

Public Comment Proposal

Proposal to Establish Code of Conduct and Whistleblower Protection Bylaws

OPTN Executive Committee

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Proposal to Establish Code of Conduct and Whistleblower Protection Bylaws

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| <i>Affected Bylaws:</i> | <i>Bylaw 2.7 OPTN Code of Conduct</i> <i>Bylaw 2.9 Public Statements by Directors</i> <i>Bylaw 2.10 Whistleblower Protection</i> <i>Bylaw 2.11 Relationship between OPTN Board and OPTN Contractor(s) Board</i> <i>Bylaw 7.8 OPTN Code of Conduct</i> <i>Bylaw 7.9 Public Statements by Committee Members</i> <i>Bylaw 9.5 Review Boards</i> |
| <i>Sponsoring Committee:</i> | <i>Executive</i> |
| <i>Public Comment Period:</i> | <i>April 17, 2024 – May 17, 2024</i> |

Executive Summary

This proposal seeks to specifically document and codify existing practices that encourage participation in the OPTN and establish 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, providing a neutral and independent pathway for an initial review of concerns about the OPTN by an outside party, i.e. the Secretary of HHS.¹

According to well-established principles of nonprofit corporation law, nonprofit board members and volunteer leaders should meet certain standards of conduct and commitment to fulfill their role in representing an organization.^{2,3,4} 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.⁵ Similarly, OPTN volunteers currently serving on committees and organ-specific review boards sign an attestation to certify confidentiality and conflict of interest.⁴

¹ 42 CFR § 121.4 (d)

² 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)

³ Iowa Principles and Practices for Charitable Nonprofit Excellence (revised 2016) <https://inrc.law.uiowa.edu/sites/inrc.law.uiowa.edu/files/pp-2016ed-web.pdf> (accessed on March 18, 2024)

⁴ National Council of Nonprofits. <https://www.councilofnonprofits.org/running-nonprofit/ethics-accountability/ethical-leadership-nonprofits> (accessed on March 18, 2024)

⁵ OPTN Website. <https://optn.transplant.hrsa.gov/about/how-to-get-involved/> (accessed on March 20, 2024)

This proposal also includes a defined pathway for reporting and addressing potential wrongdoing. This includes the appointment of a Director as OPTN Compliance Officer. The Compliance Officer will manage the review and assessment of all potential Code of Conduct violations. Similarly, a pathway is outlined for investigating reported violations or suspected violations reported by a whistleblower in addition to protections for the reporter.

Purpose

The purpose of these newly created 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 (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:

- 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 meeting⁶, the Executive 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 process and protections, 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 Executive Committee met on August 14, 2023⁷ to review potential policy language. The Committee wished to make clear that the OPTN welcomes and encourages different viewpoints on how the OPTN can improve in the interest of the patients and donors that the OPTN serves. The Executive Committee also wanted to make explicit the position that the OPTN will not retaliate against any individual who in good faith reports an ethics violation, suspected violation of law, such as a complaint of discrimination, suspected fraud, or suspected violation of any regulation governing the operations of the OPTN. The Committee agreed that differences of opinion and viewpoint are not the type of concerns this policy is intended to address, but rather the protection from organizational retaliation against an individual who reports an ethical or legal violation about the OPTN or any of its leadership. The Committee also emphasized that if the whistleblower's concern involved the OPTN Executive Director or any other subordinate Officer of the OPTN, that 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 Executive Committee ultimately approved a Whistleblower Protection Policy on September 8, 2023.⁸

⁶ OPTN Executive Committee Meeting Summary, June 25, 2023.

https://optn.transplant.hrsa.gov/media/djgpu1w2/20230625_executive-committee_summary.pdf (accessed 3.18/2024).

⁷ OPTN Executive Committee Meeting Summary, August 14, 2023.

https://optn.transplant.hrsa.gov/media/mirncqz2/20230814_executive-committee-meeting-summary.pdf (accessed 3/28/2024).

⁸ OPTN Executive Committee Meeting Summary, September 8, 2023.

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

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 Executive Committee to reconsider the need for public comment for this policy change.⁹ As a result, the policy was not implemented. While Bylaw 11.1.A (*The Public Comment Period*)⁵ 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 later notified the OPTN that the Whistleblower Protection Policy has member burden implications and would require public comment.

The Executive 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 Executive Committee expanded on other ideas to be addressed. This included the recommendation of 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 broader Whistleblower language, 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, 2024.¹⁰ 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 that 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 BoardSource¹¹ and the National Council of Nonprofits.¹¹ Work group members discussed who should be subject to the provisions of the Code of Conduct (i.e. full Board versus Board Leadership, Committees, Members, Volunteers, etc.), considered review and investigation of concerns, and enforcement of the Code as part of the bylaws development effort.

The OPTN does have a Meeting Code of Conduct that was developed in response to resuming in-person meetings during the COVID-19 pandemic.¹² 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.

⁹ OPTN Executive Committee Meeting Summary, December 3, 2024. https://optn.transplant.hrsa.gov/media/qzibvs04/20231203_executive-committee_summary.pdf (accessed on March 18, 2024)

¹⁰ 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 (accessed on March 18, 2024)

¹¹ National Council of Nonprofits. <https://www.councilofnonprofits.org/running-nonprofit/ethics-accountability/codes-ethicsvalues-statements-nonprofits> (accessed on March 18, 2024)

¹² OPTN Meeting Code of Conduct. <https://optn.transplant.hrsa.gov/media/z0ggux0x/optn-meeting-code-of-conduct.pdf> (accessed 4/1/2024)

During its February 27, 2024 meeting¹³, the Work Group spent considerable time studying and discussing the provisions of duty of care, duty of loyalty, duty of compliance, and the provisions that would be included under each, as well as examples from other nonprofit and for profit organizations were reviewed (i.e. Accenture¹⁴, American Society of Transplantation¹⁵, and example documents from the National Council of Nonprofits¹⁶) as it explored the components of a Code of Conduct and what might be included. After discussion, the Work Group decided to include the following provision pertaining to duty of loyalty:

- Respect the outcome of a direction taken by the Board of Directors or committee. Respect those that respectfully dissent.

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 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 2024¹⁷, the Work Group determined that the Code of Conduct will be applicable to those serving the OPTN as Directors, Committee members, and volunteers (i.e. organ specific review board members, subject matter experts not currently serving on committees asked to participate in work groups or task forces).

The OPTN currently has online and phone pathways available for reporting concerns, including the Member Reporting Hotline (866-787-4909), the patient safety portal (within the OPTN Computer System for member access) and the patient services email and phonenumber (patientservices@unos.org or 888-894-6361).¹⁸ Any concerns or reports of potential violations may also be reported directly to the OPTN Executive Director, President, or Compliance Officer.

¹³ 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 (accessed April 1, 2024)

¹⁴ Accenture Code of Business Ethics. <https://www.accenture.com/us-en/about/company/business-ethics> (accessed on April 1, 2024)

¹⁵ American Society of Transplantation Code of Conduct. <https://www.myast.org/code-conduct> (accessed on April 1, 2024)

¹⁶ National Council of Nonprofits: Codes of Ethics/Values Statements for Nonprofits.

<https://www.councilofnonprofits.org/running-nonprofit/ethics-accountability/codes-ethicsvalues-statements-nonprofits> (accessed on April 1, 2024)

¹⁷ Executive Committee Meeting Summaries, OPTN Website. <https://optn.transplant.hrsa.gov/about/committees/executive-committee-board-of-directors/> (accessed April 15, 2024)

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

Overview of Proposal

Code of Conduct

This proposal creates *Bylaw 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 a current Director to be appointed as OPTN Compliance Officer. The Compliance Officer 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; and
- Outlines how reported violations will be reviewed, evaluated, resolved, and reported.

This proposal creates *Bylaw 7.8: OPTN Code of Conduct*, which requires all OPTN Committee members to abide by the Code of Conduct as outlined in Article 2.7 OPTN Code of Conduct.

This proposal adds language to *Bylaw 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 Code of Conduct (see Appendix) is meant to apply to all Directors, Committee members, and Volunteers serving the OPTN. General attendance 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 an appointed Compliance Officer position on the Board of Directors. This role will ideally be filled by a current Director in good standing with human resources or personnel management experience. The Compliance Officer will serve a term of at least one year and 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 accused Director of the reported violation, giving the Director 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 and assembling a group of members of the OPTN Board to review reports of potential violations as needed. This group of members must include the OPTN Past President, unless a conflict is present;

- Recommending an appropriate resolution for all confirmed violations to the OPTN Executive Committee, who will ultimately decide the action appropriate for the violation (up to and including removal from office); 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 *Bylaw 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 to specifically not purpose and duration of 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.

This proposal creates *Bylaw 7.9: Public Statements by Committee Members*, 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 is authorized to speak and the duration of this authorization; and
- Establishes limits on Committee members using their OPTN position or title to avoid implication that the OPTN has authorized a statement or body of work.

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 enforcing responsibilities such as this was also recognized as part of the discussion. Work Group members were supportive of the OPTN President as authorized to make 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 to clarify that specific authorization from the OPTN President is needed in order to make statements on behalf 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 title may be used when publishing a scientific or professional journal with Executive Committee notification and the inclusion of a disclaimer to note that the views expressed do not necessarily represent the views of the OPTN.

New Bylaws language clearly defines that Directors and Committee members must have written authorization from the OPTN President to make public statements on behalf of the OPTN. Limits are also established for both Directors and Committee members in using their OPTN position or title to avoid the implication of OPTN support or authorization of a statement or body of work (i.e. scientific manuscripts, etc.). Executive Committee notification and an OPTN-approved disclaimer that notes the views expressed do not necessarily represent the OPTN must be completed and included prior to publication.

Whistleblower Protection

This proposal creates *Bylaw 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 the OPTN 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 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.

NOTA and Final Rule Analysis

The Executive 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...”¹⁹ As described throughout the proposal, the proposed changes are consistent with applicable provisions of NOTA²⁰ and the OPTN Final Rule.²¹

Implementation Considerations

OPTN Operations

This proposal does not impact histocompatibility laboratories, OPOs, or transplant centers operations.

Potential Impact on Select Patient Populations

This proposal has no known impact on select patient populations.

¹⁹ 42 U.S.C. §274(a)

²⁰ 274 USC (b)(1)(B)

²¹ 42 CFR 121.3(a)(1)

Projected Fiscal Impact

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

Post-implementation Monitoring

Member Compliance

The OPTN Contractor will maintain a record of signed Code of Conduct forms for Directors, Committee Members, and Review Board Members. 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 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 start 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 any updates as frequently as needed, but at least once every three years.

Conclusion

The goal of this proposal is to 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 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.

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 bylaws will be updated as necessary.

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 Compliance Officer will serve a term of at least one year and is 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 Officer, who has 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 Officer will notify the Director accused of the violation, giving the Director seven days to respond to the report. The OPTN Compliance Officer may assemble a group of

38 members of the OPTN Board to review reports of potential violations as needed. This group of
39 members must include the OPTN Immediate Past President, unless a conflict is present.

40
41 The OPTN Compliance Officer will notify the OPTN President of all potential violations of the
42 Code of Conduct within two days of receipt of a report and report confirmed violations to the
43 OPTN Board of Directors on a quarterly basis. For confirmed violations of Duty of Loyalty and
44 Duty to Ensure Compliance of the OPTN, the OPTN Compliance Officer will notify the OPTN
45 Board of Directors within two days of the confirmation.

46
47 The OPTN Compliance Officer will recommend an appropriate resolution for all confirmed
48 violations to the OPTN Executive Committee, who will ultimately decide the action
49 appropriate for the violation. Confirmed violations of the OPTN Code of Conduct can result in
50 consequences up to and including removal from office, according to Bylaw 2.5.

51 52 **2.78 Conflicts of Interest**

53
54 [...]

55 56 **2.9 Public Statements by Directors**

57
58 The OPTN President is authorized to make public statements on behalf of the OPTN. Any other Director
59 must be specifically authorized to do so by the OPTN President. If authorized, the OPTN President will
60 provide written authorization that clearly states the purpose for which the Director is authorized to
61 speak on behalf of the OPTN and the duration of the authorization.

62
63 Directors shall not use or permit the use of the OPTN position or title in a manner that could reasonably
64 be construed to imply that the OPTN has authorized the statement. Directors are permitted to use the
65 Director's position or title in conjunction with an article published in a scientific or professional journal,
66 provided the Director notifies the OPTN Executive Committee prior to submitting the publication, and
67 includes an OPTN approved disclaimer, addressing the views expressed in the article do not necessarily
68 represent the views of the OPTN.

69 70 **2.10 Whistleblower Protection**

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

76 77 **2.10.A No Retaliation**

78
79 Neither the OPTN nor any of its representatives or OPTN Contractors shall retaliate against
80 any person who in good faith reports concerns about 1) a suspected ethics violation; 2) a
suspected

81 violation of law, such as a complaint of discrimination, or suspected fraud; or 3) a suspected
82 violation of any regulation governing the operations of the OPTN.

84 **2.10.B Reporting Procedure**

85
86 The OPTN has an open-door policy and encourages anyone to share their questions, concerns,
87 suggestions or complaints with the OPTN Executive Director or, in the instance the concern
88 involves the OPTN Executive Director, with the OPTN President. Complaints or concerns about
89 suspected ethical, legal, or regulatory violations should be submitted in writing to the OPTN
90 Executive Director, or the OPTN President, as applicable, who has the responsibility to
91 investigate all reported complaints. The OPTN Executive Director or the OPTN President, if
92 applicable, will advise the OPTN President, or the OPTN Board of Directors, respectively, of all
93 complaints and their resolution and will report at least annually to the OPTN Finance
94 Committee on compliance activity relating to accounting or alleged financial improprieties.

96 **2.10.C Accounting and Auditing Matters**

97
98 The OPTN Executive Director, or the OPTN President, as applicable, shall immediately notify
99 the OPTN Treasurer of any concerns or complaints regarding OPTN accounting practices,
100 controls or auditing and work with the OPTN Finance Committee until the matter is resolved.

102 **2.10.D Acting in Good Faith**

103
104 Anyone submitting a complaint concerning a violation or suspected violation must be acting in
105 good faith and have reasonable grounds for believing the information disclosed indicates a
106 violation.

108 **2.10.E Confidentiality**

109
110 Violations or suspected violations may be submitted confidentially by the complainant.
111 Reports of violations or suspected violations will be kept confidential to the extent possible,
112 consistent with the need to conduct an adequate investigation.

114 **2.10.F Review of Reported Violations**

115
116 The OPTN Executive Director, or the OPTN President, as applicable, will notify the person who
117 submitted a complaint and acknowledge receipt of the reported violation or suspected
118 violation. All reports will be promptly investigated, and appropriate corrective action will be
119 taken if warranted by the investigation. The OPTN Executive Director, or the OPTN President, as
120 applicable, may engage independent accountants, counsel, or other experts, at their discretion
121 to aid in any investigation of the reported violation or suspected violation.

123 **2.811 Relationship between OPTN Board and OPTN Contractor(s) Board**

125 **7.8 OPTN Code of Conduct**

126
127 All OPTN Committee members must agree to abide by the OPTN Code of Conduct and the process for
128 handling of potential violations thereof, as described in Article 2.7: OPTN Code of Conduct. Agreements
129 must be signed and submitted prior to the beginning of a Committee member’s service and on an annual
130 basis thereafter Individuals who do not sign agreements by the start of their terms of service and
131 annually thereafter will not be permitted to serve as Committee members.

132 133 **7.9 Public Statements by Committee Members**

134
135 OPTN Committee members must have specific authorization from the OPTN President to make public
136 statements on behalf of the OPTN. If authorized, the OPTN President will provide written authorization
137 that clearly states the purpose for which the Committee member is authorized to speak on behalf of the
138 OPTN and the duration of the authorization.

139
140 Committee members shall not use or permit the use of the OPTN position or title in a manner that could
141 reasonably be construed to imply that the OPTN has authorized the statement. Committee members are
142 permitted to use their Committee position or title in conjunction with an article published in a scientific
143 or professional journal, provided the Committee member includes an OPTN approved disclaimer,
144 addressing the views expressed in the article do not necessarily represent the views of the OPTN.
145 Committee Chairs and Vice Chairs must also notify the OPTN Executive Committee prior to submission of
146 the article if using their Committee position or title in conjunction with the article.

147 148 **9.5 Review Boards**

149
150 The OPTN establishes review boards to review requests for exceptionss that are permitted by policy.
151 These review boards provide confidential medical peer review of transplant candidates placed on the
152 waiting list at a more urgent status than the standard listing criteria jusifies. As part of these reviews,
153 review boards may perform the following tasks:

- 154
- 155 ▪ Review justification forms submitted by the transplant hospital that document the
 - 156 candidate’s 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
162 Review boards are formed under the direction of the Committees and Board of Directors. Review boards
163 can operate and perform peer review fuunctions as determined by the Board of Directors. The Board of
164 Directors and Committees may establish other guidelines for review board organization and function as
165 necessary.

166
167 All OPTN Review Board members must agree to abide by the OPTN Code of Conduct and the process for
168 handling of potential violations thereof, as described in Article 2.7: OPTN Code of Conduct. Agreements

169 must be signed and submitted prior to the beginning of a Review Board member's service and on an
170 annual basis thereafter Individuals who do not sign agreements by the start of their terms of service
and 171 annually thereafter will not be permitted to serve as Review Board members.

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Appendix: 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:

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 and to
 - 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 Visting 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 when making decisions as stewards of the OPTN. This includes the following duties:

- To offer my advice, opinions, votes, and decisions exclusively 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 potentially violations of the Code of Conduct by other Directors, Committee members, or volunteers directly to the OPTN Compliance Officer.

- 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 Officer 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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