing the Match**. (https://portal.unos.org/DonorNet/help/donornet/Complete_PTR_Close_Match.htm)	7.6
Data Submission Requirements http://optn.transplant.hrsa.gov/PoliciesandBylaws2/policies/pdfs/policy_23.pdf	7.6
2009 OPTN/UNOS Computer Registration Fees Memo http://optn.transplant.hrsa.gov/SharedContentDocuments/2009_OPTN_and_UNOS_Fee_Letter.pdf	11.0
Resources on Living Donation http://www.unos.org/living_donation.asp	12.0
2013 Webinar: New Living Kidney Donor Program Requirements: Standardizing Patient Care http://italy.vs.odu.edu/webinars/United_Network_for_Organ_Sharing/	12.2 12.3.3 12.3.4 12.4

Resource Materials	Policy / Bylaw Reference
	12.4.1 12.10
OPTN presentation outlining TIEDI system changes for ABO verification of living donors https://www117.livemeeting.com/cc/unos/view?id=WWZ5H9	12.3 12.8.1
Standardized organ shipping container labels http://store.unos.org/category.php?category=CAT1019 or by navigating to the UNOS website (www.UNOS.org) and selecting *Patient and professional resources*	12.7
Training on organ packaging and labeling http://dl.odu.edu/video/protected/unos-web-conference Log on with: user: webconference (all one word); password: UNOS2011 (use capital letters). The webcast is listed under "Events."	12.7 12.7.4
Guidance for Developing and Implementing Procedures to Collect Post-Donation Follow-up Data from Living Donors http://optn.transplant.hrsa.gov/ContentDocuments/Guidance_Post_Donation_Donor_Follow-Up.pdf	12.8.3.1
KPD Operational Guidelines http://transplantpro.org/wp-content/uploads/KPDPP_Operational_Guidelines.pdf	13.2.2 13.8 13.9
Chart 4 – Policy enforcement options http://optn.transplant.hrsa.gov/SharedContentDocuments/Chart_4_EvaluationPlanChartA-2a.pdf	N/A
Chart 5 – Policy enforcement options (2) http://optn.transplant.hrsa.gov/SharedContentDocuments/Chart_5_EvaluationPlanChartA-2b.pdf	N/A
Chart 6 – Time periods for hearings, interviews, appellate reviews http://optn.transplant.hrsa.gov/SharedContentDocuments/Chart_6_EvaluationPlanTimePeriodChart.pdf	N/A
Chart 7 - Reimbursement by OPTN/UNOS Members for Non-routine Member Reviews http://optn.transplant.hrsa.gov/SharedContentDocuments/EvaluationPlan_Chart7.pdf	Bylaws

When Members Must Notify UNOS

Frequently Used Numbers

UNOS Main Number	(804) 782-4800 (phone)
Organ Center	(800) 292-9537 (phone)
Allocation Analysis	(804) 782-4660 (fax)
Member Services	(804) 782-4813 (phone)

All Members					
When this happens:	**The member must provide:**	**Within this time period:**	**In this manner:**	**Addressed to:**	**Required by:**
OPTN membership is approved *or* Any time the representative changes	The name and address of representatives to whom all notices may be sent on the New members: *OPTN/UNOS Representatives Form* Changes: *OPTN/UNOS Representatives Change Form* These forms can be obtained from your regional application related contact	Immediately[1]	Email Fax	Membership Department, Attention: Analyst PO Box 2484 Richmond, VA 23218	Bylaws 1.1(A) 1.2(A) 1.3(A) 1.4(A) 1.5(A) 1.6(A) 1.7(A) 1.8(A)

[1] Recommended time frame

Histocompatibility Laboratory Members					
When this happens:	**The member must provide:**	**Within this time period:**	**In this manner:**	**Addressed to:**	**Required by:**
Lab learns that the designated Director, Technical Supervisor, or Clinical Consultant plans to leave	The replacement's: • Name • CV • Any other membership criteria such as coverage plans for labs that do not have full time on site directors	Immediately, and at least 30 days prior to the departure	Mail Email Fax	Membership Department, Attention: Administrator PO Box 2484 Richmond, VA 23218	Bylaws C.4
Lab receives notice of a final adverse action taken by a regulatory agency or regulatory agency's designee.	Written Notification Final determination of the agency Any documents relating to the final adverse action	10 business days of receipt	Mail	Membership Department, PO Box 2484 Richmond, VA 23218	Bylaws C.5.D

OPO Members					
When this happens:	**The member must provide:**	**Within this time period:**	**In this manner:**	**Addressed to:**	**Required by:**
OPO wants to export an organ	*Organ Export Form,* including verification that there is no suitable recipient for the organ on the waiting list This form can be obtained from the Organ Center	Prior to exportation	Fax and Add to donor attachments in UNet[SM]	Organ Center Ph: (800) 292-9537 Fax: (804) 697-4372	Policy 3.2.1.4
Pre-procurement tissue typing is not initiated	Written explanation of the reasons	10 business days[1]	Email Fax	Allocation Analysts Fax: (804) 782-4660	Policy 3.5.3.2
OPO has changes to current Patient Safety Contact information	Primary and secondary contact information, including phone and email for each.	Immediately[1]	Email	patientsafetycontact@unos.org	Policy 4.4
OPO learns of new or updated donor information relevant to acute recipient care that could result in donor-derived transmission	Notification, including all available details and supporting documentation (final lab results, imaging studies, autopsy report, etc)	24 hours[1]	*Improving Patient Safety* Portal in UNet[SM]	Potential Disease Transmission	Policy 4.5

OPO Members					
When this happens:	**The member must provide:**	**Within this time period:**	**In this manner:**	**Addressed to:**	**Required by:**
OPO is contacted by a foreign source with an organ offer (and has an approved import agreement)	Notification	72 hours	Call Email	Organ Center Ph: (800) 292-9537 Email: theorgancenter@unos.org	Policy 6.4.1.1
OPO is contacted by a foreign source with an organ offer (and does not have an approved import agreement)	Documentation certifying: • The donor met brain death or (DCD) protocols in compliance with recognized US standards • Authorization from the donor or his or her legal representative • Donor ABO verification	Immediately	Call	Organ Center Ph: (800) 292-9537	Policy 6.4.2
Notification from a hospital or identification through a death record review of: • Imminent neurological deaths • Eligible deaths • Authorization not recovered deaths	Total number of deaths and patient level data	30 days from the end of the month that the death was reported or identified	Complete *Death Notification Registration* form in DonorNet[SM]	N/A	Policy 7.7

OPO Members					
When this happens:	**The member must provide:**	**Within this time period:**	**In this manner:**	**Addressed to:**	**Required by:**
OPO receives notice of a final adverse action taken by a regulatory agency or regulatory agency's designee	Written Notification Final determination of the agency Any documents relating to the final adverse action	10 days	Mail	Membership Department, PO Box 2484, Richmond, VA 23218	Bylaws B.1
OPO learns that one or both of the Executive/Medical Director(s) plan(s) to leave	The replacement's: • Name • Documentation of credentials • Current CV Effective date of the change	Immediately, and at least 30 days prior to the departure (if possible)	Mail Email Fax	Membership Department, Attention: Administrator PO Box 2484, Richmond, VA 23218	Bylaws B.4(D)

Transplant Hospital Members					
When this happens:	**The member must provide:**	**Within this time period:**	**In this manner:**	**Addressed to:**	**Required by:**
Organ Center facilitates a candidate's listing or modification due to computer and/or Internet failure	A detailed explanation of the event		Fax	Organ Center Ph: (800) 292-9537 Fax: (804) 697-4372	Policy 3.1.4.1
Candidate receives transplant or dies	Notification	24 hours	Remove candidate from *Waitlist*SM in UNetSM	N/A	Policies 3.2.4.1 3.6.6 3.7.13 3.8.7 3.11.5
Recipient centers has changes to current Patient Safety Contact information	Primary and secondary contact information, including phone and email for each.	Immediately[1]	Email	patientsafetycontact@unos.org	Policy 4.4
Recipient suspected to have, confirmed positive for, or died from, a transmissible disease that is suspected to be of donor origin	Details available regarding potential transmission event and any supporting documentation currently available (lab results, imaging studies, autopsy report, etc)	24 hours	*Improving Patient Safety* Portal in UNetSM	Potential Disease Transmission	Policy 4.5
Extra vessels are shared with the transplant hospital	Detailed explanation of reason for sharing	10 days[1]	Email Fax	Allocation Analysts Fax: (804) 782-4660	Policy 5.10.1

Transplant Hospital Members					
When this happens:	**The member must provide:**	**Within this time period:**	**In this manner:**	**Addressed to:**	**Required by:**
Extra vessels are used or destroyed	*Vessel Transplantation/ Destruction Form*	At least monthly[1]	Email Fax	Research Department/Data Quality Fax: (804) 782-4809. Email: dataquality@unos.org	Policy 5.10.1
Hospital is contacted by a foreign source with an organ offer (and does not have an approved import agreement)	Documentation certifying: • The donor met brain death or (DCD) protocols in compliance with recognized US standards • Authorization from the donor or his or her legal representative • Donor ABO verification	Immediately	Call	Organ Center Ph: (800) 292-9537	Policy 6.4.2
Hospital becomes aware of a living donor death or living donor organ failure within 2 years after donation	Notification, including all available details	72 hours	*Improving Patient Safety* Portal in UNet[SM]	Living Donor Adverse Event	Policy 12.8.4
Living donor organ is recovered, but not transplanted into the intended recipient	Notification, including all available details	72 hours (of recovery)	*Improving Patient Safety* Portal in UNet[SM]	Living Donor Adverse Event	Policy 12.8.5

Transplant Hospital Members					
When this happens:	**The member must provide:**	**Within this time period:**	**In this manner:**	**Addressed to:**	**Required by:**
Hospital receives notice of a final adverse action taken by a regulatory agency or regulatory agency's designee	Written Notification Final determination of the agency Any documents relating to the final adverse action	10 days	Mail	Membership Department, Post Office Box 2484 Richmond, VA 23218	Bylaws D.1
Hospital learns that the designated primary transplant surgeon or primary transplant physician plans to leave or is not substantively able to participate in the program for 15 or more consecutive days	Written Notice and *Key Personnel Change Application*, including documentation that the new surgeon or physician meets the Bylaws requirements This form can be obtained from your regional application related contact	Written notice: 7 business days Key Personnel Change Application: At least 30 days before the surgeon or physician's departure. If that's not possible, then 30 days from receipt of the Key Personnel Change Application	Email Fax	Your regional application related contact	Bylaws D.6

Transplant Hospital Members					
When this happens:	**The member must provide:**	**Within this time period:**	**In this manner:**	**Addressed to:**	**Required by:**
Hospital cannot serve patients for 15 or more consecutive days	Letter to the OPTN Executive Director, including: • Intent to voluntarily inactivate • Effective date • Reasons for change in program status • Steps that have been or will be taken to notify candidates on the waiting list	Immediately	Mail	OPTN Executive Director, Membership Department, Post Office Box 2484 Richmond, VA 23218	Bylaws K.3.A
Hospital wishes to voluntarily give up its Designated Transplant Program status temporarily (up to 12 months), or permanently	Letter to the OPTN Executive Director, including: • Intent to withdraw Designated Transplant Status • Effective date • Reasons for the withdrawal	30 days	Mail	OPTN Executive Director, Membership Department, Post Office Box 2484 Richmond, VA 23218	Bylaws K.4.A

Change Log

The table below lists updates to the Evaluation Plan by publication date.

Document Reference and Description of Key Updates	Page Number	Addition, Change, Clarification or Deletion	Evaluation Plan Publication Date
Throughout - updated links	Throughout	Clarification	2/1/2013
Policy 3.2.11: Add back in guidance on notification letters that had previously been in bylaws	52	Addition	2/1/2013
Policies 4.5, 4.5.1 & 4.5.2: Require reporting of unexpected potential or proven disease transmission involving living organ donors	229-232	Addition	2/1/2013
Policy 5.4.2 & 12.7.4: Require documentation of any unique identifier used	243, 302	Addition	2/1/2013
Policies 7.2 & 12.8.3.1: Add specific requirements for living donor follow-Up	265, 315	Addition	2/1/2013
Policy 12.2, 12.2.1, 12.4 & 12.4.1: Add specific requirements for the informed consent of living kidney donors	280-282, 290-291	Addition	2/1/2013
Policies 12.3.3 & 12.3.4: Add specific requirements for the medical and psychosocial evaluations of living kidney donors	286-287	Addition	2/1/2013
Policy 12.7.10: Specify that consent is only required for vessel recovery from living donors when vessels are actually recovered	308	Change	2/1/2013
Policy 12.10: Specify that recovery hospitals must have internal living donor protocols	320	Addition	2/1/2013
Policies 13.2.2, 13.8 & 13.9:Add kidney paired donation requirements	321-323	Addition	2/1/2013
Bylaws and Policies 7.1.5 & 12.8.3: Bylaws rewritten	324-342; 262; 313	Change	9/1/2012
Policies 6.0 and 3.2.1.4: Changes to citizenship definitions and elimination	253-257; 44	Change	9/1/2012

of 5% review threshold			
Policies 5.1.3 & 5.3: Added requirement that profusion machines be labeled with OPTN label	238; 240	Change	9/1/2012
Bylaws and Policies 2.1; 2.2.3.2-2.2.3.5; 2.4; 3.3; 3.5; 5.5; 5.10; 7.0; & 7.7: Change "consent" to "authorization"	10; 16; 2.4;60; 244; 249; 259; 275; 324-342	Change	9/1/2012
Polices 3.1.7-3.1.12		Deletion	9/1/2012
Policy 11.0: Updated registration letter and bylaws reference	11.0	Change	9/1/2012
Policies 3.2.4.1; 3.6.6; 3.7.13; 3.8.7: Clarification of monitoring for removal from the waitlist within 24 hours of transplant or death	49; 146; 188; 205	Change	9/1/2012
Policy 3.5.6.1: Change cross-reference	78	Change	9/1/2012
Policies 3.7.3 & 3.7.4: Added requirement to downgrade a heart candidate when they no longer qualify for Status 1A and added clarifying language regarding 1A VAD time	159; 161	Addition	9/1/2012
Policy 5.2: Clarification of monitoring of watertight packaging bags	239	Change	9/1/2012
Policy 5.6: Updated link to packaging verification form	245	Addition	9/1/2012
Policy 5.10: Add guidance on reporting discarded vessels	249	Addition	9/1/2012
Notification table: Updated	349	Change	9/1/2012
Added OPO performance metrics	Bylaws-6	Addition	5/23/2012
Removed outdated system notice link	3.2-1	Deletion	5/23/2012
Removed requirement that first living donor time out occur after organ	12.0-17	Deletion	5/23/2012

recovery			
Required update of certain clinical factors every 14 days for lung transplant candidates with LAS's of at least 50	3.7-12	Change	2/29/2012
Changed expiration date for interim TAH policy	3.7-5	Change	2/29/2012
Changed liver-intestine transplant allocation			2/29/2012
Added AAS for segmental liver allocation	3.6-47	Addition	2/29/2012
Eliminated requirement that pediatric liver candidates must be located in a hospital's ICU to qualify as Status 1A or Status 1B	3.6-13	Change	2/29/2012
Modified to allow non-metastatic hepatoblastoma pediatric liver candidates to be listed as Status 1B	3.6-14	Change	2/29/2012
Modified policies for verifying, packaging, labeling, and shipping living donor organs and vessels	3.1-3 3.2-3 12.0-5 through 12.0-19	Addition	2/29/2012
Added a requirement for a second ABO subtyping test when a donor is identified as non-A1 or non-A1B	3.1-2 5.0-5 5.0-7 5.0-10 5.0-12 5.0-13 5.0-16 12.0-1 12.0-19 12.0-20	Change	2/29/2012
Prohibited storage of hepatitis C antibody positive and hepatitis B surface antigen positive extra vessels	5.0-15	Change	2/29/2012
Standardized label requirements for vessel transport and storage	5.0-2 5.0-15 5.0-16	Change	2/29/2012
Addition of links to Membership Applications	V-6	Addition	12/31/2011
Addition of guidance on Costs and	Bylaws-4	Addition	12/31/2011

Reimbursements			
Clarification of ABO documentation requirements	3.1-2	Clarification	12/31/2011
Deletion of reserved Policy 3.5.10	n/a	Deletion	12/31/2011
Changed expiration date for interim TAH policy	3.7-5	Change	12/31/2011
Addition of Chart 7- Reimbursement by OPTN/UNOS Members for Non-routine Member Reviews	XI-1	Addition	12/31/2011
Dissolution of Organ Availability Committee	VI-10	Deletion	09/30/2011
Responsibility for elements of living donation process/reporting requirements	Bylaws-21	Addition	09/30/2011
Addition of deceased donor HIV screening requirements	2.0-7, 8	Addition	09/30/2011
Adult Status 1 Changes	3.7-4	Addition	09/30/2011
Pediatric Incompatible ABO Blood Type Heart Candidates	3.7-18,19,20	Addition	09/30/2011
Deletion of Policy 3.7.13-Status 1 Listing Verification	n/a	Deletion	09/30/2011
Verification of extra vessel compatibility with recipient prior to transplant	5.0-15	Addition	09/30/2011
Responsibility for elements of living donation process/reporting requirements	7.0-1	Addition	09/30/2011
Responsibility for elements of living donation process/reporting requirements	12.0-4	Addition	09/30/2011
Clarified information on source documents necessary for required tests on potential deceased donors	2.0-10	Clarification	06/30/2011
Added information and link related to new requirements for ABO verification of living donors	12.0-1 12.0-5	Addition	06/30/2011

Added link for 2010-2011 Committee Goals	VI-11	Change	03/31/2011
Clarification of transplant center requirements to remove a multiple-listed candidate who received transplant at another center	Bylaws-16	Clarification	03/31/2011
Modifications related to disease transmission policies	2.0-3-11 2.0-16-17	Change	03/31/2011
Modifications related to reporting of potential disease transmissions	4.0-1-9	Change	03/31/2011
Removal of living donor policies-3.3.7, 7.3.2, 7.3.3-relocated to Policy 12.	n/a	Deletion	03/31/2011
Modifications related to packaging and labeling of vessels, repackaging of organs; added link to Live Meeting training	5.0-1 5.0-10	Change	03/31/2011
Added detailed information regarding the donor documentation that must accompany an organ	5.0-11	Addition	03/31/2011
Clarification of vessel disposition by the 14th day	5.0-17	Clarification	03/31/2011
Added information on placement of non-directed living donor kidneys	12.0-2	Addition	03/31/2011
Added all types of transport containers allowed for external transport of living donor organs	12.0-5	Clarification	03/31/2011
Added guidance information related to submission of Living Donor Death and Organ Failure Data	12.0-9	Clarification	03/31/2011
Updated information on UNet℠ reporting requirements for non-utilized or re-directed living donor organs	12.0-10, 12.0-11	Clarification	03/31/2011
Replacement of references to “Data Subcommittee” or “DSC” with or “PAIS”	Bylaws-5,6,7	Change	12/31/2010
Time of Waiting	3.5-28	Clarification	12/31/2010

Adult Candidate Status	3.7-4	Clarification	12/31/2010
Vessels	5.0-9	Clarification	12/31/2010
Medical Evaluation of Living Donors-ABO Identification	12.0-1	Clarification	12/31/2010
Patient Notification	Bylaws-15	Change	09/30/10
Kidney Transplant Programs that Perform Living Donor Kidney Transplants—Protocols	Bylaws-21	Change	09/30/10
Performing Pertinent Tests on all Potential Donors	2.0-5	Change	09/30/10
Time of Waiting	3.5-28	Change	09/30/10
(Lung) Candidates Age 0-11	3.7-11	Change	09/30/10
Sequence of Pediatric Donor Lung Allocation	3.7-26	Change	09/30/10
Living Donor Policies	344	Addition	09/30/10
Patient Notification	Bylaws-15	Change	06/30/10
Evaluation of Potential Donors	2.0-2	Change	06/30/10
Transplant Center	3.1-2	Change	06/30/10
Waiting List	3.1-4	Change	06/30/10
Waiting Time Transferal and Multiple Listing	3.2-2	Change	06/30/10
Match System Access	3.2-3	Change	06/30/10
Adult Candidate Statues	3.6-8	Change	06/30/10
Data Submission Requirements	7.0	Change	06/30/10
Standardized Packaging and Transporting of Organs, Vessels and Tissue Typing Materials	5.0-1	Change	03/31/10
Submitting Standardized MELD/PELD Exception Scores	3.6-23	Change	03/31010

National Lung Allocation (LAS) Score Percentiles for the month of December 2009 and Primary Pulmonary Hypertension Guidelines	3.7-15	Change	03/31/10
Data Subcommittee (DSC) changes name to Performance Analysis and Improvement Subcommittee (PAIS)	III-3-4, IV-3	Change	12/31/09
Calculated Panel Reactive Antibody (CPRA) Listing Requirement	3.5-4. 3.5-7, 3.5-8. 3.5-31. 3.5-33, 3.5-36	Change	12/31/09
Stand-Alone Kidney Program Audits to Begin	VI-4	Add	12/31/09
Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership	Bylaws-4	Change	12/31/09
Key Personnel	Bylaws-11-14	Change	12/31/09
Adult Candidate Status - *clarification*	3.6-9	Change	12/31/09
Liver Candidates with Exceptional Cases - *clarification*	3.6-19	Change	12/31/09
Communication of Donor History - *clarification*	4.0-3	Change	12/31/09
Functional Inactivity	Bylaws 5-6	Change	09/30/09
Inactive Transplant Program Status, Relinquishment or Termination of Designated Transplant Program Status	Bylaws 7-9	Change	09/30/09
Evaluation Plan Overview • Updated to highlight significant changes in current publication	Overview-1	Change	06/30/09
Patient Notification Bylaw • Modification to require the use of the UNOS Patient Information Letter as part of patient notification	Bylaws 7-8	Change	06/30/09

requirements			
Policy 2.1 Host OPO • Removed requirement for Host OPO to verify pronouncement of death • New responsibility to make reasonable attempts to obtain medical/behavioral history on the donor	2.0-1	Change	06/30/09
Policy 2.2 Evaluation of Potential Donors • Entire section re-numbered • New responsibilities regarding documentation and evaluations • Modifications to tests required for all donors, renal donors, liver donors, heart donors, pancreas donors, and lung donors	2.0-2 through 2.0-5	Change	06/30/09
Policy 2.3 Donor Maintenance • Clarification that the Host OPO must make reasonable efforts to maintain the deceased donor, document these efforts, and communicate this information to the OPO or transplant center	2.0-6	Change	06/30/09
Policy 2.5 Organ Procurement Quality • Certain subsections are renumbered and reorganized • Modification that minimum standards of quality include documentation of all items in policy section 2.2 • New requirements regarding record keeping of flush solutions and additives and donor medications administered (new number 2.5.3) • New requirement for OPOs and	2.0-8 through 2.0-11	Change	06/30/09

histocompatibility labs to define and document minimum tissue typing material requirements (new number 2.5.4) • Updates to list of documentation required to accompany each organ (new number 2.5.6) • Moves language about donor medications and flush solutions from 2.5.7 to 2.5.3 (new numbers)			
Policy 2.6 Initiating Organ Procurement and Placement • Removes statement that tissue typing is initiated only after the consent of either the donor by previous designation or the next of kin	2.0-12	Change	06/30/09
2.7.1 Multiple Abdominal Organ Procurement • Modifications to state that all authorized organs should be procured from a donor and OPOs are required to document the specific reason for non-recovery. Cooperation among all organ recovery teams is required.	2.0-14	Change	06/30/09
2.8 Organ Recovery from a DCD Donor • Sets standards for organ recovery from a DCD donor	2.0-15	Add section 2.8	06/30/09
2.9 Multi-Cultural and Diversity Issues • Renumbered (was section 2.8)	2.0-16	Numbering change	06/30/09
3.1.13 Definition of Directed Donation • Added new policy regarding allocation of an organ(s) to a specific transplant candidate named by the person who authorized the donation, unless prohibited by state	3.1-13	Add section 3.1.13	06/30/09

law			
3.2.4 Match System Access • Modification that transplant centers are to maintain documentation when transplanting a candidate who does not appear on the match run	3.2-3 and 3.2-4	Change	06/30/09
3.8.1 Pancreas Organ Allocation • Added new subsection 3.8.1.1, Local Whole Pancreas Allocation and renumbered other subsections	3.8-3	Add section 3.8.1.1	06/30/09
3.8.1.6 Islet Allocation Protocol • Modifications to define medical suitability of an islet preparation, devine active and inactive candidate status, and establish a protocol for updating candidate status and removal from the waiting list • Renumbering of policy sections	3.8-6 through 3.8-8	Change	06/30/09
3.8.5 through 3.8.9 – policy sections renumbered	3.8-11 through 3.8-15	Change	06/30/09
Policy 5.7 Vessel Recovery, Storage and Transplant • Updated link to revised Vessels Transplantation/Destruction Information Sheet	5.0-9	Change	06/30/09
Evaluation Plan Overview • Updated to highlight significant changes in current publication	Overview-1	Change	03/31/09
Patient Notification, Appendix B to OPTN Bylaws, section II.F • Language modification to clarify patient notification requirements	Bylaws-7	Change	03/31/09
Transplant Surgeon and Physician, Program Coverage Plan, Attachment I to	Bylaws-8	Change	03/31/09

Appendix B of OPTN Bylaws, section VII • Clarification to explain when candidates are to receive a written summary of the program coverage plan			
Policy 3.1.2, Transplant Center • Clarification to explain requirements to verify donor ABO, recipient ABO, and UNOS donor ID after receipt of an organ and prior to its implantation	3.1-2	Change	03/31/09
Policy 3.1.4, Waiting List • Clarification to highlight definition of ABO typing on "two separate occasions"	3.1-3	Change	03/31/09
Policy 3.2.3, Waiting Time Transferal and Multiple Listing • Clarification to explain that certain written materials are to be provided to the candidate during the evaluation process	3.2-2	Change	03/31/09
Policy 3.5.11.3, Panel Reactive Antibody • Clarification to explain at least one unacceptable HLA antigen must be entered into UNet^{SM} for sensitized candidates to receive additional points	3.5-31	Change	03/31/09
Policy 3.7.4, Pediatric Candidate Status • Clarification to point out that OPTN policy does not require pediatric heart candidates to be admitted to the listing transplant center to be listed as status 1A	3.7-6	Change	03/31/09
Policy 3.7.6.3.2, Updating Candidate Variables • Clarification to explain how to enter information about diabetes into the	3.7-14	Change	03/31/09

LAS calculator			
Policy 3.7.17, Crossmatching for Thoracic Organs	3/7-34	Change	03/31/09
Policy 5.5, Standard Organ Package Specifications • Clarification from the OPO Committee that 6-piece insulation panels serving as the inner liner of a shipping box may be considered a container	5.0-7	Change	03/31/09
Policy 5.7, Vessel Recovery, Storage, and Transplant • Members are to submit Vessel Transplantation/Destruction Information Sheet to UNOS Research Department/Data Quality rather than Department of Information Management Services	5.0-9	Change	03/31/09
Section XII, Member Requirements for OPTN Notifications, OPTN Bylaws, Appendix B, Section III, General • Clarification that Histocompatibility Labs need to send written notice regarding adverse actions to the UNOS Membership Department	Notifications Document-3	Change	03/31/09
Section XII, Member Requirements for OPTN Notifications, OPTN Bylaws, Appendix B, Section I, General • Clarification that OPOs need to send written notice regarding adverse actions to the UNOS Membership Department	Notifications Document-6	Change	03/31/09
Section XII, Member Requirements for OPTN Notifications, OPTN Bylaws, Appendix B, Section I, General • Members are to submit Vessel Transplantation/Destruction Information Sheet to UNOS	Notifications Document-8	Change	03/31/09

Research Department/Data Quality rather than Department of Information Management Services			
Section XII, Member Requirements for OPTN Notifications, OPTN Bylaws, Appendix B, Section II.A, General • Clarification that Transplant Centers need to send written notice regarding adverse actions to the UNOS Membership Department	Notifications Document-9	Change	03/31/09
Evaluation Plan Overview • Updated to highlight significant changes in current publication	Overview-1	Change	12/31/08
VI. OPTN/UNOS Committee Statements on Organ Allocation Policy Goals	VI-11	Change	12/31/08
Policy 3.3.7, Acceptance and Transplant of Living Donor Organs • New section to describe requirement for accepting/transplanting living donor organs	3.3-7	Add	12/31/08
Policy 3.7.6, Lung Candidates • Included guidance on entering PCO_2 and CVP values	3.7-9 through 3.7-10	Change	12/31/08
Policy 3.7.6.3, Lung Candidate Variables in UNet^{SM} • Updated description of purpose	3.7-12	Change	12/31/08
Policy 3.7.6.4, Lung Candidates with Exceptional Cases • Updated guidance to explain candidates with an approved exception score will appear on lung matches according to the approved exception score	3.7-15	Change	12/31/08
Policy 7.1.3, Data Submission on	7.0-2	Change	12/31/08

Recipient Follow-up • Updated requirements to reflect recently implemented policy change			
Policy 7.8.1, Data Submission • Included instructions on how to access new Compliance Report	7.0-18	Change	12/31/08
Section XII, Resource Materials • Updated link to Committee Goals	XII-1	Change	12/31/08
Evaluation Plan Overview • Updated to highlight significant changes in current publication	Overview-1	Change	09/30/08
OPTN Bylaws Appendix A, 3.01A, 5.05A, 5.07A • New section to describe restoration of Membership privileges	Bylaws-3	Add	09/30/08
UNOS Bylaws Appendix B, Attachment I, Section XIII, D.(2) • Included new requirement of living donor kidney programs	Bylaws-10	Change	09/30/08
UNOS Bylaws Appendix B, Attachment I, Section XIII, D.(4) • Included new requirement of living donor liver programs	Bylaws-11	Change	09/30/08
UNOS Bylaws, Appendix B, Attachment I, Section XIII, D. (4), c. • New section to describe requirements of living donor liver programs granted conditional approval	Bylaws-13	Add	09/30/08
Policy 2.2.8, Performing Pertinent Tests for All Donors • Updated to reflect policy change	2.0-5	Change	09/30/08

regarding donor screening tests			
Policy 3.1.4, Waiting List • Updated instructions on adding and verifying a candidate's ABO in Waitlist[SM]	3.1-4	Change	09/30/08
Policy 3.2.1.2, Permissible Access to UNet[SM] • New section to provide instructions for Institutional Members giving third parties access to UNet[SM]	3.2-1	Add	09/30/08
Policy 3.2.4, Match System Access • Updated instructions on how to find reason candidate does not appear on the match run	3.2-4	Change	09/30/08
Policy 3.5.3, Mandatory Sharing of Zero Antigen Mismatched Kidneys • Updated to provide reference to detailed requirements in Policy 3.5.3.5	3.5-4	Change	09/30/08
Policy 3.5.3.3.1, Zero Antigen Mismatched Kidney Allocation Sequence • Updated to reflect policy change allowing OPOs to place zero antigen mismatched kidneys without contacting Organ Center	3.5-8	Change	09/30/08
Policy 3.5.3.3.2, Zero Antigen Mismatched Kidney Allocation Sequence • Included policy reference on page 3.5-8 and deleted duplicate information	3.5-9	Delete	09/30/08
Policy 3.5.3.4, Kidney/Non-Renal	3.5-9	Change	09/30/08

Exception • Updated to provide reference to detailed requirements in Policy 3.5.3.5			
Policy 3.5.3.5, Organ Offer Limit • Updated to reflect policy change from number of hours to number of offers and payback accounting procedural changes	3.5-10	Change	09/30/08
Policy 3.5.4.1, Mandatory Sharing • Updated to provide reference to detailed requirements in Policy 3.5.3.5 and Policy 3.8.1.6.1	3.5-12	Change	09/30/08
Policy 3.6.4, Degree of Medical Urgency • Updated to give instructions about rounding laboratory values when performing data entry	3.6-7	Change	09/30/08
Policy 3.6.4.1, Adult Candidate Status • Updated to reflect policy clarification regarding CVVHD and the MELD score calculation	3.6-9	Change	09/30/08
Policy 3.6.4.8, Combined Liver-Intestine Allocation • Added to correspond with newly added policy language intended to clarify existing requirements	3.6-24	Add	09/30/08
Policy 3.7.3, Adult Candidate Status • Added clarification about entering inotrope dosages and documentation requirements	3.7-4	Change	09/30/08
Policy 3.7.4, Pediatric Candidate Status • Added clarification about entering inotrope dosages and	3.7-5	Change	09/30/08

documentation requirements			
Policy 3.8.1.6.1 Organ Offer Limit • Updated to reflect policy change from number of hours to number of offers and payback accounting procedural changes	3.8-8	Change	09/30/08
Policy 3.8.7 Waiting Time Reinstatement for Pancreas Recipients • Updated to reflect policy and procedural changes regarding waiting time reinstatement	3.8-14	Change	09/30/08
Policy 3.9.3, Organ Allocation to Multiple Organ Transplant Candidates • Added link to Kidney Payback Sheet and included policy references for heart-lung and liver-intestine allocation	3.9-4	Change	09/30/08
Policy 3.11, Intestinal Organ Allocation • Updated to include clarification regarding combined intestine-liver allocation, and updated description of monitoring efforts	3.11-3, 3.11-5, 3.11-6	Change	09/30/08
Policy 4.1.1, Communication of Donor History • Updated to include reference to guidelines document and additional information about informed consent	4.0-3 through 4.0-4	Change	09/30/08
Policy 4.6, Screening Potential Organ Donors • Updated to reflect policy change regarding donor screening tests	4.0-15	Change	09/30/08
Policy 5.2, Standard Labeling Specifications	5.0-4	Change	09/30/08

• Deleted links to labels not valid for use as of 9/30/08			
Policies 5.4 and 5.5.2, Organ Packaging • Updated to reflect policy change regarding red plastic biohazard bag	5.0-6, 5.0-7	Change	09/30/08
Policy 5.7, Vessel Recovery, Storage, and Transplant • Updated to include expectation that documentation is maintained	5.0-8	Change	09/30/08
Policy 11.0, Registration Fee • Updated to include latest Candidate Registration and UNOS Computer Registration Fees	11-1	Change	09/30/08
Section XII, Resource Materials • Updated to reflect additional resources linked to Evaluation Plan	XII-1 through XII-3	Change	09/30/08
Section XII, Resource Materials • New section – Member Requirements for OPTN Notifications	Pages 1-11	Add	09/30/08
Evaluation Plan Overview • Updated to highlight significant changes in current publication	Overview-1	Change	06/30/08
Section III. Interested and Affected Entities • Updated description of MPSC	III-3 through III-5	Change	06/30/08
Bylaws Document • Reformatted document to include description and table of contents	Bylaws-1 through Bylaws-10	Change	06/30/08
OPTN Bylaws Appendix B, II.B, Survival Rates	Bylaws-3	Add	06/30/08

• New section to describe OPTN/UNOS review of transplant outcomes and associated expectations of transplant centers			
OPTN Bylaws Appendix B, II.C, and OPTN Bylaws Appendix B, Attachment I, Section II., Inactive Status • New section to describe OPTN/UNOS review inactive program status and associated expectations of transplant centers	Bylaws-4 through Bylaws-5	Add	06/30/08
OPTN Bylaws Appendix B, II.F, Patient Notification • Additional clarification regarding Patient Notification requirements	Bylaws-6	Change	06/30/08
UNOS Bylaws Appendix B, Attachment I, Section XIII, D.(2), Living Donor Kidney Transplant Programs • New link to resource document	Bylaws-9	Change	06/30/08
UNOS Bylaws Appendix B, Attachment I, Section XIII, D.(4), Living Donor Liver Transplant Programs • New link to resource document	Bylaws-10	Change	06/30/08
Policy number 3.1.2 • Additional clarification regarding transplant center responsibilities	3.1-2	Change	06/30/08
Policy number 3.2.4.1, Removal of Kidney Transplant Candidates from Kidney Waiting Lists when Transplanted or Deceased • New description of how UNOS will monitor compliance • New detailed guidance section	3.2-4	Change	06/30/08

Policy 3.5.11.3, Panel Reactive Antibody • Additional clarification about how to access the Live Meeting training module	3.5-33	Change	06/30/08
Policy number 3.5.11.6, Donation Status • New detailed guidance section about requesting donation status points for a kidney candidate who is a prior living donor	3.5-37	Change	06/30/08
Policy number 3.6.4, Degree of Medical Urgency • Updated link to resource material	3.6-9 through 3.6-10, 3.6-13	Change	06/30/08
Policy numbers 3.6.4.1and 3.6.4.2, Liver Candidate Status (Adult and Pediatric) • Additional information added to detailed guidance section	3.6-9, 3.6-13	Change	06/30/08
Policy number 3.7.6, Lung Allocation • Updated link to resource material	3.7-7, 3.7-10 through 3.7-12	Change	06/30/08
Policy number 3.7.14, Removal of Thoracic Organ Transplant Candidates from Thoracic Waiting Lists when Transplanted or Deceased • New description of how UNOS will monitor compliance • New detailed guidance section	3.7-28	Change	06/30/08
Policy number 3.8.6, Removal of Pancreas Transplant Candidates from Pancreas Waiting Lists when Transplanted or Deceased • New description of how UNOS will monitor compliance • New detailed guidance section	3.8-13	Change	06/30/08

Policy number 3.11.5, Removal of Intestinal Transplant Candidates from Intestine Waiting Lists when Transplanted or Deceased • New description of how UNOS will monitor compliance • New detailed guidance section	3.11-8	Change	06/30/08
Policy number 5.2, Standard Labeling Specifications • New shipping labels are required as of October 1, 2008	5.0-3 through 5.0-4	Change	06/30/08
Policy number 5.7, Vessel Recovery, Storage, and Transplant • New detailed guidance section • Link to Vessel Transplantation / Destruction Information Sheet	5.0-8 through 5.0-9	Change	06/30/08
Policy numbers 7.0, 7.6, and 7.7, Data Submission • Updated links to resource material	7.0-1, 7.0-12, and 7.0-17	Change	06/30/08
Section X. Communications • Updated description of electronic communication	X-1	Change	06/30/08
Section XII. Resource Materials • Reformatted document to cross-reference linked resources to Plan sections	XII-1 through XII-3	Change	06/30/08
Evaluation Plan Overview	Overview-1	Change	03/31/08
OPTN Bylaws, Appendix B, Attachment I, Section VII	Bylaws-1	Changes	03/31/08
OPTN Bylaws, Appendix B, Attachment III	Bylaws-5	Change	03/31/08

Policy number 2.2.8.1	2.0-5	Change	03/31/08
Policy number 2.5.5	2.0-9	Change	03/31/08
Policy number 2.7.1	2.0-14	Change	03/31/08
Policy number 3.1.4.2	3.1-3, 3.1-4	Change	03/31/08
Policy number 3.5.9	3.5-27	Change	03/31/08
Policy number 3.7.6	3.7-7	Change	03/31/08
Policy number 4.1.1	4.0-3, 4.0-4	Change	03/31/08
Policy number 5.2	5.0-4	Change	03/31/08
Policy number 5.4	5.0-6	Change	03/31/08
Policy number 7.0	7.0-1	Change	03/31/08
Policy number 7.1.5	7.0-3	Change	03/31/08
Policy number 7.1.7	7.0-5	Add	03/31/08
Policy number 7.3.2	7.0-8	Change	03/31/08
Policy number 7.3.3	7.0-9	Change	03/31/08
Policy number 7.7	7.0-17	Change	03/31/08
XII. Resource Materials	XII-2	Change	03/31/08
Consolidated PDF of entire Evaluation Plan	N/A	Add	03/31/08
Evaluation Plan Overview	Overview-1	Change	12/31/07
Policy number 2.2	2.0-2 through 2.0-4	Change	12/31/07
Policy number 3.1.4.2	3.1-3, 3.1-4	Change	12/31/07
Policy number 3.2.4	3.2-2, 3.2-3	Change	12/31/07

Policy numbers 3.5.3.5, 3.5.6.3, 3.5.11.1, 3.5.11.3	3.5-11, 3.5-12, 3.5-23, 3.5-30, 3.5-33,	Change	12/31/07
Policy numbers 3.6.4.1, 3.6.4.2, 3.6.4.2.1, 3.6.6, 3.6.11	3.6-8, 3.6-9, 3.6-12 through 3.6-14, 3.6-26, 3.6-32	Change	12/31/07
Policy number 5.7	5.0-8, 5.0-9	Add	12/31/07
Bylaws – Appendix B, Attachment I, Section XIII, D.(2)	Bylaws-2	Add	12/31/07
Bylaws, Appendix B, Attachment I, Section XIII, D.(4)	Bylaws-3	Add	12/31/07
Bylaw – Appendix B, Section II.F	Bylaws-4	Change	12/31/07
III. Interested and Affected Entities	III-1	Change	12/31/07
IV. Membership Criteria and Evaluation of Applications	IV-1, IV-6,	Change	12/31/07
V. Designated Transplant Program to Receive Organs for Transplantation	V-2, V-3	Change	12/31/07
VI. OPTN/UNOS Committee Statements on Organ Allocation Policy Goals	VI-11	Change	12/31/07
XII. Resource Materials	XII-1, XII-2	Change	12/31/07
Evaluation Plan Overview	Overview-1	Change	09/30/07
Policy number 3.1.2	3.1-2	Change	09/30/07
Policy number 3.3.6	3.3-6	Change	09/30/07
Policy numbers 5.0, 5.2, 5.3, 5.4, 5.5	5.0-1, 5.0-3 through 5.0-7	Change	09/30/07

Policy number 7.3.3	7.0-8	Add	09/30/07
Bylaw – Appendix A to OPTN Bylaws, Section 2.06A	Bylaws-4	Add	09/30/07
XII. Resource Materials	XII-1	Change	09/30/07
Evaluation Plan Overview	Overview-1	Add	06/30/07
VII. Measuring Compliance – Cover Page	VII-1	Change	06/30/07
Policy number 3.5.9	3.5-27	Change	06/30/07
Policy number 3.6.2.2	3.6-5	Change	06/30/07
Policy number 3.6.4.2	3.6-12	Change	06/30/07
Policy number 3.6.4.7	3.6-22	Change	06/30/07
Policy number 3.7.2	3.7-3	Change	06/30/07
Policy number 3.11.4.2	3.11-7	Add	06/30/07
Policy number 7.6	7.0-10	Change	06/30/07
Bylaw – Attachment I to Appendix B of OPTN Bylaws, section VII	Bylaws-1	Add	06/30/07
Bylaw – Appendix B to OPTN Bylaws, section II.F	Bylaws-2	Add	06/30/07
Bylaw – Attachment III to Appendix B of OPTN Bylaws	Bylaws-3	Add	06/30/07
XII. Resource Materials	XII-1	Change	06/30/07
XIII. Evaluation Plan Change Log	XIII-1	Add	06/30/07
Evaluation Plan	All	Revised plan	03/31/07

Background: The Final Rule and the OPTN Contract

The Department of Health and Human Services (HHS) published the Final Rule governing the operation of the Organ Procurement and Transplantation Network (OPTN) in April 1998. Further comment was invited regarding its provisions and the Rule's provisions took effect in March 2000. Many Members of the transplant community, both through that formal regulatory comment process and through the OPTN committee process, have expressed concern and interest in how to promote compliance with OPTN Policies, thereby ensuring to the greatest extent possible the equitable treatment of all candidates and increasing the public's confidence that the national system works in the best interest of the candidates awaiting transplant.

Several sections of the Final Rule address compliance issues. Section 121.10 of Title 42 of the Code of Federal Regulations requires the OPTN to review OPTN Membership applications and applications for transplant program "designated" status. The Rule specifies that the OPTN will design appropriate survey instruments, a peer review process, and data systems for those purposes. Upon the approval of the Secretary of Health and Human Services, the OPTN will distribute to each Member Organ Procurement Organization (OPO) and Transplant Center the review plans and procedures, and will also send future revisions after their review and approval by the Secretary. The OPTN, using those plans and procedures, is required to review and evaluate each Member OPO and transplant program for compliance with the Final Rule and OPTN Policies.

In addition, if the Secretary has reason to believe that Member OPOs or Transplant Centers are not in compliance with OPTN Policies, or may be acting in a manner that poses a risk to candidate health or safety, he or she may request that the OPTN conduct a special review. The special review would be in accordance with a schedule specified by the Secretary. The OPTN would make periodic reports regarding the progress of the special reviews.

Section 121.10 also has specific provisions regarding notice to the Secretary regarding activities of the OPTN and compliance. Section 121.10 (b)(4) requires that the OPTN notify the Secretary within three days of all OPTN/UNOS Committee and Board of Director meetings at which compliance with the Final Rule or OPTN Policies is discussed. In addition, Section 121.10 (c) requires the OPTN Board of Directors to advise the Secretary when the Board makes a determination, based upon the review and evaluation processes described above, of noncompliance with the Final Rule or OPTN Policies, or that a risk to candidate health or public safety exists. This section also requires that the OPTN recommend appropriate enforcement actions the Secretary might take in those circumstances.

The United Network for Organ Sharing (UNOS) serves as the OPTN. The Evaluation Plan describes in detail how UNOS acting as the OPTN will meet these requirements of the Final Rule. As the OPTN contractor, UNOS is also required to submit an evaluation plan pursuant to

its OPTN Contract Task 2 for the purpose of reviewing applications submitted for Membership in the OPTN; reviewing applications submitted to be designated a transplant program; and, conducting ongoing and periodic reviews and evaluations of each Member OPO, Histocompatibility Lab and Transplant Center for compliance with OPTN Policies and applicable federal law. This document is submitted in satisfaction of that requirement.