OPTN Executive Committee Meeting Summary May 23, 2024 Webex

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

Introduction

The OPTN Executive Committee met via Webex teleconference on 05/23/2024 to discuss the following agenda item:

- 1. Welcome and Announcements
- 2. New Projects from the Policy Oversight Committee (POC)*
- 3. Establish Code of Conduct and Whistleblower Protection Bylaws*
- 4. Non-Discrimination HHS Directive

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

1. Welcome and Announcements

Dianne LaPointe Rudow, Chair of the Executive Committee, welcomed the committee to the meeting and presented the agenda.

2. New Projects from the Policy Oversight Committee (POC)*

Erika Lease, Vice-Chair of the Policy Oversight Committee (POC) presented a new project from the Lung Transplantation Committee to Promote Efficiency of Lung Donor Testing and a new project from the Liver & Intestinal Organ Transplantation Committee on Updates to National Liver Review Board Guidance and Further Alignment with LI-RADS.

Dr. Lease explained that the new project from the Lung Transplantation Committee to Promote Efficiency of Lung Donor Testing promotes efficiency of lung allocation by considering changes to lung donor testing in *OPTN Policy 2.11.D: Required Information for Deceased Lung Donors* and guidance on requested deceased donor information. Dr. Lease shared the metrics, the technical implementation plan, the strategic plan alignment, the cost benefit score, and feedback from the POC on the proposal.

Dr. Lease then presented the new project from the Liver & Intestinal Organ Transplantation Committee on Updates to National Liver Review Board Guidance and Further Alignment with LI-RADS. Dr. Lease shared that the purpose of the project is to:

- Update the Adult MELD Exception Review guidance document to review content based on new literature as well as adding associated score recommendations,
- Update HCC policy and guidance to add contrast-enhanced ultrasound as an acceptable adjunct diagnostic tool for HCC, and
- Update HCC imaging classification criteria to align with LIRADS-5 terminology.

Dr. Lease presented the key metrics, the technical implementation plan, the strategic plan alignment, the cost benefit score, and feedback from the POC on the proposal.

Summary of Discussion:

When discussing the new project from the Lung Transplantation Committee, the committee noted the role of efficiency in the implementation of continuous distribution.

When discussing the new project from the Liver & Intestinal Organ Transplantation Committee, the committee discussed how the project aligns to the strategic plan, and how the OPTN should approach projects that are important but do not fall specifically under one of the strategic goals. A committee member asked what the threshold is for cost when the POC is performing the cost benefit analysis for new projects. Dr. Lease and contractor staff explained that the POC determines whether a project is high or low effort as it relates to other projects and the entire implementation portfolio. A committee member asked if the POC could share the implementation effort in hours and a calculated dollar amount.

The committee discussed how projects are organized within the OPTN project portfolio and discussed how the Prioritization Work Group has discussed how to enhance this process.

Vote:

The Executive Committee approved the initiation of two projects from the Policy Oversight Committee (POC):

- Promote Efficiency of Lung Donor Testing (Lung)
- Updates to National Liver Review Board Guidance and Further Alignment with LI-RADS (Liver & Intestinal Organ)

3. Establish Code of Conduct and Whistleblower Protection Bylaws*

Contractor staff presented the proposal to Establish Code of Conduct and Whistleblower Protection Bylaws. Contractor staff presented feedback received during public comment and shared the suggested changes that have been made to the proposal post-public comment. Contractor staff shared that the themes seen throughout public comment included feedback on: the compliance officer, adjudicating reports and appeals, public statements, and the proposed language overall.

Contractor staff then shared the changes that the work group made post-public comment based on the feedback the proposal received. These changes include:

- Added additional resource for individuals to respond to allegations
- Broadened options for incorporating independent third parties
- Clarified public statement expectations
- Provided social media guidelines
- Clarified what would constitute retaliation
- Modified what falls under "duty of care" in the Code of Conduct
- Clarified language throughout

The committee reviewed the policy language within the proposal and highlighted changes that the work group made post-public comment.

Summary of Discussion:

The committee discussed staggering the terms of the two compliance officers to ensure that there is always one compliance officer that has at least one year of experience. The committee discussed how this would not be relevant for the first year the policy is in place but for the years after. The committee agreed that this would be a good detail to include in the policy. The committee also discussed whether they needed to consider recruiting individuals with expertise to serve as a compliance officer when recruiting and identifying new Board members. The committee reviewed the policy language during the meeting and committee members made suggestions on how to modify the proposed language. Committee members suggested modifications to the language on volunteers making public statements on behalf of the OPTN, appointing compliance officers, reviewing reported events, and designating voting privileges to members and whether these can be revoked for any reason.

Vote:

The committee approved recommending the proposal to Establish Code of Conduct and Whistleblower Protection Bylaws Proposal to the OPTN Board of Directors for consideration, pending any non-substantive edits approved by the OPTN President.

4. Non-Discrimination HHS Directive

Contractor staff presented on the Health and Human Services (HHS) Office for Civil Rights (OCR) and the Centers for Medicare and Medicaid Services (CMS) Nondiscrimination Rule. Contractor staff shared that the HHS OCR and CMS published their final rule on nondiscrimination in the Federal Register under Section 1557 of the Affordable Care Act. The rule prohibits discrimination in health programs or activities that receive federal funding including Medicare and Medicaid, and it prohibits discrimination on the basis of: race, color, national origin, sex, age, or disability.

Contractor staff explained that the rule applied to entities, which include all health programs or activities that receive HHS funding, and health programs or activities administered by HHS. They shared that this rule can be interpreted to include the OPTN and other covered entities such as hospitals, health clinics, health insurance issuers, state Medicaid agencies, community health centers, physicians' practices, and home healthcare agencies. Contractor staff explained that at a high-level the rule requires covered entities to have policies and procedures that comply with the nondiscrimination requirements, and to identify and mitigate nondiscrimination in the use of patient care decision support tools.

Contractor staff recommended that staff and committee members review all OPTN policy, bylaw, and guidance language. Contractor staff suggested that OPTN members review patient care support tools that may be used as inputs in the OPTN Computer System. After the analysis of OPTN documents is complete, staff will report to the Board on the findings, and include proposed language edits if necessary. Contractor staff will begin work on a project plan and proposed timeline. Contractor staff shared that the proposed project plan will be shared during a future Executive Committee meeting.

Summary of Discussion:

The committee discussed the directive and how this may affect their practice. Some committee members made suggestions on how HHS should inquire about data. The committee also discussed the OPTN's role as it pertains to the directive.

Attendance

• Committee Members

- o Andrea Tietjen
- o Dianne LaPointe Rudow
- o Ginny McBride
- o Jerry McCauley
- o Jim Sharrock
- o Linda Cendales
- o Melissa McQueen
- o Richard Formica
- o Valinda Jones

• HRSA Representatives

- o Adrienne Goodrich-Doctor
- o Christopher McLaughlin
- o Frank Holloman

• UNOS Staff

- o Anna Messmer
- o Dale Smith
- o Jacqui O'Keefe
- o Kaitlin Swanner
- o Kelley Poff
- o Lindsay Larkin
- o Liz Robbins Callahan
- o Maureen McBride
- o Morgan Jupe
- o Roger Brown
- o Shandie Covington
- o Susan Tlusty
- o Susie Sprinson

• Other Attendees

o Erika Lease