At-a-Glance

- **Proposal to Change Requirements for Labeling and Packaging Organs Procured by Visiting Transplant Center Teams and for OPO Labeling of Tissue Typing Materials**

- **Affected Policy: Policy 5.0 (Standardized Packaging, Labeling and Transporting of Organs, Vessels and Tissue Typing Materials)**

- **Organ Procurement Organization (OPO) Committee**

- The Committee is seeking comment on two proposed modifications to Policy 5.0. Current policy assigns responsibility for packaging and labeling of organs to the OPO. In certain situations, recovery teams may arrive from transplant centers to procure hearts and lungs. Due to the effects of prolonged cold ischemic time on these organs, these recovery teams sometimes forgo the labeling procedure, which leaves the OPO out of compliance with Policy 5.0. The proposed modification to Policy 5.0 transfers the responsibility of packaging and labeling of organs to the transplant center when its recovery team elects to recover organ(s) and transport the organ(s) directly to their transplant center for transplant. This should be done in collaboration with the OPO.

  Additionally, current policy requires that tissue-typing material containers be labeled with one unique identifier. The Joint Commission (JC) requirements for accreditation stipulate that tissue-typing material be labeled with *two* unique identifiers. This proposal seeks to realign OPTN policy with JC requirements by changing the requirement from one to two unique identifiers. This modification is anticipated to enhance patient safety while reducing the confusion that members face when attempting to comply with several requirements from different regulatory bodies.

- **Affected Groups.** OPO Executive Directors and Directors of Procurement, Transplant Center Administrators, Transplant Surgeons, Histocompatibility Laboratory Directors and staff, and all OPO and Transplant Center staff who are involved with the packaging, labeling and transporting of organs, vessels and tissue typing materials.

- **Specific Requests for Comment.** The Committee is seeking input on this proposed change that would require the recovery team, in collaboration with the OPO, to be responsible for packaging and labeling an organ when they elect to recover an organ(s) and transport it directly to their transplant center for transplant.

  - Do the proposed policy changes clarify and adequately define the OPO and transplant center staff responsibilities in packaging and labeling?
  - Are there any specific issues that might need to be considered when the recovery team is responsible for labeling and packaging the organ they procure?
  - Will requiring two unique identifiers for tissue-typing material containers pose any particular difficulties or have an impact on the way they are packaged?

Proposal to Change Requirements for Labeling and Packaging Organs Procured by Visiting Transplant Center Teams and for OPO Labeling of Tissue Typing Materials

Affected Policy: 5.0 (Standardized Packaging, Labeling and Transporting of Organs, Vessels and Tissue Typing Materials)

Organ Procurement Organization (OPO) Committee

Summary and Goals of the Proposal:

The proposed modification to Policy 5.0 transfers the responsibility of packaging and labeling of organs to the transplant center when the center elects to recover an organ(s) and transport the organ(s) to their transplant center. Labeling is completed in collaboration with the OPO. This proposal is in response to recent public comments for changes made to Policy 5.0 and related observations of the OPO Committee that suggest that some recovery teams (e.g. heart and lung recovery teams) may leave the operating room without the benefit of labeling the organs. Furthermore, some recovery teams do not provide the OPO with the opportunity to label the organs. The Committee has observed that current policy assigns this responsibility to the OPO but the OPO may not have any control over this situation. The goal of this proposal is to promote patient safety by clearly assigning responsibility of labeling and packaging to the transplant center when its recovery team elects to procure organs and transport the organ(s) directly to their transplant center for transplant.

Additionally, current policy requires only one identifier for tissue-typing material containers. This proposed modification requires OPOs to label tissue typing materials with two unique identifiers (e.g. donor initials, donor hospital ID, donor date of birth) in order to optimize a safe testing environment.

Background and Significance of the Proposal:

In February 2009, proposed modifications to Policy 5.0 were distributed for public comment. The goals of those changes were to:

- define terms
- promote safe and efficient packaging and labeling
- clearly list the requirements for the recovery, storage and use of vessels in solid organ transplant recipients, and
- clarify responsibility for packaging and labeling

In response to comments made during the February 2009 public comment period, the Committee is proposing several changes to Policy 5.0.

Currently, the Host OPO is responsible for packaging and labeling deceased donor organs. Recent comments received by the OPO Committee suggest that the recovery teams (especially heart and lung recovery teams) are more likely to leave the operating room (OR) without the benefit of labeling the organs. Furthermore, these recovery teams may not provide the OPO with the opportunity to perform these tasks. Members of the OPO Committee confirmed that these occurrences are common.

Since current policy assigns this responsibility to the OPO, the OPO is non-compliant with policy when the organs leave the OR without the appropriate labeling. The proposed modification to Policy 5.0

transfers the responsibility of packaging and labeling of organs to the transplant center when the transplant center elects to recover organ(s). The Committee members agree that packaging and labeling should be a collaborative effort between the recovery team and the OPO. This proposed policy change will place responsibility on the recovery teams. The intent of the proposed policy change is to improve patient safety by ensuring that all organs that leave an OR are labeled properly with the correct donor information.

The Committee did not identify specific weaknesses of the proposed changes to the policy, but anticipate that transplant teams will say that when they recover the organ and carry it back to their own transplant center, that it should not need a label.

The second proposed change requires that OPOs label tissue-typing materials with two unique identifiers (e.g. Donor Initials, Donor Hospital ID, Donor Date of Birth). Currently, OPTN policy only requires one identifier for tissue-typing materials. However, the Joint Commission (JC) National Patient Safety Goals requires two patient identifiers for blood samples and other specimens for clinical testing as a requirement for accreditation for hospital based OPOs and histocompatibility labs. Therefore, labs that accept samples labeled with only one identifier are out of compliance with the JC. The Committee agreed that this change will optimize a safe testing environment.

The strengths of the proposed policy change are:

1) Improved patient safety by requiring that all organs that leave an OR are labeled properly with the correct information from the donor.
2) Hospital based OPOs and labs will be in compliance with the JC Patient Safety Goals by ensuring that the tissue typing materials they receive are labeled with two unique identifiers.

Supporting Evidence and/or Modeling:

There is not a body of evidence that specifically indicates how frequently recovery teams leave the OR prior to labeling of organs. The Committee received two comments from members of the transplant community regarding this situation in response to a previous public comment proposal that recommended language changes to OPTN/UNOS Policy 5.0. While data are not readily available as to the frequency of these situations, Committee members, especially those involved with OPOs, agreed that they have all experienced this situation with some regularity.

Expected Impact on Program Goals, Strategic Plan, and Adherence to OPTN Final Rule:

The proposed changes are consistent with the Final Rule[1] and will meet HHS Program Goals by:

- Increasing the number of transplanted organs by eliminating organ wastage due to labeling or transportation errors.

The changes meet the Strategic Plan Goals as they will:

- Increase the number of transplants by eliminating wastage due to labeling or transportation errors.
- Improve compliance through clarification of the policies in order to protect patient safety and preserve public trust.
- Improve patient safety.

[1]The Final Rule, Chapter 1-Public Health Service, Department of Health and Human Services, Part 121- Organ Procurement and Transplantation Network. Section 121.7 Identification of Organ Recipient, Section C Transportation of organ to potential recipient.

Plan for Evaluating the Proposal:

Over a two year period, the OPO Committee will request information regarding policy violations relative to labeling at six month intervals to determine the frequency of labeling issues and the trend in the number identified.

- ***What questions or hypotheses are guiding the evaluation of the proposal?*** The hypothesis for this policy change is that the changes in policy 5.0 will result in a reduction in packaging and transportation policy violations.
- ***Policy Performance Measures:*** The Committee will review and evaluate the number and type of labeling and packaging policy violations documented by the UNOS Department of Evaluation and Quality (DEQ) during the next two years to determine if there is a decrease in the number of violations. The type of violations will be studied to determine if there is an inherent problem with the labeling system or confusion over the policy language.
- ***Time Line for Evaluation:*** The Policy Review Subcommittee will review the policy violations every six months for two years following implementation.

Additional Data Collection:

This proposal does not require additional data collection.

Expected Implementation Plan:

OPO and Transplant Center staff will need to review their individual policies and modify those policies as necessary to ensure congruency. Transplant teams may require education regarding the accurate completion of the transport labels.

UNOS site surveyors will also need to assess whether the appropriate documentation is provided.

This proposal will not require programming in UNet^{SM}.

Communication and Education Plan:

Communication Activities			
Type of Communication	**Audience(s)**	**Deliver Method(s)**	**Timeframe**
Policy Notice	Appropriate OPO and TX center staff.	Email from the UNOS Communications mailbox	30 days after the board meeting where the changes are approved.

Monitoring and Evaluation:

OPOs and transplant centers will be expected to comply with this policy. UNOS DEQ will evaluate member compliance with this policy.

Transplant centers and OPOs are expected to:

- Follow policy requirements regarding external and internal packaging.
- Follow policy requirements regarding external and internal labeling.
- Follow policy requirements for documentation accompanying the organ or vessel.
- Establish and implement procedures for verifying labeling and documentation included with the organ.
- Establish and implement procedures for verifying certain information upon receipt of an organ.
- Establish and implement policies and procedures addressing tissue-typing specimen, medium, and shipping requirements and have an agreement with an OPTN member laboratory.
- Establish and implement policies and procedures addressing living or deceased donor organs that remain in the same operating room suite as the intended candidate(s).
- Establish and implement policies and procedures addressing vessel recovery and transplant and vessel storage requirements.
- Pay transportation costs as required by policy.

UNOS DEQ staff may detect potential violations of this proposed policy by:

- Conducting site surveys.
- Researching confidential reports of complaints received through the OPTN Member Reporting Line or Patient Services Line.
- Reviewing OPTN data.
- Receiving referrals from OPTN/UNOS Committees, OPTN/UNOS staff, or OPTN/UNOS members.

During site surveys, UNOS staff may do any or all of the following:

- Request and review copies of member policies and procedures addressing Policy 5.0 requirements.
- Request a demonstration of internal and external packaging and labeling procedures.
- Review records to verify appropriate internal and external labeling.
- Verify that disposable shipping boxes meet requirements.
- Verify that reusable coolers are properly cleaned and sanitized.
- Verify that mechanical preservation machines are properly labeled.
- Interview staff to verify knowledge of procedures and that staff follow procedures.
- Review OPO agreements with OPTN member laboratories.
- Review vessel recovery consent forms.
- Review vessel storage records.
- Review vessel refrigeration temperature logs.
- Verify the implanting transplant program notified the OPO and the OPTN of final disposition of the vessels.
- Review any other available documentation and records to verify compliance with Policy 5.0.

DEQ staff will explore all potential policy violations and forward any results to the OPTN/UNOS Membership and Professional Standards Committee for confidential medical peer review.

Policy or Bylaw Proposal

Please note that all of the language that appears in the policy below is <u>proposed</u> language which has not been approved by the Board of Directors. The Committee is asking for input on the proposed language shown in <u>double underlines</u> which has been modified based on public comments.

5.0 STANDARDIZED PACKAGING, LABELING AND TRANSPORTING OF ORGANS, VESSELS, AND TISSUE TYPING MATERIALS

The purpose of policy 5.0 and its subsections is to:

- state requirements for packaging and labeling organs, tissue typing specimens, and vessels to prevent wastage (and/or to promote safe and efficient use);
- define terms and responsibilities related to packaging, labeling, and transporting organs, tissue typing specimens, and vessels; and
- state requirements for recovering, storing, and using vessels in solid organ recipients.

The responsibility for packaging and labeling deceased donor organs is assigned to the Host OPO~~.~~ unless a transplant center elects to recover an organ(s) and transport it to their transplant center for transplantation. In this case, the transplant center is responsible for packaging and labeling the organ(s) in collaboration with the Host OPO. The OPO must document in the donor record any instance when an organ is not properly labeled and/or packaged, or if the OPO did not have the opportunity to verify the accuracy or presence of a label(s). The responsibility for packaging and labeling living donor organs is assigned to the donor ~~T~~transplant ~~C~~center. For the purposes of this policy, the term organ includes organ segments and pancreas islets.

5.1 – 5.4.1 [No Changes]

5.4.2 Tissue typing materials

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

5.4.3 – 5.11 [No Changes]