

Notice of OPTN Bylaws Changes

Establish Code of Conduct and Whistleblower Protection Bylaws

Sponsoring Committee:	<i>Executive Committee</i>
Bylaws Affected:	<i>2.7 OPTN Code of Conduct 2.9 Public Statements by Directors 2.10 Whistleblower Protection 7.8 OPTN Code of Conduct 7.9 Public Statements by Committee Members and OPTN Volunteers 9.5 Review Boards</i>
Public Comment:	<i>April 17, 2024 – May 17, 2024</i>
Board Approved:	<i>June 12, 2024</i>
Effective Date:	<i>July 1, 2024</i>

Purpose of Bylaw Changes

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

- Establish 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.
- Creation of two Compliance Officer roles to manage the review and investigation of any reported Code of Conduct violation.
- Clarity regarding authority to make public statements on behalf of the OPTN
- Whistleblower protections for those reporting potential violations as outlined in the Whistleblower Protection Bylaw.

Proposal History

The Executive Committee sought to document and codify existing practices and establish new processes and protections within the OPTN Bylaws for OPTN members, volunteers, and others.

June 25, 2023

- OPTN Executive Committee sought to develop policy or bylaw codifying the OPTN’s existing position on whistleblower protections.

August 2023 – December 2023

- OPTN Executive Committee discussed Whistleblower protections, developing proposed language.
- When it was determined that public comment was needed for these changes, the Committee decided to broaden the proposal to establish a Code of Conduct as well.

February – April 2024

- The Executive Committee created a Code of Conduct Work Group in February 2024
- This work group met several times to review examples of other organizations’ Codes of Conduct and develop proposed bylaws language for both Whistleblower Protections and Code of Conduct proposal .

April 14, 2024

- The Executive Committee reviewed the Code of Conduct Work Group’s proposal and approved it going out for a special 30-day public comment.

April 17 – May 17, 2024

- Code of Conduct and Whistleblower Protections proposal open for public comment.

May 10, 2024

- Code of Conduct Work Group continued to meet, reviewing public comment submitted to date and continuing to make recommendations regarding language changes and implementation of processes related to the Bylaws.

May 23, 2024

- The Executive Committee reviewed and approved modifications to the proposal developed by the Code of Conduct Work Group resulting from public comment feedback and additional documentation to help operationalize this new process. The Committee voted to send the revised proposal to the Board for final approval.

June 12, 2024

- The OPTN Board of Directors approved the proposal with one amendment to:
 - Specify that public statement authorization must be issued in advance (“prior”)
 - Clarify that neither the OPTN nor anyone participating in the work of the OPTN shall retaliate against any person who in good faith reports concerns protected under the whistleblower protection bylaw
 - Further specified the concerns that could be reported under the whistleblower protection bylaw
 - Added requirement of HRSA approval for the Compliance Officers, OPTN Executive Director, or OPTN President to engage experts for review of reports

Summary of Changes

The Board of Directors approved the creation of Bylaws that address the following:

For Code of Conduct, the new bylaws:

- Establish a Code of Conduct for volunteers
- Require review and attestation of agreement to uphold and abide by these duties and responsibilities on an annual basis
- Require review of the Code of Conduct and updates as frequently as needed, but at least once every three years
- Create two OPTN Compliance Officer positions, to be appointed from the OPTN Board of Directors, who will be responsible for reviewing and responding to all reported potential violations of the OPTN Code of Conduct
- Outline a pathway for reporting potential violations
- Outline how reported violations will be reviewed, evaluated, resolved, and reported
- Describe opportunities for an individual accused of a violation to respond

For public statements by Directors and volunteers, the new bylaws:

- Codify the OPTN President's responsibility to make public statements on behalf of the OPTN and permit any other Director or volunteer to do so only when authorized by the OPTN President in writing, including the purpose and duration of authorization
- Establish limits on Directors and volunteers using their OPTN position or title to avoid implication that the OPTN has authorized a statement or body of work
- State that without authorization, the Director or volunteer must state they are commenting in an individual capacity and not on behalf of the OPTN
- Establish limits on volunteers using their OPTN position or title to avoid implication that the OPTN has authorized a statement or body of work.

For Whistleblower protections, the new bylaws:

- Acknowledge the high standard of business and personal ethics expected from Directors, Committee members, and volunteers in conducting the OPTN duties and responsibilities
- Encourage anyone seeking to raise concerns regarding actions or behavior within OPTN the before seeking resolution externally
- Put forth a clear statement against retaliation
- Codify reporting procedure of 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
- Allow for external subject matter experts to be included in an investigation if warranted; and
- Establish that whistleblowers must act in "good faith, having reasonable grounds for believing the information disclosed is a violation"
- Protect the confidentiality of the whistleblower
- Outline the review process for reported violations

Implementation

All OPTN Volunteers, including members of the Board of Directors, Committees, Task Forces, and Review Boards, must agree to abide by the OPTN Code of Conduct by signing an attestation noting review and agreement. This is in addition to the current Conflict of Interest attestation that is signed annually by all OPTN volunteers.

The Code of Conduct will be circulated to all Directors, Committee members, Task Force members, and Review Board members for review and attestation. The OPTN will create an attestation form similar to the process used for the Conflict of Interest. This will be circulated to all returning and incoming volunteers with service commitments as of July 1, 2024. All volunteers will be required to review and submit this document prior to July 1, 2024 to begin their term of service as planned.

The OPTN will provide mechanisms for anyone to report concerns about potential violations of the OPTN Code of Conduct or concerns protected under the Whistleblower Protection bylaws.

Affected Bylaw Language

New language is underlined (example) and language that is deleted is struck through (~~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 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 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 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:

1. The reasons the individual is requesting an informal discussion
2. A summary of what the individual would like to present to the OPTN Compliance Officer
3. 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 experts at their discretion, with approval from HRSA, to aid in any review of reported violations. 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. Confirmed violations of the OPTN Code of Conduct can result in consequences up to and including removal from 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 prior 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 anyone participating in the work of the OPTN shall retaliate against any person who in good faith reports concerns about 1) a suspected ethics violation; 2) a suspected violation of law that is not specific to the organ donation or transplant context, such as a complaint of discrimination, or suspected fraud; or 3) a suspected violation of NOTA or 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 with approval from HRSA, may engage 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 prior 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.

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.

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.