

**OPTN Executive Committee  
Meeting Summary  
November 14, 2024  
Webex**

**Richard Formica, MD, Chair**

## **Introduction**

The OPTN Executive Committee met via Webex teleconference on 11/14/2024 to discuss the following agenda item:

1. Welcome & Announcements
2. OPTN Strategic Plan Review Process
3. Patient Affairs Committee: Patient Awareness of Listing Status Project\*
4. Revised Bylaws and Management and Membership Policies Post Public Comment Analysis\*
5. Closed Session

The following is a summary of the Committee's discussion.

### **1. Welcome & Announcements**

Richard Formica, Chair of the Executive Committee, welcomed the committee to their meeting and presented the agenda.

### **2. OPTN Strategic Plan Review Process**

Contractor staff presented a proposed OPTN Strategic Plan review process for the committee to discuss. The committee was asked to consider key elements to efficiently, effectively, and routinely review the OPTN Strategic Plan. Contractor staff reviewed the current plan's four goals, presented challenges and opportunities within the plan, and provided insights and examples on how the committee could pursue reviewing the strategic plan. Contractor staff asked the committee to review data on the plan's metrics to ensure they match the committee's original intent and will provide actionable insights.

#### Summary of Discussion:

The committee discussed the importance of understanding how current OPTN projects interact with one another and potentially influence the strategic plan metrics. Committee members noted that the strategic plan metrics could be reviewed by assessing current projects and how they may influence the trends and metrics in the strategic plan. Committee members made suggestions on metric visualizations, such as a suggestion to include more analysis and information on whether the metrics are statistically significant.

The committee discussed the challenges and opportunities, noting the unknown circumstances in reviewing the strategic plan with a new OPTN Board support contractor. Committee members asked whether the Board would have access to the same data for the strategic plan metrics under the new contracting model. Contractor staff shared that the answer was unknown at this time.

The committee discussed resource allocation and how changes in allocation could impact the strategic plan. A committee member suggested that the Policy Oversight Committee (POC) be involved in

reviewing the strategic plan because they serve as the first step in evaluating new projects, and it is important that they are aligned with the Executive Committee.

Next Steps:

Committee members will fill out a questionnaire to share their feedback on the strategic plan review process and metrics.

**3. Patient Affairs Committee: Patient Awareness of Listing Status Project\***

Garrett Erdle, Immediate Past Chair of the Patient Affairs Committee (PAC) presented a project from the committee on Patient Awareness of Listing Status (PALS). Michel Brown, PAC Member, presented his personal connection to the project. Mr. Erdle and Mr. Brown shared that the PAC saw a potential need for this project after hearing anecdotal accounts that some candidates were not aware when they were made inactive on the waiting list.

Contractor staff shared background information on the project and presented the three different approaches the PAC has considered for the project. The PAC is now asking the Executive Committee to consider these options:

1. Policy requirement for transplant programs to notify candidates of changes in waitlist status,
2. Policy requirement and to consider changes to existing APIs to provide waiting list status in real time to patients, or
3. Develop an OPTN smartphone application to share information directly to transplant patients.

Contractor staff shared that the PAC discussed advancing a policy solution to address these concerns expeditiously while assessing additional technical solutions in parallel, however, the committee declined this approach. Contractor staff presented the potential pros and cons for each approach and shared a fourth approach for the Executive Committee to consider. The fourth potential approach is to both develop a policy requirement and develop an OPTN smartphone application. Contractor staff shared that the PAC was most interested in a smartphone application, but this would be the more complicated approach for the OPTN to implement given concerns around patient data.

Summary of Discussion:

The committee discussed the four proposed approaches to the project. Committee members voiced their concerns regarding developing a smartphone application given the OPTN's role within governance and policy. Committee members suggested the PAC pursue a policy pathway to ensure that the practice is adopted by all OPTN members and is not an application that members may selectively use.

Multiple committee members shared their concerns with a smartphone application serving as the main source of notification to patients because not all patients will have access to a smartphone. Many committee members shared the importance of considering all levels of health literacy when developing a resource for patients. A committee member shared that it is also important to consider communication issues with a smartphone application due to geographic differences. A committee member shared that it is important to consider different forms of communication with patients and the committee should consider whether a patient is notified in verbal or written form.

Dr. Formica asked representatives from HRSA to share whether there were any budget concerns regarding this project. A representative from HRSA shared that if the PAC pursued the policy approach, then more resources could be available. A committee member asked for the estimated timeline for the project, and Mr. Erdle shared that the committee has not developed timelines for the four potential approaches.

Many committee members shared their support for the PAC to pursue the policy development route to ensure that the policy is enforceable and that the project is impactful for the greatest number of patients. The committee noted that the project has not been evaluated by the Policy Oversight Committee (POC).

Committee members suggested that the PAC pursue a formal policy project, aligned to the policy development process, and to develop a smartphone application simultaneously. A committee member suggested that until the policy is implemented, and the application is in use, it would be important for the OPTN to encourage centers to notify patients of their status changes. The committee voted on the below resolution.

Vote:

WHEREAS the Executive Committee supports the concept of the PAC's Patient Awareness of Listing Status project, the Executive Committee finds that the project is most appropriate as a policy proposal with an application component.

NOW, THEREFORE BE RESOLVED, that should the PAC agree to continue the project in light of the finding above, the project should proceed through the OPTN policy development process for proper consideration of the project in the OPTN's portfolio of work.

Next Steps:

Dr. Formica asked PAC leadership to share the Executive Committee's support for their efforts. The PAC will develop a formal policy proposal to go through the formal policy development process.

**4. Revised Bylaws and Management and Membership Policies Post Public Comment Analysis\***

Dr. Formica presented the post-public comment analysis on the Revised Bylaws and Management and Membership policies. Dr. Formica shared that during public comment, the proposal saw general support for OPTN modernization efforts, concerns around transparency in the development of the proposal, concerns around transparency and trust in the future state, and recommendations on content changes to the bylaws. Dr. Formica shared that the suggested changes were focused on indemnification expansion, a request for more information on "special" elections, a need to modify duplicative "policy" reference language, clarity on making public statements in a personal capacity, recommendations on family and patient centered language, and feedback on Board and committee composition.

The committee discussed feedback received on special elections. It was noted that special elections are not referenced anywhere in the current OPTN Bylaws, nor the proposed new Bylaws and Management and Membership Policies. The bylaws do not differentiate between the type of election, but they differentiate based on who is being elected. Contractor staff also shared background information regarding elections and the Nominating Committee from NOTA, the Final Rule, and OPTN Bylaws.

Summary of Discussion:

In response to public comment, Dr. Formica asked HRSA to release the OPTN designation agreement so the document could be shared with the broader community. Dr. Formica stated that sharing the designation agreement may help the community understand the proposal more clearly. The committee discussed proposed changes to the indemnification language to ensure that all volunteers were included in the coverage. The committee discussed and agreed to make post-public comment changes to the proposal to incorporate broader indemnification language.

Committee members asked questions about the OPTN Nominating Committee. Committee members asked whether a new Nominating Committee would be formed and whether the composition of the

committee would be different than the compositional requirements the OPTN currently follows. Information on OPTN elections found in NOTA, the Final Rule, and OPTN Bylaws, was shared and noted that the designation agreement states that the HHS Secretary has the ability to hold a “special” election for the OPTN Board of Directors, though the terms “special” election and “special” election parameters are undefined. The committee member shared that although the designation agreement states the Secretary has this ability, the OPTN is still held to its governing documents-- NOTA, the Final Rule, and the OPTN Bylaws. The committee member suggested that the election be held in a similar manner to other OPTN elections to ensure proper governance of the OPTN. The committee member asked HRSA to explain the difference between the designation agreement and the three main governing documents of the OPTN. The committee member suggested that HRSA share any clarifying information they have ahead of the Board taking action on the proposal. Dr. Formica shared that these questions are not about whether an election will take place, but it is about the governance of the election, and to ensure the OPTN is following proper policies and procedures. A representative from HRSA shared that this topic is a legal matter being discussed at HRSA. The representative shared that holding a “special” election is a desire from Congress and the HHS Secretary, and that they intend for the new nominating committee to be appointed by HRSA. Dr. Formica shared that it is important that the process of the “special” election be shared with the community and that it is clear how the election will take place to ensure trust in the current and future state of the OPTN.

The committee discussed whether the HHS Secretary has the authority to hold a “special” election and how this complies with NOTA and the Final Rule to do so. Dr. Formica shared that during this transition, the community has concerns about the continuity of knowledge, leadership, and the level of governmental oversight. Contractor staff shared that there are no proposed changes to the proposal to create a “special” election or exempt the process from current OPTN bylaws. Dr. Formica asked HRSA to consider the committee’s discussion and asked that HRSA share any outstanding feedback with the committee ahead of the Board meeting.

The committee discussed the overlap in policy terminology between the two documents. Contractor staff presented different options for the committee to consider adopting to clarify the terminology and structure. The committee chose to replace the references in Management and Membership Policies 1-6 with letters to match the appendix reference terms. Committee members shared that this was the best approach to avoid confusion and reduce member burden associated with renaming.

When discussing transparency and trust in the future state of the OPTN, Dr. Formica shared that this would depend on the government. A representative from HRSA shared that they are working to collaborate with OPTN Board Leadership to manage the process.

The committee then took action on whether to incorporate the proposed post-public comment feedback and whether to send the proposal to the full Board of Directors to take action on during their December Board meeting.

Vote:

The committee unanimously approved the following items:

Does the Executive Committee approve amending the proposal with the following updates:

- Changes to the indemnification clause to represent applicability to all OPTN volunteers
- Changes to the terminology related to Management and Membership Policies
- Clarification that, if approved, the OPTN will have adopted the INVEST Bylaws as the OPTN Bylaws, superseding the OPTN’s previous Bylaws

Does the Executive Committee recommend the amended proposal Revised Bylaws and Management and Membership Policies be considered by the OPTN Board of Directors?

Next Steps:

The OPTN Board will consider the Revised Bylaws and Management and Membership policies during their in-person meeting in December. The Board will be provided a briefing paper outlining the changes proposed by the Committee for their consideration. Typically, briefing papers are provided 10 business days in advance of the meeting, but given the timing of collaboration and review by HRSA, the 10-day notice to the Board has been waived by HRSA.

**5. Closed Session**

The committee met in a closed session.

The meeting adjourned.

**Upcoming Meetings:**

- December 12, 2024

## Attendance

- **Committee Members**
  - Andrea Tietjen
  - Dianne LaPointe Rudow
  - Emily Blumberg
  - Erika Demars
  - George Surratt
  - Jennifer Muriett
  - Lloyd Ratner
  - Macey Levan
  - Richard Formica
  - Silas Norman
- **HRSA Representatives**
  - Chris McLaughlin
  - Frank Holloman
  - Raymond Lynch
- **UNOS Staff**
  - Anna Messmer
  - Dale Smith
  - Jacqui O'Keefe
  - Kaitlin Swanner
  - Kimberly Uccellini
  - Krissy Laurie
  - Lauren Mauk
  - Liz Robbins Callahan
  - Maureen McBride
  - Morgan Jupe
  - Rebecca Murdock
  - Roger Brown
  - Susie Sprinson
  - Trish Jasion
- **Other Attendees**
  - Garrett Erdle
  - Michael Brown