

## OPTN Policies Plain Language Rewrite

### Overview

Member surveys and other feedback have long noted the complex wording and organization of OPTN policies. The OPTN Policies Plain Language Rewrite addresses these concerns. Our aim is to make the documents more readable and easier for transplant professionals, patients, and the public to understand and use. It also will help establish clarity and organizational standards for future OPTN materials. Revisions made as part of this rewrite are only intended to affect organization and writing, and should not alter the substance or meaning of the existing material. The reorganization should help the transplant community to more quickly and easily find the information needed.

### Rewrite Process

Select OPTN members, advisors, and UNOS staff contributed to the preliminary rewrite drafts. Plain language guidelines were followed as much as possible, as outlined at [www.plainlanguage.gov](http://www.plainlanguage.gov). Multiple drafts were circulated among stakeholders and input was incorporated to ensure that plain language edits did not affect the meaning and requirements of the current policies. Further, as part of the OPTN Bylaws and Policies Plain Language Rewrites, some sections of the OPTN and UNOS policies were moved to OPTN policies and portions of the OPTN policies were deleted because identical requirements already existed in the OPTN bylaws.

### Policy Framework Improvements

All OPTN Policies were affected by the rewrite, which includes any Policies previously approved by the Board of Directors or that will be voted on in November 2012. Policy sections were moved, consolidated, or split and then reorganized by topic. In the current policies, readers may have to visit multiple sections to find relevant information. For example, a reader would need to read no less than a dozen policies to find the list of information that an OPO must report for a donor. In the rewrite, this information is consolidated into one table. Additionally, a new numbering schema has been used to organize the policies. Some features and benefits of the rewritten OPTN Policies are:

- Plain language so that policies and bylaws are clear and precise
- Centralized definitions

**D**

#### Data

Information submitted by Members to the OPTN Contractor about candidates, recipients, potential donors, and donors and information derived from such data

- Simplified and consistent structure

- Reorganization of material around topics. This includes new policies for histocompatibility and multi-organ transplantation.
- Additional tables to facilitate complex rules and lists
- Annotations and change histories for policies

### History

*Policy 3.1: Definitions* 6/23/2003; 11/20/2003; 6/24/2004; 11/18/2004; 6/29/2006; 6/26/2007; 2/20/2008;

### Notes

- For patient notification requirements for inactive programs due to natural disasters, see Bylaws, appendix B, § II(C)(2)(b)(ii).

- Table of contents to find material quicker

### Policy 1: Administrative Rules and Definitions

1.1 Rules of Construction	1
1.2 Definitions	2
1.3 Variances	17
1.4 Allocation of Organs During Emergencies	20

- Subject matter indexes

## L

### *Liver*

Acceptance Criteria	72
Adult Status 1A	127
Allocation of	121
MELD Score	129

- One document to facilitate easier searching

### What You Need to Know

Policy numbers and titles have changed. Members responsible for compliance with OPTN Policy need to be aware of the new policy numbers and titles and the need to update documents, forms, or other materials used at their institution. Detailed crosswalks are included at the end of the policy proposal to

assist you in identifying these changes. If the rewritten policies are approved, UNOS staff will update the Evaluation Plan to reflect the new policy numbers and titles.

### What We Need From You

- The public is invited to review proposed changes and to provide input through a brief, web-based survey. The survey and specially-designed website will allow you to access a document that catalogs the changes for each section of the rewritten policies.
- view the rewritten language and the current language as responses are submitted to the survey.
- comment for every section individually, only certain sections, or for the entire document.

Since the rewrite is intended to only clarify and reorganize existing language, please comment on whether the new language accurately reflects the old language, if it is easier to locate information, and if it's easier to understand. Reviewers may also directly comment on the rewrite by sending an email to [publiccomment@unos.org](mailto:publiccomment@unos.org).

The review of policies will be open from July 2-August 31, 2012. After the public comment period closes, UNOS will compile the feedback and make additional changes, in consultation with appropriate committees and staff. Revised and reformatted documents will then be presented to the OPTN Board of Directors for final approval.

### Substantive Policy Changes to Address in Future Projects

The rewrite incorporates the [public comment proposals](#) that are scheduled for Board approval at the same time as the rewrite (November 12, 2012). However, the rewrite does not include the living donation policy because the Living Donor committee and Board are considering several substantive proposals to current Policy 12 (Living Donation). Substantive changes to policies that have not been out for public comment are not addressed in the rewrite. Areas of policy requiring substantive changes to content will be addressed through the OPTN policy development process by the relevant OPTN committees.

Some of the identified areas that may require substantive changes include the following:

#### *Common Areas of Ambiguity*

Current policy uses phrases that are difficult to implement or enforce. While there are numerous such issues, most of the issues result from the use of a few vague phrases. Examples include:

- A member *should* do X action – It is not clear if these policies contain requirements or recommended actions.
- This committee will *review* X action – Some committees interpret *review* to mean approve whereas others interpret it to mean discuss or analyze. If there is a requirement in policy to *review* something, there should be an explanation about the standard to be used and what will happen with the review.
- *Several, periodic,<sup>1</sup> immediately,<sup>2</sup> and timely fashion<sup>3</sup>*– These does not convey precise timeframes.

<sup>1</sup> Policy 4.1(C)(3) *Detection of Antibodies*

<sup>2</sup> Policy 17.2(C) *Ad Hoc Organ Import*

<sup>3</sup> Policy 15.5(C)(1) *Transplant Program's Responsibilities*

- *Try to resolve a discrepancy*<sup>4</sup> - To *try* is a vague term.
- The Transplant Hospital *must verify*<sup>5</sup> the donor vessel's... *Verify* is a vague term. To some readers, *verify* means compare two documents and ensure that they match. To other reads, *verify* means to run a separate test to confirm the results.

### *Practice not Matching Policy*

The rewritten policies reflect the same rules and requirements found in existing policies and were not updated to reflect differences in practices. There were a few situations where the prevailing interpretation of a policy did not match the policy language. Similar to above, these differences will be sent to the committees to determine the appropriateness of updating the policies. Examples include:

- The match system uses additional sorting criteria that are not in the organ specific policies.
- Policy 2.4(C) *Requested Organ Specific Information* – Policy mentions a *wedge biopsy* but some OPOs would rather use a *needle biopsy*.
- Policy 9.3 *Kidney Points* – The match system uses a more precise phrase for “geographical distribution” in the waiting time formula.

### *Inconsistent Use of Terminology or Policy*

One part of the plain language rewrite project was to standardize the use of terminology across various OPTN resources. Some terminology changes are stylistic whereas other changes impart meaning. Additionally, some policies are organ specific because of biological differences in the organs. However, there are existing policies with organ specific differences without any apparent biological differences in the organs. Examples include:

- The policies use a mixture of different time standards: hours, days, weeks, months, and years. It would be beneficial to standardize the time standards as much as possible. For example, 30 days instead of one month.
- Donor Information<sup>6</sup> – The plain language rewrite consolidates the list of donor information that OPOs must provide. By consolidating this information, it became apparent that the list of information is not consistent across organs.
- Local conflicts<sup>7</sup> – This rule appears in all of the organ specific policies except for pancreas. To be consistent, it should apply to all of the organ types.
- Lung Policy (Priority Levels)<sup>8</sup> – Other organ systems use "status" instead of "priority." In practice, they operate the same way and should therefore use similar terminology.

<sup>4</sup> Policy 4.4 *Resolving Discrepant Donor and Recipient HLA Typing Results*

<sup>5</sup> Policy 16.8(A) *Vessel Recovery and Transplant*

<sup>6</sup> Policy 2.4(B) *Donor Information*

<sup>7</sup> Policy 5.2(G) *Local Conflicts*

<sup>8</sup> Policy 11.1 *Priorities and Scores*