

*Briefing to the OPTN Board of Directors on*  
**Establish Code of Conduct and  
Whistleblower Protection Bylaws**

*OPTN Executive Committee*

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# Establish Code of Conduct and Whistleblower Protection Bylaws

<i>Affected Bylaws:</i>	<p>2.7 OPTN Code of Conduct</p> <p>2.9 Public Statements by Directors</p> <p>2.10 Whistleblower Protection</p> <p>7.8 OPTN Code of Conduct</p> <p>7.9 Public Statements by Committee Members and OPTN Volunteers</p> <p>9.5 Review Boards</p>
<i>Sponsoring Committee:</i>	Executive
<i>Public Comment Period:</i>	April 17, 2024 – May 17, 2024
<i>Board of Directors Meeting:</i>	June 12, 2024

## Executive Summary

This proposal documents and codifies existing practices that encourage participation in the OPTN, and establishes processes and protections within the OPTN Bylaws for OPTN members, volunteers, and others to raise any concerns about suspected violations of the law, ethics, or governing regulations by a Director, Committee member or other OPTN volunteer. This will include the creation of Bylaws to define:

- 1) OPTN Code of Conduct for Directors, Committee members, and other volunteers (i.e. Review Board members) and how any potential violations are to be addressed;
- 2) Clarity regarding authority to make public statements on behalf of the OPTN; and
- 3) Whistleblower protections for those who report suspected violations.

These processes are in addition to the critical comment process contained within the OPTN Final Rule, which provides a neutral and independent pathway for an initial review of concerns about the OPTN by an outside party, i.e. the Secretary of HHS.<sup>1</sup>

Currently, the OPTN requires Board members to sign an attestation of responsibilities as a member of the Board of Directors, recognizing duty of confidentiality and conflict of interest avoidance.<sup>2</sup> Similarly, OPTN volunteers currently serving on committees and organ-specific review boards sign an attestation to certify confidentiality and to disclose any potential conflicts of interest.<sup>4</sup>

This proposal was updated in response to public comment feedback, including the following changes:

- Updates to how the OPTN Compliance Officer will be selected, including consultation with HRSA and the addition of a second compliance officer.
- Additional recourse for individuals accused of violating the Code of Conduct, including:
  - Opportunity for the accused individual to request an informal discussion with an OPTN Compliance Officer, and to request the presence of a third party at the informal discussion.
  - Ability for OPTN Compliance Officers to engage other experts at their discretion to aid in any review of reported violations.

<sup>1</sup> 42 CFR § 121.4 (d)

<sup>2</sup> OPTN Website. <https://optn.transplant.hrsa.gov/about/how-to-get-involved/> (accessed on March 20, 2024)

- Additional detail on adjudication of reports, including which actions are determined by the OPTN Executive Committee versus the OPTN Board of Directors.
- Clarification on public statements to note that, without authorization, when commenting on OPTN matters, OPTN volunteers must state that they are commenting in an individual capacity and not on behalf of the OPTN.
- Clarified definition of retaliation in the whistleblower protection bylaw
- Code of Conduct
  - Separated courtesy behavioral expectations from Duty of Care
  - Clarified that Duty of Loyalty applies *when* making decisions as stewards of the OPTN, whether this be in Board calls or meetings, Committee calls or meetings, or other volunteer roles within the organization.
- Added OPTN Social Media Guidelines to clarify the distinction between speaking on behalf of the OPTN versus sharing personal experience and opinion.

Other non-substantive, clarifying edits were made through the document to improve the reader's experience. This includes making Compliance Officer plural where appropriate throughout the Bylaws.

## Purpose

The purpose of the proposed Bylaws is to: (1) document existing practices that encourage participation in the OPTN, outlining certain standards of conduct for OPTN members and volunteers to carry out responsibilities to the organization in the Bylaws; (2) establish processes and protections for anyone to raise concerns with the OPTN about suspected violations of the law, ethics, or governing regulations and policies (i.e. NOTA, Final Rule, OPTN Bylaws, OPTN policies); and (3) document a pathway for reporting and review of potential Code of Conduct violations. This will include the creation of Bylaws to define:

- Requirements for an OPTN Code of Conduct for Directors, Committee members, and other volunteers (i.e. Review Board members) and how any potential violations are to be addressed;
- Clarity regarding authority to make public statements on behalf of the OPTN; and
- Whistleblower protections for those reporting potential violations as outlined in the Whistleblower Protection Bylaw.

## Background

At its June 25, 2023 meeting,<sup>3</sup> the OPTN Executive Committee (Committee) supported the development of a policy codifying the OPTN's existing position on whistleblower protections. The Committee acknowledged and discussed the need to review current processes and protections and state laws protecting whistleblowers, and the importance of clearly communicating any changes in this area to make reporting pathways and protections clear and actionable.

The Committee met on August 14, 2023<sup>4</sup> to review potential policy language. The Committee wished to make clear that the OPTN welcomes and encourages different viewpoints on how the OPTN can best promote interests of the patients and donors that the OPTN serves. The Committee also wanted to make explicit the position that the OPTN will not retaliate against any individual who in good faith makes a whistleblower report, defined as reporting an ethics violation; suspected violation of law, such as a complaint of discrimination; suspected fraud; or suspected violation of any regulation or policy governing the operations of the OPTN. The Committee recognized that differences of opinion are valued in debate and discussion but noted that a disagreement of opinion does not constitute whistleblowing. Accordingly, the intent of the whistleblower protection bylaw is to protect an individual who reports an ethical or legal violation about the OPTN or any of its leadership from organizational retaliation. The Committee also emphasized that if the whistleblower's concern involves the OPTN Executive Director or any other subordinate officer of the OPTN, the complaint should go directly to the OPTN President rather than to the OPTN Executive Director. Finally, it was suggested that the policy should authorize the OPTN President and OPTN Executive Director to engage independent accountants, counsel, or other experts, at their discretion, to aid in any investigation and additional language was added to the proposed policy to reflect this suggestion. The Committee approved a Whistleblower Protection Policy on September 8, 2023.<sup>5</sup>

During its December 3, 2023 meeting, the Committee reviewed a timeline of this effort to date. After the September 2023 approval of the Whistleblower policy, further discussion and HRSA feedback led the

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<sup>3</sup> OPTN Executive Committee Meeting Summary, June 25, 2023.

[https://optn.transplant.hrsa.gov/media/djgpu1w2/20230625\\_executive-committee\\_summary.pdf](https://optn.transplant.hrsa.gov/media/djgpu1w2/20230625_executive-committee_summary.pdf) (accessed 3/18/2024).

<sup>4</sup> OPTN Executive Committee Meeting Summary, August 14, 2023.

[https://optn.transplant.hrsa.gov/media/mirngcz2/20230814\\_executive-committee-meeting-summary.pdf](https://optn.transplant.hrsa.gov/media/mirngcz2/20230814_executive-committee-meeting-summary.pdf) (accessed 3/28/2024).

<sup>5</sup> OPTN Executive Committee Meeting Summary, September 8, 2023.

[https://optn.transplant.hrsa.gov/media/msuf3vfj/20230908\\_executive-committee-meeting-summary.pdf](https://optn.transplant.hrsa.gov/media/msuf3vfj/20230908_executive-committee-meeting-summary.pdf) (accessed 3/18/2024)

Committee to reconsider the need for public comment for this policy change.<sup>6</sup> As a result, the policy was not implemented. While Article 11.1.A (*The Public Comment Period*)<sup>5</sup> does allow proposals that reflect administrative or non-substantive procedural changes that do not change the intent of policy or impact transplant community operations to advance without public comment, HRSA notified the OPTN that the Whistleblower Protection Policy has member burden implications and would require public comment.

The Committee's goal was to codify the existing reporting process and share this update in a manner transparent and available to the community, not just to members subject to OPTN policies. As the Whistleblower language was reconsidered, the Committee expanded on other ideas to be addressed. This included the recommendation for a Code of Conduct for volunteers serving the OPTN on its Board, Committees, and organ-specific Review Boards to codify current practice and create a pathway for anyone to report any potential violations of the Code. This pathway is separate from the whistleblower reporting pathway, as it delineates the more specific process and procedure for evaluation and handling of concerns specific to the Code of Conduct.

A Code of Conduct Work Group, including representatives from the Executive Committee, was established and held its first meeting on February 7, 2024.<sup>7</sup> The Work Group was tasked with considering the unique position of the OPTN and the duty to honor different viewpoints across the community through the creation of a Code of Conduct in addition to revisiting the whistleblower protections in the policy that was proposed in 2023. In subsequent meetings, Work Group members reviewed current OPTN attestation forms, common components of a Code of Conduct, and practice recommendations from various sources. Work Group members discussed who should be subject to the provisions of the Code of Conduct, considered review and investigation of concerns, and processes for upholding the Code as part of the bylaws development effort.

During its February 27, 2024 meeting,<sup>8</sup> the Work Group spent considerable time studying and discussing the provisions of duty of care, duty of loyalty, duty of compliance,<sup>9</sup> and the provisions that would be included under each, as well as examples from other nonprofit and for profit organizations were reviewed as it explored the components of a Code of Conduct and what might be included. Duty of Loyalty obligates a board member to give undivided allegiance when making decisions affecting the organization. This means that a board member can never use information obtained as a member for personal gain but must act in the best interests of the organization. The Work Group decided not to include a provision stating that volunteers must always represent the organization in a positive and supportive manner. Work Group members decided that this point was duplicative of other provisions.

The Work Group also discussed the definition of "duty of compliance" and how this could relate to OPTN Code of Conduct. A Work Group member suggested that the group continue to examine the definition of duty of compliance and explicitly define the term "compliance" to avoid confusion. The Work Group then discussed provisions pertaining to duty of compliance that received mixed feedback. The Work

<sup>6</sup> OPTN Executive Committee Meeting Summary, December 3, 2024.

[https://optn.transplant.hrsa.gov/media/qzibvs04/20231203\\_executive-committee\\_summary.pdf](https://optn.transplant.hrsa.gov/media/qzibvs04/20231203_executive-committee_summary.pdf) (accessed on March 18, 2024)

<sup>7</sup> OPTN Executive Committee Code of Conduct Work Group Meeting Summary, February 7, 2024.

[https://optn.transplant.hrsa.gov/media/4ilfq50c/20240207\\_executive-committee\\_code-of-conduct-work-group\\_summary.pdf](https://optn.transplant.hrsa.gov/media/4ilfq50c/20240207_executive-committee_code-of-conduct-work-group_summary.pdf) (accessed on March 18, 2024)

<sup>8</sup> OPTN Code of Conduct Work Group Meeting Summary, February 27, 2024.

[https://optn.transplant.hrsa.gov/media/jpnmqkwa/20240227\\_executive-committee\\_code-of-conduct-work-group\\_summary.pdf](https://optn.transplant.hrsa.gov/media/jpnmqkwa/20240227_executive-committee_code-of-conduct-work-group_summary.pdf) (accessed April 1, 2024)

<sup>9</sup> BoardSource. <https://boardsource.org/wp-content/uploads/2022/05/Code-of-Conduct-Ethics-1.pdf?hsCtaTracking=508c16c3-f23d-48cb-87e3-e72111881869%7Ce9e66529-f81f-4def-81c1-8973c53d66bc> (Accessed March 15, 2024)

Group decided that the provision to accept fiduciary responsibility for supporting OPTN activities may be better suited for a volunteer “roles and responsibilities” document, rather than the Code of Conduct.

As work on developing proposed Bylaws language continued in March 2024, the Work Group determined that the Code of Conduct will be applicable to those serving the OPTN as Directors, Committee members, and volunteers (e.g. organ specific review board members and subject matter experts not currently serving on committees asked to participate in work groups or task forces). The Code of Conduct will also apply to ex officio members of these bodies, including the OPTN Executive Director.

The OPTN also has a separate Meeting Code of Conduct that was developed in response to resuming in-person meetings during the COVID-19 pandemic.<sup>10</sup> This document was drafted to help create a safe and comfortable meeting experience for participants but has not been codified in the Bylaws to date.

In addition to the pathways described in this proposal, the OPTN currently has online and phone pathways available for reporting various concerns, including the Member Reporting Hotline (866-787-4909), the patient safety portal<sup>11</sup> (within the OPTN Computer System for member access) and the patient services email and phonenumber ([patientservices@unos.org](mailto:patientservices@unos.org) or 888-894-6361).<sup>12</sup> OPTN member organizations may also have their own pathways for reporting concerns.

## Proposal for Board Consideration

### Code of Conduct

This proposal creates *Article 2.7: OPTN Code of Conduct*, which does the following:

- Establishes a Code of Conduct for Directors;
- Requires review and attestation of agreement to uphold and abide by these duties and responsibilities on an annual basis; and
- Requires review of the Code of Conduct and updates as frequently as needed, but at least once every three years; and
- Allows two current Directors to be appointed as OPTN Compliance Officers. The Compliance Officers will be responsible for reviewing and responding to all reported potential violations of the OPTN Code of Conduct; and
- Outlines pathway for reporting potential violations;
- Outlines how reported violations will be reviewed, evaluated, resolved, and reported; and
- Describes opportunities for an individual accused of a violation to respond.

This proposal creates *Article 7.8: OPTN Code of Conduct*, which requires all OPTN Committee members and volunteers (e.g. Task Force members) to abide by the Code of Conduct as outlined in *Article 2.7 OPTN Code of Conduct*.

This proposal adds language to *Article 9.5 Review Boards* which requires all OPTN Review Board members to abide by the Code of Conduct as outlined in *Article 2.7 OPTN Code of Conduct*.

The OPTN Code of Conduct (see **Appendix A**) is meant to apply to all Directors, Committee members, and volunteers serving the OPTN, as well as ex officio members of those bodies. General attendance

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<sup>10</sup> OPTN Meeting Code of Conduct. <https://optn.transplant.hrsa.gov/media/z0ggux0x/optn-meeting-code-of-conduct.pdf> (accessed 4/1/2024)

<sup>11</sup> [https://optn.transplant.hrsa.gov/media/y5zjsep0/mpsc\\_require-reporting-of-patient-safety-events\\_bp\\_dec23.pdf](https://optn.transplant.hrsa.gov/media/y5zjsep0/mpsc_require-reporting-of-patient-safety-events_bp_dec23.pdf)

<sup>12</sup> UNOS website. <https://unos.org/contact/> (accessed March 18, 2024)

requirements do vary slightly by role within the organization, but Duty of Care, Duty of Loyalty, and Duty to Ensure Compliance of the OPTN remain the same for all serving the OPTN. Proposed Bylaw language requires that the OPTN Board of Directors review the Code of Conduct and adopt updates as frequently as needed, but at least once every three years. As a result, the Committee proposes maintaining the Code of Conduct outside of the Bylaws so that it may be updated on a more frequent basis as needed.

The Work Group recommended the creation of two appointed Compliance Officer positions on the Board of Directors. This role will ideally be filled by current Directors with compliance experience. The Compliance Officers will serve terms of at least one year, with terms likely extending the duration of the Officers' terms on the Board of Directors. The Compliance Officers will be responsible for reviewing and responding to all reported violations of the OPTN Code of Conduct. This will include:

- Reviewing all submitted reports of potential violations of the OPTN Code of Conduct and notifying OPTN President of all potential violations within two days of receipt of report;
- Notifying the accused of the reported violation, giving the individual seven days to respond to the report;
- Determining if the facts supporting the potential violation warrant an immediate report to the OPTN Board of Directors. Potential violations of Duty of Loyalty and Duty to Ensure Compliance of the OPTN must be reported to the OPTN Board of Directors, including HRSA, within 2 days of confirmation;
- Investigating the alleged conduct, which may include engaging experts or assembling a group of members of the OPTN Board to review reports of potential violations as needed. If assembling members of the Board, this group must include the OPTN Past President, unless a conflict is present;
- Recommending an appropriate resolution for all confirmed violations to the OPTN Executive Committee; and
- Providing a quarterly report of confirmed violations to the OPTN Board of Directors.

As outlined in the Code of Conduct, violations may ultimately lead to suspension of voting privileges or service role for a period of time, or result in removal according to the OPTN Bylaws.

## Public Statements by Directors and Committee Members

This proposal creates *Article 2.9: Public Statements by Directors*, which does the following:

- Codifies the OPTN President's responsibility to make public statements on behalf of the OPTN and permits any other Director to do so only when authorized by the OPTN President in writing, noting the specific purpose and duration of this authorization; and
- Establishes limits on Directors using their OPTN position or title to avoid implication that the OPTN has authorized a statement or body of work.
- Provides that without authorization by the OPTN President, a Director must state they are commenting in an individual capacity and not on behalf of the OPTN.

This proposal creates *Article 7.9: Public Statements by Committee Members and OPTN Volunteers*, which does the following:

- Codifies the requirement of specific written authorization from the OPTN President to make public statements on behalf of the OPTN. This authorization will clearly state the purpose for which the Committee member or OPTN volunteer is authorized to speak and the duration of this authorization; and

- Establishes limits on Committee members or volunteers using their OPTN position or title to avoid implication that the OPTN has authorized a statement or body of work.
- Provides that without authorization by the OPTN President, the Committee member or volunteer must state they are commenting in an individual capacity and not on behalf of the OPTN.

As part of its discussion regarding the Duty of Loyalty, the Work Group discussed whether volunteers should be authorized to make statements on behalf of the OPTN. The difficulty in upholding responsibilities such as this was also recognized as part of the discussion. Work Group members were supportive of the OPTN President making public statements on behalf of the OPTN and other Directors speaking on behalf of the organization only when specifically authorized to do so in writing by the OPTN President. Similar language was proposed for Committee members and other volunteers to clarify that specific authorization from the OPTN President is needed to make statements on behalf the OPTN, but Directors, Committee members, and volunteers may express their personal opinions as long as it is clear that they are not commenting on behalf of the OPTN.

As this language was finalized in March 2024, Work Group members also discussed whether Directors or Committee members should be permitted to use their OPTN titles in work outside of the OPTN, and whether this may imply OPTN authorization of the work or statement. After discussion, the Work Group agreed that titles may be used when publishing a scientific or professional journal with the inclusion of a disclaimer to note that the views expressed do not necessarily represent the views of the OPTN. The Work Group agreed that a Director, Committee Chair, or Vice Chair intending to use their title in a journal article must notify the OPTN Executive Committee prior to submitting the article.

A disclaimer may also be used when giving presentations in non-OPTN forums, for example, at conferences or in presentations to patient groups. An example disclaimer is provided below:

*Disclaimer: The views expressed in this presentation are my own and do not necessarily reflect the official policy or position of the Organ Procurement and Transplantation Network (OPTN), nor any other organization of which I am affiliated.*

Additional guidance for personal and non-OPTN business social media use is provided in the OPTN Social Media Guidelines enclosed in **Appendix B**.

## Whistleblower Protection

This proposal creates *Article 2.10: Whistleblower Protection*, which does the following:

- Acknowledges the high standard of business and personal ethics expected from Directors, Committee members, and volunteers in conducting the OPTN duties and responsibilities; and
- Encourages anyone seeking to raise concerns regarding actions or behavior within OPTN the before seeking resolution externally; and
- Puts forth a clear statement against retaliation; and
- Codifies reporting procedure of violations or potential violations of relevant ethics, legal standards, or regulations to the OPTN Executive Director, or to the OPTN President if concerns are involving the Executive Director; and
- Outlines separate path for reporting potential accounting/audit concerns,
- Establishes that whistleblowers must act in "good faith, having reasonable grounds for believing the information disclosed is a violation;" and
- Protects the confidentiality of the whistleblower; and
- Outlines the review process for reported violations.



The Whistleblower language was relocated from the 2023 proposed policy to the Bylaws to clearly reflect that this language applies to all – including those participating as Directors, Committee members and volunteers as well as the general public (and not only to members subject to OPTN policies). It also clarifies the open-door policy for reporting, noting that anyone may make a report in good faith and will be protected from retaliation. In employment contexts, retaliation typically refers to discriminating against job applicants or employees. For OPTN purposes, retaliation was defined as part of a post-public comment change as removal from position or barring a person from service due to reporting concerns in good faith about a suspected ethics violation; a suspected violation of law, or suspected fraud; or a suspected violation of any regulation governing the operations of the OPTN.

## Overall Sentiment from Public Comment

The proposal received 29 comments during a 30-day public comment from April 17 to May 17, 2024. This is shorter than the usual public comment period,<sup>13</sup> which the Committee approved with the goal of submitting the proposal to the OPTN Board of Directors so that, if approved, the proposal may be implemented in time for new volunteer terms starting on July 1, 2024.

Respondents were able to participate through a virtual Town Hall held on April 25, 2024,<sup>14</sup> in committee communications and meetings, and a form on the OPTN website. Demographic information was collected from all individual respondents, including state of origin and stakeholder represented. The comments received represented at least 19 states across the country and five member types, with the greatest participation coming from individual comments, as regional meetings or calls were not held for this proposal. Comments were provided by patient and donor family representatives, transplant hospitals, organ procurement organizations, stakeholder organizations, one OPTN committee,<sup>15</sup> and members of the general public, though there were no comments from histocompatibility laboratories.

Generally, public comment sentiment was mixed but leaned supportive, as indicated by the total sentiment score of 3.5 for 22 of the 29 total comments (**Figure 1**). The following graphic shows sentiment received from respondents by their stated member type.

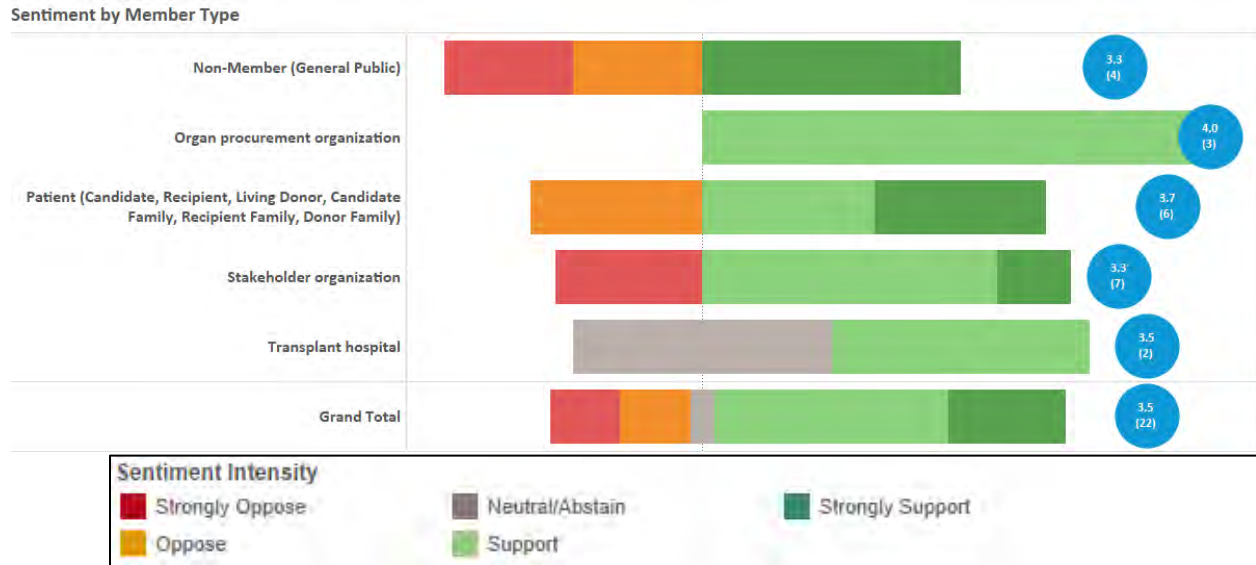
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<sup>13</sup> OPTN Bylaw 11.1.A: The Public Comment Period. While proposals are “usually” distributed for at least a 45-day public comment period, *NOTA*, the OPTN Final Rule, and the OPTN Bylaws do not specify a minimum time period for public comment. This proposal does not meet the criteria for “Emergency Action” under OPTN Bylaw 11.7, nor “Expedited Action” under OPTN Bylaw 11.8.

<sup>14</sup> “Special public comment period to Establish Code of Conduct and Whistleblower Protection Bylaws,” OPTN, accessed May 29, 2024, <https://optn.transplant.hrsa.gov/news/special-public-comment-period-to-establish-code-of-conduct-and-whistleblower-protection-bylaws/>.

<sup>15</sup> For comments submitted on behalf of the committees, the public comment item is discussed at the meeting, OPTN staff draft a summary of the discussion, and the Committee leadership reviews the comment, confirming it is an accurate representation of the discussion that occurred.

**Figure 1: Sentiment by Member Type, Establish Code of Conduct and Whistleblower Protection Bylaws**



Of the 29 comments submitted, 7 did not include sentiment scores. Out of those 7 comments, 4 shared positive comments, 2 were opposed, and the final was supportive in concept but noted concerns related to proposed language. This is not reflected in the sentiment score.

In addition to the sentiment score, items out for public comment also provide the opportunity for respondents to submit a substantive written comment. Comments, in general, were supportive of the concept of the OPTN putting a Code of Conduct and Whistleblower Protections into place, but many noted concerns or shared ideas on how to improve upon the proposal. Of the 29 comments submitted, 27 included substantive written comment.

Commenters covered many different topics, including the following themes:

- Concerns about a member of the Board serving as a compliance officer
- Clarity regarding review and adjudication of reports and clarity regarding due process for reported individuals, including a pathway for appeals
- Clarity needed about speaking on behalf of the OPTN and what this specifically means
- Concerns regarding “Duty of Care” language being outside of legal definition

Each theme is described based on the feedback provided. Comments have been separated to outline those specific to the proposed Bylaws language versus the proposed Code of Conduct. The Executive Committee addressed the following themes identified in public comment:

## Compliance Officer as Member of the OPTN Board of Directors

The proposal called for the creation of a Compliance Officer to be filled by a member of the OPTN Board of Directors, preferably with human resources experience. Commenters raised concerns regarding the need for neutrality and the optics of managing the review of concerns internally. Additionally, some commenters questioned whether an acting Director would have the time to manage this effort in addition to the work of the Board and their full-time roles.

The Executive Committee acknowledged these concerns but noted that the added expense of an external resource for case intake and investigation did not seem necessary at this time, as the volume of

reports is expected to be low. There was agreement that this approach may be reconsidered if the volume of reports becomes burdensome, but an external resource will not be pursued at implementation of this new process, if approved.

The Executive Committee recommended additions to the proposed Bylaws to address concerns related to filling this role that include:

- Changes to how compliance officers are selected, with additions to proposed language in *Bylaw 2.7.A Compliance Officer*. This updated selection process will engage the OPTN President, OPTN Vice President and OPTN Vice President of Patient and Donor Affairs, in consultation with HRSA, to determine best skillset in the Board for this role. This group will recommend two members of the OPTN Board of Directors to serve as Compliance Officers for appointments by the OPTN Executive Committee. Executive Committee members acknowledged the importance of seeking related experience in compliance as part of the recruitment and appointment process in the future.
- The addition of a second compliance officer in *Article 2.7.A Compliance Officer*. The Executive Committee aims to give these positions staggered terms to allow for ample coverage and experience. This will create redundancy and succession planning for review and response to reported violations.

Specific to concerns related to a Board Director's ability to provide neutrality in reviewing reports and managing an investigation, the Committee made the following changes:

- Accused individuals may request an informal discussion with one of the OPTN Compliance Officers (in addition to the original response within seven days included in the proposal). The reported individual may request the presence of a third party at the informal discussion. These proposed modifications are captured in *Article 2.7.B.ii Review of Reported Violations*.
- The Compliance Officers may engage other experts at their discretion to aid in any review of the reported violation (in addition to the group of OPTN Board members and Immediate Past President noted in the original proposal). This new language is also included in *Article 2.7.B.ii Review of Reported Violations*.

The Committee also discussed that the individual who made the report to the Compliance Officer(s) may also request a meeting to discuss their concerns.

## Clarity Regarding Review and Adjudication of Reports, and Due Process

The proposal included a brief outline of the process to be used to receive and consider reported violations of the Code of Conduct or Whistleblower reports. Reviewers shared concern regarding the lack of detail in the structure for review and adjudication of reports as well as the lack of apparent due process for reported individuals. The Executive Committee considered these reports and offers the following Bylaws modifications in *Article 2.7.B.ii Review of Reported Violations* to address them:

- As noted in the previous section, accused individuals will have the opportunity to request informal discussion with an OPTN Compliance Officer. Prior to this meeting, the individual must submit: (1) the reasons the informal discussion is requested, (2) a summary of what the individual would like to present to the Compliance Officer; and (3) any information the individual would like the Compliance Officer to consider in advance of the informal discussion. The individual may also request the presence of a third party at the informal discussion.
- The Executive Committee will decide the action appropriate for the violation after hearing the recommended appropriate resolution for confirmed violations from the OPTN Compliance

Officer who reviewed the report. The exception to this will be if the recommendation is to remove a Director, Committee Chair, or Committee Vice Chair from their position. In this case the OPTN Executive Committee may recommend that the OPTN Board of Directors remove the individual (according to *Article 2.5 Removals*).

- The accused individual may request to appear before the OPTN Executive Committee when the Compliance Officer is recommending action on a confirmed violation.
- An accused individual may request to appear before the OPTN Board of Directors when the Executive Committee recommends that the OPTN Board of Directors remove the individual, according to Article 2.5.

## Speaking on Behalf of the OPTN

The proposal outlines that volunteers must have specific authorization from the OPTN President to make public statements on behalf of the OPTN. It also includes information regarding the use of OPTN titles when publishing articles in scientific or professional journals. A number of concerns were shared regarding the need for clarity on this topic, as some readers read this to be silencing of personal opinion. The patient and donor family community, in particular, was concerned about its ability to speak on OPTN topics in other organizations or roles they may have. It was never the intent of the Committee to chill free speech. The Committee only wishes to delineate when an OPTN volunteer is speaking on behalf of the organization versus sharing personal thoughts and opinions. The Committee reviewed this feedback carefully and offers the following updates for consideration:

- Additional language was added to *Article 2.9 Public Statements by Directors* and *Article 7.9 Public Statements by Committee Members and OPTN Volunteers* to note that, without authorization, when commenting on OPTN matters, the OPTN volunteers must state that they are commenting in an individual capacity and not on behalf of the OPTN.
- A new OPTN Social Media Guidelines document (**Appendix B**) previously referenced in the public comment proposal is also included. This document is anticipated to speak to many of the concerns raised in individual comments submitted on this proposal related to sharing personal experiences and opinions.

## Concerns Related to the Proposed Code of Conduct

The proposal included a Code of Conduct for all OPTN volunteers, including the Board of Directors, Committee members, and review board participants, and ex officio members of those bodies. A number of concerns were raised regarding “Duty of Care” as outlined in the proposal. The Executive Committee reviewed the comments and offers the following modifications:

- The proposed “Duty of Care” language was revised to move conduct expectations related to behavior and courtesy to a standalone introductory section. The Duty of Care section now includes only obligations for the benefit of Board service.
- The proposed “Duty of Loyalty” language was clarified to make clear that this duty is expected *when* making decisions as stewards of the OPTN, whether this be in Board calls or meetings, Committee calls or meetings, or other volunteer roles within the organization.

Two commenters noted opposition to attendance requirements outlined within the proposal. The Committee notes that these requirements are aligned with the attendance requirements listed in Board and committee service expectations on the OPTN website,<sup>16</sup> which have also been shared in

<sup>16</sup> <https://optn.transplant.hrsa.gov/about/how-to-get-involved/>

appointment letters and learning modules over many previous years.

## Whistleblower Protections

While not a specific theme in comments, the Committee acknowledged that commenters appeared to mistake reporting behavioral concerns for true whistleblower events. These types of concerns related to courtesy or respectful treatment would be potential violations of the Code of Conduct. Whistleblower events are specific to 1) a suspected ethics violation; 2) a suspected violation of law, such as a complaint of discrimination, or suspected fraud; or 3) a suspected violation of any regulation governing the operations of the OPTN. The Executive Committee offers updated language to *Article 2.10.A No Retaliation* to clarify what is meant by retaliation and what whistleblower reports should focus on. The reporting submission form will allow for an individual to select the appropriate pathway for their concern.

## Compliance Analysis

The Committee offers the proposed changes to the OPTN Bylaws under the authority of NOTA, which states that “The Secretary shall by contract provide for the establishment and operation of an Organ Procurement and Transplantation Network...”<sup>17</sup> As described throughout the proposal, the proposed changes are consistent with applicable provisions of NOTA and the OPTN Final Rule.

## Implementation Considerations

### OPTN Operations

This proposal does not impact histocompatibility laboratories, OPOs, or transplant centers operations. The OPTN will reach out to OPTN Directors, Committee members, and volunteers with terms starting or continuing on July 1, 2024 to request that they sign the Code of Conduct prior to July 1, 2024. The OPTN will provide a mechanism for intaking reports related to potential Code of Conduct violations as well as for concerns protected under the whistleblower protection bylaws.

### Potential Impact on Select Patient Populations

This proposal has no known impact on select patient populations.

### Projected Fiscal Impact

This proposal is not anticipated to have any fiscal impact on members.

## Post-implementation Monitoring

### Member Compliance

OPTN Contractor support staff will maintain a record of signed Code of Conduct forms for Directors, Committee Members, Review Board Members, and other OPTN volunteers. Code of Conduct forms will be provided to volunteers at the notification of their appointment or election and must be completed prior to the start of their term and reaffirmed annually for the duration of their term. Failing to

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<sup>17</sup> 42 U.S.C. §274(a)

complete the Code of Conduct will disqualify a volunteer from serving in the appointed or elected position at that time, but will not preclude them from serving in the future if all OPTN obligations are met. The OPTN Contractor will assist volunteers in becoming compliant with this requirement through reminders prior to the state of their term and annually for the duration of their term.

## Bylaws Evaluation

The Board of Directors shall review the Code of Conduct and adopt updates as frequently as needed, but at least once every three years. The Executive Committee anticipates that the Board of Directors will review this language and the frequency of reported violations more frequently following the initial implementation to ensure that the outlined process for managing these reports is appropriate.

## Conclusion

This proposal would create Bylaws language to: (1) document existing practices that encourage participation in the OPTN, outlining certain standards of conduct for OPTN members and volunteers to carry out responsibilities to the organization in the Bylaws; (2) establish processes and protections for anyone to raise concerns with the OPTN about suspected violations of the law, ethics, or governing policies and regulations (i.e. NOTA, Final Rule, OPTN Bylaws); and (3) document a pathway for reporting and review of potential Code of Conduct violations. New Bylaws language was drafted to define:

- Requirements for an OPTN Code of Conduct for Directors, Committee members, and other volunteers (i.e. Review Board members) and how any potential violations are to be addressed;
- Clarity regarding authority to make public statements on behalf of the OPTN; and
- Whistleblower protections for those reporting potential violations as outlined in the Whistleblower Protection Bylaw.

Several changes were made to the proposal in response to public comment feedback, as delineated in **Appendix C**.

## Bylaws Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary.

### 1 **2.7 OPTN Code of Conduct**

2 All Directors must agree to abide by the OPTN Code of Conduct. Agreements must be signed and  
3 submitted prior to the beginning of a Director’s service and on an annual basis thereafter. Individuals  
4 who do not sign agreements by the start of their terms of service and annually thereafter will not be  
5 permitted to serve as Directors.

6 The following must be addressed in the OPTN Code of Conduct, in addition to other duties and  
7 responsibilities determined to be relevant by the OPTN Board of Directors:

- 8
- 9 • Duty of care to the OPTN
  - 10 • Duty of loyalty to the OPTN, which must include requirements to abide by the OPTN’s Conflict of  
11 Interests Bylaw, the OPTN’s Confidentiality Agreement, and to sign the OPTN Attestation
  - 12 • Duty to ensure the OPTN’s compliance with all applicable Federal laws and regulations

13 The OPTN Board of Directors shall review the OPTN Code of Conduct and adopt updates as frequently as  
14 needed, but at least once every three years. Adoption of updates will be considered effective upon  
15 notice to Directors.

#### 15 **2.7.A Compliance Officer**

16 The OPTN President, OPTN Vice President, and OPTN Vice President of Patient and Donor Affairs,  
17 in consultation with HRSA, will recommend two members of the OPTN Board of Directors to  
18 serve as the OPTN Compliance Officers for appointment by the OPTN Executive Committee. The  
19 OPTN Compliance Officers will serve terms of at least one year and are responsible for reviewing  
20 and responding to all reported violations of the OPTN Code of Conduct, according to Bylaw  
21 2.7.B.

#### 22 **2.7.B Violations of the OPTN Code of Conduct**

##### 23 **2.7.B.i Reporting Violations**

24 Anyone may submit a complaint or concern about a potential violation of the OPTN Code of  
25 Conduct. The submitter should submit the complaint in writing to the OPTN Compliance Officers,  
26 who have the responsibility to review all reports. The submitter must be able to submit the  
27 report anonymously.

28 **2.7.B.ii Review of Reported Violations**

29 The OPTN Compliance Officers will notify the Director, Committee member, or OPTN volunteer  
30 accused of the violation, giving the individual seven days to respond to the report. The individual  
31 may request an informal discussion with one of the OPTN Compliance Officers. Individuals  
32 requesting an informal discussion must submit all of the following:

- 33 1. The reasons the individual is requesting an informal discussion
- 34 2. A summary of what the individual would like to present to the OPTN Compliance Officer
- 35 3. Any information the individual would like the OPTN Compliance Officer to consider in  
36 advance of the informal discussion

37 The individual may request the presence of a third party at the informal discussion. The OPTN  
38 Compliance Officer will accept or decline an individual's request for an informal discussion  
39 within seven days of receiving the individual's request.

40 The OPTN Compliance Officers may assemble a group of members of the OPTN Board to review  
41 reports of potential violations and may engage other experts at their discretion to aid in any  
42 review of reported violations, as needed. This group of members must include the OPTN  
43 Immediate Past President, unless a conflict is present.

44 The OPTN Compliance Officers will notify the OPTN President of all potential violations of the  
45 Code of Conduct within two days of receipt of a report and report confirmed violations to the  
46 OPTN Board of Directors on a quarterly basis. For confirmed violations of Duty of Loyalty and  
47 Duty to Ensure Compliance of the OPTN, the OPTN Compliance Officers will notify the OPTN  
48 Board of Directors within two days of the confirmation.

49 The OPTN Compliance Officers will recommend an appropriate resolution for all confirmed  
50 violations to the OPTN Executive Committee. Confirmed violations of the OPTN Code of Conduct  
51 can result in consequences up to and including removal from OPTN service. The OPTN Executive  
52 Committee will decide the action appropriate for the violation unless the recommendation is to  
53 remove a Director, Committee Chair, or Committee Vice Chair from their position, in which case  
54 the OPTN Executive Committee may recommend that the OPTN Board of Directors remove the  
55 individual according to Bylaw 2.5. Committee members and other volunteers may be removed  
56 from their position by the OPTN Executive Committee or according to review board operational  
57 guidelines.

58 An individual may request to appear before the OPTN Executive Committee when a Compliance  
59 Officer is recommending action on a confirmed violation.

60 An individual may request to appear before the OPTN Board of Directors when the OPTN  
61 Executive Committee recommends that the OPTN Board of Directors remove the individual,  
62 according to Bylaw 2.5.

63 **2.78 Conflicts of Interest**

64 [...]



## 65 **2.9 Public Statements by Directors**

66 The OPTN President is authorized to make public statements on behalf of the OPTN. Any other Director  
67 must be specifically authorized to do so by the OPTN President. If authorized, the OPTN President will  
68 provide written authorization that clearly states the purpose for which the Director is authorized to  
69 speak on behalf of the OPTN and the duration of the authorization. Without such authorization, when  
70 commenting on OPTN matters, the Director must state that they are commenting in an individual  
71 capacity and not on behalf of the OPTN.

72 Directors shall not use or permit the use of the OPTN position or title in a manner that could reasonably  
73 be construed to imply that the OPTN has authorized the statement. Directors are permitted to use the  
74 Director’s position or title in conjunction with an article published in a scientific or professional journal,  
75 provided the Director notifies the OPTN Executive Committee prior to submitting the publication, and  
76 includes an OPTN approved disclaimer, addressing the views expressed in the article do not necessarily  
77 represent the views of the OPTN.

## 78 **2.10 Whistleblower Protection**

79 Directors, Committee members, and OPTN volunteers must observe high standards of business and  
80 personal ethics in the conduct of their OPTN duties and responsibilities. Directors, Committee members,  
81 OPTN volunteers, and others are encouraged and enabled to raise concerns within the OPTN before  
82 seeking resolution outside the OPTN. This Bylaw is in addition to any non-retaliation requirements  
83 required by law and the “critical comment” procedures described in the OPTN Final Rule at 42 C.F.R.  
84 §121.4(d).

### 85 **2.10.A No Retaliation**

86 Neither the OPTN nor any of its representatives or OPTN Contractors shall retaliate against any  
87 person who in good faith reports concerns about 1) a suspected ethics violation; 2) a suspected  
88 violation of law, such as a complaint of discrimination, or suspected fraud; or 3) a suspected  
89 violation of any regulation governing the operations of the OPTN.

90 Retaliation may include but is not limited to removing a Director, Committee member, or OPTN  
91 volunteer from their position or barring a person from service as a Director, Committee  
92 member, or OPTN volunteer. A Director, Committee Chair, or Committee Vice Chair who in good  
93 faith reports concerns about suspected ethical, legal, or regulatory violations may still be  
94 removed from service for non-retaliatory reasons, according to Bylaw 2.5. A Committee member  
95 or OPTN volunteer who in good faith reports concerns about suspected ethical, legal, or  
96 regulatory violations may still be removed from service for non-retaliatory reasons, according to  
97 Bylaw 2.7.B.ii.

### 98 **2.10.B Reporting Procedure**

99 The OPTN has an open-door policy and encourages anyone to share their questions, concerns,  
100 suggestions, or complaints with the OPTN Executive Director or, in the instance the concern  
101 involves the OPTN Executive Director, with the OPTN President. Complaints or concerns about  
102 suspected ethical, legal, or regulatory violations should be submitted in writing to the OPTN  
103 Executive Director, or the OPTN President, as applicable, who has the responsibility to  
104 investigate all reported complaints. The OPTN Executive Director or the OPTN President, if  
105 applicable, will advise the OPTN President, or the OPTN Board of Directors, respectively, of all  
106 complaints and their resolution and will report at least annually to the OPTN Finance Committee  
107 on compliance activity relating to accounting or alleged financial improprieties.

## 108 **2.10.C Accounting and Auditing Matters**

109 The OPTN Executive Director, or the OPTN President, as applicable, shall immediately notify the  
110 OPTN Treasurer of any concerns or complaints regarding OPTN accounting practices, controls or  
111 auditing and work with the OPTN Finance Committee until the matter is resolved.

## 112 **2.10.D Acting in Good Faith**

113 Anyone submitting a complaint concerning a violation or suspected violation must be acting in  
114 good faith and have reasonable grounds for believing the information disclosed indicates a  
115 violation.

## 116 **2.10.E Confidentiality**

117 Violations or suspected violations may be submitted confidentially by the complainant. Reports  
118 of violations or suspected violations will be kept confidential to the extent possible, consistent  
119 with the need to conduct an adequate investigation.

## 120 **2.10.F Review of Reported Violations**

121 The OPTN Executive Director, or the OPTN President, as applicable, will notify the person who  
122 submitted a complaint and acknowledge receipt of the reported violation or suspected violation.  
123 All reports will be promptly investigated, and appropriate corrective action will be taken if  
124 warranted by the investigation. The OPTN Executive Director, or the OPTN President, as  
125 applicable, may engage independent accountants, counsel, or other experts, at their discretion  
126 to aid in any investigation of the reported violation or suspected violation.

## 127 **2.811 Relationship between OPTN Board and OPTN Contractor(s) Board**

## 128 **7.8 OPTN Code of Conduct**

129 All OPTN Committee members and OPTN volunteers must agree to abide by the OPTN Code of Conduct  
130 and the process for handling of potential violations thereof, as described in Article 2.7: OPTN Code of  
131 Conduct. Agreements must be signed and submitted prior to the beginning of a Committee member's or

132 OPTN volunteer’s service and on an annual basis thereafter. Individuals who do not sign agreements by  
133 the start of their terms of service and annually thereafter will not be permitted to serve as Committee  
134 members or OPTN volunteers.

## 135 **7.9 Public Statements by Committee Members and OPTN Volunteers**

136 OPTN Committee members and OPTN volunteers must have specific authorization from the OPTN  
137 President to make public statements on behalf of the OPTN. If authorized, the OPTN President will  
138 provide written authorization that clearly states the purpose for which the Committee member is  
139 authorized to speak on behalf of the OPTN and the duration of the authorization. Without such  
140 authorization, when commenting on OPTN matters, the Committee member or OPTN volunteer must  
141 state that they are commenting in an individual capacity and not on behalf of the OPTN.

142 Committee members and OPTN volunteers shall not use or permit the use of the OPTN position or title  
143 in a manner that could reasonably be construed to imply that the OPTN has authorized the statement.  
144 Committee members and OPTN volunteers are permitted to use their Committee or volunteer position  
145 or title in conjunction with an article published in a scientific or professional journal, provided the  
146 Committee member or OPTN volunteer includes an OPTN approved disclaimer, addressing the views  
147 expressed in the article do not necessarily represent the views of the OPTN. Committee Chairs and Vice  
148 Chairs must also notify the OPTN Executive Committee prior to submission of the article if using their  
149 Committee position or title in conjunction with the article.

## 150 **9.5 Review Boards**

151 The OPTN establishes review boards to review requests for exceptions that are permitted by policy.  
152 These review boards provide confidential medical peer review of transplant candidates placed on the  
153 waiting list at a more urgent status than the standard listing criteria justifies. As part of these reviews,  
154 review boards may perform the following tasks:

- 155       ▪ Review justification forms submitted by the transplant hospital that document the candidate’s  
156       current condition and decide if the requested status is appropriate.
- 157       ▪ Refer transplant hospitals to the appropriate OPTN Committee for review of candidates listed  
158       and transplanted at an inappropriate status. The Committee may then, if necessary, refer the  
159       hospital to the Membership and Professional Standards Committee (MPSC).
- 160       ▪ Serve other peer review functions as determined by the Board of Directors.

161 Review boards are formed under the direction of the Committees and Board of Directors. Review boards  
162 can operate and perform peer review functions as determined by the Board of Directors. The Board of  
163 Directors and Committees may establish other guidelines for review board organization and function as  
164 necessary.

165 All OPTN Review Board members must agree to abide by the OPTN Code of Conduct and the process for  
166 handling of potential violations thereof, as described in Article 2.7: OPTN Code of Conduct. Agreements  
167 must be signed and submitted prior to the beginning of a Review Board member’s service and on an

168 annual basis thereafter. Individuals who do not sign agreements by the start of their terms of service and  
169 annually thereafter will not be permitted to serve as Review Board members.

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## Appendix A: OPTN Code of Conduct Language

The OPTN Board of Directors will review this OPTN Code of Conduct and adopt updates as frequently as needed, but at least once every three years.

### OPTN Code of Conduct

In my service to the OPTN, I shall do my utmost to ensure that the OPTN performs its mission and achieves its goals. As such, I understand and agree to the following:

- To act with honesty and integrity
- To speak up about disrespectful, inappropriate, fraudulent, unethical or illegal behavior
- To consider and respect the interests of all those in the transplant community, not just those in my area of expertise
- To value diversity in thought and opinion
- To not discriminate
- To collaborate with others to do the work of the OPTN
- To display courteous conduct in all OPTN meetings
- To respect the individual and opinions of those who serve the OPTN alongside me

### Duty of Care

I agree that all OPTN Directors, Committee members, and volunteers owe a duty to exercise reasonable care when making decisions as stewards of the OPTN. This includes the following duties:

- To always act for the good of the OPTN
- To leave my personal biases out of all OPTN discussions
- To act as a representative of the OPTN
- To follow OPTN Social Media Guidelines
- To abide by the Roles and Responsibilities of OPTN Directors, Committee members, and volunteers, which are as follows:
  - To attest to the following:
    - The completion of orientation training prior to commencement of service
    - The completion of annual training thereafter, as assigned
  - To adhere to general attendance requirements:
    - For Directors and Committee members:
      - Attendance at each semiannual meeting
      - 80% attendance rate across all other OPTN meetings on which I am assigned, including service as a Visiting Board member
    - For Directors
      - Attendance in at least one regional meeting per public comment cycle
      - As a Regional Councillor, to chair my region's regional meetings
    - For Committee members who represent regions
      - Attendance at the regional meeting I represent per public comment cycle
    - For Committee members in at-large positions

- Attendance is encouraged at one regional meeting per public comment cycle
- To prepare for OPTN meetings by reviewing agendas and supporting materials, ask informed questions, and contribute to the discussion during meetings
- To actively participate in Board Committees, work groups, and other special projects as requested
  - For Review Board Members
    - Participation as outlined in the respective Review Board Operational Guidelines

## **Duty of Loyalty**

I agree that all OPTN Directors, Committee members, and volunteers owe a duty of loyalty to the OPTN while making decisions as stewards of the OPTN. This includes the following duties:

- To offer my advice, viewpoints, recommendations, and votes in furtherance of my obligations to the OPTN
- To protect the confidential information of the OPTN, to use confidential information only as permitted, and to agree to abide by the OPTN Confidentiality Agreement
- To act in accordance with the OPTN Conflicts of Interests Bylaw, to disclose to the OPTN in writing of any employment, investment, familial relationships, or other activities that might provide personal or financial gain related to outcomes of matters affecting the OPTN, particularly with regard to member compliance issues or OPTN policies or bylaws of specific applicability, and will promptly disclose any changes or additions to this list once known to me.
- To take any corrective action that is deemed appropriate by the OPTN Board of Directors upon being informed of any concern that I have an actual conflict of interests or the appearance of a conflict of interests.
- To recuse myself from any meeting, part of a meeting, or vote with respect to any deliberation of action of any Board, Committee, or other OPTN forum or action, in which I may have a conflict of interest, regardless of whether the OPTN has knowledge of such conflict or has taken actions on such conflict.

## **Duty to Ensure Compliance of the OPTN**

I agree that OPTN Directors, Committee members, and volunteers are responsible for ensuring the OPTN's compliance with all applicable Federal laws and regulations, as well as the OPTN Bylaws. By signing this document, I acknowledge that by serving the OPTN, I must carry out the responsibilities of the OPTN authorized by the National Organ Transplant Act of 1984, as amended (NOTA) (42 U.S.C. § 273, et seq.) and the OPTN Final Rule (42 C.F.R. part 121). I will follow NOTA, the OPTN Final Rule, and the OPTN Charter and OPTN Bylaws.

Further, I understand and agree to the following:

- I agree to report any potential violations of the Code of Conduct by other Directors, Committee members, or volunteers directly to the OPTN Compliance Officers.

- I understand that if a report is received about a potential violation of the Code of Conduct by me, I will be notified and given seven days to respond to the allegation. I agree to respond within that time period.
- I understand that if a report is received about a potential violation of the Code of Conduct, the OPTN President will be informed.
- I understand that if a report is received about a confirmed violation of a Duty of Loyalty or Duty of Compliance, the OPTN Board of Directors, including HRSA, will be informed.
- I understand that if I violate the Code of Conduct, the OPTN could require any or all of the following:
  - Notice to the OPTN Board of Directors of my violation
  - A letter of explanation
  - A corrective action plan
  - Suspension of my voting privileges for a period of time
  - Suspension of my service for a period of time
  - Removal from my position, according to OPTN Bylaws
- I agree to cooperate with the OPTN Compliance Officers in review of the report of a potential violation and to respect the outcome of the decision regarding the alleged behavior.

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## Appendix B: OPTN Social Media Guidelines Language

### OPTN Social Media Guidelines

OPTN Directors, Committee members, and volunteers may use unofficial social media, including personal and non-OPTN business accounts. In doing so, OPTN Directors, Committee members, and volunteers must adhere to the OPTN Code of Conduct, including protecting the confidential information of the OPTN, and abide by the OPTN Bylaws regarding public statements to avoid any appearance of endorsement by the OPTN, including the Board of Directors and its committees. The following guidelines apply:

- OPTN Directors, Committee members, volunteers may share personal experiences and opinions on personal social media accounts.
- OPTN Directors, Committee members, volunteers must ensure that personal and non-OPTN business social media accounts avoid the use of OPTN titles in a way that could imply OPTN endorsement of the content.
- Where confusion or doubt is likely to arise regarding the personal nature of social media activities, OPTN Directors, Committee members, volunteers are encouraged to include a disclaimer clarifying that their social media communications reflect only their personal views and do not necessarily represent the views of the OPTN. For example, OPTN Directors, Committee members, volunteers may consider adding a disclaimer to the biography section of social media accounts stating, “Views are my own,” or “All opinions are my own.”
- OPTN Directors, Committee members, volunteers may use personal and non-OPTN business social media accounts to forward, like, or link to official OPTN information, provided it is done in a manner that does not express or imply that the OPTN has authorized any personal content shared with the official information.

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## Appendix C: Post-Public Comment Changes

New language that was proposed following public comment is underlined and highlighted (example); language that is proposed for removal following public comment is struck through and highlighted (example).

### 2.7 OPTN Code of Conduct

All Directors must agree to abide by the OPTN Code of Conduct. Agreements must be signed and submitted prior to the beginning of a Director's service and on an annual basis thereafter. Individuals who do not sign agreements by the start of their terms of service and annually thereafter will not be permitted to serve as Directors. The following must be addressed in the OPTN Code of Conduct, in addition to other duties and responsibilities determined to be relevant by the OPTN Board of Directors:

- Duty of care to the OPTN
- Duty of loyalty to the OPTN, which must include requirements to abide by the OPTN's Conflict of Interests Bylaw, the OPTN's Confidentiality Agreement, and to sign the OPTN Attestation
- Duty to ensure the OPTN's compliance with all applicable Federal laws and regulations

The OPTN Board of Directors shall review the OPTN Code of Conduct and adopt updates as frequently as needed, but at least once every three years. Adoption of updates will be considered effective upon notice to Directors.

#### 2.7.A Compliance Officer

~~The OPTN Executive Committee will appoint a member of the OPTN Board of Directors to serve as the OPTN Compliance Officer. The OPTN President, OPTN Vice President, and OPTN Vice President of Patient and Donor Affairs, in consultation with HRSA, will recommend two members of the OPTN Board of Directors to serve as the OPTN Compliance Officers for appointment by the OPTN Executive Committee.~~ The OPTN Compliance Officers will serve terms of at least one year and ~~is~~ are responsible for reviewing and responding to all reported violations of the OPTN Code of Conduct, according to Bylaw 2.7.B.

#### 2.7.B Violations of the OPTN Code of Conduct

##### 2.7.B.i Reporting Violations

Anyone may submit a complaint or concern about a potential violation of the OPTN Code of Conduct. The submitter should submit the complaint in writing to the OPTN Compliance Officers, who have the responsibility to review all reports. The submitter must be able to submit the report anonymously.

##### 2.7.B.ii Review of Reported Violations

The OPTN Compliance Officers will notify the Director, Committee member, or OPTN volunteer accused of the violation, giving the Director-individual seven days to respond to the report. The individual may request an informal discussion with one of the OPTN Compliance Officers. Individuals requesting an informal discussion must submit all of the following:

4. The reasons the individual is requesting an informal discussion
5. A summary of what the individual would like to present to the OPTN Compliance Officer
6. Any information the individual would like the OPTN Compliance Officer to consider in advance of the informal discussion

The individual may request the presence of a third party at the informal discussion. The OPTN Compliance Officer will accept or decline an individual's request for an informal discussion within seven days of receiving the individual's request.

The OPTN Compliance Officers may assemble a group of members of the OPTN Board to review reports of potential violations and may engage other experts at their discretion to aid in any review of reported violations, as needed. This group of members must include the OPTN Immediate Past President, unless a conflict is present.

The OPTN Compliance Officers will notify the OPTN President of all potential violations of the Code of Conduct within two days of receipt of a report and report confirmed violations to the OPTN Board of Directors on a quarterly basis. For confirmed violations of Duty of Loyalty and Duty to Ensure Compliance of the OPTN, the OPTN Compliance Officers will notify the OPTN Board of Directors within two days of the confirmation.

The OPTN Compliance Officers will recommend an appropriate resolution for all confirmed violations to the OPTN Executive Committee, who will ultimately decide the action appropriate for the violation. Confirmed violations of the OPTN Code of Conduct can result in consequences up to and including removal from office, according to Bylaw 2.5 OPTN service. The OPTN Executive Committee will decide the action appropriate for the violation unless the recommendation is to remove a Director, Committee Chair, or Committee Vice Chair from their position, in which case the OPTN Executive Committee may recommend that the OPTN Board of Directors remove the individual according to Bylaw 2.5. Committee members and other volunteers may be removed from their position by the OPTN Executive Committee or according to review board operational guidelines.

An individual may request to appear before the OPTN Executive Committee when a Compliance Officer is recommending action on a confirmed violation.

An individual may request to appear before the OPTN Board of Directors when the OPTN Executive Committee recommends that the OPTN Board of Directors remove the individual, according to Bylaw 2.5.

## 2.78 Conflicts of Interest

[...]

## 2.9 Public Statements by Directors

The OPTN President is authorized to make public statements on behalf of the OPTN. Any other Director must be specifically authorized to do so by the OPTN President. If authorized, the OPTN President will provide written authorization that clearly states the purpose for which the Director is authorized to speak on behalf of the OPTN and the duration of the authorization. Without such authorization, when commenting on OPTN matters, the Director must state that they are commenting in an individual capacity and not on behalf of the OPTN.

Directors shall not use or permit the use of the OPTN position or title in a manner that could reasonably be construed to imply that the OPTN has authorized the statement. Directors are permitted to use the Director's position or title in conjunction with an article published in a scientific or professional journal, provided the Director notifies the OPTN Executive Committee prior to submitting the publication, and includes an OPTN approved disclaimer, addressing the views expressed in the article do not necessarily represent the views of the OPTN.

## 2.10 Whistleblower Protection

Directors, Committee members, and OPTN volunteers must observe high standards of business and personal ethics in the conduct of their OPTN duties and responsibilities. Directors, Committee members, OPTN volunteers, and others are encouraged and enabled to raise concerns within the OPTN before seeking resolution outside the OPTN. This Bylaw is in addition to any non-retaliation requirements required by law and the "critical comment" procedures described in the OPTN Final Rule at 42 C.F.R. §121.4(d).

### 2.10.A No Retaliation

Neither the OPTN nor any of its representatives or OPTN Contractors shall retaliate against any person who in good faith reports concerns about 1) a suspected ethics violation; 2) a suspected violation of law, such as a complaint of discrimination, or suspected fraud; or 3) a suspected violation of any regulation governing the operations of the OPTN.

Retaliation may include but is not limited to removing a Director, Committee member, or OPTN volunteer from their position or barring a person from service as a Director, Committee member, or OPTN volunteer. A Director, Committee Chair, or Committee Vice Chair who in good faith reports concerns about suspected ethical, legal, or regulatory violations may still be removed from service for non-retaliatory reasons, according to Bylaw 2.5. A Committee member or OPTN volunteer who in good faith reports concerns about suspected ethical, legal, or regulatory violations may still be removed from service for non-retaliatory reasons, according to Bylaw 2.7.B.ii.

### 2.10.B Reporting Procedure

The OPTN has an open-door policy and encourages anyone to share their questions, concerns, suggestions, or complaints with the OPTN Executive Director or, in the instance the concern involves the OPTN Executive Director, with the OPTN President. Complaints or concerns about suspected ethical, legal, or regulatory violations should be submitted in writing to the OPTN Executive Director, or the OPTN President, as applicable, who has the responsibility to investigate all reported complaints. The OPTN Executive Director or the OPTN President, if applicable, will advise the OPTN President, or the OPTN Board of Directors, respectively, of all complaints and their resolution and will report at least annually to the OPTN Finance Committee on compliance activity relating to accounting or alleged financial improprieties.

### **2.10.C Accounting and Auditing Matters**

The OPTN Executive Director, or the OPTN President, as applicable, shall immediately notify the OPTN Treasurer of any concerns or complaints regarding OPTN accounting practices, controls or auditing and work with the OPTN Finance Committee until the matter is resolved.

### **2.10.D Acting in Good Faith**

Anyone submitting a complaint concerning a violation or suspected violation must be acting in good faith and have reasonable grounds for believing the information disclosed indicates a violation.

### **2.10.E Confidentiality**

Violations or suspected violations may be submitted confidentially by the complainant. Reports of violations or suspected violations will be kept confidential to the extent possible, consistent with the need to conduct an adequate investigation.

### **2.10.F Review of Reported Violations**

The OPTN Executive Director, or the OPTN President, as applicable, will notify the person who submitted a complaint and acknowledge receipt of the reported violation or suspected violation. All reports will be promptly investigated, and appropriate corrective action will be taken if warranted by the investigation. The OPTN Executive Director, or the OPTN President, as applicable, may engage independent accountants, counsel, or other experts, at their discretion to aid in any investigation of the reported violation or suspected violation.

## **2.811 Relationship between OPTN Board and OPTN Contractor(s) Board**

[...]

## **7.8 OPTN Code of Conduct**

All OPTN Committee members and OPTN volunteers must agree to abide by the OPTN Code of Conduct and the process for handling of potential violations thereof, as described in Article 2.7: OPTN Code of Conduct. Agreements must be signed and submitted prior to the beginning of a Committee member's or OPTN volunteer's service and on an annual basis thereafter. Individuals who do not sign agreements by the start of their terms of service and annually thereafter will not be permitted to serve as Committee members or OPTN volunteers.

## **7.9 Public Statements by Committee Members and OPTN Volunteers**

OPTN Committee members and OPTN volunteers must have specific authorization from the OPTN President to make public statements on behalf of the OPTN. If authorized, the OPTN President will provide written authorization that clearly states the purpose for which the Committee member is authorized to speak on behalf of the OPTN and the duration of the authorization. Without such authorization, when commenting on OPTN matters, the Committee member or OPTN volunteer must state that they are commenting in an individual capacity and not on behalf of the OPTN.

Committee members and OPTN volunteers shall not use or permit the use of the OPTN position or title in a manner that could reasonably be construed to imply that the OPTN has authorized the statement. Committee members and OPTN volunteers are permitted to use their Committee or volunteer position or title in conjunction with an article published in a scientific or professional journal, provided the Committee member or OPTN volunteer includes an OPTN approved disclaimer, addressing the views expressed in the article do not necessarily represent the views of the OPTN. Committee Chairs and Vice Chairs must also notify the OPTN Executive Committee prior to submission of the article if using their Committee position or title in conjunction with the article.

## **9.5 Review Boards**

The OPTN establishes review boards to review requests for exceptions that are permitted by policy. These review boards provide confidential medical peer review of transplant candidates placed on the waiting list at a more urgent status than the standard listing criteria justifies. As part of these reviews, review boards may perform the following tasks:

- Review justification forms submitted by the transplant hospital that document the candidate's current condition and decide if the requested status is appropriate.
- Refer transplant hospitals to the appropriate OPTN Committee for review of candidates listed and transplanted at an inappropriate status. The Committee may then, if necessary, refer the hospital to the Membership and Professional Standards Committee (MPSC).
- Serve other peer review functions as determined by the Board of Directors.

Review boards are formed under the direction of the Committees and Board of Directors. Review boards can operate and perform peer review functions as determined by the Board of Directors. The Board of Directors and Committees may establish other guidelines for review board organization and function as necessary.

All OPTN Review Board members must agree to abide by the OPTN Code of Conduct and the process for handling of potential violations thereof, as described in Article 2.7: OPTN Code of Conduct. Agreements must be signed and submitted prior to the beginning of a Review Board member's service and on an annual basis thereafter. Individuals who do not sign agreements by the start of their terms of service and annually thereafter will not be permitted to serve as Review Board members.

## OPTN Code of Conduct

In my service to the OPTN, I shall do my utmost to ensure that the OPTN performs its mission and achieves its goals. As such, I understand and agree to the following:

- To act with honesty and integrity
- To speak up about disrespectful, inappropriate, fraudulent, unethical or illegal behavior
- To consider and respect the interests of all those in the transplant community, not just those in my area of expertise
- To value diversity in thought and opinion
- To not discriminate
- To collaborate with others to do the work of the OPTN
- To display courteous conduct in all OPTN meetings
- To respect the individual and opinions of those who serve the OPTN alongside me

## Duty of Care

I agree that all OPTN Directors, Committee members, and volunteers owe a duty to exercise reasonable care when making decisions as stewards of the OPTN. This includes the following duties:

- ~~• To act with honesty and integrity~~
- ~~• To speak up about disrespectful, inappropriate, fraudulent, unethical or illegal behavior~~
- To always act for the good of the OPTN
- ~~• To consider and respect the interests of all those in the transplant community, not just those in my area of expertise~~
- ~~• To value diversity in thought and opinion~~
- ~~• To not discriminate~~
- ~~• To collaborate with others to do the work of the OPTN~~
- To leave my personal biases out of all OPTN discussions
- ~~• To display courteous conduct in all OPTN meetings~~
- ~~• To respect the individual and opinions of those who serve the OPTN alongside me~~
- To act as a representative of the OPTN
- To follow OPTN Social Media Guidelines
- To abide by the Roles and Responsibilities of OPTN Directors, Committee members, and volunteers, which are as follows:
  - To attest to the following:
    - The completion of orientation training prior to commencement of service
    - The completion of annual training thereafter, as assigned
  - To adhere to general attendance requirements:

- For Directors and Committee members:
  - Attendance at each semiannual meeting
  - 80% attendance rate across all other OPTN meetings on which I am assigned, including service as a Visiting Board member
- For Directors
  - Attendance in at least one regional meeting per public comment cycle
  - As a Regional Councillor, to chair my region's regional meetings
- For Committee members who represent regions
  - Attendance at the regional meeting I represent per public comment cycle
- For Committee members in at-large positions
  - Attendance is encouraged at one regional meeting per public comment cycle
- To prepare for OPTN meetings by reviewing agendas and supporting materials, ask informed questions, and contribute to the discussion during meetings
- To actively participate in Board Committees, work groups, and other special projects as requested
  - For Review Board Members
    - Participation as outlined in the respective Review Board Operational Guidelines

## Duty of Loyalty

I agree that all OPTN Directors, Committee members, and volunteers owe a duty of loyalty to the OPTN while when making decisions as stewards of the OPTN. This includes the following duties:

- To offer my advice, opinions, votes, viewpoints, recommendations, and decisions exclusively votes in furtherance of my obligations to the OPTN
- To protect the confidential information of the OPTN, to use confidential information only as permitted, and to agree to abide by the OPTN Confidentiality Agreement
- To act in accordance with the OPTN Conflicts of Interests Bylaw, to disclose to the OPTN in writing of any employment, investment, familial relationships, or other activities that might provide personal or financial gain related to outcomes of matters affecting the OPTN, particularly with regard to member compliance issues or OPTN policies or bylaws of specific applicability, and will promptly disclose any changes or additions to this list once known to me.
- To take any corrective action that is deemed appropriate by the OPTN Board of Directors upon being informed of any concern that I have an actual conflict of interests or the appearance of a conflict of interests.
- To recuse myself from any meeting, part of a meeting, or vote with respect to any deliberation of action of any Board, Committee, or other OPTN forum or action, in which I may have a conflict of interest, regardless of whether the OPTN has knowledge of such conflict or has taken actions on such conflict.

## Duty to Ensure Compliance of the OPTN

I agree that OPTN Directors, Committee members, and volunteers are responsible for ensuring the OPTN's compliance with all applicable Federal laws and regulations, as well as the OPTN Bylaws. By

signing this document, I acknowledge that by serving the OPTN, I must carry out the responsibilities of the OPTN authorized by the National Organ Transplant Act of 1984, as amended (NOTA) (42 U.S.C. § 273, et seq.) and the OPTN Final Rule (42 C.F.R. part 121). I will follow NOTA, the OPTN Final Rule, and the OPTN Charter and OPTN Bylaws.

Further, I understand and agree to the following:

- I agree to report any potential violations of the Code of Conduct by other Directors, Committee members, or volunteers directly to the OPTN Compliance Officers.
- I understand that if a report is received about a potential violation of the Code of Conduct by me, I will be notified and given seven days to respond to the allegation. I agree to respond within that time period.
- I understand that if a report is received about a potential violation of the Code of Conduct, the OPTN President will be informed.
- I understand that if a report is received about a confirmed violation of a Duty of Loyalty or Duty of Compliance, the OPTN Board of Directors, including HRSA, will be informed.
- I understand that if I violate the Code of Conduct, the OPTN could require any or all of the following:
  - Notice to the OPTN Board of Directors of my violation
  - A letter of explanation
  - A corrective action plan
  - Suspension of my voting privileges for a period of time
  - Suspension of my service for a period of time
  - Removal from my position, according to OPTN Bylaws
- I agree to cooperate with the OPTN Compliance Officers in review of the report of a potential violation and to respect the outcome of the decision regarding the alleged behavior.

### **OPTN Social Media Guidelines**

OPTN Directors, Committee members, and volunteers may use unofficial social media, including personal and non-OPTN business accounts. In doing so, OPTN Directors, Committee members, and volunteers must adhere to the OPTN Code of Conduct, including protecting the confidential information of the OPTN, and abide by the OPTN Bylaws regarding public statements to avoid any appearance of endorsement by the OPTN, including the Board of Directors and its committees. The following guidelines apply:

- OPTN Directors, Committee members, volunteers may share personal experiences and opinions on personal social media accounts.
- OPTN Directors, Committee members, volunteers must ensure that personal and non-OPTN business social media accounts avoid the use of OPTN titles in a way that could imply OPTN endorsement of the content.
- Where confusion or doubt is likely to arise regarding the personal nature of social media activities, OPTN Directors, Committee members, volunteers are encouraged to include a disclaimer clarifying that their social media communications reflect only their personal views and do not necessarily represent the views of the OPTN. For example, OPTN Directors, Committee



members, volunteers may consider adding a disclaimer to the biography section of social media accounts stating, “Views are my own,” or “All opinions are my own.”

- OPTN Directors, Committee members, volunteers may use personal and non-OPTN business social media accounts to forward, like, or link to official OPTN information, provided it is done in a manner that does not express or imply that the OPTN has authorized any personal content shared with the official information.