

**OPTN Patient Affairs Committee  
Meeting Summary  
May 1, 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 1, 2024, discussion.

### **1. May 1, 2024 Public Comment Discussion**

Two new members for the 2024-2025 cycle joined the meeting to observe. The Chair welcomed their participation and thanked them for their early commitment.

The Committee received a presentation of the public comment proposal and then shared comments as a group.

#### 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 3, 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:

- Is this the OPTN's first Code of Conduct?
  - OPTN Contractor staff noted that this proposal seeks to codify some pieces that have been in place but not consolidated. References were made to the attendance requirement that has been in place for a long time.
- Does the Conflict of Interest fall under this as well?
  - OPTN Contractor staff shared the link to access section 2.7 of the OPTN Bylaws, *Conflicts of Interest*<sup>1</sup>, in the meeting chat and noted that the attestation document signed by all volunteers would be circulated after the call. The Conflict of Interest is not part of this

---

<sup>1</sup> OPTN Bylaws. [https://optn.transplant.hrsa.gov/media/lgbbmahi/optn\\_bylaws.pdf](https://optn.transplant.hrsa.gov/media/lgbbmahi/optn_bylaws.pdf) (accessed May 1, 2024)

proposal and already requires an attestation as outlined in the enclosed "OPTN Volunteer Confidentiality Agreement and COI Certification.

- The Code of Conduct appears to have been developed using non-profit resources. Were for profit examples also reviewed from the business world?
  - OPTN Contractor staff noted that various examples of nonprofit codes of conduct and two from other organizations were used as examples of what might be desired.
- A Committee member voiced concern regarding the Code of Conduct impacting someone's willingness to volunteer, especially if there could be legal consequences.
- Request for more clarity regarding the pathway for individuals accused of code of conduct violations. Understanding that they are notified of the report, what is their pathway for rebuttal or appeal? Should an attorney be hired to protect them from allegations?
  - OPTN Contractor staff noted the pathway in the Bylaws: someone accused of a Code of Conduct violation would be notified and have the opportunity to respond. The Compliance Officer will review the report and response. The Compliance Officer may assemble other members of the Board to review the report as needed. This group must include the immediate OPTN Past President unless a conflict is present. If the violation were confirmed, a recommended resolution would be proposed to the Executive Committee. The Executive Committee will ultimately decide the action appropriate for the violation. Confirmed violations can result in consequences up to and including removal from office.
    - An attendee noted that this should be made clear.

Specific to the Compliance Officer:

- Concerns regarding the Compliance Officer being a member of the Board, noting that this should be someone separate who the members and public see as completely neutral in their decision making to have trust in the process. Members said that the optics of filling the compliance officer role internally are poor if there is a desire to foster trust in this process. This could also be seen as a conflict of interest if the responsibility remains an internal assignment.
  - This concern was echoed by several participants.
  - There was also concern from a patient volunteer perspective, noting that individuals may be intimidated to raise concern without feeling that they might be "in trouble" for being a part of raising concerns or questions. The new Code of Conducts were seen as overwhelming for new patient volunteers.
- Comments that a third party should be used for review and adjudication to avoid retaliation or retribution if managed internally.

Specific to Statements on Behalf of the OPTN:

OPTN Contractor staff noted that the intent here is not to stifle or censor a volunteer, but rather to make it clear that an individual is not authorized to speak on behalf of the OPTN unless authorized to do so. Diverse thoughts and opinions are valued and welcomed. Staff asked if there were any suggestions on how to make this clearer in policy, noting that this would be taken back to the Executive Committee.

- Concern and confusion about what this means for individuals sharing personal thoughts. As an example, "If I am a patient member of the Board and I comment on something as a patient on my Facebook page, is that going to be a violation?"
- Concern related to free speech being stifled as a patient volunteer. What about when we are sharing with other patient organizations that we serve or belong to?

- A Committee member noted differences between being openly critical of a process within the protections of a committee meeting versus speaking disparagingly about a process outside of the protections of the committee. The latter was seen as potentially problematic, recognizing the value of a code of conduct as a participant. The member noted that the Code of Conduct is how you conduct yourself as a volunteer, but not outside of that volunteer activity.
- Questions were raised regarding approval of articles before submission. OPTN Contractor staff clarified that there is not approval of the article or manuscript but rather making the Executive Committee aware that the article is coming out and including the disclaimer language if you are using your OPTN title/affiliation to make it clear that the OPTN is not endorsing the thoughts included in the article or manuscript. It was noted that this is common practice in medical journals, as physicians and other medical professionals note the disclaimers to establish between industry, society or other organization or even employer as appropriate.

Specific to the Whistleblower Protections:

- A member sought examples of violations. They questioned whether fraud pertained to lying about needing an organ here, noting that, as a patient, they may not even know that something is a violation. OPTN Contractor staff noted that the whistleblower bylaw is focused more on reporting of bad actors or bad behavior within the Board.
- A member noted that this makes reporting easy, but how would an anonymous patient making a report know that their concern about something happening within their institution was received and that something happened or changed because of it? OPTN Contractor staff noted that the whistleblower policy is focused on the OPTN and its volunteers. Complaints specific to a donation or transplantation organization would follow a different path, potentially using the OPTN's patient safety reporting or through that institution's own ethics hotline or reporting process.
- If a patient makes a report, how do they have assurance that something is going to be followed through? OPTN Contractor staff noted that the Bylaws indicate that the OPTN Executive Director or President will acknowledge receipt of the report.

Common themes garnered from the discussion include:

- A strong opinion that the compliance officer should not be part of the Board of Directors, but rather an independent entity to promote trust in the process.
- More clarity is needed around speaking on behalf of the OPTN. There were concerns raised by multiple individuals that their ability to educate regarding OPTN topics in other patient-centered groups will be curtailed here.
- Clarity is needed regarding the pathway for an individual reported as violating the Code of Conduct. Beyond the 7 days to respond, there is no description of opportunity to respond to comments or appeal a decision.
- Include examples of what is and is not appropriate to make it clear to volunteers what is acceptable and what is not.

Next steps:

These comments will be compiled with those received on May 3, 2024, to create a Committee comment for this proposal.

Members were encouraged to submit individual comments as they felt led. It was noted that several Committee members had already done so 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 1, 2024 Attendance

- **Committee Members**
  - Garrett Erdle
  - Lorrinda Gray-Davis
  - Densie Abbey
  - Calvin Henry
  - Cathy Ramage
  - Kristen Ramsay
  - Cheri Coleman
- **HRSA Representatives**
  - Mesmin Germain
  - Robert Johnson
  - Arjun Naik
- **UNOS Staff**
  - Shandie Covington
  - Houlder Hudgins
  - Kaitlin Swanner
  - Desiree Tenenbaum
- **Other**
  - Karlett Para
  - Michael Brown