

**OPTN Patient Affairs Committee
Meeting Summary
May 3, 2024
Conference Call**

**Garrett W. Erdle, Chair
Molly J. McCarthy, Vice Chair**

Introduction

The Patient Affairs Committee members were offered two opportunities to meet via WebEx teleconference, on May 1 or May 3, 2024, to discuss the Proposal to Establish Code of Conduct and Whistler Protection Bylaws, a special public comment out for consideration from April 17 – May 17, 2024. The two sessions were held to allow Committee members who may not have attended the Town Hall presentation led by the OPTN President to hear the proposal presented and discuss as a group.

Feedback from these discussions will be combined to develop a Committee response to the proposal.

The following is a summary of the Committee's May 3, 2024, discussion.

1. May 3, 2024 Public Comment Discussion

Presentation Summary:

OPTN Contractor staff presented slides outlining the public comment proposal. As an overview, this proposal offers the following:

- In the OPTN Bylaws:
 - Requirement to abide by Code of Conduct
 - Reporting and review of violations
 - Role of Compliance officer (a new role)
 - How public statements are to be handled (media and manuscripts)
 - Whistleblower protections
- A New Code of Conduct
 - Codifying current practice
 - A document to be signed by all volunteers (Board of Directors, Committee and Task Force members, Review Boards, Ex Officio members, Executive Director)
 - Outlines all provisions to be covered.

The Bylaws outline the pathway for reporting Code of Conduct violations. Anyone may submit a complaint. The complaint may be submitted anonymously but must be in writing. All complaints will be received by the OPTN Compliance Officer, a new role to be filled by a member of the Board of Directors to be served for a term of at least one year. The pathway for review of a reported Code of Conduct violation appears below:

1. Compliance Officer receives report.
2. Compliance Officer notifies volunteer accused of violation.
3. Volunteer has 7 days to respond.
4. Compliance Officer investigates the report and may assemble a group of Directors to review.
5. Compliance Officer recommends resolution of a confirmed violation.

6. Executive Committee decides on appropriate action.

In addition to Code of Conduct application, the proposed Bylaws additions also outline appropriate use of OPTN titles. The proposed bylaws state that Directors and Committee members are not permitted to use their positions or titles in a way that implies statements that they make are authorized by the OPTN. Permission to speak on behalf of the OPTN may be granted, in writing, only by the President. Directors and Committee members may use their position or title in conjunction with scientific or professional journal articles if an OPTN-approved disclaimer is used. However, Directors and Committee Chairs and Vice Chairs must notify the OPTN Executive Committee prior to article submission if using their OPTN position or title.

The proposed Bylaws language also lays out protections for whistleblowers reporting concerns regarding suspected violations of ethics, laws, or regulations governing the operation of the OPTN in good faith. This proposed bylaw is in addition to any non-retaliation requirements required by law and the critical comment procedures described in the Final Rule. Whistleblowers reporting any violations may submit confidentially in good faith with reasonable grounds for believing that the information disclosed indicates a violation. These reported violations will go to the OPTN Executive Director. If the report is regarding or involving the Executive Director, the report will go to the OPTN President. Reports will be kept confidential to the extent possible. The pathway for review of a violation reported by a whistleblower appears below:

1. OPTN Executive Director or President acknowledges receipt.
2. Report is promptly investigated. The Executive Director or President may engage independent accountants, counsel, or other experts at their discretion to aid in the investigation.
3. Appropriate corrective action is taken.

Discussion Summary:

No decisions were made. This feedback will be combined with that collected during the May 1, 2024, call to develop a Committee response to the public comment proposal.

Committee members shared the following thoughts during the presentation and after its review:

Specific to the Code of Conduct:

- Concern that there is no due process included here (other than 7 days to comment), but no give and take included related to the review process.
- Per the proposed Bylaw, a review Code of Conduct at least every three years. This is a new document and a newly separated organization. It should be reviewed annually, at least as a start.

Specific to the Compliance Officer:

- Concern related to the Compliance Officer coming from within the OPTN Board of Directors. An independent, neutral third party would be beneficial here. Corporate codes of conduct often have HR departments that these go through (rather than a peer). The military uses an Inspector General that works independently to review the report, speak with the individual and review the evidence before reporting findings to the Board of Directors. This allows for independent assessment.
- The Compliance Officer position could be expanded as a voluntary position and should be 3–5-year appointment to make decisions without end of term concerns. This could be a teach/mentor/train position to provide serve as a counselor or advisor that could address some

of these items before they become an issue. "I want to make this proposal, what do you think." This enhanced position could function as an intermediary between director and person making complaint- more OPTN HR type support perhaps here, working for the organization but independent of the leadership.

Specific to Statements on Behalf of the OPTN:

- The Committee sees a need to clarify what people are free to say/do and what they are not. Just because you are on a committee does not mean that you lose your individuality. You are free to say what you want under law (not censoring people) as long as you make it clear that you are not speaking on behalf of the OPTN.
- Language (page 8) regarding the use of OPTN titles. Defining this is too constrictive (currently noted as publishing articles). Much of this Committee's work carries into other patient organizations. Is it safe to assume that talking to outside entities as an advocate is still allowable here? Clarification is needed here to note that this type of outreach work remains permissible. This could be cumbersome, but perhaps noting that you are part of the OPTN and sharing a disclaimer that statements made are your own and you are not speaking on behalf of the OPTN.

Specific to the Whistleblower Protections:

- Concern related to page 4 of policy that speaks to no retaliation concept. A Committee member noted that vocal individuals with a difference of opinion should not be haunted by their statements. Some of the comments have been bright and insightful and have advanced the cause and transplanted in general. These types of comments should not lead to any retaliation over differences of opinion. This is important with everything going on within the OPTN.

Next Steps:

Feedback from the two calls will be combined to develop a Committee response. The draft response will be shared with the Committee and approved by the Committee's leadership, as the next Committee call falls after the public comment period ends.

Members were reminded of the opportunity to share individual comments on the proposal on the OPTN website.

2. Public Forum

No public forum items were offered for discussion.

Upcoming Meetings

- May 21, 2024 conference call
- June 18, 2024 conference call (tentative)

May 3, 2024 Attendance

- **Committee Members**
 - Steve Weitzen
 - Justin Wilkerson
 - Andreas Price
- **HRSA Representation**
 - Mesmin Germain
 - Arjun Naik
- **SRTR Representatives**
 - Katie Audette
- **UNOS Staff**
 - Shandie Covington
 - Kaitlin Swanner
 - Desiree Tenenbaum
 - Kimberly Uccellini
 - Laura Schmitt
- **Other**
 - Michael Slipowitz