

**OPTN Executive Committee  
Meeting Summary  
December 20, 2023  
Webex**

**Dianne LaPointe Rudow, ANP-BC, DNP, FAAN, Chair**

## **Introduction**

The OPTN Executive Committee met via Webex teleconference on 12/20/2023 to discuss the following agenda item:

1. Expedited Placement Variance Proposal\*
2. Closed Session

The following is a summary of the committee's discussions.

### **1. Expedited Placement Variance Proposal\***

James Alcorn, Senior Policy Strategist, presented the expedited placement variance proposal from the Expeditious Task Force. He shared that the task force is proposing pilot studies focused on increasing organ utilization, with the first pilot focusing on alternative allocation pathways for hard-to-place organs. Mr. Alcorn shared the definition of a variance is and the associated protocol to help frame the conversation. He shared that variances are mentioned in NOTA and are an experimental policy approved by the OPTN. He noted that any variance must comply with the requirements in the OPTN Final Rule and *OPTN Policy 1.3: Variances*. He shared that the variance in this specific proposal requires the Executive Committee to approve specific protocols.

Mr. Alcorn shared the structure of the pilot with the committee. He shared that the Board or the Executive Committee will approve an open variance, special public comment will take place for approximately 30 days, this time will include a time limited study, and members will be able to opt-in to the variance. Mr. Alcorn shared that if the committee approved of the proposal, the proposal will be sent out for public comment almost immediately and run from December 22, 2023, until January 21, 2024. Mr. Alcorn shared that protocols will be collected from the community, the task force will develop a framework to select protocols to test, and these protocols will live outside of policy but be accessible to the community. The task force will then test protocols to assess the most effective one. Test protocols will include evaluation plans with objective criteria to measure the variance's success and members will submit information required by the variance.

Mr. Alcorn shared that within the structure of a protocol, each protocol must include the following four items:

1. Criteria for organs eligible for expedited placement
2. Criteria for candidates eligible to receive expedited placement offers
3. Conditions for the use of expedited placement
4. OPO and transplant hospital responsibilities

Mr. Alcorn asked the committee about the length of a variance. He shared that the OPTN Final Rule requires variances have a specific end date, however they may be extended, modified, or terminated

early. The committee was asked to consider how long the variance should last. Mr. Alcorn suggested the committee consider the variance last one year.

Mr. Alcorn shared changes to variance governance. He shared that variances are governed by the OPTN Final Rule and OPTN Policies. Mr. Alcorn stated that there have been some modifications made on how variances change, and he shared what aspects of a variance were removed. Mr. Alcorn shared proposed changes for the committee to consider, which included clarification regarding the creation of variances, removing the requirement to solicit agreement prior to public comment, and changing the frequency of reporting requirements as this is important for short, iterative variances.

#### Summary of Discussion:

Many committee members suggested that a calculation be developed to measure the success of a protocol. They agreed that there needed to be a way to measure and compare the success of a protocol. The committee discussed the length of the variance. A committee member suggested that the one-year variance timeline was too short. The committee discussed extending a variance timeframe and that if a variance is extended, the Executive Committee would not need to create a new variance but would extend the termination date in policy and submit this for special public comment. Contractor staff suggested that if the committee is concerned about the one-year timeframe, they extend the timeframe to 18-months or 2-years before voting on the language.

The committee discussed what happens if a protocol is successful and there is no longer a need to test more protocols. Contractor staff explained that if this occurs, then other protocols would not need to take place and they could make the successful protocol policy.

A representative from HRSA asked how the public will be informed of the different protocols. The Chair noted that the information would be accessible on the Expedious Task Force website, presented during regional meetings, and discussed during town halls. The representative from HRSA suggested there be an official comment and response process associated with the protocols to ensure transparency and public input. They asked if there would need to be a recurring special public comment for the protocols for a predetermined length of time. In response to this, a committee member suggested the OPTN operate a real time public comment platform to ensure there is an ongoing feedback loop. Contractor staff clarified that the comments would be posted on the Expedious Task Force website as the task force is reviewing the comments, and before the Executive Committee has made final decisions on the use of the protocol. A representative from HRSA supported this plan. A representative from HRSA asked that an explanation on the real time public comment be included in the proposal so the community understands the process. The representative from HRSA asked that the proposal include language on how these protocols will be sent out for public comment and that there be a clear place for the public to submit a comment and that a response will be administered to the commenter.

A patient representative on the Executive Committee commented that they did not have any concerns with the variance proposal from a patient perspective.

The Committee Chair suggested that the variance timeframe change from 12-months to 18-months and that the variance receive continuous public comment feedback.

A representative from HRSA asked why the proposal would be out for public comment for 30 days. Mr. Alcorn explained that OPTN Bylaws do not set a minimum requirement for the length of special public comment. He explained that the 30-day timeframe is specified in other parts of OPTN Policies. He noted that a 30-day timeframe would also allow the special public comment period to end before the winter 2024 public comment cycle begins. A representative from HRSA asked that information on the 30-day timeframe be included in the proposal.

A representative from HRSA asked if there was any consideration to include what happens if there are any negative outcomes from the protocols and what kind of monitoring measures will be in place. Mr. Alcorn explained that this information can be found in the evaluation and research plan. He noted that the OPTN Final Rule requires that the variance have a research plan and the task force will be analyzing and monitoring protocols throughout the variance timeframe.

Vote:

The committee approved the following resolution:

**RESOLVED**, the OPTN Executive Committee approves distributing the proposed Expedited Placement Variance proposal for special public comment from December 21, 2023 to January 21, 2024.

**2. Closed Session**

The committee met in a closed session.

The meeting was adjourned.

## Attendance

- **Committee Members**
  - Andrea Tietjen
  - Dianne LaPointe Rudow
  - Ginny McBride
  - Manish Gandhi
  - Melissa McQueen
  - Richard Formica
  - Silas Norman
  - Wendy Garrison
- **HRSA Representatives**
  - Adrienne Goodrich-Doctor
  - Christopher McLaughlin
  - Daniel Thompson
- **UNOS Staff**
  - Ann-Marie Leary
  - Anna Messmer
  - James Alcorn
  - Lauren Mauk
  - Liz Robbins Callahan
  - Maureen McBride
  - Morgan Jupe
  - Roger Brown