

At-a-Glance

Improving the OPTN Policy Development Process

- **Affected/Proposed Bylaws:** Article 11.1.A (The Public Comment Period); 11.6 (Developing Organ Allocation Policies)

- **Executive Committee**

This proposal includes changes to the OPTN Bylaws intended to improve the OPTN policy development process and provide the OPTN/UNOS Board of Directors and committees more flexibility in addressing different types of problems identified by the transplant community. The proposal includes the creation of two new policy development tracks designed to allow the OPTN/UNOS Board to address emergency and non-controversial issues in a more efficient and expedient manner, while continuing to maintain the OPTN's cornerstone principles of transparency and community consensus.

- **Affected Groups**

No specific patient populations are affected. This will impact the manner in which the OPTN/UNOS Board and Committees schedule the public comment period on policy proposals.

- **Number of Potential Candidates Affected**

Not applicable.

- **Compliance with OPTN Strategic Plan and Final Rule**

This proposal is intended to further the OPTN strategic goal of promoting efficient management of the OPTN and, in particular, the objective to improve responsiveness of OPTN policy to a changing environment.

Improving the OPTN Policy Development Process

Affected/Proposed Policy: Article 11.1.A (The Public Comment Period); 11.6 (Developing Organ Allocation Policies)

Executive Committee

Public Comment Response Period: September 29-December 5, 2014

Summary and Goals of the Proposal:

This proposal includes changes to the OPTN/UNOS Bylaws intended to improve the OPTN/UNOS policy development process and provide the OPTN/UNOS Board of Directors (the Board) and committees more flexibility in addressing different types of problems identified by the transplant community. The proposal includes the creation of two new policy development tracks designed to allow the OPTN/UNOS Board to address emergency and non-controversial issues in a more efficient and expedient manner, while continuing to maintain the OPTN's cornerstone principles of transparency and community consensus in the process. Specifically, the proposal includes the following:

- Clarifies the process the Board will follow to address 'emergency actions' that fall into one of the three below categories:
 1. A proposal necessitated by a pending statutory or regulatory change.
 2. A proposal required due to an emergent public health issue or patient safety factors.
 3. A proposal necessitated by a new medical device or technology that affects organ allocation.

This proposed Bylaws change would clarify that the Board can take action on a policy change in these limited instances, but requires the Board to specify a sunset date that is no more than 12 months beyond the policy's effective date and distribute the policy for public comment no more than 6 months after approval.

- Creates the following new process for non-controversial and routine policy changes:
 1. The sponsoring Committee distributes a public comment proposal (following the normal policy development process) for a new or existing policy and specifies in the policy language areas that will be eligible for future expedited updates.
 2. The Board approves the proposal, including policy language specifying that the particular policy section is eligible for expedited updates.
 3. At a later date, the sponsoring Committee develops a proposal for expedited action.
 4. The proposal is distributed for public comment. This public comment period can be shorter than the normal public comment period but must be at least 30 days.
 5. The sponsoring committee considers public comments and recommends final adoption of the proposal.
 6. If an objection to the use of the expedited action is received during the public comment period by five members of the public, another OPTN committee, or four members of the Board of Directors, then the sponsoring Committee will notify the

Executive Committee of the objections and the proposal will follow the normal OPTN policy development process.

7. If the specified number of objections in #6 above are not received during the public comment period, then the process will proceed as follows:
 - a) If no objections were raised during the public comment period, the proposal will become effective upon notice to the OPTN membership unless a different date is specified.
 - b) If one or more objections were raised, then the sponsoring Committee will submit the proposal for final action according to 11.2 Submitting Policy Proposals to the Board of Directors. This will require a review by the Board or Executive Committee before the proposal is adopted.

Background and Significance of the Proposal:

One of the key goals in the current OPTN strategic plan is to promote the efficient management of the OPTN. As part of achieving this goal, the Board identified an objective of “improving responsiveness of OPTN policy to a changing environment”. In 2013, the OPTN/UNOS Executive Committee (“the Committee”) appointed a policy development process improvement workgroup (“workgroup”) to examine the OPTN policy development process and recommend changes for improvement. This workgroup was comprised of Executive Committee members that represented different OPTN member perspectives (transplant programs, OPOs, and histocompatibility laboratories), as well as a few former OPTN/UNOS committee chairs who have experience with the current policy development process. The workgroup met several times from January-May 2014 and identified several problems with the current process. This proposal addresses some of the problems identified through this effort.

The Current OPTN Policy Development Process

It’s important to note that the OPTN policy development process is governed by the National Organ Transplant Act (NOTA), the OPTN Final Rule, the OPTN Contract, and the OPTN Bylaws. All of these documents specify different rules that must be followed in the process. The Executive Committee considered each of these requirements in formulating this proposal.

The normal policy development process can be described, at a high level, in the following steps:

1. An OPTN/UNOS Committee defines a problem that exists in the transplant community.
2. The Committee discusses the problem and possible solutions, collaborating with other interested stakeholders.
3. The Committee presents the problem and possible solutions to the OPTN/UNOS Policy Oversight and Executive Committees to get approval to deploy OPTN resources to address the problem.
4. If approval is obtained, the Committee finalizes the proposal and solutions for a public comment proposal.
5. The Committee distributes the proposal for public comment (this includes presenting the proposal at all regional meetings and to other OPTN Committees for feedback). The public comment period is currently, on average, around 90 days long.
6. Once the public comment period closes, the Committee reviews all the comments, collaborates with interested stakeholders, and makes a final recommendation to the Board of Directors.
7. The Board of Directors considers the Committee recommendations, along with all the comments, and takes final action on the proposal.

At present, it takes an OPTN Committee approximately 1 ½ to 2 years to complete this full process.

The Executive Committee determined that the current 'one size fits all' process for policy development does not provide flexibility for addressing different types of problems, especially those that are urgent or non-controversial. This model is inefficient and does not meet the needs of the transplant community. The Committee reviewed other policy development models to determine whether multiple policy development tracks could help the OPTN in being more responsive to needed policy changes. As a result of the review, the Executive Committee is recommending Bylaws changes to create two new policy development processes.

Emergency Actions

The Committee discussed recent situations that have necessitated the Board or Executive Committee (acting on behalf of the Board) take immediate action to change or create a policy. The recent Final Rule change to include vascular composite allografts (VCA) under the definition of organ allocation necessitated such action, because the federal regulation became effective before new VCA membership and allocation rules could be approved and implemented under the normal OPTN policy development process. The recent controversy around pediatric and adolescent lung allocation rules is another example. The Executive Committee took emergency action to address this problem. Finally, the Committee discussed the example of Total Artificial Heart (TAH) where a change in medical device required emergency policy changes.

In each of these cases, the Board or the Executive Committee took action to approve policy changes, instituted a sunset date for the policy, and subsequently distributed the policy for public comment. The Committee is proposing that the OPTN Bylaws be amended to specify the process that such emergency actions follow. This Bylaws change would require the Board to specify a sunset date that is no more than 12 months beyond the policy's effective date and distribute the policy for public comment no more than 6 months after approval. Once the Board approves a new policy, the changes would be communicated to the transplant community consistent with communication of other changes (for example, through the policy notice) and often includes outreach to regions or specific programs that will be impacted.

The Committee considered making these timelines even shorter, however, a shorter timeline for public comment and approval is not realistic under the current policy development calendar. Even with improvements being made to the calendar (see Other Solutions below), these are minimum timeframes for public comment and Board approval.

Expedited, Non-Controversial Actions

The Committee also determined that the normal policy development process is too lengthy for non-controversial and routine policy changes. There were several examples discussed for this category. One example was for complex allocation algorithms like the Calculated Panel Reactive Antibody (CPRA) score, used in kidney allocation, where frequencies are based on a cohort of deceased donors from a specific time period. The time period used for the donor cohort needs to be updated in order for the CPRA score to be as accurate as possible. These algorithms commonly become outdated because of the long process that must be followed. Another example discussed was a section in OPTN Bylaws, Appendix C, which requires histocompatibility laboratories to comply with requirements found in documents published by histocompatibility accrediting agencies. The Bylaws reference a date certain for these documents, in order to ensure that any changes to these requirements are released for public comment. The lengthy policy development process results in the date referenced consistently being one or more years behind. There has previously been little to no dissent in the public comment period for these

proposed updates, but there is currently no other option for getting the update approved in a more efficient manner.

The Committee reviewed other policy development models for examples that allow for expedited approval of such changes. After review, the Committee is recommending changes to the Bylaws that would create an expedited policy development track. The Committee discussed the importance of this process only being utilized for changes that had little to no controversy and defined a process that includes mechanisms to ensure this. Other rulemaking bodies that employ expedited pathways typically limit the pathway to non-controversial proposals. The most frequent methods to limit the availability of the pathway are to 1) have a body review and approve the proposal for expedited pathway before it is released 2) have a body review and approve the proposal for expedited pathway before it is implemented, and 3) describe the topics when an expedited pathway is or is not permissible. The workgroup agreed that this pathway should be limited but was unable to describe all of the situations when it should be permissible. It therefore limited this pathway by requiring the Board to first pre-approve the policy section for expedited review and place limits on the amount of opposition received during public comment.

Under the proposed changes, any proposal being considered for an expedited review would have to first follow the normal policy development process and the policy language would have to specify that future updates would be eligible for an expedited review. The Committee is also recommending an additional measure that allows a certain number of objections to make the proposal ineligible for the expedited process. Furthermore, if the proposal receives any objections but not the number required to make it ineligible for the expedited process, the sponsoring Committee must get approval from the Executive Committee or the Board to proceed with the change.

See Summary and Goals of the Proposal above for the detailed process steps.

In developing this change, the Committee discussed how to determine whether a proposal is controversial and decided that the community would determine this through the public comment process. The Committee achieved this by establishing an appropriate number of objections that would cause the proposal to be removed from the expedited process. They chose the number of objections from specific groups by examining data on public comments from the past several years and determining the average number of opposing comments for each.

UNOS staff presented data showing that the average Board proposal receives 90% approval from Board members. This led the Committee to choose a 10% threshold (4) for the number of Board members that could object to the proposal and it would be considered too controversial for the expedited process. The Committee took a similar approach with the number of members of the public (5) who could object to the proposal, reviewing the average number of individual opposing comments on proposals in the last five years.

For individual and Board objections, the Committee decided to specify a fixed number over a percentage. This is due to the fact that it would not be easy to determine whether the threshold percentage had been met until the public comment process was complete. For example, if a 10% threshold was specified, UNOS staff would not know the total number of comments until the public comment process closed and therefore could not calculate 10% of the number until there was a total number of comments. If the proposal reached the required number of objections early in the public comment process, the Committee wanted the proposal removed from the expedited path as quickly as possible.

The Committee also decided that a proposal should not be eligible for the expedited process if another OPTN committee (by a majority of voting members) opposed the proposal. There was consideration for specifically mentioning professional transplant society objections but, due to some difficult logistical issues associated with this, it was determined that any transplant society opposed to a policy proposal would likely be able to obtain four signatures to meet the individual threshold. In addition, there is already a process in place for transplant societies to request a separate review of proposed policies.

To be clear, the expedited process is only intended for policy changes that are determined to be non-controversial to the transplant community. The proposal will allow the Board to act in a more expedient manner when the transplant community identifies a need for routine and non-controversial changes.

Other Solutions

The above solutions are the only actions taken by the Executive Committee that propose to change the OPTN Bylaws and, therefore, require public comment. However, the Executive Committee identified other improvements worth noting to the community.

The Executive Committee is concerned with the fact that the length of the OPTN policy development process has grown significantly over the last 5-7 years. This has resulted in an increase in the amount of time it takes for the Board to respond to needed policy changes. For example, UNOS staff estimates that it took approximately 90-104 days from the start of a proposal to Board approval from 2001-2005. By 2014, it was 243-291 days. A similar trend can be seen in the length of the public comment period and from the end of the public comment period to Board approval.

The Committee determined that there are multiple reasons for the increase in the length of the process. One of the main reasons identified is that the OPTN policy development calendar does not strategically line up with the Board meetings. For example, the two main public comment periods are not scheduled in advance of the Board meeting, with time between for a committee to make final recommendations for approval. One public comment period even overlaps a Board of Directors meeting. And, the Board meetings are not scheduled with enough time in between to complete a full public comment cycle. This means that a committee cannot distribute a proposal for public comment and present a final recommendation to the Board at their next meeting. Instead, they must wait for an additional 5 or more months after the public comment period has closed to present the final proposal to the Board.



The Committee directed UNOS staff to develop a new policy development calendar that allows for a six month period between each Board meeting and schedule the two annual public comment periods and internal review processes around the Board schedule. Beginning in January 2015, this new calendar will be operationalized.

Supporting Evidence and/or Modeling:

UNOS Staff and the workgroup cataloged and reviewed the policy development calendars from 2001-2014. The review validated the perceived problem and focused the workgroup as they reviewed potential solutions (Exhibit A).

In reviewing potential solutions, the workgroup reviewed policy development models used by other rulemaking bodies. The federal government and several states utilize similar pathways for emergency and noncontroversial proposals. For example, the Administrative Procedure Act contains a good cause exemption to its public comment requirements:

Except when no hearing is required by statute, this subsection does not apply...

(B)when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefore in the rules issued) that notice and public procedure are impracticable, unnecessary, or contrary to the public interest.

Examples of other emergency actions include:

- Code of Virginia, § 2.2-4011 (Emergency regulations; publication; exceptions).
- California Government Code, § 11346.1(b)(2)
- Federal interim Final Rules

Examples of other expedited, non-controversial actions include:

- Code of Virginia, § 2.2-4012.1 (Fast-track rulemaking process) (2014).
- Federal direct Final Rules

Administrative Conference of the United States (ACUS) Recommendation 95-4 (Procedures for Noncontroversial and Expedited Rulemaking) ([60 CFR 43110 \(August 18, 1995\)](#)) contains several recommendations for emergency and non-controversial rulemaking pathways.

Expected Impact on Living Donors or Living Donation:

Not applicable.

Expected Impact on Specific Patient Populations:

Not applicable.

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

This proposal is intended to further the OPTN strategic goal of promoting efficient management of the OPTN and, in particular, the objective to improve responsiveness of OPTN policy to a changing environment.

Plan for Evaluating the Proposal:

The Board and Executive Committee, along with UNOS staff, will assess whether the changes are having their intended effect by tracking:

- How many proposals utilize the emergency pathway
- How many proposals utilize the expedited pathway

Additional Data Collection:

No additional data collection is required under this proposal.

Expected Implementation Plan:

If public comment is favorable, this proposal will be submitted to the Board of Directors in June 2015 and, if approved, will be effective September 1, 2015.

Compliance Monitoring:

Not applicable

Policy or Bylaw Proposal:

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~). Only sections of policy that contain proposed changes or are referenced in the changes are included below.

Article XI: Adoption of Policies

11.1 Creating and Submitting Policy Proposals

Committees develop proposals for new policies or changes to existing policies and submit them to the Board of Directors for consideration. Committees developing proposals may also request review and comment from one or more additional Committees if necessary. For more information about OPTN Committees, see of these Bylaws.

Committees analyze policy proposals using select data to measure the effect of the proposal on the transplant community. The analysis includes baseline data that reflects how current policy is performing as well as projected outcomes to estimate the impact of the policy proposal. Data, analysis, and other information requested by the Committees are provided by the OPTN Contractor and Scientific Registry of Transplant Recipients (SRTR) contractor, as specified in their contracts with the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS).

Policy proposals include a summary that provides background information to explain the purpose of the proposal and the issues that were considered in developing the proposal.

A. The Public Comment Period

The public, including the transplant community, is usually included in the OPTN policy development process through the public comment process. Proposals to change organ allocation or membership requirements require public comment. However, some policy proposals do not require public comment, including:

- ~~Proposals that require immediate action due to patient health and safety factors.~~
- Proposals that clarify or correct existing policy rather than changing the intent or adding to the policy.
- Proposals that reflect administrative or non-substantive procedural changes that do not change the intent of the policy or do not impact the operations of the transplant community.

~~The public comment period is usually 45 days. The sponsoring Committee may set a shorter period if a proposal needs to be expedited for patient health and safety reasons, but will make every effort to set a reasonable period to receive comments.~~

Proposals issued for public comment are distributed in the following ways:

1. Posted to the OPTN website at <http://optn.transplant.hrsa.gov> or mailed to all OPTN members and anyone who requests to be placed on the list.
2. Provided at regional meetings of the members.
3. Provided at meetings of interested Committees.

Comments received during the public comment period will be reviewed and addressed by the sponsoring Committee. Comments received after the end of the set public comment period may be reviewed and addressed at the discretion of the Chair of the sponsoring Committee.

Based on the comments received, the Committee may make modifications to the proposal, including withdrawal of the proposal. Should the Committee choose to recommend the policy proposal to the Board, the proposal will be updated to include the public comments and the Committee's responses and then presented to the Board of Directors as a final proposal.

11.2 Submitting Policy Proposals to the Board of Directors

After the sponsoring Committee completes the policy proposal and any necessary public comment process, the Committee submits the proposal to the Board of Directors. The Board of Directors may take *any* of the following actions:

- Approve the proposal without amendment.
- Amend and then approve the proposal.
- Reject the proposal.
- Refer the proposal back to the sponsoring Committee or to other Committees for additional consideration.
- Any other action the Board decides is appropriate.

These actions may also be considered and implemented by the Executive Committee between meetings of the Board of Directors. For more information, see *Article IV: Executive Committee* of these Bylaws.

Policies approved by the Board of Directors with or without amendment and recommended as non-mandatory will be implemented as described below.

Policies approved by the Board of Directors and recommended to be enforced as mandatory policies are forwarded to the Secretary of HHS for review and comment according to the OPTN Final Rule, *section 121.4(b)(2)* at least 60 days before implementation.

11.6 Emergency Actions

Policy proposals that meet *at least one* of the following criteria may be adopted by the Board of Directors prior to public comment:

- A proposal that is necessitated by a pending statutory or regulatory change.
- A proposal that is required due to an emergent public health issue or patient safety factors.
- A proposal that is necessitated by a new medical device or technology that affects organ allocation.

Instead, the policy development process for these proposals will require *all* of the following steps:

1. The sponsoring Committee submits the proposal according to *11.2 Submitting Policy Proposals to the Board of Directors*.
2. The proposal designates a future date upon which the policy will expire, not more than 12 months beyond the policy's effective date.
3. The policy is distributed for public comment no more than 6 months after approval. This public comment period can be shorter than the normal public comment period but must be at least 30 days.

11.7 Expedited Actions

Policy proposals that are expected to be non-controversial may be adopted according to the following process:

1. The Board approves a new or revised policy that includes specific policy language defining components of the policy that will be eligible for future expedited updates as well as the anticipated frequency of updates.
2. At a later date (as directed by the policy timeline), the sponsoring Committee develops a proposal for expedited action as stipulated in the policy.
3. The proposal is distributed for public comment. This public comment period can be shorter than the normal public comment period but must be at least 30 days.
4. The sponsoring committee considers public comments and recommends final adoption of the proposal.
5. If an objection to the use of the expedited action is received during the public comment period by five members of the public, another OPTN committee, or 4 members of the Board of Directors, then the sponsoring Committee will notify the Executive Committee of the objections and proceed with the normal OPTN policy development process.
6. If the specified number of objections in #5 above are not received during the public comment period, then the process will proceed as follows:
 - a. If no objections were raised during the public comment period, the proposal will become effective upon notice to the OPTN membership, unless a different date is specified.
 - b. If one or more objections were raised, then the sponsoring Committee will submit the proposal for final action according to 11.2 Submitting Policy Proposals to the Board of Directors.

11.611.8 Developing Organ Allocation Policies

Policy proposals affecting organ allocation must specify the organ or combination of organs addressed in the policy and summarize how the proposal meets requirements of the OPTN Final Rule, *42 CFR Part 121*.