

One of the core functions of the OPTN is policy development. NOTA, the OPTN Final Rule, OPTN Bylaws, and the OPTN Contract all contain specific requirements for our policy development processes. These policies drive the work in many departments: ex. the OPTN educates members on our policies; programs the policies into the IT system; monitors member compliance with the policies; researches the impact of the policies; etc. We typically discuss the process as a 10-step process.

10-STEP POLICY DEVELOPMENT PROCESS

Step #1: Idea - All Board and committee projects



begin with an idea. Ideas can come from multiple different sources, such as Board and committee members,

COR representatives, UNOS staff, Transplant Conferences, Innovation Events, and the community. Ideas can include requests for allocation changes; membership changes; changes in data collection; patient safety requirements; issues facing pediatric transplantation; or consideration of ethical issues in organ procurement and transplantation as they pertain to processes and policy development, all in keeping with the requirements of NOTA and the Final Rule.



Staff in the UNOS Policy and Community Relations (PCR) Department will document all project ideas in an electronic system (Hereinafter referred to as “project forms”). Each idea will contain information regarding the source of the idea, the problem facing the transplant community, and any proposed solutions. PCR department leadership and OPTN Committee leadership will review ideas on a regular basis to prioritize ideas based upon which have the most potential benefit for the transplant community, align with the OPTN’s strategic goals, and are within the scope of the OPTN.

Step #2: Problem Analysis – Once prioritized, UNOS staff will work with an assigned committee to



analyze the problem. The OPTN conducts evidence-based problem analysis; therefore, the focus is on defining the problem, not the solution, at this stage. This may involve descriptive data requests fulfilled by the Research department, literature reviews, Failure Mode Effects Analysis (FMEA), or other tools to understand the problem. This analysis will result in a written problem statement in the project form. This problem statement will help define the scope of the project as well as serve as a means to evaluate potential solutions.

Step #3: Project Approval - All committee projects require review and approval from the Policy



Oversight Committee (POC) and Executive Committee (EC). Following an analysis of the problem, UNOS staff will update the project form that includes evidence of the problem, a

project plan (including a plan for collaborating with stakeholders from critical constituencies), alignment with the Strategic Plan, and estimated resource requirements to develop and implement the proposal. Once this is complete, committee leadership will decide whether to send the project for approval. Additionally, staff will use the NOTA and OPTN Final Rule checklist as described below.

The POC and EC will receive copies of the project forms. After review of the project form, the POC will assign the primary strategic goal to each project so that the OPTN can balance resources across the five OPTN strategic goals. The POC will discuss the merits of each project. During the discussion they may make recommendation concerning the project plan (ex. how to involve key constituencies) or the proposed solution. The POC will then make a recommendation to the EC about whether to approve the project. The EC will review the project forms with the POC's recommendations and make a decision about whether to approve the project at this time.

Step #4: Evidence Gathering – In this phase, the committees and UNOS support staff are developing and



analyzing potential solutions for projects approved by the POC and EC but not yet distributed for public comment. This starts with the EC approval of the project and finishes when the committee votes to distribute the proposal for public comment or for final consideration (for those projects that do not require public comment). The focus is on analyzing and building evidence-based solutions for the earlier defined problem. During this phase, the committee often seeks input from, and builds consensus with, stakeholders. Each project plan is unique to the special needs of the project and may include inferential modeling from the SRTR, wireframe models from UNOS IT, consensus conferences, reviews of policy language, etc.

During this time, UNOS support staff for the sponsoring committee will reach out and solicit input from key constituencies as needed. If no committee contains sufficient background or expertise, the OPTN will supplement the committee with additional committee or community members. As needed, staff will coordinate conversations between different committees to develop the proposals. For example, ethical topics may be discussed by the Ethics Committee, pediatric topics may be discussed by the Pediatric Committee, and issues impacting vulnerable populations may be discussed by the Minority Affairs Committee.

Step #5: Public Comment Approval – Prior to public comment, projects are submitted to the POC and



EC for review and approval. This starts after the committee votes to distribute its proposal for public comment and finishes at the end of the EC meeting. UNOS support staff will draft a public comment proposal that contains the proposed policy language from the committee and a summary of the analysis performed by the committee. The POC and EC will receive these proposals for review. The POC's approval requires satisfaction of the same factors listed in the project-approval phase, but includes an additional review to determine whether ample stakeholder engagement occurred during the development of the solution, and whether the solution is tailored to the problem. The EC also considers high-level fiscal implications of the proposals before approving them for public comment.

Step #6: Public Comment – There is a four-pronged approach to gathering public comment: 1) specific outreach to relevant stakeholder organizations (both transplant professionals and patient groups); 2) comment from other OPTN committees; 3) in-person meetings in the 11 regions; and 4) open, online public comment on the OPTN website. Prior to and during public comment, the UNOS Communications Department uses online tools such as the OPTN website and social media to notify the general public of public comment opportunities.



The OPTN will collect both qualitative and quantitative feedback during public comment. This may take the form of sentiment polls, calls for specific feedback, and requests for general public. Attendees at regional and committee meetings will have the opportunity to provide information similar to what is requested on the OPTN website. All comments will be logged in a central electronic system. Before comments are posted on the OPTN website, staff will review them according to the following principles:

- Be respectful. Personal attacks, profanity, and aggressive behavior are prohibited. Instigating arguments in a disrespectful way is also prohibited.
- No patient identified, peer review privileged, or other confidential information. (However, we will permit patient identified information if the comment appears to be posted with a person whom has permission to release that information.)
- No vulgar, obscene, or profane language, or “hate speech,” which is defined as language intended to foster hatred against individuals or groups based on race, religion, gender, sexual preference, place of national origin, or other improper classification
- No language that would violate the law if published
- No suggestion or encouragement of illegal activity
- No seeking of medical advice
- No solicitations or comments that promote a particular service or product. This includes solicitations for commercial activity within ANY industry, transplant-related or not. This does not include solicitation of support for or against a specific OPTN proposal.

Any comments that might violate these principles will be reviewed by UNOS leadership. If UNOS leadership agrees that the comment does not meet these principles, the comment will be logged in the central system and not posted to the OPTN website, but will be shared with the sponsoring committee. UNOS staff will not modify any comments without the express written permission of the submitter.

Certain OPTN committees will review proposals from the perspective of their subject matter expertise or constituency. Some examples might include:

The Ethics Committee will focus their review on ethical considerations

The Minority Affairs Committee will focus their review on vulnerable population issues

The MPSC will focus their review on overall network performance and monitoring issues

The Patient Affairs Committee will focus their review on patient specific perspectives

The Pediatric Committee will focus their review on pediatric issues

Additionally, the OPTN will convene a workgroup during public comment to review the fiscal impact of the proposals on members. This analysis begins when the project is first proposed to the POC and EC and is refined now that the committees have defined solutions. We will include representatives of the

three major member types (Organ Procurement Organizations, transplant hospitals, and histocompatibility laboratories) in this analysis. This analysis will be summarized for the sponsoring committees and Board.

Step #7: Pending Board Approval - Projects that have finished public comment but have not yet been



submitted to the Board are in this phase. During this phase, UNOS staff will analyze and summarize the feedback collected from public comment from different constituencies or demographics (ex. by regional meeting, committee, member type, or patients vs. physicians).

The committees will receive the UNOS staff analyses along with all of the feedback received during public comment. Based upon the evidence of how the solutions address the problem statement, the committee will modify the proposal as necessary to meet the goals of the project. If the committee desires to make changes that exceed the logical outgrowth of the public comment proposal, they will resubmit the proposal for an additional round of public comment. Once the committee agrees upon the updated concept, they will vote to send the updated policy language to the Board.

Additionally, UNOS departments will refine their estimates for the level of resources needed to implement the proposal. They will also report the ongoing cost of maintaining these proposals (ex. if additional resources will be needed to monitor member compliance).

Step #8: Board Approval – The Board will consider proposals recommended by the committees.



Approval requires evidence that the proposal addresses the stated problem, complies with NOTA and the Final Rule, and agrees with the Strategic Plan. UNOS staff will document the background of the proposal and all relevant analysis into a briefing paper for the Board. UNOS staff also provide the Board with a fiscal impact analysis for each proposal, which highlights the potential fiscal impact to the OPTN and its members, so the Board can make fully informed decisions.

Prior to the Board meeting, UNOS support staff and committee leaders will brief Board members on the action items before the Board. During these briefings, the Board members will recommend whether the proposal is on the consent vs. discussion agenda and whether the Board should adopt the proposal. Following these meetings, staff will brief Board leadership on the agenda of the Board and finalize the agenda for the meeting.

At the Board meeting, UNOS staff and the committee chair will present the proposals to the Board. Following discussion, the Board will decide whether to adopt, amend, or table any proposal.

Step #9: Implementation – In this phase, the OPTN and members are implementing projects that the



Board has adopted. The planning for implementation of projects begins early in the policy development process and is tailored to the needs of each project. After the Board adopts policy proposals, the OPTN will notify the community through a policy notice, which will be archived on the OPTN website. Implemented policies are known as “OPTN policies.” Multiple departments will develop implementation tools that could include changes to the computer system, educational materials, etc.

The UNOS Professional Education Department will seek the advice of members on the sponsoring committee about the key information on which to educate the community about the policy changes. The UNOS Professional Education Department will then develop an education plan specific to the needs of each proposal. This could include written material such as Frequently Asked Questions, online modules, or webinars, as appropriate.

Step #10: Post Implementation Review – In this phase, the OPTN is reviewing the effectiveness of implemented policies. The plan for this review is agreed upon by committee leadership and is documented in the Board briefing paper. The UNOS Research Department presents this analysis to the sponsoring committee and interested stakeholders. This may result in new projects to refine the policy even further.



OTHER PATHWAYS FOR POLICY DEVELOPMENT

While most proposals will follow the above 10-step process, the OPTN will use other pathways for a minority of policy changes.

- 1) Emergency
- 2) Clarifications
- 3) Clerical Non-Substantive Changes
- 4) Expedited

Emergency Changes

OPTN Bylaw 11.7 covers emergency changes to the policies. These include:

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,

The policy development process for these proposals will require all of the following steps:

The sponsoring Committee submits the proposal according to 11.2 Submitting Policy Proposals to the Board of Directors.

The proposal designates a future date upon which the policy will expire, not more than 12 months beyond the policy's effective date.

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.

Clarifications

OPTN Bylaw 11.1(A) cover which policy clarifications can be adopted without public comment. These include:

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. For these changes, UNOS staff will review the proposal with leadership of the appropriate subject matter committee. They will then draft a mini brief for the EC. This will explain the EC authority to make the change and the rationale for the change. If approved, the change will be posted to the OPTN website.

Clerical Non-Substantive Changes

OPTN Bylaw 11.5 covers non-substantive changes to the policies. These include:

Capitalization or punctuation, as needed to maintain consistency with current policy

Typographical, spelling, or grammatical errors

Lettering and numbering of a rule or the subparts of a rule, according to style conventions in current policy

Cross-references to rules or sections that are cited incorrectly because of subsequent repeal, amendment, or reorganization of the sections cited

UNOS staff will review these changes with UNOS leadership. If approved, UNOS staff will make these changes to the policies and update the policies on the website. The EC will retrospectively review these changes to ensure that staff changes do not exceed the scope of the Bylaw.

Expedited Changes

OPTN Bylaw 11.8 covers expedited changes to the policies. These are proposals that are expected to be non-controversial in nature. They will be adopted according to the following process:

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.

At a later date (as directed by the policy timeline), the sponsoring Committee develops a proposal for expedited action as stipulated in the policy.

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.

The sponsoring committee considers public comments and recommends final adoption of the proposal. 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 proceed with the normal OPTN policy development process.

If the specified number of objections in #5 above are not received during the public comment period, then the process will proceed as follows:

- 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.
- 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.