Improving the OPTN Policy Development Process

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Policy Development Process Improvement Workgroup
Ad Hoc Policy Development Workgroup

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Key goal: Promote efficient management of the OPTN

- Objective: Improve responsiveness of OPTN policy to a changing environment
Purpose

Examine the OPTN policy development process

Recommend changes to improve efficiency and responsiveness
Governing Documents

OPTN policy development

OPTN Bylaws

Final Rule

OPTN Contract

NOTA
2 Main Problems

1. **Length of process increased significantly in last 5-7 years**

2. ‘**One size fits all**’ process with no flexibility for solving different types of problems
Problem

1. Length of process increased significantly in last 5-7 years
Currently, on average, there are...

- 60 days between PC upload and PC distribution
- 90 days for public comment period
- 240 days between PC distribution and BOD meeting
- 300-360 days between PC upload and BOD meeting
- 480 days between POC committee project review and BOD meeting
Length of Process Over Time
(from project start to BOD)
Length of Process Over Time
(length of public comment)
## Current Policy Development Calendar

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<th>Month</th>
<th>Action</th>
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Recommended Policy Development Calendar

Policy Development Process

BOD Meeting
Comm. decision
IT Estimate 1
POC
ExCom
Public Comment
Comm. decision
IT Estimate 2
Prepare docs
BOD Review
BOD Meeting

Jun Jul Aug Sep Oct Nov Dec Jan Feb Mar Apr May Jun

BOD Meeting
Comm. decision
IT Estimate 1
POC
ExCom
Public Comment
Comm. decision
IT Estimate 2
Prepare docs
BOD Review
BOD Meeting

Jun Jul Aug Sep Oct Nov Dec Jan Feb Mar Apr May Jun
UNOS Staff to communicate new calendar to incoming committee chairs and flesh out necessary details

New calendar plans will be included in fall regional meeting UNOS updates

New schedule to be implemented with Spring 2015 public comment cycle
Problems

2. ‘One size fits all’ process with no flexibility for solving different types of problems
Board is compelled to act before public comment and normal policy development process can be completed.
Proposals to change organ allocation or membership requirements require public comment. Exceptions include:

- Proposals that require immediate action due to patient health or safety factors
- Proposals that clarify or correct existing policy rather than changing the intent or adding to 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
Virginia Emergency Rule-Criteria

Promulgated if there is an emergency situation or regulation must be implemented within 280 days.

Effective for up to 18 months, and this period may be extended up to 6 months by the Governor.

Usually replaced with a permanent regulation.
Agency adopts reg and submits to Exec Branch for review

If Exec Branch approves (Gov), it becomes effective on the date of filing unless other date is specified

Public is notified via the state regulatory public comment system

30-day public comment period begins
Proposed New OPTN Emergency Track

Limited eligibility—patient safety, statutory/regulatory change/new medical technology

Board must specify a sunset date no more than 12 months after approval

Policy must be submitted for public comment within 6 months of Board action
Non-controversial, routine changes are needed in a timely manner to be efficient.
For proposed regulations that are expected to be non-controversial (determined by the agency and Executive Branch)

Becomes effective 15 days after the close of the public comment period
Virginia Expedited (Fast-Track) Criteria

If, during the public comment period, an objection to the rule is received from:

Any member of the applicable standing committee of the State Senate or House of Delegates;

Any member of certain commissions;

or 10 or more members of the public

Then the standard, full rulemaking process is followed.
Agency adopts rule and submits to Exec Branch for review.

If Exec Branch approves (Gov), the agency notifies members of public signed up for email notifications ten days before public comment is to begin.

30 day public comment period begins.

15 days after the close of the public comment period, the regulation becomes effective (unless withdrawn or a later effective date is specified).
Committee distributes public comment proposal for new or existing policy and specifies in policy language areas that will be eligible for future expedited update.

Board approves the policy including expedited process language.

At a later date, committee submits expedited proposal as stipulated by original policy. Expedited proposals require public comment of at least 30 days.

If no objections are received, policy changes become effective upon notice to the OPTN membership.
Proposed New OPTN Expedited Path

If, during the public comment period, an objection to the policy is received from:
Another OPTN committee;
5 members of the public;
or
4 members of the Board of Directors…

then the change must go through the normal policy development process.
If *one or more* objections were received but not enough to meet the threshold specified in the Bylaws, then the Executive Committee must review and act on the proposal.
Next Steps

Executive Committee sponsored Policy Proposal to be submitted for Fall Public Comment Cycle
Back Up Slides
The OPTN shall establish membership criteria and medical criteria for allocating organs and provide members of the public an opportunity to comment with respect to such criteria.
Final Rule

The OPTN Board of Directors must...

- provide opportunity for the OPTN membership and other interested parties to comment on proposed policies
- take into account the comments received in developing and adopting policies
OPTN Bylaws

- Proposals to change organ allocation or membership requirements require public comment. Exceptions include:
  - Proposals that require immediate action due to patient health or safety factors
  - Proposals that clarify or correct existing policy rather than changing the intent or adding to 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
OPTN Bylaws

- 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 or safety reasons, but will make every effort to set a reasonable period to receive comments

- Public comment distributed in the following ways:
  - Posted to the OPTN website
  - Mailed to all OPTN members and anyone who requests to be placed on the list
  - Provided at regional meetings
OPTN Contract

- Requires materials to be posted 14 days in advance of any Board or committee meeting
Board Actions By Date

Nov-10 | Jun-11 | Nov-11 | Jun-12 | Nov-12 | Jun-13 | Nov-13

- **Withdrawn**
- **Tabled**
- **Defeated**
- **Consent**
- **Approved**

| Nov-10 | 64% | 21% |
| Jun-11 | 63% | 37% |
| Nov-11 | 64% | 29% |
| Jun-12 | 60% | 25% |
| Nov-12 | 69% | 19% |
| Jun-13 | 53% | 41% |
| Nov-13 | 56% | 33% |
Board Actions by Committee

Board Actions by committee

- Withdrawn
- Tabled
- Defeated
- Consent
- Approved

OPTN
Themes

- Not engaging all interested stakeholders early enough
- IT programming $$$$$$
- Last minute concerns from stakeholders