UNOS DONATE LIFE
UNITED NETWORK FOR ORGAN SHARING

Since 1984 — sharing organs, sharing data, sharing life.

700 North 4th Street, Richmond, VA 23219
P.O. Box 2484, Richmond, VA 23218
tel: 804-782-4800
fax: 804-782-4817
www.unos.org

IMPORTANT POLICY NOTICE

To: Transplant Professionals

From: James B. Alcorn
Director, Policy

RE: Summary of action taken by OPTN/UNOS Executive Committee by on January 30, 2014

Date: January 31, 2014

The attached report summarizes changes to OPTN Policy approved by the OPTN/UNOS Executive Committee on January 30, 2014. This policy notice provides the specific policy changes and the corresponding implementation date. When reviewing the language changes, please note that underlined language is new and what will be in effect upon implementation and language that is ~~struck~~ will be deleted upon implementation. The policy language used to denote the changes approved by the Executive Committee reflects the most recent version of policy that has been approved, to be implemented on February 1, 2014.

This policy notice, as well as changes from previous Board of Directors meetings, can be found at optn.transplant.hrsa.gov (click on "News," and then select "View all Policy Notices").

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

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

Clarification regarding DonorNet® Documentation for Public Health Service (PHS) Guideline

Sponsoring Committee: Ad Hoc Disease Transmission Advisory Committee (DTAC)

Policy Affected: Policy 2.2 (OPO Responsibilities)

Distributed for Public Comment: No

Effective Date: February 1, 2014

Problem Statement
On November 12, 2013, the Board approved a proposal regarding the PHS Guideline. The proposal: • updated the definition of the PHS Guideline to only apply to the 2013 document • removed a requirement to note within the Donor Highlights section of DonorNet® for each specific donor what version of the PHS Guideline was used to determine increased risk of disease transmission. At the end of this same meeting, a comprehensive plain language rewrite of all OPTN policy was approved by the Board. This rewrite was meant to include all of the changes to policies approved prior to and at that Board meeting. While it updated the PHS Guideline definition to only permit the use of the 2013 Guideline, it did not remove the requirement to document in the Donor Highlights section of DonorNet®, which version of the Guideline was used. This created an unnecessary requirement for OPOs.

Changes
This policy change removes the requirement that OPOs must report to the OPTN Contractor which version of the PHS Guideline was used to evaluate a particular donor.

Member Actions
Beginning February 1, 2014, the policy references to PHS Guideline applies to *only* the 2013 version, and will include increased risk for HBV and HCV. OPOs are not required to document in the Donor Highlights section that the 2013 PHS Guideline was used to evaluate a donor for increased risk of disease transmission. If a donor meets increased risk criteria based upon the current PHS Guideline, OPOs denote this in a check box already provided in DonorNet®.

Affected Policy Language:

Proposed new language is underlined (<u>example</u>) and language that is proposed for removal is struck through (~~example~~).

2.2 OPO Responsibilities

~~For each organ donor, OPOs must report to the OPTN Contractor which version of the U.S. Public Health Service (PHS) Guideline (either 1994 or 2012) it used to evaluate that particular donor. This must be documented for each donor in UNet℠, in the *Donor Highlights* section.~~

The host OPO is ~~also~~ responsible for *all* of the following:

1. Identifying potential deceased donors.
2. Providing evidence of authorization for donation.
3. Evaluating deceased donors.
4. Maintaining documentation used to exclude any patient from the imminent neurological death data definition or the eligible data definition.
5. Verifying that death is pronounced according to applicable laws.
6. Establishing and then implementing a plan to address organ donation for diverse cultures and ethnic populations.
7. Clinical management of the deceased donor.
8. Assuring that the necessary tissue-typing material is procured, divided, and packaged.
9. Assessing deceased donor organ quality.
10. Preserving, packaging, and transporting the organs.
11. Reporting to the OPTN Contractor all deceased donor information required for organ placement, including the donor's human leukocyte antigen (HLA) type.
12. Executing the match run and using the resulting match for each deceased donor organ allocation.
13. Documenting and maintaining complete deceased donor information for seven years for all organs procured.
14. Ensuring that written documentation of the deceased donor evaluation, donor management, authorization for donation, death pronouncement, and organ procurement quality accompanies the organ as described in *Policy 16: Organ and Vessel Packaging, Labeling, Shipping, and Storage.*
15. Maintaining a serum sample for each deceased donor for at least 10 years after the date of organ transplant and ensuring the serum sample is available for retrospective testing. The host OPO must document the type of sample in the deceased donor medical record and, if possible, should use qualified specimens.

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