Interim Report
Policy Oversight Committee

June 11, 2012
Live Meeting/ Teleconference

The following is a summary of the Policy Oversight Committee (POC) meeting on June 11, 2012 held via Live Meeting and teleconference.

1. **Plain Rewrite Public Comment Drafts**

James Alcorn, UNOS Director of Policy, provided the POC with background information on the policy rewrite project and the new features used in drafting the re-written policies. The first goal of the policy rewrite project is to make the policies easier to understand by making it easier to find the important information and to allow for clarity under scrutiny. The result is increased compliance and an improved organ transplant system. The second goal is to maintain the intent of each policy. The intent of the policy is based on the adopted policies and not upon practice. In cases where practice differed substantially from the policy language, such as variances and waiting time modifications, substantive rewrites were distributed for public comment.

There are several new features to the rewritten policies. The purposes of these features are to:

- Make policies easier to understand,
- Make it easier to find relevant information, and
- Make it easier to maintain the policies

These new features include:

- *One document*: The policies will be available as one searchable document. If needed, UNOS can also publish individual policies
- *Headings*: There is a mixture in the current policies. In the rewrite, every section and subsection will have a heading.
- *New numbering format*: The rewrite has a structure familiar to statutes and regulations.
- *Table of Contents*: There will be one table of contents for all policies then another for each individual policy.
- *Tables*: Similar rules will be consolidated into tables. The tables will have a consistent style, be numbered, and have labels. There also will be a master list of all tables.
- *Lists*: More rules will be written into lists.
- *Variances*: Policies are structured to accept variance language.
  Central Definitions: Definitions are currently scattered across the policies. All definitions were relocated to Policy 1. For the most part, these are the same definitions that exist in current policy (largely Policy 3.1). Some new terms were defined for clarity (e.g., day vs business day).
  If a term was defined by NOTA or the Final Rule, that definition was adopted. Staff attempted to coordinate definitions between the policy rewrite, bylaws rewrite, and the Chrysalis project.
- *Consistent terms*: The rewrite will use consistent terminology to express similar concepts. (Ex. ABO vs blood type.)

- *Index*: There is an index at the end of the policies, which is sorted by topic as opposed to location. This index can grow over time. The goal is to make it easier for people to find information.
- *Change History*: With better structured policies, it is easier to track changes. A change history is included for each policy. The old/current policies only show the Board date. There is a parenthetical after the new policy, which can be used to indicate the implementation date and to show where the Board has passed a policy change that has not yet been implemented. Underlines and strikethroughs will no longer be used to indicate policy language that is approved but not yet implemented.
- *Cross References & Notes*: There is a reserved place at the end of each policy to include cross-references to other policies, statutes, regulations, academic papers, etc. These references are currently in footnotes or in the policy text.
- *508 Compliant*: Proper use of styles, bookmarks, and graphics will make the final documents accessible.
- *Canons of Construction*: This explanation memorializes drafting rules into policy.

One of the more noticeable features of the policy rewrite to members will be the general movement of policies due to the outdated numbering format, lack of organization of current policies, and the need for a structure that could accommodate growth in the body of policy. The new overall structure includes:

- New numbering format
- New policies:
    - Histocompatibility
    - KPD
    - Split heart and lung
    - Multi-organ allocation
- UNOS and OPTN versions

The new structure adopts allocation tables. Previously, readers had to combine lists and prose to determine the allocation sequence. Staff used a different set of documentation called 'match documentation' to program the system. The policy language and match documentation did <u>not</u> match in all circumstances.

The organ-specific policies also have a new format, which limits these policies to candidate ranking. Waiting time modifications, donor information, and candidate screening were all moved to a central location for all organs. Each organ-specific policy follows a similar structure, which will facilitate cross-organ discussion.

The schedule for the policy rewrite project is:

- Executive Committee: June 25, 2012
- Special Public Comment: July 2 – Aug 30, 2012
    - Committees will review (but not vote on) proposal during this period

    - Live Meetings available for Members
- POC review and respond to public comment: Fall 2012
- Board of Directors: November 2012
- Effective: February 1, 2013

The POC will receive another version of the rewritten policies that contains only those policies that will be implemented and in effect in November 2012. Some of the largest changes will be in the pancreas policy.

Stuart Sweet, MD, PhD, Chair of the Committee, led a discussion of the rewritten policies to be distributed for public comment. The POC agreed to grant UNOS staff the ability to fix typos and make any other non-substantive changes to policy language after the call. POC members stressed the importance of focusing public comment on whether the rewritten policies had changed in intent, rather than whether the members liked the actual policy or whether the policies reflect current practice. The POC recommended including a list of places where the policies differ from practice in the public comment document. Additionally, the public comment document should explain what types of substantive policy issues were discovered as part of the policy rewrite but will be addressed separately by committees as substantive public comment proposals. Finally, the POC recommended having a back-up plan for policies, such as the Living Donor Committee proposals, that are scheduled for Board approval in June in the event that these proposals are not approved.

Dr. Sweet reviewed the consent agenda with the POC. The policies on the consent agenda were previously reviewed by the POC and had no substantive comments submitted by POC members to be reviewed during the meeting.

Consent Agenda:

- Policy 1: Administrative Rules and Definitions
- Policy 2: Organ Procurement
- Policy 3: Candidate Registrations, Modifications, and Removals
- Policy 4: Histocompatibility
- Policy 5: Organ Offer and Acceptance
- Policy 6: Multi-Organ Allocation
- Policy 13: Living Donation
- Policy 14: Kidney Paired Donation
- Policy 15: Identification of Transmissible Diseases in Organ Recipients
- Policy 16: Packaging, Labeling, Shipping, and Storage
- Policy 18: Data Submission Requirements
- Policy 19: Release of Data
- Policy 20: Travel Expense and Reimbursement

POC members pulled the following policies from the consent agenda:

- Policy 2: Organ Procurement
- Policy 6: Multi-Organ Allocation
- Policy 15: Identification of Transmissible Diseases in Organ Recipients

Policy 2: Organ Procurement
The POC recommended making the following revisions to Policy 2 prior to public comment:

- Policy 2.2.4- Clarify that a wedge biopsy is desirable but not required.
- Clarify that the ability for a transplant hospital to request donor HLA applies to both heart and lung.

Jean Davis and Richard Pietroski volunteered to work with UNOS staff on alternate policy language prior to public comment.

Policy 6: Multi-Organ Allocation
POC members were concerned that the language for multi-organ allocation was still ambiguous. They thought the language should indicate that OPO should run all matches to determine how multi-organ offers would fit in. However, there was also concern about any clarifications being a substantive change to the policy. Dr. Sweet and Meelie DebRoy volunteered to work with UNOS staff on alternate policy language prior to public comment.

Policy 15: Identification of Transmissible Diseases in Organ Recipients
The POC recommended adopting revisions submitted by the vice-chair of the Ad Hoc Disease Transmission Advisory Committee.

The POC discussed the remaining policies in more detail. The key questions for this review were:

1. Have there been any changes in intent?
2. Are there any ambiguities or conflicts in the policies?
3. Are there any changes that need to be made prior to public comment?

Policy 7: Allocation of Hearts
The POC recommended making the following revisions to Policy 2 prior to public comment:

- Define terms such as primary and secondary blood type before using them in the allocation tables.
- Section 2A on Status 1A patients- Introduce the three-day concept in this section as it is central to 1A status.
- Clarify how Status 1As differ from Status 1Bs because the language is very similar.
- Pediatric Status 1A- Use the term mechanical ventilation to be consistent with the adult policy.
- Pediatric Status 1A- Prostaglandin has been lost from the policy language and needs to be re-inserted.
- Status 1B growth failure- There has been a subtle change in the meaning. The criterion applies if there is a change in the growth rate 1.5 standard deviations less than the expected growth rate.

- Pediatric heart Status 2- The age of 18 is not relevant.

Policy 8: Allocation of Intestines
The POC had no issues with the policy language in Policy 8. POC members commented that the policy can be confusing with how it relates to the multi-organ allocation policy.

Policy 9: Allocation of Kidneys
The POC noted that the term DCD should be updated to donation after circulatory death.

Policy 10: Allocation of Livers
The POC recommended making the following revisions to Policy 10 prior to public comment:

- Table 10.1- Update classifications 15 and 16 to be a MELD of 15, not 34.
- Table 10.4- It is not clear that it is possible for a candidate to be eligible for Status 1 for hepatic artery thrombosis rather than a MELD of 40. POC members recommended adding a clause indicating the MELD of 40 was for candidates not meeting Status 1 criteria.
- Table 10.5- Keep the word "recommended" in the header for the table.
- Table 10.6- The biopsy should be the second option for identifying HCC after imaging, and the policy language should be ordered accordingly.
- Table 10.6- Clarify that the requirement is for two lesions, both of which are greater than 3 cm.
- For cholangiocarcinoma (10.3 (F) 2A), the requirement should be ≥ 100 u/mL with aneuploidy instead of two separate requirements.
- Regional Review Boards (RRB)- Status 1 cases go to the full committee for review, not the RRB. This is an area where current practice differs from policy.

Policy 11: Allocation of Lungs
The POC recommended making minor changes submitted by POC members prior to the call.

Policy 12: Allocation of Pancreas and Pancreas Islets
The POC recommended updating 12.4(B) and (C) to reflect that kidney-pancreas waiting time is not dependent on the candidate being registered for a kidney transplant. POC members noted that the issue of kidney paybacks needs to be addressed as a substantive proposal. Also, POC members pointed out that pancreas policy has major changes that are approved but not implemented. There will be a version of pancreas policy that is simply the currently implemented policy.

Policy 17: International Organ Transplantation
The POC noted that the export policy was moved to Policy 5: Organ Offer and Acceptance.

Overall, the POC recommended moving the allocation tables so that they are no longer at the beginning of each organ-specific policy. Additionally, POC members encouraged UNOS Staff to think of ways to present the policies in a view for a variety of audiences, such as someone looking for all policies relating to kidney transplantation or pediatric heart transplantation.

The POC voted to send the rewritten policies out for public comment contingent on the changes discussed on the call being made and to give license to UNOS Staff to make changes to the policy language that are not substantive. (10-Support, 0-Oppose, 0-Abstain)

Table 1: Policy Oversight Committee Attendance

POLICY OVERSIGHT COMMITTEE		JANUARY 1, 2012 - JUNE 30, 2012
	MONTH	JUNE
	DAY	11
	FORMAT	Live Meeting/ Teleconference
NAME	COMMITTEE POSITION	
Stuart Sweet, MD, PhD	Chair	X
Carl Berg, MD	Vice Chair	X
Lee Ann Baxter-Lowe, PhD, ABHI	At Large	X
Jean Davis	At Large	X
Meelie DebRoy, MD	At Large	X
Richard Formica, Jr., MD	At Large	X
Jonathan Fridell, MD	At Large	
Michael Green MD, MPH	At Large	
Heung Bae Kim, MD	At Large	
Kristie Lemmon, MBA	At Large	X
Nancy Metzler	At Large	X
Charles Mowll	At Large	
David Mulligan, MD	At Large	X
Richard Pietroski, MS, CPTC	At Large	X
Peter Reese, MD	At Large	X
Laurel Salonen, RN, BSN, MSN	At Large	X
Timothy Shain	At Large	X
Amy Waterman, PhD	At Large	
Steven Webber, MD, MBChB	At Large	X
Monica Lin PhD	Ex Officio	
Ba Lin MPH	Ex Officio	X
Christopher McLaughlin	Ex Officio	
Robert Walsh	Ex Officio	X
Chinyere Amafuele	Ex Officio	X
Ajay Israni MD, MS	SRTR Liaison	
Bertram Kasiske, MD	SRTR Liaison	X
Tabitha Leighton	SRTR Liaison	X
Susan Leppke	SRTR Liaison	X
Jon Snyder, PhD, MS	SRTR Liaison	X
Mary West	SRTR Liaison	
Robert Hunter, MPA	Committee Liaison	X
Erick Edwards, PhD	Support Staff	X

James Alcorn	Support Staff	X
Ann Harper	Support Staff	X
Vipra Ghimire	Support Staff	X
Leigh Kades	Support Staff	X
Deanna Parker	Support Staff	X
Jory Parker	Support Staff	X
Ciara Samana, MSPH	Support Staff	X
Elizabeth Sleeman, MHA	Support Staff	X
Kimberly Taylor, RN	Support Staff	X