

Briefing to the OPTN Board of Directors on **Revised Bylaws and Management and Membership Policies**

OPTN Executive Committee

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Revised Bylaws and Management and Membership Policies

<i>Affected Bylaws:</i>	<i>All OPTN Bylaws</i>
<i>Sponsoring Committee:</i>	<i>Executive</i>
<i>Public Comment Period:</i>	<i>October 25, 2024 – November 8, 2024</i>
<i>Board of Directors Meeting:</i>	<i>December 2-3, 2024</i>

Executive Summary

The Health Resources and Services Administration (HRSA) has taken a major step in modernizing the Organ Procurement and Transplantation Network (OPTN) by separating its Board of Directors from the contractor(s) supporting OPTN operations. To better serve patients and families, a new independent nonprofit organization, the Independent Network of Volunteers for Equitable and Safe Transplants (INVEST), was established on July 24, 2024 to serve as the OPTN Board of Directors through a HRSA-issued designation agreement. The OPTN Board of Directors manages membership in the OPTN, but OPTN members are not members of, or otherwise a part of, INVEST.

To support this structural change, the governance documents of the OPTN have been updated with the prior bylaws split into two distinct documents: (1) bylaws, focusing on the governance structure and roles, and (2) Management and Membership Policies, addressing operational details. These changes ensure a more flexible policy framework, but do not alter core content or organ allocation policies. This proposal was submitted for public comment to inform the community about these developments, foster transparency regarding HRSA's modernization efforts and provide an opportunity for feedback. Following public comment, the indemnification clause bylaw was amended to ensure that coverage would be extended to OPTN volunteers, not just directors and officers. The change is highlighted in the Proposed Bylaw Language section of this paper.

Background

OPTN Board Independence

For four decades, the OPTN Board of Directors (Board) has been one-and-the-same as the corporate Board for the federal government’s contractor, raising issues about potential conflicts of interest. Now, as part of the OPTN Modernization initiative, HRSA has separated the Board from the OPTN contractor so it may better serve the interests of patients and families. As part of this effort, HRSA has supported the incorporation of a new non-profit organization named Independent Network of Volunteers for Equitable and Safe Transplants Inc. (INVEST) which, through a HRSA-issued designation contract, serves as the Board.

As an independent, non-profit corporation incorporated in Delaware, INVEST is required to have bylaws that comply with the provisions and requirements of the Delaware General Corporation Law. HRSA worked with the Board and a transition working group of Board members to align existing bylaws and policies and procedures with the new structure. Specifically, the prior bylaws are now separated into two distinct governance documents: (1) bylaws and (2) Management and Membership Policies. The content for both governance documents come from the previously adopted bylaws with some minor non-substantive modifications. These changes took effect on an interim basis on July 23, 2024, afterwards on July 24, 2024, the Board was designated by HRSA through a designation agreement. It is important to note that the OPTN policies, including all organ allocation policies were entirely unchanged by the above-described separation of the prior bylaws. At this same meeting, the Board also voted on two language changes to D.12 Additional Transplant Program requirements. These changes were previously approved by the OPTN Board of Directors and were scheduled to be incorporated into the bylaws at this time.

A crosswalk showing the original location of content and the new location of the content is available later in this document.

Strengthening Independence and Transparency

For many years, the Board members concurrently served as board members of the United Network for Organ Sharing (UNOS), the OPTN contractor. Eliminating this conflict of interest has been one of the cornerstones of the OPTN Modernization efforts. Starting on March 30, 2024, UNOS selected its own Board members, independent of the OPTN Board members, and HRSA began supporting the incorporation of the non-profit entity, INVEST, to serve as the Board of the OPTN upon designation by HRSA.

On July 23, 2024, INVEST adopted bylaws and on July 24, the OPTN designation agreement between HHS and INVEST was executed. The INVEST bylaws were released for public comment to inform the community about these changes and to provide a platform for strengthening the community’s engagement on modernization efforts while providing an opportunity for feedback.

Proposal for Board Consideration

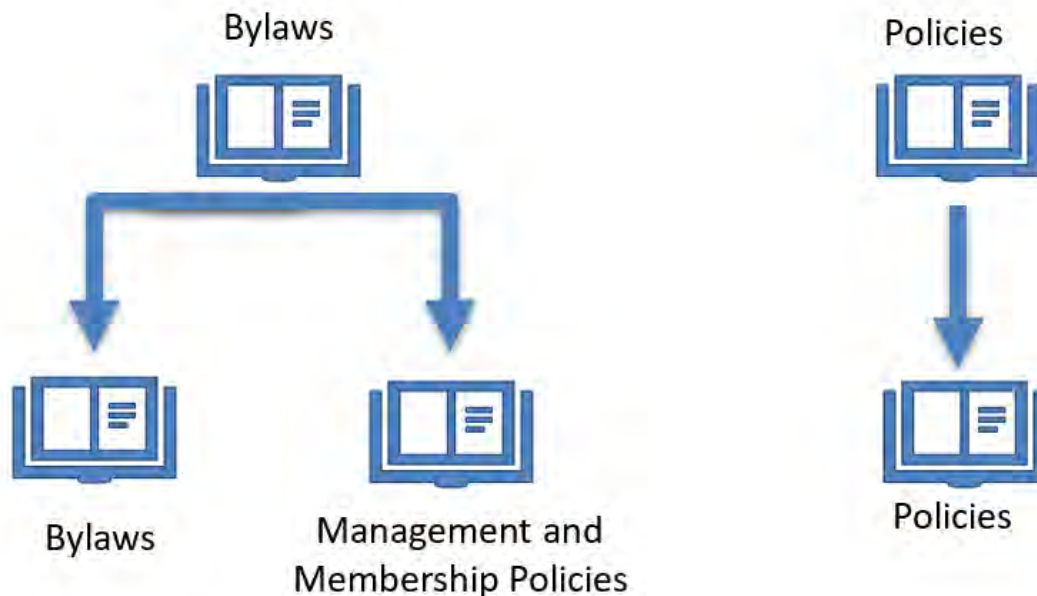
In separating the governance documents there were minimal changes to the content. These changes are explained below.

Structure of Governance Documents

The OPTN has traditionally been governed by bylaws and policies. Creation of INVEST provided an opportunity to rethink the organization of these governance documents. As a result, the bylaws are now split into two distinct documents: bylaws and Management and Membership Policies. The preexisting OPTN policies remain unchanged.

The new OPTN Governance documents are:

- **Bylaws:** The new bylaws focus exclusively on the structure and operation of the INVEST Board, which will operate as the OPTN Board, providing clear guidelines on governance, roles, and responsibilities. Additional sections, including a section with definitions, were added to comply with corporate bylaw requirements. This separation allows for a more streamlined and focused approach to organizational governance.
- **Management and Membership Policies:** Detailed operational and administrative aspects of the OPTN have been moved to the policies. This change allows for a more dynamic and responsive policy framework that can be adapted as needed without altering the foundational bylaws.



Feedback was received during public comment that the overlapping reference of “policies” within the Management and Membership Policies to existing policies in OPTN policies could be confusing. The Executive Committee proposed changing the Management and Membership Policies references to letters instead of numbers. This nonsubstantive change will be applied upon approval of the overall proposal.

Indemnification

A new section was added to the bylaws explaining INVEST’s requirements to indemnify certain individuals. The intent of the bylaw was to indemnify all OPTN volunteers for actions they take while

acting on behalf of the OPTN. Public comment feedback was received that the language should be more clear in its coverage of non-Directors and officers of the Board. The Executive Committee agreed and amended the bylaw language to include direct references to committee and other OPTN volunteers.

Officer Terms

The Board historically could extend the terms of individual Board members.¹ The Board used this authority when there were unexpected vacancies on the Board. This ability did not extend to the Officers of the Board. The new bylaws permit the Board to extend the terms of the Officers.² As part of the OPTN Modernization Initiative, HRSA has indicated its intent to hold a special election for the Board but has not announced the timing of the special election. Depending upon the timing of the special election, it might make sense to extend the terms of the Officers of the Board to align with the start of the new Board following a special election. This would avoid the need to seat new officers for a short time using the existing processes for officer elections before a special election.

Special Election

While not a part of the proposed language changes, the reference in the public comment proposal to HRSA's intention to hold a special election for the OPTN Board received public comment feedback. Several commenters opined that the bylaws that govern the OPTN's "general election" process should also govern any "special elections" and the creation of a nominating committee. The Executive Committee reviewed the OPTN's legal authority, documented in NOTA, the Final Rule, and the current bylaws, and found the following applicable provisions:

- NOTA requires the OPTN to have a board of directors "that shall establish an executive committee and other committees, whose chairpersons shall be selected to ensure continuity of leadership for the board." (42 U.S.C. §274(b)(1)(B)(ii)).
- The OPTN Final Rule requires that the OPTN "shall establish a Board of Directors" and that the Board of Directors "shall establish such other committees as are necessary to perform the duties of the OPTN." (42 C.F.R. §121.3(a)(1) and (a)(4)).
- The OPTN Final Rule also requires the OPTN Board of Directors to develop "policies for nominating officers and members of the Board of Directors." (42 C.F.R. §121.4(a)(5)).
- The OPTN Nominating Committee is appointed by the OPTN President from current Directors of the OPTN. (*OPTN Bylaw 3.1: Composition*).
- The OPTN Nominating Committee recommends candidates for election as officers and Directors. (*OPTN Bylaw Article III: Nominating Committee*).
- The voting Directors of the OPTN must approve by a majority vote the slate of nominees to be included on the national ballot for the annual meeting. (*OPTN Bylaw 2.2: Election*).
- The voting Directors are elected by vote of the OPTN members. (*OPTN Bylaw 2.2: Election*).
- A Director may be removed from office for any reason with at least two-thirds vote of all Directors at any regular or special meeting of the Board of Directors. (*OPTN Bylaw 2.5: Removals*).

Further, the OPTN bylaws do not distinguish between "general election" and "special election"; the bylaws apply to positions elected (Director, Officer, Councilor). The Committee discussed and agreed

¹ OPTN Bylaw 3.3(B) *Regional Councillor Terms* and 3.3(C) *At-Large Director Terms*.

² INVEST Bylaw 3.3(A) *Officer Terms*.

that based on its interpretation of the legal authorities outlined above, the OPTN bylaws would apply to *any* OPTN Board election. The Executive Committee noted that in order to create a mechanism for an election that was exempted from these requirements the OPTN Board of Directors would have to duly approve amendments to the OPTN Bylaws, in the process required by the Bylaws.

The Committee also discussed HRSA's ability to appoint a nominating committee and questioned whether this aligned with NOTA and the Final Rule's requirements that the "OPTN Board shall establish Committees." HRSA agreed to provide the authority support for their interpretation and recognized the benefit of having this answer prior to the Board's meeting on December 2, 2024.

Other Feedback

The proposal gathered constructive feedback in three other areas, all which were deemed by the Executive Committee as opportunities for future projects.

1. OPTN Volunteers' ability to make public statements in their personal capacity
2. Family/patient centered language
3. Board and committee composition

Substantial feedback was received regarding the composition of the OPTN Board and committees. Commenters specifically expressed concerns about histocompatibility representatives being appointed rather than elected, emphasizing that the histocompatibility representative seat should reflect the choice of the transplant community. Additionally, there was considerable concern about insufficient pediatric representation on the Board and across committees. Many commenters also underscored the importance of ensuring adequate patient and donor family involvement in the OPTN Board and committee structure. The Board agreed these are important considerations and will consider them in the future.

A commenter noted there was no evidence from public materials that the INVEST bylaws were adopted by the OPTN Board as their own bylaws in its July meeting. To ensure that the INVEST bylaws are properly adopted by the OPTN Board to be the OPTN bylaws and avoid any risk of procedural deficiencies, the Executive Committee recommends the formal adoption by the OPTN Board of the INVEST bylaws as those of the OPTN, and the specific repeal of all previous effective OPTN bylaws.

Lastly, many comments were received about HRSA's OPTN Modernization effort. While most supported the effort overall, many commenters had concerns about the future state of the OPTN, such as how the OPTN would function with multiple contractors, objections to lack of continuity in OPTN leadership in the potential seating of a new OPTN board, and more touchpoints with the community for increased awareness and transparency. While these comments proved helpful to understanding the community's comfort level with HRSA's reform efforts, the comments were not actionable as it related to this proposal, and therefore no corresponding changes were made.

Compliance Analysis

NOTA and OPTN Final Rule

NOTA requires that the Secretary of HHS provide for the OPTN, which shall have a Board.³

Establishing a separate Board from other OPTN contractors implements a key component of the Securing the U.S. Organ Procurement and Transplantation Network Act.⁴ More specifically, the Act requires that the OPTN shall “be operated through awards to public or private entities made by the Secretary that are **distinct from the awards made to support the organization tasked with supporting the board of directors**” (emphasis added).⁵ This requires the Board be independent from entities to which HHS has made awards to support the operation of the OPTN. This new corporation, INVEST, is incorporated in Delaware. As part of incorporating INVEST, the corporation must adopt new bylaws.⁶

Among other things, the OPTN Board is responsible for establishing OPTN committees,⁷ creating membership criteria,⁸ establishing policies regarding organ procurement,⁹ and collecting data concerning organ donation and transplantation.¹⁰ The governance of these processes is contained in the OPTN Final Rule¹¹, as well as new bylaws or the new Membership and Management Policies.

OPTN Strategic Plan

The proposal is aligned with the following OPTN Strategic Plan goal:

- *Support OPTN Modernization Initiatives*

Implementation Considerations

Member and OPTN Operations

Operations affecting Members

Members will need to replace any printed or electronic copies of the bylaws with the new bylaws and the Management and Membership Policies. Members will need to update any internal policies or documentation that contain references to specific bylaw sections.

Operations affecting the OPTN

An OPTN Contractor will need to update:

³ 42 U.S.C. § 274(b)(1)(B).

⁴ Securing the U.S. Organ Procurement and Transplantation Network Act. 42 U.S.C. § 201 note. Public Law 118–14, 137 Stat. 69 (2023).

⁵ 42 U.S.C. § 274 (b)(1)(a).

⁶ 8 Del. C. §101 et.seq.

⁷ 42 U.S.C. § 274 (b)(1)(B)(ii).

⁸ 42 U.S.C. § 274(b)(2)(B).

⁹ 42 U.S.C. § 274(b)(2)(E).

¹⁰ 42 U.S.C. § 274(b)(2)(I).

¹¹ 42 C.F.R. Part 121.

- The OPTN website to reflect the change from bylaws and policies to new bylaws, Management and Membership Policies, and policies.
- Help documentation in the OPTN computer system and membership applications that contain any references to the bylaws.
- References to bylaws in the OPTN Evaluation Plan.
- References to the bylaws in the MPSC letter templates.
- References to the bylaws in the OPTN Charter.

Potential Impact on Select Patient Populations

There are no expected positive or negative impacts on any particular population.

Projected Fiscal Impact

Projected Impact OPTN Members

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

Projected Impact on the OPTN

It is estimated that \$10,617 would be needed to develop this proposal. Development would involve committee preparation and facilitation, proposal development, and presentations. It is estimated that \$179,422 would be needed to implement this proposal. Implementation would involve communications, educational materials, updates to OPTN documents, templates, processes, and web pages. It is estimated that \$1,768 will be needed for ongoing support. Ongoing support includes web and monitoring report updates. The total for development, implementation, and ongoing support is estimated to be \$191,807.¹²

Post-implementation Monitoring

Member Compliance

This proposal is not intended to change routine member compliance or monitoring activities.

Policy Evaluation

Not applicable.

Conclusion

To support an independent Board that will effectively address the needs of patients and families, the governance documents of the OPTN have been updated. The prior bylaws have been split into two distinct documents: the bylaws, focusing on the governance structure and roles, and the Management and Membership Policies, addressing operational details. These changes will ensure a more flexible policy framework, but do not alter any core content or organ allocation policies.

¹² Resource estimates are calculated by the current contractor for that contractor to perform the work. Estimates are subject to change depending on a number of factors, including which OPTN contractor(s) will be performing the work, if the project is ultimately approved.

Crosswalk of Changes

This proposal restructures all the bylaws and splits them into two documents: (1) bylaws and (2) Management and Membership policies.¹³

Original Bylaw Section	Location of Material in New Governance Documents
<i>New</i>	Bylaws Article I: Purpose and Definitions
<i>New</i>	Bylaws Article II: Members of INVEST
Article II: Board of Directors	Bylaws Article III: Board of Directors
Article III: Nominating Committee	Bylaws Article IV: Nominating Committee
Article IV: Executive Committee	Bylaws Article V: Executive and other Committees
Article V: Executive Director	Bylaws Article VI: Executive Director
Article VI: Officers	Bylaws Article VII: Officers
<i>New</i>	Bylaws Article VIII: Indemnification
Article X: Amendment of Charter and Bylaws	Bylaws Article IX: Amendment of Bylaws
<i>New</i>	Management and Membership Policies: Introduction
Article VIII: Permanent Standing Committees	Management and Membership Policy 1: Permanent Standing Committees
Article VIII: Financial Considerations	Management and Membership Policy 2: Financial Considerations
Article IX: Regions	Management and Membership Policy 3: Regions
Article 7.7 Conflicts of Interest, 7.8 OPTN Code of Conduct, and 7.9: Public Statements by Committee Members and OPTN Volunteers	Management and Membership Policy 4: Code of Conduct
Article XI: Adoption of Policies	Management and Membership Policy 5: Adoption of Policies
Article I: Membership	Management and Membership Policy 6: Membership
Appendix A: Membership Application and Review	Management and Membership Policies: Appendix A: Membership Application and Review
Appendix B: Membership Requirements for Organ Procurement Organizations (OPOs)	Management and Membership Policies: Appendix B: Membership Requirements for Organ Procurement Organizations (OPOs)
Appendix C: Membership Requirements for Histocompatibility Laboratories	Management and Membership Policies: Appendix C: Membership Requirements for Histocompatibility Laboratories
Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs	Management and Membership Policies: Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs

¹³ Feedback was received during public comment that the overlapping reference of “policies” within the Management and Membership Policies to existing policies in OPTN policies could be confusing. The Executive Committee proposed changing the Management and Membership Policies references to letters instead of numbers. This nonsubstantive change will be applied upon approval of the overall proposal.

Original Bylaw Section	Location of Material in New Governance Documents
Appendix E: Membership and Personnel Requirements for Kidney Transplant Programs	Management and Membership Policies: Appendix E: Membership and Personnel Requirements for Kidney Transplant Programs
Appendix F: Membership and Personnel Requirements for Liver Transplant Programs and Intestine Transplant Programs	Management and Membership Policies: Appendix F: Membership and Personnel Requirements for Liver Transplant Programs and Intestine Transplant Programs
Appendix G: Membership and Personnel Requirements for Pancreas and Pancreatic Islet Transplant Programs	Management and Membership Policies: Appendix G: Membership and Personnel Requirements for Pancreas and Pancreatic Islet Transplant Programs
Appendix H: Membership and Personnel Requirements for Heart Transplant Programs	Management and Membership Policies: Appendix H: Membership and Personnel Requirements for Heart Transplant Programs
Appendix I: Membership and Personnel Requirements for Lung Transplant Programs	Management and Membership Policies: Appendix I: Membership and Personnel Requirements for Lung Transplant Programs
Appendix J: Membership and Personnel Requirements for Vascularized Composite Allograft (VCA) Transplant Programs	Management and Membership Policies: Appendix J: Membership and Personnel Requirements for Vascularized Composite Allograft (VCA) Transplant Programs
Appendix K: Transplant Program Inactivity, Withdrawal, and Termination	Management and Membership Policies: Appendix K: Transplant Program Inactivity, Withdrawal, and Termination
Appendix L: Reviews and Actions	Management and Membership Policies: Appendix L: Reviews and Actions
Appendix M: Definitions	Management and Membership Policies: Appendix M: Definitions