

Improving the OPTN Policy Development Process

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Executive Committee

*Policy Development Process Improvement
Workgroup*

Ad Hoc Policy Development Workgroup

- Tracey Evans-Walker
- John Friedewald
- Simon Horslen
- Christopher Jones
- Mary Nachreiner
- Marilyn Pollack
- Susan Stuart
- Gena Boyle
- Shandie Covington
- James Alcorn

OPTN Strategic Plan

Key goal:

Promote efficient management of the
OPTN

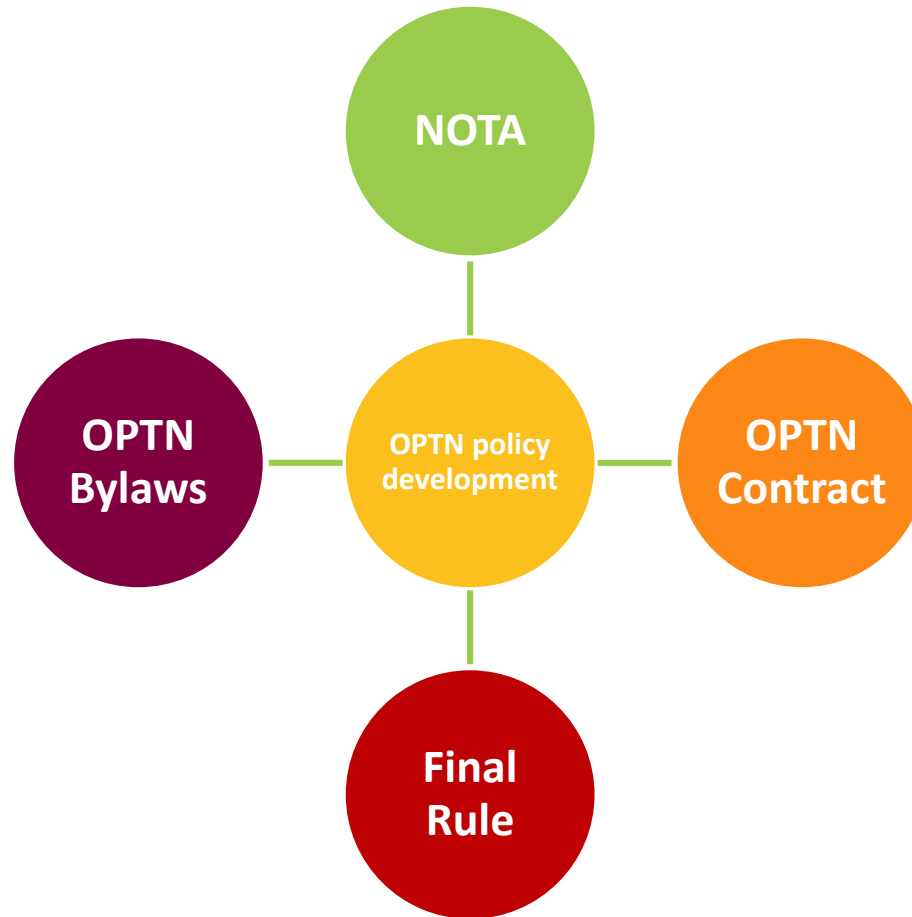
- Objective: Improve responsiveness of OPTN policy to a changing environment

Purpose

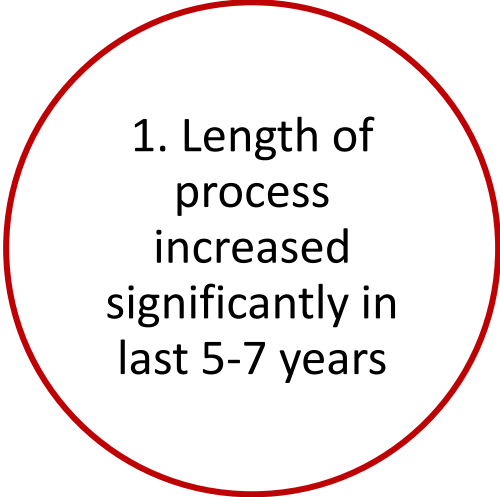
Examine the OPTN policy development process

Recommend changes to improve efficiency and responsiveness

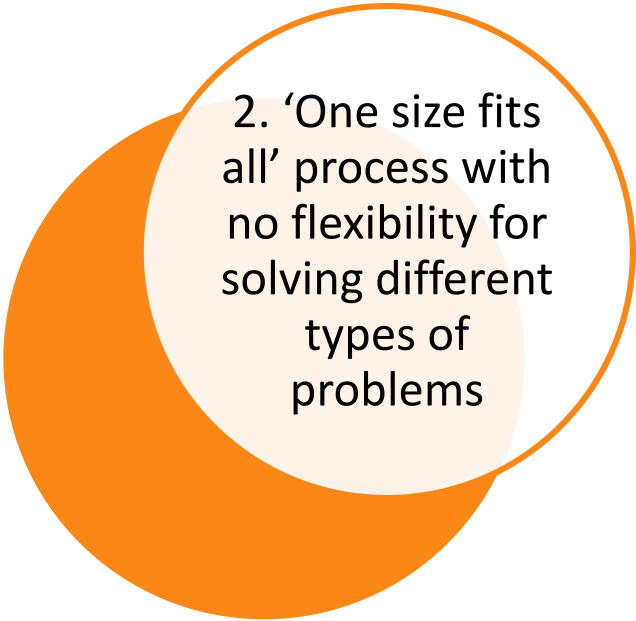
Governing Documents



2 Main Problems

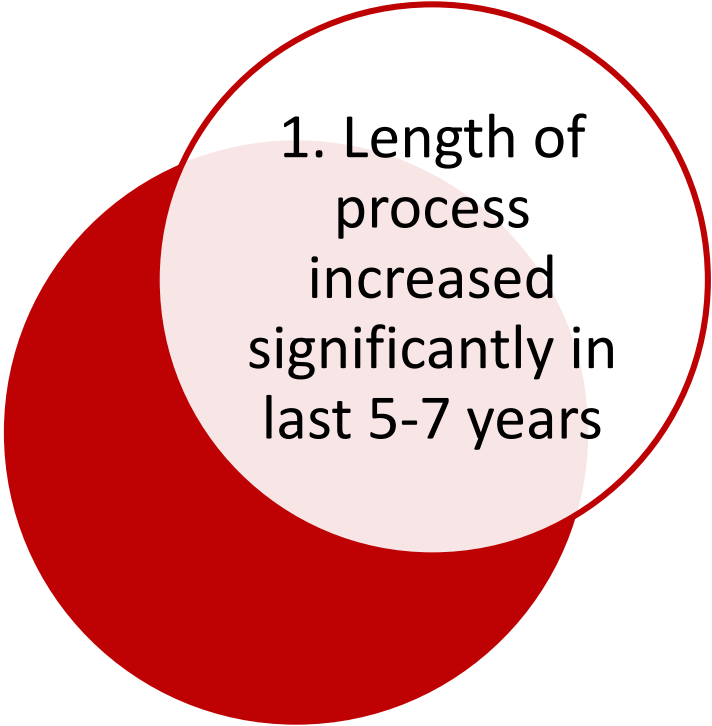


1. Length of process increased significantly in last 5-7 years



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

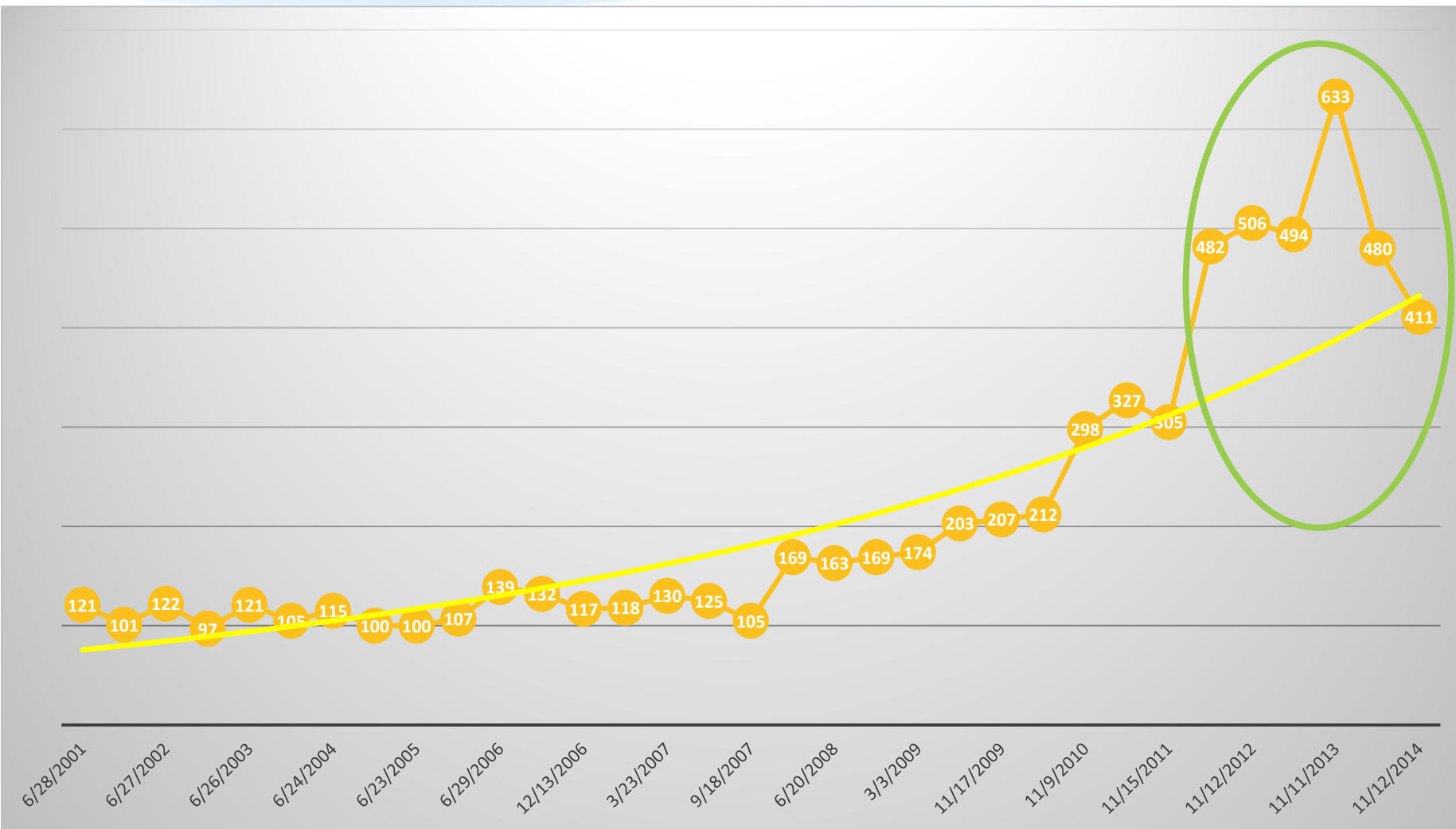
90 days for public comment period

240 days between PC distribution
and BOD meeting

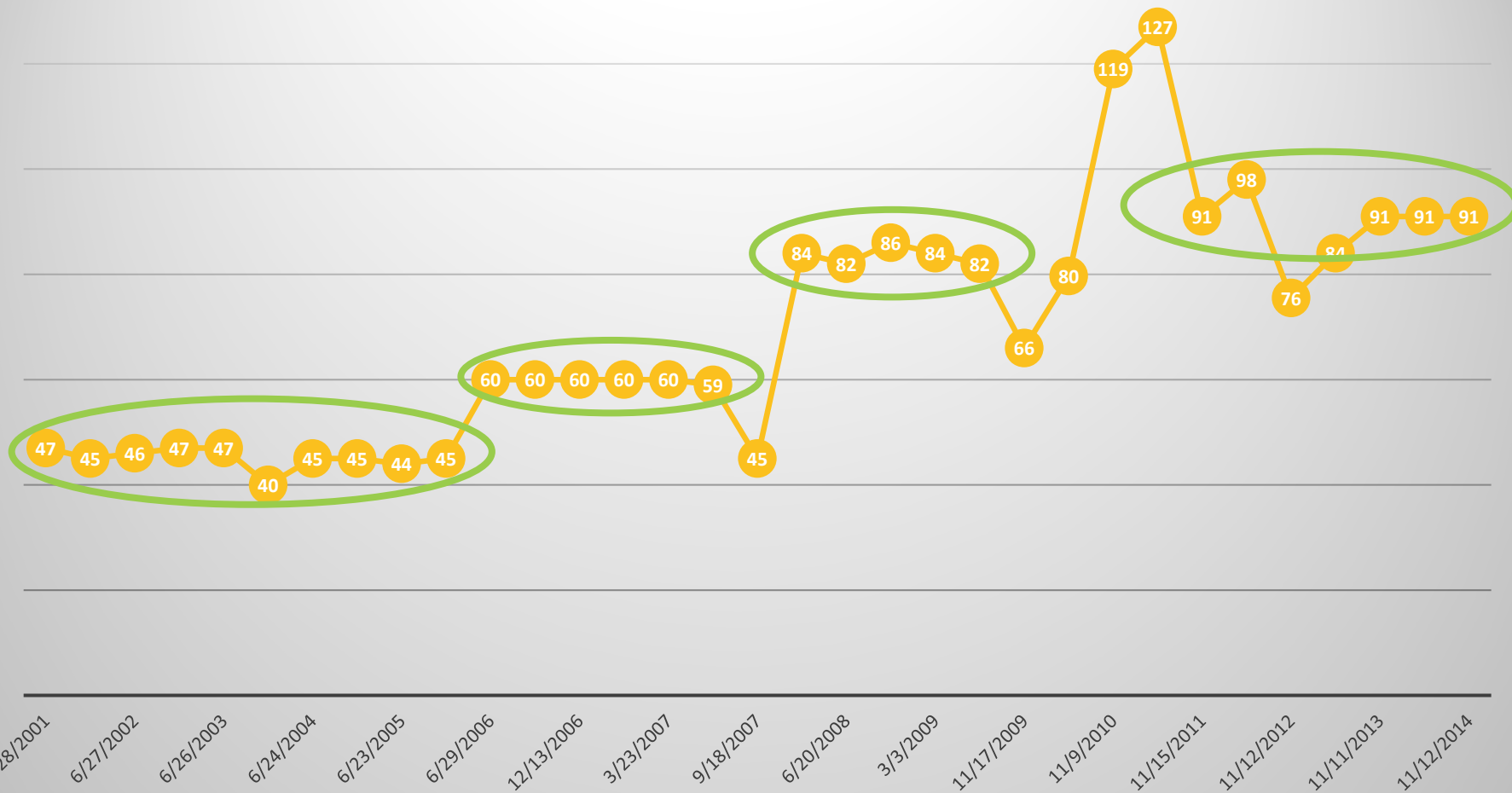
300-360 days between PC upload
and BOD meeting

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

January

February

March

April

Public Comment

May

June

July

August

September

October

Public Comment

November

December

BOD Meeting

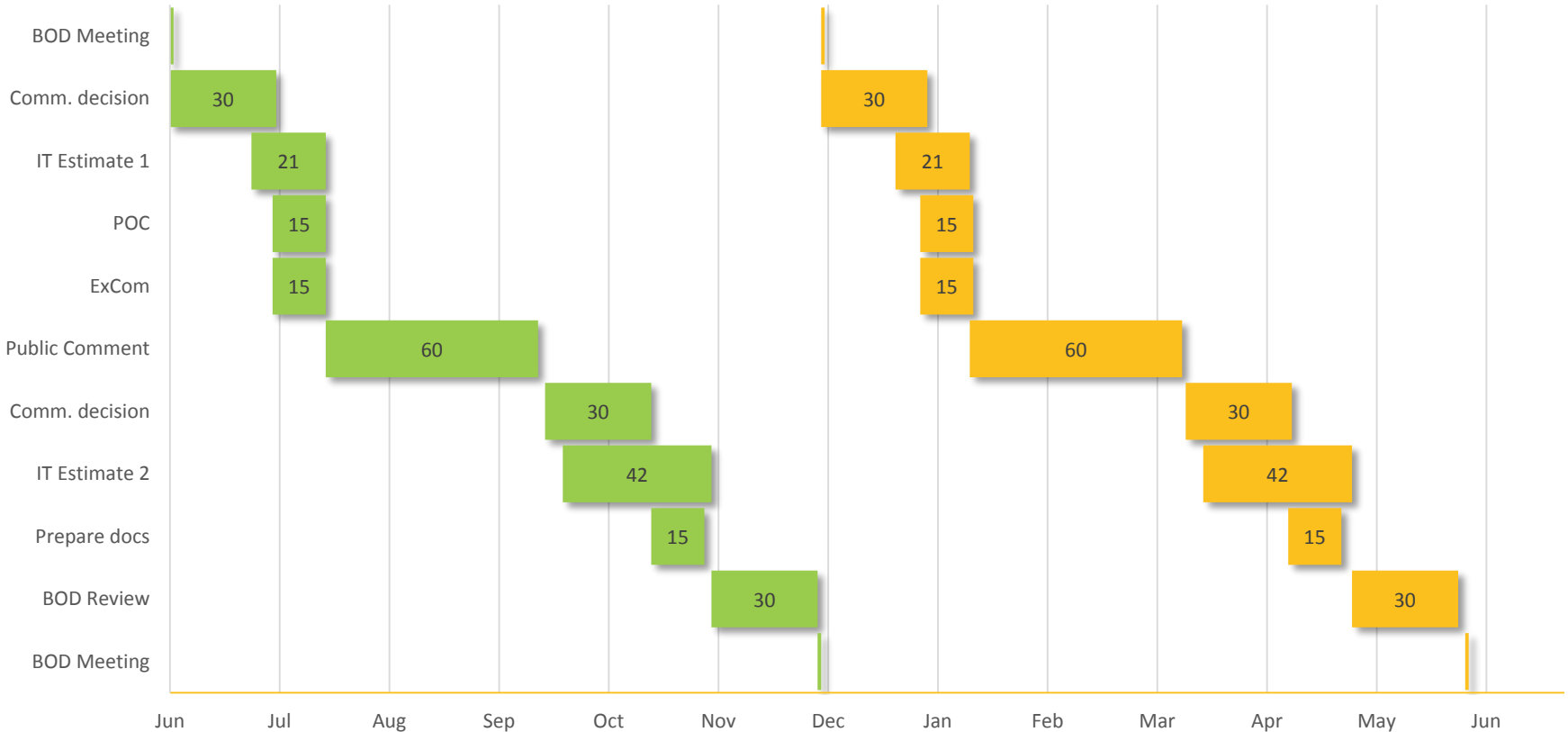


BOD Meeting



Recommended Policy Development Calendar

Policy Development Process



Next Steps

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

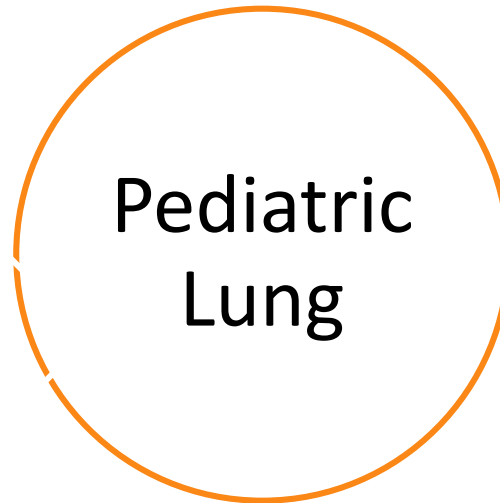
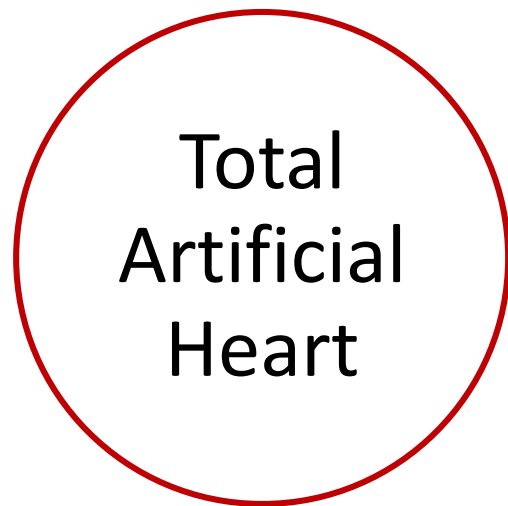


New schedule to be implemented with Spring 2015 public comment cycle

Problems

2. 'One size fits all' process with no flexibility for solving different types of problems

Emergency Actions



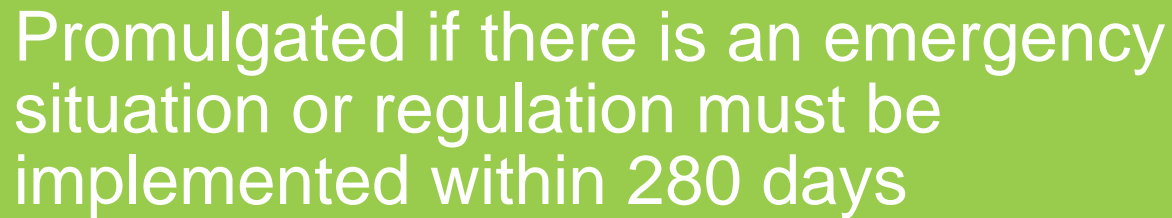
Board is compelled to act before public comment and normal policy development process can be completed.

OPTN Bylaws

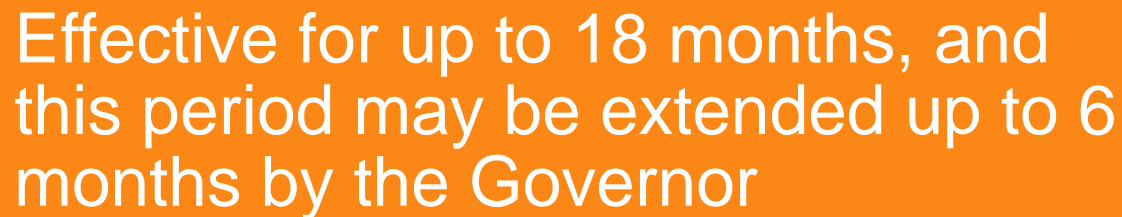
- Proposals to change organ allocation or membership requirements require public comment. Exceptions include:
 - Proposals that require immediate action due to patient health or safety factors
 - Proposals that clarify or correct existing policy rather than changing the intent or adding to policy
 -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

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



Virginia Emergency Rule-Process

Agency adopts reg and submits to Exec Branch for review


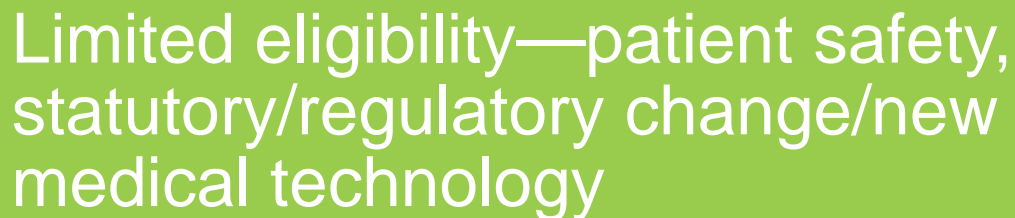
If Exec Branch approves (Gov), it becomes effective on the date of filing unless other date is specified

Public is notified via the state regulatory public comment system

30-day public comment period begins

Proposed New OPTN Emergency Track

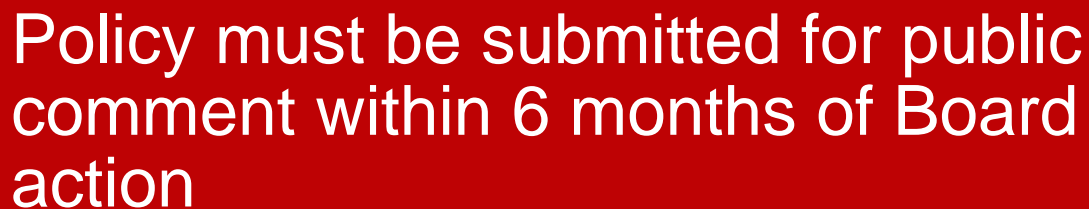
Limited eligibility—patient safety, statutory/regulatory change/new medical technology



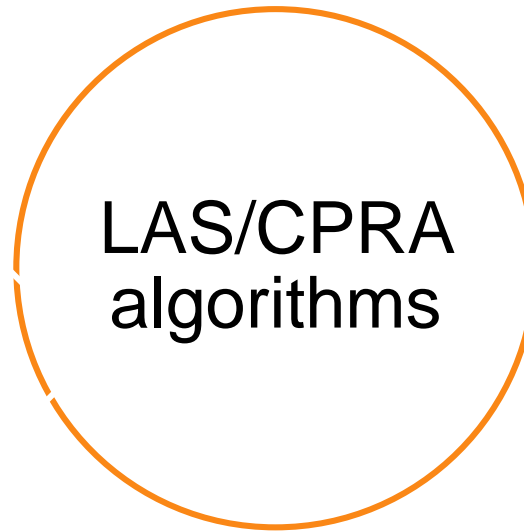
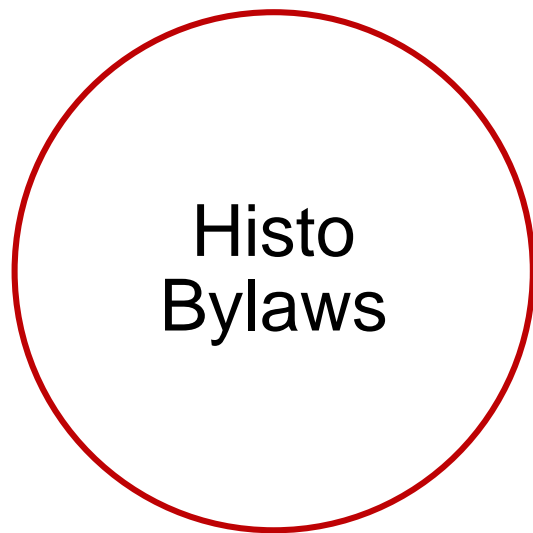
Board must specify a sunset date no more than 12 months after approval



Policy must be submitted for public comment within 6 months of Board action



Non-controversial Actions



Non-controversial, routine changes are needed in a timely manner to be efficient

Virginia Expedited (Fast-Track) Criteria

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

Virginia Expedited (Fast-Track) Rule Process

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)

Proposed New OPTN Expedited Path

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.

Proposed New OPTN Expedited Path

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

NOTA

- 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

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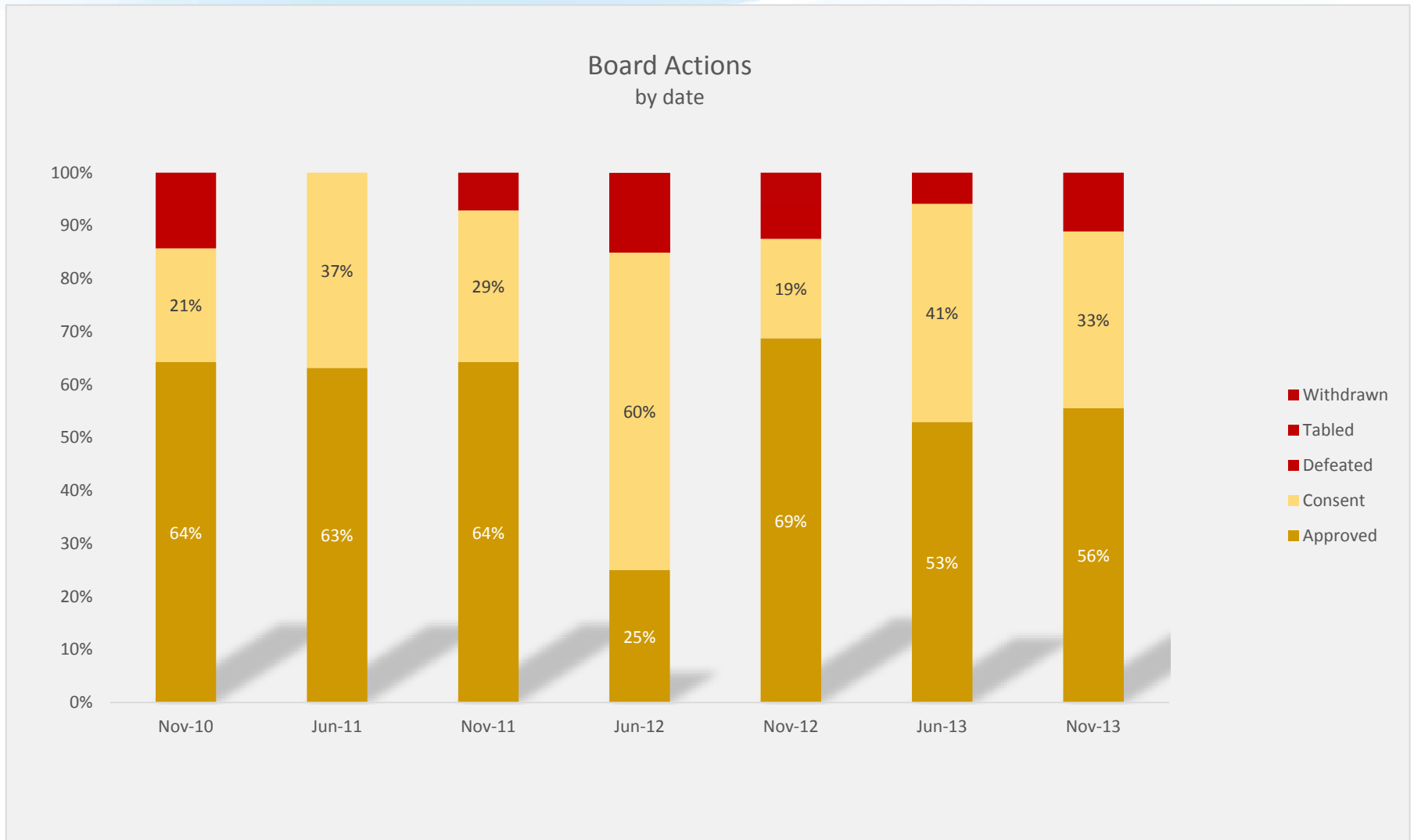
OPTN Bylaws

- 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

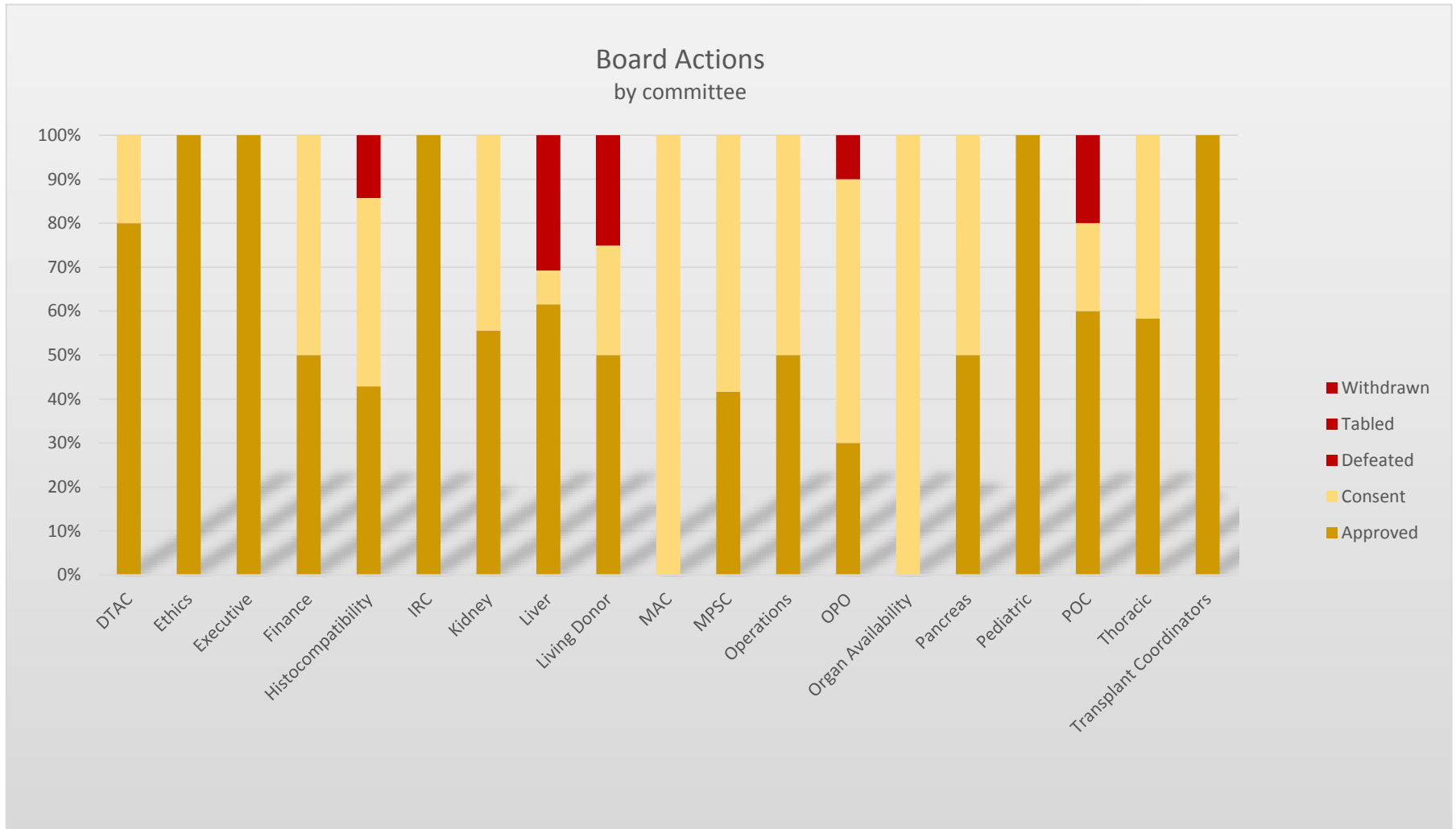
OPTN Contract

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

Board Actions By Date



Board Actions by Committee



Themes

Not engaging
all interested
stakeholders
early enough

IT
programming
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Last minute
concerns
from
stakeholders