

OPTN/UNOS Policy Notice

Appendix L Revisions

Sponsoring Committee:	Membership and Professional Standards
Bylaws Affected:	OPTN Bylaws Article 1.1 (Membership Guidelines) and 1.2.E (Removal of Transplant Hospital Members), and Appendices A.1 (General Membership Requirements), A.2 (Designated Transplant Program Requirement), A.3 (Applying for Membership in the OPTN), B.1 (OPO Compliance), B.2 (OPO Performance Requirements), B.4 (Facilities and Services), B.5 (OPO Personnel), C.1 (Histocompatibility Laboratory Compliance), C.5 (Changes in Key Laboratory Personnel), C.6 (Histocompatibility Laboratory Policies and Procedures), D.1 (Transplant Hospital Compliance), D.2 (Geographic Requirements for Transplant Hospitals), D.8 (Changes in Key Transplant Program Personnel), D.10 (Investigation of Transplant Personnel), D.11 (Review of Transplant Program Functional Activity), D.12 (Additional Transplant Program Requirements), G.2 (Primary Pancreas Transplant Surgeon Requirements), G.3 (Primary Pancreas Transplant Physician Requirements), I.2 (Primary Lung Transplant Surgeon Requirements), I.3 (Primary Lung Transplant Physician Requirements), L (Reviews, Actions, and Due Process), and M (Definitions)
Public Comment:	January 22, 2018 – March 23, 2018
Board Approval Date:	June 12, 2018
Effective Date:	June 12, 2018

Problem Statement

Appendix L of the OPTN Bylaws details actions that the OPTN, through the Membership and Professional Standards Committee (MPSC) and Board of Directors, may take when OPTN members fail to meet membership requirements. *Appendix L* also outlines members' rights when the MPSC or Board of Directors is considering taking certain actions. The current OPTN *Bylaws Appendix L (Reviews, Actions, and Due Process)* requires the MPSC to engage with members through predetermined steps and timelines. As a result, the MPSC and members are sometimes required to interact in ways that do not provide significant value. Additionally, the current Bylaws include conflicting requirements, lack consistent and sufficient detail, and are organized confusingly.

Summary of Changes

The Board of Directors approved an overhaul of OPTN *Bylaws Appendix L*, and other associated changes throughout the *Bylaws* for alignment with the new language in *Appendix L*. These changes improve the OPTN review process and describe it in a way that is more detailed and easier for members to understand. The new language in *Appendix L* does retain some of the previous language, but organizes it differently (for example, language related to the involvement of the U.S. Secretary of Health and Human Services (HHS) and the “Costs and Expenses” section).

What Members Need to Do

No specific actions are required of members in response to these changes. The changes address how members who are noncompliant with OPTN Obligations are reviewed. Members are currently responsible for complying with OPTN Obligations and responding to MPSC requests, and these changes do not change these expectations.

Affected Policy Language

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

Article I: Membership

1.1 Membership Requirements Guidelines

E. Member Compliance

By accepting membership in the OPTN, each member agrees to comply with all OPTN Obligations, which include ~~all of the following applicable provisions of the:~~

- ~~1. All Applicable provisions of the:~~
 - ~~a. National Organ Transplant Act, as amended, 42 U.S.C. 273 *et seq.*~~
 - ~~b. OPTN Final Rule, 42 CFR Part 121~~
 - ~~c. OPTN Bylaws~~
 - ~~d. OPTN Policies~~
- ~~2. Acting to avoid risks to patient health or public safety~~
- ~~3. Fulfilling all requests for information~~

F. Member Reviews and Evaluations

The OPTN will conduct ongoing periodic reviews and evaluations of each transplant hospital, histocompatibility, and OPO member for compliance with OPTN Obligations, ~~the OPTN Final Rule, OPTN Bylaws and OPTN Policies~~. All OPTN members are monitored for compliance with ~~the OPTN Final Rule, OPTN Bylaws and OPTN Policies~~. All compliance monitoring is performed using guidelines developed by the OPTN Contractor. ~~Any member who no longer qualifies as an OPTN member according to the requirements of these Bylaws will be dealt with according to Appendix L: Reviews, Actions and Due Process of these Bylaws.~~

G. Reporting Potential Noncompliance with OPTN Obligations

Any member who becomes aware of a potential noncompliance of OPTN Obligations must inform the OPTN as soon as the member becomes aware of the issue, including potential noncompliance by the member itself.

All incidences of potential noncompliance are referred for further review as outlined in these Bylaws. Any member who fails to comply with OPTN Obligations may be subject to actions as set forth in these Bylaws.

~~At the request of the Secretary of HHS, the OPTN will conduct special reviews of members when the Secretary has reason to believe that the member may be acting in a way that poses a risk to patient health or public safety.~~

FH. Affiliated Organizations

The OPTN Bylaws do not in any way require an OPTN member to:

1. Become a member of any organization that is a parent, sponsor, contractor, or affiliated organization of the OPTN.
2. Comply with bylaws of any parent, sponsor, contractor, or affiliated organization of the OPTN.
3. Assume any corporate duties or obligations of any parent, sponsor, contractor, or affiliated organization of the OPTN.

GI. Removal of Members

Transplant hospital members who no longer qualify as an OPTN member will be ~~treated~~ reviewed according to Appendix L: Reviews and Actions. ~~Appendix L: Reviews, Actions, and Due Process of these Bylaws.~~

All other OPTN members who no longer qualify for OPTN membership may be removed as members through any of the following procedures:

- The member itself may request to voluntarily withdraw from OPTN membership by forwarding a written request to the Executive Director.
- The OPTN may notify the member in writing that, unless the member demonstrates within ~~sixty (60)~~ days of notification that it continues to meet applicable membership criteria, the member's OPTN membership will be terminated, even if the member does not request removal.

If, within ~~sixty (60)~~ days of notification, the member demonstrates, to the satisfaction of the OPTN, that the member meets OPTN membership requirements, the OPTN will withdraw its notice of termination.

If the member fails to demonstrate that it continues to meet OPTN membership requirements, its membership in the OPTN will terminate on the 60th day after notification of termination by the OPTN. The member can appeal this decision to the Secretary of the U.S. Department of Health and Human Services (HHS). In the event a member exercises this right of appeal, the member will notify the OPTN Contractor of this by any method that can be tracked and provides proof of receipt, such as:

- Commercial overnight delivery service
- Secure electronic communication
- Registered or certified mail, return receipt requested

Pending a decision on the appeal, the removal process will continue unless the Secretary of HHS directs otherwise. If the appeal is denied, the process will be continued or reinitiated, as applicable. Any other decision by the Secretary of HHS will be submitted to the Membership and Professional Standards Committee (MPSC) or Board of Directors to act on the Secretary's decision.

Any member removed from OPTN membership for any reason may later reapply for membership.

The Board of Directors will periodically review these requirements and update these Bylaws with additional membership requirements for members. Failure to fulfill such requirements will be cause for any corrective action described in Appendix L: Reviews and Actions. ~~Appendix L: Reviews, Actions, and Due Process of these Bylaws.~~

1.2 Transplant Hospital Members

A transplant hospital member is any hospital that currently performs organ transplants and has current approval as a designated transplant program for at least one organ.

E. Removal of Transplant Hospital Members

Transplant hospital members who no longer meet the qualifications as an OPTN member will be ~~treated~~ reviewed according to Appendix L: Reviews and Actions. ~~Appendix L: Reviews, Actions, and Due Process of these Bylaws.~~

Appendix A: Membership Application and Review

This appendix outlines the application process for membership in the OPTN. It includes information about completing the membership application, the application review process, and application approval for transplant hospital, organ procurement organization (OPO), histocompatibility laboratory, individual, Medical/Scientific, public organization, and business members.

A.1 General Membership Requirements

~~To become a member and maintain membership status in the OPTN, organizations and individuals must do all of the following:~~

- ~~1. Complete the OPTN membership application process.~~
- ~~2. Consistently meet all OPTN obligations established by the OPTN Board of Directors.~~
- ~~3. Comply with the OPTN Charter, Bylaws, and Policies.~~

For more information on membership types, terms, voting privileges, and responsibilities, see *Article I: Membership* of these Bylaws.

A.2 Designated Transplant Program Requirement

~~Every transplant hospital member must have current approval as a designated transplant program for at least one organ. A transplant hospital can receive approval as a designated transplant program for one or more organs through the application process described in this Appendix A. Transplant hospitals must complete separate applications for each organ-specific designated transplant program at the hospital.~~

A.13 Applying for Membership in the OPTN

The Membership and Professional Standards Committee (MPSC) reviews each application for membership ~~under confidential medical peer review~~ and makes recommendations ~~for approval or rejection of the application~~ to the Board of Directors.

The Board of Directors makes all final decisions regarding membership and designated transplant program applications.

Every transplant hospital member must have current approval as a designated transplant program for at least one organ. Any hospital applying for transplant hospital membership must also submit the required application for approval as a designated transplant program for at least one organ.

Applications for OPTN Membership and designated transplant program approval must be submitted on the form provided by the OPTN Contractor, and signed by a representative of the applicant who can certify that the information, including any supporting documents, is accurate.

A. Conditions for Application

By submitting a signed application for membership in the OPTN, each applicant and member agrees to *all* of the following:

1. That any and all information collected as part of the application may be released to the Department of Health and Human Services (HHS). Members also agree that any and all information provided as part of the monitoring and enforcement of OPTN membership requirements, policies and Federal regulations may be released to HHS.
2. If an adverse ruling is made regarding membership or designated transplant program approval, the member will exhaust the administrative remedies provided in these Bylaws and applicable Federal regulations before resorting to formal legal action.
3. That the applicant has received and read the current OPTN Charter, Bylaws, and Policies and agrees to be bound by the terms of these documents during the application process and if granted membership.
4. That transplant hospital, OPO, and histocompatibility laboratory members will provide evidence of current liability insurance of at least one million dollars from an insurer that is either licensed or approved by the insurance regulatory agency of the state where the applicant's principal office is located. A current certificate of insurance must be available and provided to the OPTN Contractor on request. In place of liability insurance, the member can provide proof of coverage through a self-insurance fund, and must provide documentation that the fund provides equivalent coverage.
5. To accept the conditions of the Statement of Release and Immunity from Liability as written below.

Statement of Release and Immunity from Liability

As used in this section, the following definitions apply:

1. *OPTN Contractor and its representatives* means the corporation currently operating the OPTN under contract with HHS, its officers, its Board of Directors, its appointed representatives or employees, consultants, the Contractor's attorneys, assistants or designees, and all members, organizations or other persons who have any responsibility for obtaining or evaluating applicant or member qualifications or acting upon the application for membership or

designated transplant program status. This includes any authorized representative of any of the entities or persons noted in this paragraph.

2. *A third party means* all individuals or government agencies, organizations, associations, partnerships and corporations, from whom information has been requested by the OPTN Contractor or its authorized representatives. This includes anyone who requests or receives information from the OPTN and its authorized representatives.

The following are conditions that apply to any applicant or OPTN member. An applicant accepts the following conditions throughout the application process, whether or not the applicant is granted membership or approval as a designated transplant program:

- a. To the fullest extent permitted by law, the applicant or member gives absolute immunity to, and releases the OPTN Contractor, its representatives, and any third party from any and all liability resulting from any acts, communications, reports, recommendations, or disclosures involving an applicant or member. This includes disclosures to, from, or by any third party, including other members, concerning activities within the scope of the OPTN Contract including but not limited to:
 - i. Applications for membership or designation as a transplant program;
 - ii. Proceedings regarding monitoring and enforcement of membership requirements, change in membership or designated transplant program status, termination of membership, or other policies of or regulations concerning the OPTN
 - ~~iii. Hearings and appellate reviews~~
 - iv. Other committee activities relating to the membership status or designated transplant program status of an applicant or member. This includes statements, investigations, materials provided, or inquiries, oral or written, relating to an applicant's or member's qualifications, as well as the review of all relevant records and documents
- b. Any act, communication, report, recommendation or disclosure, with respect to any applicant or member made in good faith and at the request of the OPTN Contractor and its representatives, anywhere and at any time, for the purposes described in (a) above are privileged to the fullest extent permitted by law as part of the OPTN medical peer review. The medical peer review privilege extends to any third parties who either supply or are supplied information and are authorized to receive, release or act upon the same.
- c. The immunity and release from liability provided in this section shall not apply to acts of willful misconduct by the OPTN Contractor and its representatives.

B. Initial Review of the Membership Application

To initiate the review of any new membership application, the applicant must deliver a completed application, including all requested supporting documentation to the Chair of the MPSC, the Executive Director, or their designated representative. The MPSC will not accept applications for review that are incomplete or missing supporting documentation.

Designated staff of the OPTN Contractor will conduct a preliminary review of all submitted applications to ensure that they are complete. This initial review will occur for all application types.

New membership applications that are not completed correctly or are missing information will be considered incomplete. The OPTN Contractor will not forward incomplete applications to the MPSC for review. The MPSC Chair, the Executive Director, or their designated representative will notify the applicant if an application is incomplete and provide guidelines for correctly completing the application. It is ultimately the applicant's responsibility to obtain and submit the missing information necessary for the application to be reviewed.

C. MPSC Review of the Completed Membership Application

The Board of Directors makes all final decisions regarding membership and transplant program applications. Before being considered by the Board, the MPSC reviews all applications and submits a written report with recommendations regarding the application to the Board of Directors. The MPSC Chair, or a chosen representative, may appoint an MPSC subcommittee of at least four MPSC members to review the completed application and supporting documentation. The MPSC subcommittee may make recommendations regarding applications for membership or approval as a designated transplant program. The MPSC subcommittee's recommendations are advisory to the MPSC and the Board of Directors.

MPSC Subcommittee Review and Recommendation

A unanimous decision of approval by the MPSC subcommittee reviewing the application will result in interim approval of the application. Interim approval means that the member may function as an OPTN member while awaiting review by the entire MPSC and the Board of Directors. A member granted interim approval does not have voting privileges on OPTN matters.

If any member of the MPSC subcommittee recommends rejection of the application, the applicant will not receive interim approval, and the application will be reviewed by the entire MPSC at its next meeting.

MPSC Review and Recommendation

All applications reviewed by the MPSC subcommittee are sent to the entire MPSC for review at its next meeting. Based on the review at this meeting, the Chair will submit a written report with recommendations regarding the application to the Board of Directors. This report includes:

1. The reason for each recommendation, supported by citations to the completed application and any other documentation considered by the MPSC.
2. All dissenting or minority views that differ from the final recommendation, also supported by citations to the completed application and any other documentation considered by the MPSC.

Interim MPSC Approval of the Membership Application

An application approved by the entire MPSC receives interim approval until final review by the Board of Directors. This approval is in effect until a final determination is made by the Board of Directors.

Interim approval will:

1. Grant the applicant OPTN membership or designated transplant program approval, as applicable.
2. Expire when and if the full Board rejects the interim action.

Interim MPSC Rejection of the Membership Application

The MPSC must offer the applicant an interview if the MPSC recommends that the Board of Directors rejects a membership application. The applicant may also be entitled to a hearing with the MPSC and an appearance before the Board of Directors prior to the Board of Directors taking a final action on any MPSC recommendation. Any interviews, hearings, or Board of Directors appearances that occur as part of the membership application process will be held according to *Appendix L: Reviews and Actions*.

~~Any applicant rejected for membership by the MPSC may request due process. For more information about the due process options available after a membership rejection, see *Appendix L: Reviews, Actions, and Due Process* of these Bylaws. If it is going to do so, the applicant must exercise its due process rights before the adverse recommendation is submitted to the Board of Directors by the MPSC.~~

D. Final Board of Director's Review of the Membership Application

When the MPSC recommends that an application be approved, the MPSC Chair will forward the MPSC's report and recommendation to the Board of Directors.

The Board of Directors will review the application and act on it during its next regular meeting if the following conditions are met:

1. The Board of Directors receives the recommendation from the MPSC at least 10 business days before the meeting.
2. A quorum is present at the meeting.

Any application not received at least 10 business days before the meeting will not be considered until the next regular Board meeting at which a quorum is present. If the MPSC gave the application interim approval, a decision to defer the matter will continue the interim approval until the next regular meeting of the Board of Directors where a quorum is present.

A majority vote of the Directors present at any meeting at which a quorum is present is required to approve a new member.

~~A recommendation for rejection by the Board of Directors entitles the applicant to due process as specified in *Appendix L: Reviews, Actions, and Due Process* of these Bylaws. The applicant may also make a written appeal to the Secretary within 30 days of the final rejection of the application by the Board of Directors.~~

E. Appeals to the Secretary

Applicants rejected for membership in the OPTN or for designation as a transplant program may appeal to the Secretary. Appeals shall be submitted in writing within 30 days of rejection of the application. The Secretary may deny the appeal or direct the OPTN to take action consistent with the Secretary's response to the appeal.

Appendix B: Membership Requirements for Organ Procurement Organizations (OPOs)

An OPO member is any OPO that has been designated by the Secretary of the U.S. Department of Health and Human Services (HHS) under *Section 1138(b)* of the Social Security Act or any organization that meets all requirements under *Section 1138(b)*, except for OPTN membership.

Only independent OPOs (IOPO) have voting privileges in the OPTN. An IOPO is defined as one that has a distinct governing body separate from any transplant hospital or commonly controlled group of transplant hospitals it serves.

A hospital-based OPO is not independent from the transplant hospital it serves. Hospital-based OPOs are held to the same standards and requirements as OPO members, but do not have a vote on OPTN business separate from the vote granted the transplant hospital member that controls it.

For more information on membership types, terms, voting privileges, and responsibilities, see *Article I: Membership* of these Bylaws.

B.1 OPO Compliance

By accepting membership in the OPTN, OPOs agree to comply with all OPTN Obligations according to Article 1.1.E: Member Compliance. ~~applicable provisions of the:~~

- ~~1. National Organ Transplant Act, as amended, 42 U.S.C. 273 et seq.~~
- ~~2. OPTN Final Rule, 42 CFR Part 121~~
- ~~3. OPTN Bylaws~~
4. OPTN Policies

~~The OPTN will conduct ongoing periodic reviews and on-site evaluations of each OPO for compliance with the OPTN Final Rule, OPTN Bylaws and OPTN Policies. OPOs must also fulfill all requests for information from the OPTN Contractor as required to determine compliance. All compliance monitoring is performed using procedures developed by the OPTN Contractor. Any OPO that no longer qualifies as an OPTN member according to the requirements of these Bylaws will be dealt with according to Appendix L: Reviews, Actions, and Due Process of these Bylaws.~~

If any regulatory agency takes a final adverse action against an OPO, the OPO must notify the OPTN Contractor in writing within 10 business days. The OPO must also provide all documents relating to the final adverse action to the OPTN Contractor.

B.2 OPO Performance Requirements

The Membership and Professional Standards Committee (MPSC) will evaluate all OPOs to determine if the difference in observed and expected organ yield can be accounted for by some unique aspect of the Donation Service Area or OPO in question. ~~The evaluation may include a peer visit to the OPO at the OPO's expense.~~

Those OPOs whose observed organ yield rates fall below the expected rates by more than a specified threshold will be reviewed. The absolute values of relevant parameters in the formula may be different for different organs, and may be reviewed and modified by the MPSC after distribution to the transplant community and subsequent Board approval.

The initial criteria used to identify OPOs with lower than expected organ yield, for all organs as well as for each organ type, will include *all* of the following:

1. More than 10 fewer observed organs per 100 donors than expected yield (Observed per 100 donors - Expected per 100 donors < -10).

2. A ratio of observed to expected yield less than 0.90.
3. A two-sided p-value is less than 0.05.

All three criteria must be met for an OPO to be identified for MPSC review.

If an OPO's organ yield rate cannot be explained by donor mix or some other unique clinical aspect of the OPO or Donation Service Area in question, the member, in cooperation with the MPSC, will adopt and promptly implement a plan for performance improvement. The member's failure to adopt and promptly implement a plan for quality improvement will be considered a noncompliance with OPTN Obligations and may result in an OPTN action according to Appendix L: Reviews and Actions. ~~The member's failure to do so will constitute a violation of OPTN obligations.~~

As part of this process, the MPSC may conduct a peer visit to the OPO at the member's expense. The MPSC may also require, at its discretion, that the member participate in an informal discussion. The informal discussion will be conducted according to Appendix L: Reviews and Actions.

B.4 Facilities and Services

OPOs must have extensive facilities to be fully operational. OPOs must also provide a number of services as part of their daily operations. These required facilities and services are described in the sections that follow.

E. Organ Allocation Plans

Each OPO is responsible for equitable and efficient organ allocation within their DSAs that adheres to OPTN obligations. To meet this requirement, each OPO must have the necessary procedures and technology to communicate information to distribute organs to transplant candidates at transplant hospitals within and beyond its service area.

Each OPO must have a plan to equitably allocate donated organs among transplant patients that is consistent with the obligations of the OPTN. An OPO must demonstrate ~~is-it~~ has policies and procedures that meet or exceed OPTN obligations. An OPO's failure to comply with these requirements will be considered a noncompliance with OPTN Obligations that may result in an OPTN action according to Appendix L: Reviews and Actions. ~~Failure to comply with these requirements could result in corrective action as described in Appendix L: Reviews, Actions, and Due Process of these Bylaws, if applicable, or result in a recommendation to the Board of Directors to notify the Secretary of HHS.~~

B.5 OPO Personnel

Each OPO must have personnel who are qualified to effectively recover organs from all donors in its DSA. Each OPO must have the necessary staff to recover and distribute organs according to OPTN obligations, including an administrative director, a medical director, an organ donation coordinator, and an organ procurement specialist.

E. Failure to Report Changes in Key OPO Personnel

An OPO's failure to notify the OPTN Contractor of a change in the administrative or medical director will be considered a noncompliance with OPTN Obligations that may result in an OPTN action according to Appendix L: Reviews and Actions.

~~Failure to inform the OPTN Contractor of changes in the administrative director or medical director may result in corrective action as described in Appendix L: Reviews, Actions, and Due Process of these Bylaws, including adverse actions as defined in L.15. OPTN Determinations and Actions.~~

The OPO must notify the MPSC if it has not filled a vacant administrative or medical director position within six months. The MPSC could then recommend that the OPTN Board of Directors notify the Secretary of HHS of the OPO's failure to fill the position.

Appendix C: Membership Requirements for Histocompatibility Laboratories

C.1 Histocompatibility Laboratory Compliance

Each histocompatibility laboratory member must comply with all OPTN Obligations according to Article 1.1.E: Member Compliance and both all of the following:

- ~~1. All application provisions of the National Organ Transplant Act, as amended, 42 U.S.C. 273 et seq.~~
- ~~2. All application provisions of the OPTN Final Rule, 42 CFR Part 121~~
- ~~3. The OPTN Charter~~
- ~~4. All OPTN Bylaws and Policies~~
5.
 1. The requirements in the Clinical Laboratory Improvement Amendments (CLIA) at 42 CFR § 493.1278, unless exempt
 2. The requirements, as they apply to solid organ and islet transplantation, of the American Society for Histocompatibility and Immunogenetics (ASHI) 2013 Revised Standards for Accredited Laboratories, or the College of American Pathologists (CAP) Histocompatibility Checklist, Laboratory General Checklist, Flow Cytometry Checklist, and Team Leader Assessment of Director and Quality Checklist as of April 21, 2014. This requirement does not mandate membership in either ASHI or CAP.

If any regulatory agency takes a final adverse action against a histocompatibility laboratory, the laboratory must notify the OPTN Contractor in writing within 10 business days. The histocompatibility laboratory must also provide all documents relating to the final adverse action to the OPTN Contractor.

C.5 Changes in Key Laboratory Personnel

B. Failure to Notify the OPTN Contractor of Key Personnel Changes

A histocompatibility laboratory's failure to inform the OPTN Contractor of a change in the laboratory director, technical supervisor, general supervisor, or clinical consultant or to submit the required Personnel Change Application within the periods specified will be considered a noncompliance with OPTN Obligations that may result in an OPTN action according to Appendix L: Reviews and Actions.

~~Any histocompatibility laboratory that fails to inform the OPTN Contractor of a change in the laboratory director, technical supervisor, general supervisor, or clinical consultant or to submit the required Personnel Change Application within the periods specified above will be reviewed by the MPSC. The MPSC may impose a sanction, including, but not limited to, any of the following:~~

- ~~1. Notice of Uncontested Violation~~
- ~~2. Letter of Warning~~
- ~~3. Letter of Reprimand~~

~~Failure to inform the OPTN Contractor of changes in key personnel or to submit the required Personnel Change Application will result in a recommendation that the Board of Directors take~~

~~appropriate adverse actions. Additionally, the Board of Directors may notify the Secretary of Health and Human Services (HHS) of the violation.~~

C. Rejected Key Personnel Change Applications

~~The MPSC must offer the applicant an interview if the MPSC rejects a Key Personnel Change application. The applicant may also be entitled to a hearing with the MPSC and an appearance before the Board of Directors. Any interviews, hearings, or Board of Directors appearances that occur as part of the Key Personnel Change application process will be conducted according to Appendix L: Reviews and Actions.~~

C.6 Histocompatibility Laboratory Policies and Procedures

C. Periodic Reviews

~~In order to determine compliance with the requirements and regulations according to C.1. Histocompatibility Laboratory Compliance, histocompatibility laboratory members will be reviewed, including on-site reviews, and must fulfill any requests for information from the OPTN Contractor. Failure to comply with these rules and requirements will be cause for corrective action as described in Appendix L: Reviews, Actions, and Due Process of these Bylaws.~~

D. Regulatory Agency Adverse Actions

~~If any regulatory agency takes a final adverse action against a histocompatibility laboratory, the laboratory must notify the OPTN Contractor within 10 business days. The histocompatibility laboratory must also provide any documents relating to the final adverse action to the OPTN Contractor, along with the final determination of the regulatory agency.~~

C.E. Inactive Status

A histocompatibility laboratory that is voluntarily inactive, declared inactive or withdraws from membership will be ineligible and may not provide histocompatibility testing to any OPTN members.

Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs

D.1 Transplant Hospital Compliance

By accepting membership in the OPTN, transplant hospitals agree to comply with all OPTN Obligations according to Article 1.1.E: Member Compliance.

If any regulatory agency takes a final adverse action against a transplant hospital, the transplant hospital must notify the OPTN Contractor in writing within 10 business days. The transplant hospital must also provide all documents relating to the final adverse action to the OPTN Contractor.

Transplant hospital members agree to:

- ~~1. Review and abide by the OPTN Final Rule, Bylaws, Policies and applicable provisions of the National Organ Transplant Act, as amended, 42 U.S.C. 273 *et seq.*~~
- ~~2. Comply with all obligations of OPTN membership.~~
- ~~3. Submit to reviews and on-site evaluations to monitor compliance with membership requirements.~~
- ~~4. Fulfill all requests for information.~~

- ~~5. Notify the OPTN Contractor within 10 business days if any regulatory agency takes a final adverse action against the transplant hospital and then provide any documents relating to the final adverse action to the OPTN Contractor.~~

~~For more information, see *Article I: Membership of these Bylaws.*~~

D.2 Geographic Requirements for Transplant Hospitals

A transplant hospital must be entirely within a single donation service area (DSA) and all of its operating room facilities used for organ transplantation must be under common executive leadership and governance oversight, demonstrated to the satisfaction of the OPTN.

All transplant hospital operating rooms where transplants are performed must also meet at least *one* of these requirements:

- Are within a geographically contiguous campus
 - Are within a one mile walking distance from the main hospital's physical address
- Each operating room that the transplant hospital may use to perform transplants must be documented with the OPTN prior to its use for transplant surgery. This operating room documentation requirement includes any additional transplant operating rooms that are not listed on the transplant hospital's initial application. Documentation of the operating rooms where organ transplants may occur must at least include *all* of the following:

1. Maps that illustrate the transplant hospital campus and the location of each operating room facility
2. Building name and address
3. Floor number
4. Unit identifier

~~Transplant hospitals that do not meet these requirements will not be approved as a single transplant hospital and will require separate OPTN memberships, unless the transplant hospital is approved according to *D.2.A: Approval of Transplant Hospitals with Operating Rooms Beyond the Established Geographic Boundaries.* Any application recommended for rejection by the MPSC or the Board of Directors entitles the applicant to due process as specified in *Appendix L: Reviews, Actions, and Due Process of these Bylaws.*~~

C. Review of Pediatric Transplant Activity at Transplant Hospitals that Share a Campus

Transplant hospitals that primarily serve pediatric patients, and that share a campus with another transplant hospital, will be reviewed periodically by the MPSC to verify that it performed 50 percent or more of its transplants in patients less than 18 years of age during the previous 12 months. Any transplant hospital that is identified as not meeting this 50 percent threshold in any 12 month period will have the opportunity to explain its pediatric inactivity in a report to the MPSC.

~~As part of its review of pediatric transplantation activity at transplant hospitals that share a campus, the MPSC may require that the member participate in an informal discussion. The informal discussion will be conducted according *Appendix L: Reviews and Actions.* The informal discussion may be with the MPSC, a subcommittee, or a work group, as determined by the MPSC. The informal discussion will be conducted according to the principles of confidential medical peer review, as described in *Appendix L: Reviews, Actions, and Due Process of these Bylaws.* The discussion is not an adverse action or an element of due process. A member who participates in an informal discussion with the MPSC is entitled to receive a summary of the discussion.~~

The MPSC may recommend that a transplant hospital sharing a campus with another transplant

hospital inactivate due to one hospital no longer primarily serving pediatric patients. A member's failure to inactivate when the MPSC recommends it do so will be considered a noncompliance with OPTN Obligations that may result in an OPTN action according to Appendix L: Reviews and Actions. ~~If the hospital fails to inactivate when the MPSC recommends it do so, the MPSC may recommend that the Board of Directors take appropriate action as defined in Appendix L: Reviews, Actions, and Due Process of these Bylaws.~~

D.8 Changes in Key Transplant Program Personnel

E. Failure to Notify the OPTN Contractor of Key Personnel Changes

A member's failure to notify the OPTN of a primary surgeon or physician change or to submit the required Personnel Change Application within the periods specified will be considered a noncompliance with OPTN Obligations that may result in an OPTN action according to Appendix L: Reviews and Actions.

~~Any member who fails to inform the OPTN Contractor of a change in the primary surgeon or primary physician or to submit the required Personnel Change Application within the periods specified above will be reviewed by the MPSC. The MPSC may impose a sanction, including any of the following:~~

- ~~■ A Notice of Uncontested Violation~~
- ~~■ Letter of Warning~~
- ~~■ Letter of Reprimand~~

~~Each of these sanctions and other adverse actions that may be taken by the MPSC are further described in Appendix L: Reviews, Actions, and Due Process of these Bylaws.~~

~~Failure to inform the OPTN Contractor of changes in primary surgeon or primary physician or to submit the required Personnel Change Application will result in a recommendation that the Board of Directors take appropriate adverse actions. Additionally, the Board of Directors may notify the Secretary of Health and Human Services (HHS) of the violation.~~

F. Processing Applications for Changes to Key Personnel

When processing applications to change key personnel, the MPSC Chair is authorized to appoint an Ad hoc Subcommittee of at least two Committee members, other than the MPSC chair. This Ad hoc Subcommittee will review the credentials of the proposed new key personnel.

The Subcommittee may grant, with agreement of the MPSC Chair, interim approval effective until review by the entire MPSC at its next meeting. Interim approval will not extend beyond the next meeting of the entire MPSC and will automatically expire if the entire MPSC does not approve the interim approval.

Designated transplant programs must have qualified key personnel for the program at all times, including during the entire application process for changes in key personnel, regardless of the status of the application.

The MPSC must offer the member an interview if the MPSC rejects a Key Personnel Change application. The member may also be entitled to a hearing with the MPSC and an appearance before the Board of Directors. Any interviews, hearings, or Board of Directors appearances that occur as part of the Key Personnel Change application process will be conducted according to Appendix L: Reviews and Actions.

D.10 Investigation of Transplant Personnel

The transplant hospital must investigate any personnel on staff at a designated transplant program if directed to do so by the MPSC. The MPSC will request an investigation to examine an individual's role in a matter reviewed or currently under review by the MPSC, and explain the reason for the investigation request to the transplant hospital. The transplant hospital must inform the MPSC when it has started the investigation and when it completes the investigation. The transplant hospital must also provide documentation that it conducted the investigation according to the requirements of these Bylaws.

The hospital's investigation must use the hospital's standard medical peer review process for conducting inquiries of potential professional misconduct and conclude with appropriate action consistent with this process.

A member's failure to investigate designated transplant program staff as directed will be considered a noncompliance with OPTN Obligations that may result in an OPTN action according to Appendix L: Reviews and Actions.

~~Failure to comply with these requirements will result in a recommendation to the Board of Directors to notify the Secretary, or a recommendation to take appropriate action according to Appendix L: Reviews, Actions, and Due Process these Bylaws.~~

D.11 Review of Transplant Program Functional Activity

A. Functional Inactivity

~~Each transplant program must remain functionally active by performing a minimum number of transplants. Transplant program functional activity will be reviewed periodically by the MPSC. Any program identified as functionally inactive will have the opportunity to explain its inactivity in a report to the MPSC. For purposes of these Bylaws, functional inactivity is defined as the failure to perform a transplant during the periods defined in the table below: according to Table D-1 below.~~

Table D-1: Functional Inactivity Periods

Program Type	Inactive Period
<i>Kidney, Liver or Heart</i>	<i>3 consecutive months</i>
<i>Pancreas or Lung</i>	<i>6 consecutive months</i>
<i>Stand-alone pediatric transplant programs</i>	<i>12 consecutive months</i>

Functional inactivity thresholds have not been established for pancreatic islet, intestinal, and VCA transplant programs.

C. Review of Member Functional Inactivity

Transplant program functional inactivity will be reviewed periodically by the MPSC. Any program identified as functionally inactive will have the opportunity to explain its inactivity in a report to the MPSC.

As part of its review of a program's functional inactivity, the MPSC may require, that the member participate in an informal discussion. The informal discussion will be conducted according to Appendix L: Reviews and Actions.

The MPSC may recommend that a program inactivate or withdraw its designated transplant program status due to the program's functional inactivity. The MPSC must offer the member an informal discussion before recommending that the program inactivate or withdraw its designated transplant program status. A program's failure to inactivate or withdraw its designated transplant program status when the MPSC recommends it do so will be considered a noncompliance with

~~OPTN Obligations and may result in an OPTN action according to Appendix L: Reviews and Actions. If the program fails to inactivate or withdraw its designated transplant program status when the MPSC recommends it do so, the MPSC may recommend that the Board of Directors take appropriate action as defined in Appendix L: Reviews, Actions, and Due Process of these Bylaws. Additionally, the Board of Directors may notify the Secretary of HHS of the program's inactivity.~~

D.12 Additional Transplant Program Requirements

A. Transplant Program Performance

Appendix D.12.A does not apply to VCA transplants.

The MPSC will conduct reviews of transplant program performance to identify underperforming transplant programs and require the implementation of quality assessment and performance improvement measures. One measure of transplant program performance is triggered through a review of the one-year graft and patient survival rates. The MPSC utilizes performance metrics produced by the Scientific Registry of Transplant Recipients (SRTR) as the principal tool to identify transplant programs that have lower than expected outcomes.

For programs performing 10 or more transplants in a 2.5 year period, the MPSC will review a transplant program if it has a higher hazard ratio of mortality or graft failure than would be expected for that transplant program. The criteria used to identify programs with a hazard ratio that is higher than expected will include *either* of the following:

1. The probability is greater than 75% that the hazard ratio is greater than 1.2.
2. The probability is greater than 10% that the hazard ratio is greater than 2.5.

For programs performing 9 or fewer transplants in a 2.5 year period, the MPSC will review a transplant program if the program has one or more events in a 2.5 year cohort.

The MPSC review will be to determine if the higher hazard ratio or events can be explained by patient mix or some other unique clinical aspect of the transplant program. If a program's performance cannot be explained by patient mix or some other unique clinical aspect of the transplant program, the program, in cooperation with the MPSC, will adopt and promptly implement a plan for quality improvement. The member's failure to adopt and promptly implement a plan for quality improvement will be considered a noncompliance with OPTN Obligations and may result in an OPTN action according to Appendix L: Reviews and Actions. ~~constitute a violation of OPTN obligations.~~

As part of this process, the MPSC may conduct a peer visit to the program at the member's expense. The MPSC may also require, at its discretion, that the member participate in an informal discussion. The informal discussion will be conducted according to *Appendix L: Reviews and Actions*. ~~The informal discussion may be with the MPSC, a subcommittee, or a work group, as determined by the MPSC. The informal discussion will be conducted according to the principles of confidential medical peer review, as described in *Appendix L* of these Bylaws. The informal discussion is not an adverse action or an element of due process. A member who participates in an informal discussion with the MPSC is entitled to receive a summary of the discussion.~~

The MPSC may recommend that a member inactivate a program, or a component of a program, or withdraw its designated transplant program status based on patient safety concerns arising from review of the program's graft and patient survival. The MPSC must offer the member an informal discussion before recommending that the program inactivate or withdraw its designated transplant program status. ~~A program's failure to inactivate or withdraw its designated transplant program status when the MPSC recommends it do so will be considered a noncompliance with OPTN Obligations and may result in an OPTN action according to *Appendix L: Reviews and*~~

~~Actions. If the program fails to inactivate or withdraw its designated transplant program status when the MPSC recommends it do so, the MPSC may recommend that the Board of Directors take appropriate action as defined in *Appendix L: Reviews, Actions, and Due Process* of these Bylaws.~~

Appendix G: Membership and Personnel Requirements for Pancreas and Pancreatic Islet Transplant Programs

G.2 Primary Pancreas Transplant Surgeon Requirements

C. Alternate Pathway for Predominantly Pediatric Programs

If a surgeon does not meet the requirements for primary pancreas transplant surgeon through either the 2-year transplant fellowship pathway or clinical experience pathway as described above, transplant programs that serve predominantly pediatric patients may petition the MPSC in writing to consider the surgeon for primary transplant surgeon if the program can demonstrate that the following conditions are met:

1. The surgeon's pancreas transplant training or experience is equivalent to the fellowship or clinical experience pathways as described in *Sections G.2.A or G.2.B* above.
2. The surgeon has maintained a current working knowledge of all aspects of pancreas transplantation and patient care, defined as direct involvement in pancreas transplant patient care within the last 2 years.
3. The surgeon submits a letter of recommendation from the training program's primary surgeon and director at the fellowship training program or transplant program last served by the surgeon outlining the surgeon's overall qualifications to act as a primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
4. The hospital participates in an informal discussion with the MPSC.

The MPSC or an Ad Hoc Subcommittee of at least 4 MPSC members appointed by the MPSC Chair is authorized to conduct the informal discussion and make an interim determination. Interim determinations are:

- Advisory to the MPSC, Board of Directors, or both, who have the final authority to grant approval of a designated transplant program.
- Effective temporarily, pending final decision by the MPSC or Board.

The MPSC must offer the member an interview if the MPSC recommends that the Board of Directors rejects a membership application. The member may also be entitled to a hearing with the MPSC and an appearance before the Board of Directors prior to the Board of Directors taking a final action on any MPSC recommendation. Any interviews, hearings, or Board of Directors appearances that occur as a part of a membership application process will be held according to *Appendix L: Reviews and Actions*.

~~Any application recommended for rejection by the MPSC or the Board of Directors may entitle the applicant to due process as specified in *Appendix L: Reviews, Actions, and Due Process* of these Bylaws.~~

G.3 Primary Pancreas Transplant Physician Requirements

C. Alternative Pathway for Predominantly Pediatric Programs

If a physician does not meet the requirements for primary physician through the transplant fellowship or clinical experience pathways as described above, transplant programs that serve predominantly pediatric patients may petition the MPSC in writing to consider the physician for primary transplant physician if the program can demonstrate that the following conditions are met:

1. That the physician's pancreas transplant training or experience is equivalent to the fellowship or clinical experience pathways as described in *Sections G.3.A and G.3.B* above.
2. The physician has maintained a current working knowledge of all aspects of pancreas transplantation, defined as direct involvement in pancreas transplant patient care within the last 2 years.
3. The physician submits a letter of recommendation from the primary physician and transplant program director at the fellowship program or transplant program last served by the physician outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
4. The hospital participates in an informal discussion with the MPSC.

The MPSC or an Ad Hoc Subcommittee of at least 4 MPSC members appointed by the MPSC Chair is authorized to conduct the informal discussion and make an interim determination. Interim decisions are:

- Advisory to the MPSC, Board of Directors, or both, which has the final authority to grant approval of a designated transplant program.
- Effective temporarily, pending final decision by the MPSC or Board.

The MPSC must offer the member an interview if the MPSC recommends that the Board of Directors rejects a membership application. The member may also be entitled to a hearing with the MPSC and an appearance before the Board of Directors prior to the Board of Directors taking a final action on any MPSC recommendation. Any interviews, hearings, or Board of Directors appearances that occur as a part of a membership application process will be held according to *Appendix L: Reviews and Actions*.

~~Any application recommended for rejection by the MPSC or the Board of Directors may entitle the applicant to due process as specified in *Appendix L: Reviews, Actions, and Due Process* of these Bylaws.~~

Appendix I: Membership and Personnel Requirements for Lung Transplant Programs

I.2 Primary Lung Transplant Surgeon Requirements

D. Alternative Pathway for Predominantly Pediatric Programs

If a surgeon does not meet the requirements for primary lung transplant surgeon through either the training or clinical experience pathways described above, hospitals that serve predominantly pediatric patients may petition the MPSC in writing to consider the surgeon for primary transplant

surgeon if the program can demonstrate that the following conditions are met:

1. The surgeon's lung transplant training or experience is equivalent to the residency, fellowship, or clinical experience pathways as described in *Sections 1.2.A through 1.2.C* above.
2. The surgeon has maintained a current working knowledge of all aspects of lung transplantation and patient care, defined as direct involvement in lung transplant patient care within the last 2 years.
3. The surgeon submits a letter of recommendation from the primary surgeon and transplant program director of the fellowship training program or transplant program last served by the surgeon outlining the surgeon's overall qualifications to act as a primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
4. The hospital participates in an informal discussion with the MPSC.

The MPSC or an Ad Hoc Subcommittee of at least 4 MPSC members appointed by the MPSC Chair is authorized to conduct the informal discussion and make an interim determination. Interim determinations are:

- Advisory to the MPSC, Board of Directors, or both, who have the final authority to grant approval of a designated transplant program.
- Effective temporarily, pending final decision by the MPSC or Board.

The MPSC must offer the member an interview if the MPSC recommends that the Board of Directors rejects a membership application. The member may also be entitled to a hearing with the MPSC and an appearance before the Board of Directors prior to the Board of Directors taking a final action on any MPSC recommendation. Any interviews, hearings, or Board of Directors appearances that occur as a part of a membership application process will be held according to *Appendix L: Reviews and Actions*.

~~Any application recommended for rejection by the MPSC or the Board of Directors may entitle the applicant to due process as specified in *Appendix L: Reviews, Actions, and Due Process* of these Bylaws.~~

I.3 Primary Lung Transplant Physician Requirements

C. Alternative Pathway for Predominantly Pediatric Programs

If a physician does not meet the requirements for primary physician through any of the transplant fellowship or clinical experience pathways as described above, hospitals that serve predominantly pediatric patients may petition the MPSC in writing to consider the physician for primary transplant physician if the program can demonstrate that the following conditions are met:

1. That the physician's lung transplant training or experience is equivalent to the fellowship or clinical experience pathways as described in *Sections 1.3.A and 1.3.B* above.
2. The physician has maintained a current working knowledge of all aspects of lung transplantation, defined as direct involvement in lung transplant patient care within the last 2 years.

3. The physician submits a letter of recommendation from the primary physician and transplant program director of the fellowship training program or transplant program last served by the physician outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
4. The hospital participates in an informal discussion with the MPSC.

The MPSC or an Ad Hoc Subcommittee of at least 4 MPSC members appointed by the MPSC Chair is authorized to conduct the informal discussion and make an interim determination. Interim decisions are:

- Advisory to the MPSC, Board of Directors, or both, which has the final authority to grant approval of a designated transplant program.
- Effective temporarily, pending final decision by the MPSC or Board of Directors.

The MPSC must offer the member an interview if the MPSC recommends that the Board of Directors rejects a membership application. The member may also be entitled to a hearing with the MPSC and an appearance before the Board of Directors prior to the Board of Directors taking a final action on any MPSC recommendation. Any interviews, hearings, or Board of Directors appearances that occur as a part of a membership application process will be held according to Appendix L: Reviews and Actions.

~~Any application recommended for rejection by the MPSC or the Board of Directors may entitle the applicant to due process as specified in Appendix L: Reviews, Actions, and Due Process of these Bylaws.~~

~~Appendix L: Reviews, Actions, and Due Process~~

~~L.1. Member Compliance~~

~~Each OPTN member agrees to comply with OPTN Obligations, which include all of the following:~~

- ~~1. National Organ Transplant Act, as amended, 42 U.S.C. 273 et seq.~~
- ~~2. OPTN Final Rule, 42 CFR Part 121~~
- ~~3. OPTN Bylaws~~
- ~~4. OPTN Policies~~

~~At any time, the OPTN Board of Directors or the OPTN Executive Committee may recommend that the Secretary of the U.S. Department of Health and Human Services (HHS) take appropriate action as outlined in the OPTN Final Rule.~~

~~A. Periodic Reviews~~

~~The OPTN will conduct ongoing periodic reviews and evaluations of each transplant hospital, histocompatibility laboratory member, and OPO member for compliance with OPTN Obligations. All compliance monitoring is performed using guidelines developed by the OPTN. Any member who fails to fulfill all the applicable OPTN Obligations may be subject to actions as set forth in these Bylaws.~~

~~B. Failure to Pay OPTN Fees~~

~~The failure of an OPO, transplant hospital, or histocompatibility laboratory member to pay, within 30 days, any OPTN fee, charge, or other monetary obligation to the OPTN Contractor will be considered a violation of OPTN Obligations.~~

~~L.2. Compliance Monitoring~~

~~The OPTN Executive Director monitors compliance of members with OPTN Obligations, and refers all incidences of potential non-compliance for further review as outlined in these Bylaws.~~

~~The Executive Director may delegate these monitoring duties to any number of designees to ensure that the necessary actions are taken to meet the requirements of these Bylaws.~~

~~L.3. Reporting Potential Violations and Non-compliance~~

~~Any member who becomes aware of a potential violation of or non-compliance with OPTN Obligations must inform the OPTN as soon as the member becomes aware of the issue, including potential violations or non-compliance by the member itself.~~

~~L.4. Methods for Correspondence and Providing Notice~~

~~Unless otherwise noted, all correspondence between members and the OPTN required by this *Appendix L* must be sent by a method that can be tracked and that provides proof of receipt, such as:~~

- ~~▪ Commercial overnight delivery service~~
- ~~▪ Secure electronic communication~~
- ~~▪ Registered or certified mail, return receipt requested~~

~~The Executive Director will send notice to members when they are required to respond to an OPTN action or request. When the member receives notice, the member must respond within the specified time, as defined in these Bylaws. Time limits specified for providing notice, including requests for interviews, hearings, and to appear before the OPTN Board of Directors, begin on the date the notice is sent from the Executive Director.~~

~~L.5. Medical Peer Review~~

~~The OPTN will conduct all deliberations and take all actions according to applicable confidential medical peer review laws. As appropriate and consistent with applicable laws, all of the following deliberations and actions of any OPTN Committee, the OPTN Executive Committee, the OPTN Board of Directors, and the OPTN Contractor will be kept confidential during the review of:~~

- ~~1. Potential violations of or non-compliance with OPTN Obligations.~~
- ~~2. Matters relating to potential threats to patient health and public safety.~~
- ~~3. Applications for membership, designated transplant program status, or a change in Key Personnel.~~

~~Members must keep these records, review activity, and documents confidential to promote quality improvement and full disclosure by OPTN members.~~

~~A. Secretary's Access to Information~~

~~The medical peer review privilege will not be extended to withhold any document from the Secretary of HHS, or the Secretary's designee. The OPTN Contractor is required to provide the Secretary with any information acquired or produced under the OPTN Contract, including~~

~~information that would otherwise be protected by the medical peer review privilege. As specified in the OPTN Final Rule, the OPTN Contractor will provide any data or documentation to the Secretary that the Secretary requests, in the format requested by the Secretary.~~

~~**B. Health Resources and Services Administration (HRSA) Representation**~~

~~The Project Officer for the OPTN Contract and the Director of the Division of Transplantation within the Health Resources and Services Administration (HRSA) of HHS, serve as *ex-officio*, non-voting members of the OPTN Executive Committee and Board of Directors. As non-voting members of the Executive Committee and Board, they, or their designees, are granted full access to all deliberations, determinations and actions. Representatives of HRSA are also *ex-officio*, non-voting members of the Membership and Professional Standards Committee (MPSC) and granted full access to all MPSC deliberations, determinations, and actions as well. Other designees of the Secretary may also attend OPTN meetings.~~

~~**L.6. Requests for Root Cause Analysis and Corrective Action**~~

~~The OPTN Board of Directors, the MPSC, or any standing subcommittee of the MPSC or their designee may require a member to take corrective action to address any potential violation or noncompliance. Corrective action can include any of the following:~~

- ~~1. Root cause analysis~~
- ~~2. Corrective action plan~~
- ~~3. Plan for quality improvement~~
- ~~4. On-site monitoring~~
- ~~5. Desk monitoring~~
- ~~6. Self-assessments~~
- ~~7. External expert consultants~~

~~**A. Initiating Corrective Action**~~

~~If it appears that an OPO, transplant hospital, or histocompatibility laboratory member may have failed to meet OPTN Obligations, the MPSC or the Board of Directors may request that the member performs a root cause analysis and then develops and implements a corrective action plan or plan for quality improvement to address any potential violations or non-compliance.~~

~~**B. Fulfilling Requests for Root Cause Analysis and Corrective Action**~~

~~The Executive Director will promptly give notice to the member when requesting any corrective action. The member must also submit any requested documentation to the Executive Director at this time.~~

~~**L.7. Special Secretarial Reviews**~~

~~The Secretary of HHS may request that the OPTN Contractor performs a Special Review under guidance from the Secretary. A Special Review is a review of the member in the manner and within the period specified by the Secretary. This may include, but is not limited to, requests for root cause analysis, corrective action, and due process proceedings completed in the period and as specified by the Secretary, and as defined Sections L.6 and L.9 through L.14 in this Appendix L. Members must fully comply with all OPTN Contractor requests as part of a Special Review.~~

~~The Secretary may impose sanctions or take other appropriate action at any time when a member poses a risk to the health of patients or to the public safety.~~

L.8.— Review Pathways for Potential Violations

The OPTN will review potential violations of and non-compliance with OPTN Obligations by one of three pathways as defined below:

1. An **Imminent Threat Review** will be conducted when the MPSC Chair determines that there is a potential violation of or non-compliance with OPTN Obligations, which may pose an urgent and severe risk to patient health or public safety. The MPSC Chair may choose this pathway when the member is not taking action to mitigate the potential threat, or the Chair believes that the potential threat may not be mitigated through routine procedures.
2. An **Expedited Review** will be conducted when the MPSC Chair determines that a potential violation of or non-compliance with OPTN Obligations may pose a potential risk to patient health or public safety, which is not currently urgent but could become urgent or severe if not addressed using an Expedited Review process. When a matter is reviewed using the Expedited Review pathway, a hearing is offered to the member on an expedited schedule.
3. A **Routine Review** will be conducted for any potential violation of or non-compliance with OPTN Obligations when the MPSC Chair determines that an Expedited Review or an Imminent Threat Review is not warranted.

When investigating any potential violation or non-compliance and determining a review pathway, the OPTN Contractor will take appropriate action as described in Sections L.9 through L.14 that follow.

L.9.— Preliminary Investigation of Potential Violations

When the OPTN learns of a possible failure of a member to comply with any aspect of applicable OPTN Obligations, the Executive Director will conduct a preliminary investigation. This investigation will consider whether the potential violation suggests a risk to patient health or public safety, and the urgency and severity of the risk.

If additional information is required in conducting the preliminary investigation of any potential violation, the member must respond to requests from the OPTN. A member's documented history of violations and non-compliance, or systemic problems and operational failures, could warrant review of the member through the Imminent Threat or Expedited Review pathway.

A.— Referral of Potential Violations to the MPSC Chair

If the preliminary investigation concludes that the potential violation may pose an urgent and severe risk to patient health or public safety, the matter will be referred to the MPSC Chair within 24 hours.

If the preliminary investigation concludes that the risk to patient health or public safety is not an urgent and severe risk, but a substantial risk remains, the matter will be referred to the MPSC Chair within 7 days.

B.— Notice to the Secretary after Preliminary Investigation

If the potential violation is referred to the MPSC Chair with a recommendation to follow the Imminent Threat Review pathway, the Executive Director will provide notice to the Secretary within 24 hours of the referral.

The OPTN will notify the Secretary within 7 days when a preliminary investigation determines that the member has not violated OPTN Obligations but that a risk to patient health or public safety exists.

~~L.10. Determination of Review Pathway~~

~~A. MPSC Chair's Determination of Urgency and Severity~~

~~The OPTN will refer a potential violation to the MPSC Chair if the preliminary investigation determines that the potential violation may pose an urgent and severe risk to patient health or public safety. The MPSC Chair will consider the available information and determine the appropriate review pathway. In making this determination, the MPSC Chair may consult with the Executive Director, OPTN President, HRSA representatives, and any others, as determined by the Chair. If the MPSC Chair is unavailable, the MPSC Vice Chair may make this determination. The MPSC Chair must make this decision within 72 hours after the preliminary investigation is completed.~~

~~B. Requests to Take Action to Mitigate Imminent Threat~~

~~If the MPSC Chair determines that an urgent and severe risk appears to be present, the MPSC Chair may request that the member voluntarily cease performing certain transplants or take a specified action to mitigate the threat to patient health or public safety. If the member takes the requested action to mitigate the threat within 24 hours, the matter may proceed through the Expedited Review pathway.~~

~~C. Notice of Chair's Determination~~

~~The MPSC Chair will provide notice to the Secretary of the Review pathway within 72 hours of the determination.~~

~~D. Changing Review Pathways~~

~~The MPSC Chair may change the review pathway of a potential violation at any time as information is gathered and the assessment of the urgency and severity of the risk to patient health or public safety changes.~~

~~L.11. OPTN Investigations~~

~~After the preliminary investigation of a potential violation or incident of non-compliance and the review pathway has been determined, additional investigation will occur as required. The investigation of any potential violation or non-compliance conducted by the OPTN may include, but is not limited to, any of the following:~~

- ~~1. Data review~~
- ~~2. Document review~~
- ~~3. Interviews with the member's representatives~~
- ~~4. On-site visits by OPTN Contractor staff~~
- ~~5. On-site visits by peer review teams~~

~~L.12. Imminent Threat Reviews~~

~~When the MPSC Chair determines that a potential violation of or non-compliance with OPTN Obligations presents an urgent and severe risk to patient health or public safety, and the member has not voluntarily taken the requested action to mitigate the risk, the potential violation will proceed through the Imminent Threat Review pathway. The OPTN Executive Director will notify the member immediately when the MPSC Chair determines that a potential violation will proceed through the Imminent Threat Review pathway.~~

A. ~~Imminent Threat Review Investigation~~

~~The OPTN must complete an investigation of the potential violation within 14 days of the initial determination by the MPSC Chair that the potential violation will proceed through the Imminent Threat Review pathway.~~

B. ~~Imminent Threat Review Committee~~

~~Within 21 days of the determination of the imminent threat review pathway, the Imminent Threat Review Committee will complete its review of the matter and forward its recommendations to the MPSC Chair.~~

1. ~~Composition of the Imminent Threat Review Committee~~

~~The Imminent Threat Review Committee may be the MPSC, any standing subcommittee of the MPSC, or an ad hoc subcommittee of the MPSC, as appointed by the MPSC Chair. A subcommittee must include at least 5 members of the MPSC, and 2 of the members must have expertise in the organ system or specific issue that is the subject of the review.~~

2. ~~Imminent Threat Review Committee Recommendation~~

~~The Imminent Threat Review Committee will determine whether the matter should continue to follow the Imminent Threat Review process.~~

~~If the Imminent Threat Review Committee determines that an urgent and severe risk to patient health or public safety no longer exists, it will determine whether the matter should proceed through the Expedited Review or Routine Review pathway.~~

3. ~~Notice after Imminent Threat Review Committee Recommendation~~

~~When the Imminent Threat Review Committee determines that a potential violation will continue through the Imminent Threat Review pathway, the OPTN Executive Director will:~~

- ~~a. Provide notice to the member of the Imminent Threat Review Committee's action within 24 hours by an approved method as described in *Section L.4. Methods for Correspondence and Providing Notice*. The member will have 24 hours after receiving notice to respond to the Executive Director regarding the Imminent Threat Review Committee's recommendations.~~
- ~~b. Provide notice of the Imminent Threat Review Committee's recommendation to the Secretary within 24 hours.~~
- ~~c. Refer the matter to the OPTN Executive Committee within 72 hours.~~
- ~~d. Include a recommendation for an adverse action, and whether the matter should be referred to the Secretary for further action.~~

C. ~~Interviews in Imminent Threat Reviews~~

~~When a potential violation proceeds through the Imminent Threat Review pathway, members are *not* entitled to an interview before the MPSC, even though the recommended action is an adverse action.~~

D. ~~OPTN Executive Committee Determination~~

~~The Executive Committee of the OPTN will convene within 7 days of the Imminent Threat Review Committee's determination.~~

~~If the Executive Committee determines that an urgent and severe risk to patient health or public~~

~~safety no longer exists, it will decide whether the matter should proceed through the Expedited Review or Routine Review pathway.~~

~~If the matter continues to proceed through the Imminent Threat Review pathway, the Executive Committee will make the following determinations:~~

- ~~1. Whether to accept the recommendation of the Imminent Threat Review Committee, or take another action. An adverse action is effective immediately upon the determination by the Executive Committee, prior to any hearing.~~
- ~~2. Whether the MPSC, Executive Committee, or Board of Directors will be the hearing body if the member requests a hearing. Members of the Imminent Threat Review Committee may also participate in the Imminent Threat Hearing Panel.~~

~~E. Notice after OPTN Executive Committee's Determination~~

~~The OPTN Executive Director will provide notice of the Executive Committee's determinations:~~

- ~~1. To the HHS Secretary within 24 hours.~~
- ~~2. To the member within 24 hours.~~

~~The Executive Committee will provide a written summary of this review to the Executive Director within 48 hours to be forwarded to the Secretary. The Executive Committee may determine when any notice to the membership or public required by Executive Committee actions will occur. The member may request a copy of the supporting documentation, which will be provided at the member's expense.~~

~~F. Requesting a Hearing in Imminent Threat Reviews~~

~~The member has 7 days following notice of the Executive Committee's determination to request a hearing as described in *Section L.18.B: Requesting a Hearing*. The hearing will occur not less than 7 days or more than 30 days from the date of the Executive Director's receipt of the request for a hearing.~~

~~G. Imminent Threat Hearing Process~~

~~If the member exercises its right to a hearing, the hearing will be conducted under the procedures described in *Section L.18: Hearings* that follows, with these modifications:~~

- ~~1. The hearing will occur after the Executive Committee's review and determination of the adverse action.~~
- ~~2. The Hearing Panel report will be issued within 14 days of the conclusion of the hearing.~~
- ~~3. If the Imminent Threat Hearing Panel determines that no adverse action is warranted, the Hearing Panel may immediately remove the designation of Member Not in Good Standing or Probation and provide appropriate notice without Board of Directors' approval.~~

~~L.13. Expedited Reviews~~

~~Any potential violation of or non-compliance with OPTN Obligations that poses a potential risk to patient health or public safety, which could become urgent or severe, will follow the Expedited Review pathway.~~

~~A. Expedited Review Investigation~~

~~The OPTN must complete an investigation of the potential violation within 21 days of the initial~~

determination by the MPSC Chair that the potential violation will proceed through the Expedited Review pathway.

B. Expedited Review Committee

Within 42 days of the determination of the expedited review pathway, the Expedited Review Committee will complete its review and forward its recommendations to the MPSC Chair.

1. Composition of the Expedited Review Committee

The Expedited Review Committee may be the MPSC, any standing subcommittee of the MPSC, or an ad hoc subcommittee of the MPSC, as appointed by the MPSC Chair. A subcommittee must include at least 5 members of the MPSC and 2 of the members should have expertise in the organ system or specific issue that is the subject of the review.

2. Expedited Review Committee Recommendations

The Expedited Review Committee will consider instances of potential non-compliance with OPTN Obligations. The Expedited Review Committee may determine that there was no violation, issue a letter of warning, or issue a notice of uncontested violation. The Expedited Review Committee may also recommend a Letter of Reprimand or an adverse action.

If the Expedited Review Committee recommends a Letter of Reprimand or an adverse action, then the member is entitled to an interview before the MPSC.

3. Notice after Expedited Review Committee's Recommendations

The MPSC Chair will provide notice of the Expedited Review Committee's determination by an approved method as described in *Section L.4: Methods for Correspondence and Providing Notice*. If the recommendation is for an adverse action, then the OPTN Executive Director will provide notice of the Expedited Review Committee's determination to the Secretary within 24 hours.

C. Interviews in Expedited Reviews

The member will be entitled to an interview before the MPSC when the Expedited Review Committee considers issuing a Letter of Reprimand or an adverse action. The member will have the right to request an interview to be held at the next in-person meeting of the MPSC. If the next in-person meeting of the MPSC is scheduled more than 60 days later, at the discretion of the MPSC Chair, a special in-person meeting may be required or an interview may be conducted by teleconference or electronic media.

If the member exercises its right to an interview, the interview will be conducted as described in *Section L.17: Interviews* that follows.

1. Requesting an Interview

The member has 14 days following notice of the Expedited Review Committee's recommendation to request an interview before the MPSC as described in *Section L.17.B: Requesting an Interview*.

D. Requesting a Hearing in Expedited Reviews

Following the interview before the MPSC, whether accepted by the member or not, the MPSC will consider the Expedited Review Committee's recommendation and may recommend to the Board

~~of Directors to impose an adverse action on the member. The MPSC will provide Notice of the recommended adverse action to the member. The member has 14 days following notice of the MPSC's recommendation for an adverse action to request a hearing as described in Section L.18.B: Requesting a Hearing.~~

~~Hearings will be scheduled no fewer than 7 days or more than 60 days from the date that the Executive Director receives the request for hearing. Hearings may be scheduled more than 60 days from the request date at the discretion of the MPSC Chair, and if the member and Chair agree on the date.~~

~~**E. Expedited Review Hearing Panel**~~

~~The Expedited Review Hearing Panel will be appointed by the MPSC Chair and composed of at least 15 MPSC members, 10 of which will constitute a quorum of the ad hoc committee. Two of the members must have expertise in the organ system or specific issue that is the subject of the review.~~

~~The Chair of the MPSC or the Chair's designee will be the presiding officer. Members of the Expedited Review Committee may also participate in the Expedited Review Hearing Panel.~~

~~**F. Expedited Review Hearing Process**~~

~~If the member exercises its right to a hearing, the hearing will be conducted under the procedures described in Section L.18: Hearings that follows, with these modifications:~~

- ~~1. The Hearing Panel report will be issued within 21 days of the conclusion of the hearing.~~
- ~~2. The Board will consider and act on the Hearing Panel report within 30 days of receiving the report.~~

~~**L.14. Routine Reviews**~~

~~A Routine Review will be conducted for any potential violation of OPTN Obligations when an Expedited Review or an Imminent Threat Review is not warranted.~~

~~**A. Routine Review Investigations**~~

~~The OPTN will complete a routine review investigation of the matter and refer it to the Routine Review Committee within 6 months.~~

~~**B. Routine Review Committee**~~

~~The Routine Review Committee will be composed of any standing subcommittee of the MPSC or, at the discretion of the MPSC Chair, the entire MPSC. The Routine Review Committee may meet by teleconference or electronic media, as needed, for the purpose of considering any new and ongoing potential policy violations.~~

~~**1. Notice after Routine Review Committee's Determinations**~~

~~The Routine Review Committee will notify the member of its determination and any recommendation for a specific action. If the Committee recommends an action that would entitle the member to an interview, members will be notified of their right to an interview at the time they are informed of the Committee's determination.~~

~~**C. Interviews in Routine Reviews**~~

~~The member will be entitled to an interview when the Routine Review Committee is considering~~

making a recommendation for a Letter of Reprimand or an adverse action. Interviews will be scheduled at the next in-person meeting of the MPSC or standing subcommittee of the MPSC.

1. Requesting an Interview

The member has 14 days to request an interview as described in *Section L.17.B: Requesting or Waiving the Right to an Interview* following notice of the Routine Review Committee's determination.

D. Hearings in Routine Reviews

1. Requesting a Hearing

The member has 14 days following notice of the Routine Review Committee's recommendation for an adverse action to request a hearing as described in *Section L.18.B: Requesting or Waiving the Right to a Hearing*.

Hearings will be scheduled no fewer than 7 days or more than 60 days from the date the OPTN Executive Director receives the request for hearing. Hearings may be scheduled more than 60 days from the request date at the discretion of the MPSC Chair, and if the member and MPSC Chair agree on the date.

2. Routine Review Hearing Panel

The Routine Review Hearing Panel will be appointed by the MPSC Chair and composed of at least 15 MPSC members, 10 of which will constitute a quorum of the ad hoc committee. Two of the members must have expertise in the organ system or specific issue that is the subject of the review.

The Chair of the MPSC or the Chair's designee will be the presiding officer. Members of the Routine Review Committee may also participate in the Routine Review Hearing Panel.

3. Routine Review Hearing Process

If the member exercises its right to a hearing, the hearing will be conducted using the procedures described in *Section L.18: Hearings*, with the following additional notifications to the member:

- a. That all documentation about the member that was generated by or submitted to the MPSC, the OPTN Executive Committee, or the OPTN Board before the recommendation or action, will be made available to the member, upon request.
- b. The Hearing Panel report will be issued within 30 days of the conclusion of the hearing.
- c. The Board of Directors will consider and act on the Hearing Panel report at its next regularly scheduled meeting following receipt of the report.

L.15. OPTN Determinations and Actions

OPTN actions may be imposed when a member:

1. Fails to comply with OPTN Obligations as described in *L.1. Member Compliance*.
2. Fails to submit or follow a corrective action plan or plan for quality improvement.
3. Fails to meet personnel requirements.

4. ~~Acts in a way that poses a risk to patient health or public safety.~~
5. ~~Fails to act as necessary to avoid risk to patient health or public safety.~~

A. ~~Determining Appropriate Action~~

~~Factors considered in reviewing potential violations and incidents of non-compliance include but are not limited to:~~

1. ~~Whether the potential violation poses an urgent and severe risk to patient health or public safety.~~
2. ~~Whether the potential violation poses a substantial risk to the integrity of or trust in the OPTN.~~
3. ~~Whether patient medical records or other documentation provide sufficient detail to determine the presence of mitigating factors at the time the potential violation occurred.~~
4. ~~Whether the member can show evidence of corrective action upon learning of the potential violation.~~
5. ~~The overall OPTN compliance history of the member, including but not limited to, MPSC reviews and actions in the member's history.~~

~~The OPTN may impose a separate action for each violation or may choose to impose a single action for all related violations that can be addressed by a single action.~~

B. ~~Corrective Action~~

~~The OPTN may require a member to take corrective action in addition to imposing an adverse action, or instead of imposing an adverse action, including:~~

1. ~~Root cause analysis~~
2. ~~Corrective action plan~~
3. ~~Plan for quality improvement~~
4. ~~On site monitoring~~
5. ~~Desk monitoring~~
6. ~~Self-assessments~~
7. ~~External expert consultants~~

~~If the MPSC or any standing subcommittee of the MPSC requires a member to take corrective action to address any issues of noncompliance, the member must take corrective action as specified and within the period provided. If the member fails to fulfill the corrective action requirements, the OPTN may make any determination or take any action as outlined in this *Appendix L*.~~

C. ~~Deferred Disposition with Monitoring Period~~

~~If the MPSC recommends an adverse action against a member, and the member has had an interview before the MPSC, the MPSC may delay proceeding with the matter for a Deferred Disposition period. Deferred Disposition will only be considered in cases where the member has implemented a corrective action plan or plan for quality improvement within the 60 days prior to the interview and where the potential violation or non-compliance under review is not egregious or severe.~~

~~Deferred Disposition is not an action, but rather a timeout period provided to the member to demonstrate its ability and willingness to meet OPTN Obligations. If the MPSC chooses to employ a Deferred Disposition, the recommendation for adverse action will not be communicated to the Board of Directors until after Deferred Disposition. The MPSC is able to revise its~~

~~recommendation at the end of the Deferred Disposition before communicating it to the Board.~~

~~Deferred Disposition is not appropriate if the member has received *either*:~~

- ~~1. A Letter of Warning, Letter of Reprimand, or an MPSC recommendation for an adverse action in the previous 2 years from the date of the interview.~~
- ~~2. Two or more Notices of Uncontested Violation in the previous 2 years from the date of the interview.~~

~~1. Additional Considerations for Deferred Disposition~~

~~The MPSC may also consider any of the following:~~

- ~~■ The overall performance and compliance history of the member, including its response to previous MPSC actions, and particularly requests for corrective action or plans for quality improvement.~~
- ~~■ Any recent changes in the member's staffing, including changes in those responsible for oversight of the member.~~
- ~~■ An MPSC assessment of the appropriateness or thoroughness of the corrective action plan or plan for quality improvement addressing the matter under review.~~

~~The MPSC is not required to offer a Deferred Disposition after an interview with the member and may proceed with its recommendation of the adverse action without a Deferred Disposition. If the member declines the Deferred Disposition, the MPSC will proceed with its recommendation of the adverse action.~~

~~2. Notice of Deferred Disposition~~

~~Notice of an MPSC determination of Deferred Disposition is not an adverse action recommendation that entitles the member to a hearing.~~

~~Deferred Disposition will include a 6-month monitoring period, beginning on the date of the interview. During this period, the member will have to demonstrate compliance with OPTN Obligations as outlined in its corrective action plan or plan for quality improvement. An on-site review of the member will be completed during the monitoring period.~~

~~3. Monitoring during Deferred Disposition~~

~~The member's compliance will be monitored by a subcommittee of the MPSC. The subcommittee will provide updates of that monitoring to the MPSC at any regular meetings of the MPSC scheduled during the Deferred Disposition.~~

~~4. Recommendation of an Adverse Action during or after Deferred Disposition~~

~~If the member does not demonstrate to the MPSC's satisfaction that the member has achieved compliance during the Deferred Disposition, the MPSC will proceed with its recommendation of an adverse action. The MPSC may proceed with its recommendation of the adverse action at any point during Deferred Disposition. If the MPSC proceeds with its recommendation of an adverse action, the member will be notified of its right to a hearing.~~

5. ~~Actions if Member Demonstrates Compliance after Deferred Disposition~~

~~The MPSC may consider imposing a non-adverse action or taking no action if the MPSC believes that the member has demonstrated compliance with OPTN Obligations or sufficient quality improvement at the end of the Deferred Disposition.~~

D. ~~MPSC Actions without Board Referral~~

~~The MPSC, or any standing subcommittee of the MPSC, may take any of the following actions or recommendations directly:~~

- ~~■ Issue a Notice of Uncontested Violation~~
- ~~■ Issue a Letter of Warning~~
- ~~■ Consider Issuing a Letter of Reprimand~~

~~These actions and recommendations do not require Board of Directors approval. The Board of Directors and the Secretary of HHS will be notified any time a Notice of Uncontested Violation, Letter of Warning, or Letter of Reprimand is issued, or anytime Deferred Disposition is offered.~~

1. ~~Notice of Uncontested Violation~~

~~The MPSC, or any standing subcommittee of the MPSC, will issue a Notice of Uncontested Violation for a violation of OPTN Obligations when:~~

- ~~a. There is substantial evidence of mitigating factors based on medical judgment.~~
- ~~b. There is believed to be no likelihood of recurrence.~~
- ~~c. The member does not challenge that the violation occurred.~~

~~The member is not entitled to an interview.~~

2. ~~Letter of Warning~~

~~The MPSC, or any standing subcommittee of the MPSC, will issue a Letter of Warning for a violation of OPTN Obligations when:~~

- ~~a. Medical judgment is credibly put forth as a partial mitigating factor.~~
- ~~b. There is believed to be no likelihood of recurrence.~~

~~Letters of Warning may also be issued in those cases where the compliance history of the member warrants an action higher than Notice of Uncontested Violation. The member is not entitled to an interview.~~

3. ~~Letter of Reprimand~~

~~The MPSC, or any standing subcommittee of the MPSC, will issue a Letter of Reprimand for a violation of OPTN Obligations when medical judgment does not appear to be a credible mitigating factor. Letters of Reprimand may also be issued in those cases where the compliance history of the member warrants an action higher than Notice of Uncontested Violation or Letter of Warning. The member is entitled to an interview before a Letter of Reprimand is issued.~~

E. Adverse Actions that Require Board Approval

The adverse actions of Probation and Member Not in Good Standing can only be imposed by the Board of Directors. If a member receives an adverse action, the Executive Director will give notice to the public of the adverse action as specified by the Board of Directors. This notice may include, but is not limited to, communication using the OPTN website.

1. Probation

The MPSC may recommend that the Board of Directors place a member on Probation, or the Board may do so on its own. Probation is an adverse action under these Bylaws, and the OPTN Executive Director will give notice to all members when a member is placed on Probation.

a. Corrective Action Requirements of Probation

The adverse action of Probation will require that the member adheres to corrective action requirements as specified by the MPSC, which may include, but are not limited to:

- i. Required development and submission of a corrective action plan or plan for quality improvement as specified by the MPSC, any standing subcommittee of the MPSC, the Executive Committee, or the Board of Directors. The member must demonstrate that it has adhered to the plan and that it has corrected any noncompliant activity within the Probation effective period.
- ii. Unscheduled on-site reviews by the OPTN Contractor staff or peer review teams throughout the Probation period.
- iii. Specified submission of reports, data, or other evidence to the OPTN that documents correction of the non-compliant activity throughout the period of Probation.

b. Notification Requirements of Probation

The adverse action of Probation will require that the member provide notice of the adverse action as follows:

If the member is a...	Then notice must be provided to ...
Transplant hospital	All patients, as defined in these Bylaws, of the designated transplant program receiving the adverse action, including any new transplant program patients, during the entire effective period of the adverse action.
OPO	All hospitals that have a contractual agreement with the OPO in the OPO's Donation Service Area (DSA).
Histocompatibility laboratory	All members that have a contractual agreement with the laboratory.

Members must provide notices as described above within 30 days of receiving notification from the OPTN that it has been given the adverse action of Probation. The notice to transplant program patients must be provided in writing, in each patient's spoken language, and as specified by the Executive Committee or Board of Directors.

2. Member Not in Good Standing

The MPSC may recommend that the Board of Directors declare the member to be a Member Not in Good Standing, or the Board of Directors may do so on its own. Member Not in Good Standing is an adverse action under these Bylaws.

~~a. Results of Member Not in Good Standing~~

The adverse action of Member Not in Good Standing will include:

- ~~i. Formal notice to the Secretary of HHS.~~
- ~~ii. Loss of member voting privileges in OPTN affairs.~~
- ~~iii. Loss of the privilege of any personnel associated with the member to serve on any Committee or the Board of Directors, or to hold office.~~
- ~~iv. Formal notification, along with any subsequent changes in status, to the entire OPTN membership.~~
- ~~v. Formal notification, along with any subsequent changes in status, to the member's Chief Executive Officer or Administrator.~~
- ~~vi. Formal notification, along with any subsequent changes in status, to the state health commissioner or other appropriate state representative with oversight of health care institutions doing business in the member's state.~~
- ~~vii. Any actions that can be taken under Probation.~~

~~b. Notification Requirements of Member Not in Good Standing~~

A member receiving the adverse action of Member Not in Good Standing must provide notice of the adverse action as follows:

If the member is a...	Then notice must be provided to ...
Transplant hospital	All transplant hospital patients as defined in these Bylaws, including any new transplant hospital patients, during the entire effective period of the adverse action.
OPO	All Hospitals that have a contractual agreement with the OPO in the OPO's Donation Service Area (DSA).
Histocompatibility laboratory	All members that have a contractual agreement with the Laboratory.

Members must provide notices as described above within 30 days of receiving notification from the OPTN that it has been given the adverse action of Member Not in Good Standing.

The notice to transplant hospital patients must be provided in writing, in each patient's spoken language, and as specified by the Executive Committee or Board of Directors.

F. Recommendations and Requests to the Secretary

The OPTN Board of Directors will advise the Secretary of the results of any ongoing or periodic reviews and evaluations, or Secretarial directed reviews, of member OPOs and transplant hospitals which, in the opinion of the Board of Directors, indicate noncompliance with OPTN Obligations or indicate a risk to the health of patients or to the public safety, and will provide any recommendations for appropriate action by the Secretary. Appropriate actions, include, but are

~~not limited to those described in the OPTN final rule, as described in Section L.16: that follows.~~

~~At any time, the Board may make recommendations to the Secretary for specific actions, on its own or after receiving a recommendation from the MPSC.~~

~~L.16. Secretarial Actions~~

~~Consistent with the OPTN Final Rule, the Secretary can take action if an OPTN member:~~

- ~~1. Violates the National Organ Transplant Act (NOTA).~~
- ~~2. Violates the OPTN Final Rule, 42 CFR Part 121.~~
- ~~3. Violates OPTN policies that have been approved by the Secretary as mandatory. For more information on mandatory policies, see Section L.16.A: OPTN Policies Approved by the Secretary as Mandatory.~~
- ~~4. Engages in behavior that poses a risk to patient health or public safety.~~

~~Termination of membership requires Secretarial approval. Membership can only be removed if the OPTN member no longer meets the requirements for membership as described in the OPTN Final Rule.~~

~~In addition to Termination of membership in the OPTN described above, the Secretary may take appropriate actions, which include, but are not limited to:~~

- ~~a. Removal of one or more of the member's designated transplant programs. After designated transplant program status is removed, the Program will no longer be eligible to receive organs for transplantation within the OPTN.~~
- ~~b. Termination of the member's reimbursement under Medicare or Medicaid.~~
- ~~c. Termination of a transplant hospital's participation in Medicare or Medicaid.~~
- ~~d. Request for information from the OPTN.~~
- ~~e. Any other action that the Secretary considers necessary.~~

~~A. OPTN Policies Approved by the Secretary as Mandatory~~

~~When and if the Secretary approves any OPTN policies as mandatory, the U.S. Department of HHS will publish lists of OPTN Policies in the Federal Register, indicating which policies are enforceable under Sec. 121.10 of the OPTN Final Rule or are subject to potential sanctions of Section 1138 of the Social Security Act. Violations of such policies can result in sanctions or other actions by the Secretary.~~

~~Section 121.11(b)(2) of the OPTN final rule requires OPTN members that are OPOs and transplant hospitals to submit to the OPTN, to the Scientific Registry, as appropriate, and to the Secretary certain information in the form required and in accordance with the schedule prescribed.~~

~~Data specified by the Secretary under this authority includes all data requested on forms approved by the Office of Management and Budget (OMB), including all applications reviewed by the OPTN. The Secretary may take an action described above for failure of a member to submit accurate and complete data as required by the Secretary (including on OMB-approved forms). Failure to submit accurate and complete data may also result in civil or criminal penalties.~~

~~B. Effective Date of Actions Recommended by the Board~~

~~Actions recommended by the OPTN Board of Directors and taken by the Secretary for non-compliance with mandatory policies will not become effective until the member has waived its right to a hearing or the applicable hearing proceedings have been concluded.~~

~~If the Board finds, based on available evidence, that the member's potential violation poses a severe and urgent risk to patient health or public safety, the Board may recommend that a Secretarial action be made effective immediately, before completing any required interview or hearing.~~

L.17. Interviews

~~An interview is not a hearing, is preliminary in nature, and is not conducted according to the procedural rules followed for hearings. The member will be informed of the reasons for the interview and may present any information it considers useful and relevant.~~

A. Members' Right to an Interview

~~The member will have the right to an interview when:~~

- ~~1. A Letter of Reprimand is recommended.~~
- ~~2. An adverse action is recommended.~~
- ~~3. A membership application or application for designated transplant program status is rejected.~~
- ~~4. A pediatric membership exception request is rejected.~~

~~However, a member has no right to an interview when a potential violation is being reviewed through the Imminent Threat Review pathway. After the interview is completed, the MPSC will promptly provide a summary of the interview to the member.~~

B. Requesting or Waiving the Right to an Interview

~~The member must submit its written interview request to the Executive Director using one of the approved methods described in L.4. *Methods for Correspondence and Providing Notice*.~~

~~A member may waive its right to an interview in writing. In addition, a member who fails to request an interview within the specified time waives any right to an interview. Waiver of the right to an interview means that:~~

- ~~1. If the recommended action is a non-adverse action, the action will be issued.~~
- ~~2. If the recommended action is an adverse action, the member is entitled to a hearing.~~

C. Notice of Interview

~~When the Executive Director receives a request for an interview from the member within the time and in the manner required, the interview will be conducted at the next in-person meeting of the MPSC.~~

D. Notice to Member after an Interview

~~The MPSC Chair will promptly provide notice to the member of the MPSC's recommendations or actions resulting from the interview. The notice will:~~

- ~~1. Briefly advise the member of the nature of the action.~~
- ~~2. Advise the member of the right to a hearing, if applicable, according to the provisions of these Bylaws.~~
- ~~3. Specify the maximum number of days that the member has to submit a request for a hearing.~~

E. Informal Discussion

The MPSC, or any subcommittee of the MPSC, may request that the member participate in an informal discussion to provide additional details regarding a potential violation of or non-compliance with OPTN Obligations or to gain additional information regarding member performance. The discussion is informal, and may be conducted by teleconference or electronic media. This informal discussion is intended to provide the member the opportunity to provide clarification of the matter, and could lead to a more timely and effective assessment and resolution of the matter.

L.18. Hearings

If the MPSC makes a recommendation for an adverse action, or the Board of Directors takes an adverse action without recommendation from the MPSC, the member is entitled to a hearing.

A. Members' Right to a Hearing

The member has a right to a hearing when an adverse action is:

1. Recommended by the MPSC.
2. Recommended by a subcommittee of the MPSC, if the action is the rejection of an initial membership application or application for designated transplant program status.
3. A result of a determination regarding a potential violation undergoing an Imminent Threat Review.
4. Taken by the Board of Directors or the Executive Committee notwithstanding a favorable recommendation by the MPSC or standing subcommittee of the MPSC under circumstances where no right to a hearing existed.
5. Taken by the Board of Directors or the Executive Committee on its own without a prior recommendation by the MPSC.

The member also has a right to a hearing when the MPSC or a subcommittee of the MPSC rejects a pediatric membership exception request.

If the Board of Directors determines, based on available evidence that a potential violation of OPTN Obligations may pose an urgent and severe risk to patient health or public safety, the Board may take action even if the member has not had the opportunity for a hearing.

B. Requesting or Waiving the Right to a Hearing

The member must submit its written hearing request to the OPTN using one of the approved methods described in *Section L.4: Methods for Correspondence and Providing Notice*.

A member may waive its right to a hearing in writing. In addition, a member who fails to request a hearing within the specified time waives any right to a hearing. Waiver of the right to a hearing means that the member accepts the adverse action or recommendation and the following outcomes will apply:

1. An adverse recommendation by the MPSC or the Executive Committee will become effective after the final decision of the Board of Directors.
2. An adverse action by the Board of Directors will become effective and considered the final decision by the Board.

If the member will be represented by an attorney at the hearing, the request for a hearing must identify by name the attorney who will represent the member, and include the attorney's business address and contact information.

C. Notice of Hearing

When the Executive Director receives a request for a hearing within the period and in the required manner, the Executive Director will send notification of the time, place, and date of the hearing to the member at least 7 days before the hearing.

The hearing notice will include a concise statement of the adverse recommendation or action that is the subject of the hearing, and be delivered to the member using an approved method as described in *Section L.4: Methods for Correspondence and Providing Notice*.

At this time, all documentation about the member that was available to the MPSC, the Executive Committee, or the Board at the time of deliberation, will be provided to the member, upon request and at the member's expense.

D. Appointment of Hearing Panels

Hearing Panels will be appointed according to the review pathway of the potential violation as described in:

- *Section L.12: Imminent Threat Reviews*
- *Section L.13: Expedited Reviews*
- *Section L.14: Routine Reviews*

Alternatively, at the discretion of the President, those Board members who are in attendance at a regular or special meeting of the Board may conduct the hearing, provided that the members comprise a quorum of the full Board. One of the members will be designated as Chair of the Hearing Panel.

E. Hearing Participants

Hearing participants will be:

1. The Hearing Panel.
2. The member being reviewed for the adverse recommendation or action.

F. Service on Hearing Panels

Hearing Panel members must avoid conflicts of interest according to *Article 2.7: Conflicts of Interest* of these Bylaws, and will be disqualified from serving on a Hearing Panel if the member has been directly involved in compiling evidence or providing expert consultation to the OPTN on the matter being reviewed.

G. Appearance and Representation at Hearings

The member who requested the hearing must appear in person at the hearing. A member who fails without good cause to appear at a requested hearing will waive its rights to a hearing. The member, the body whose recommendation resulted in the hearing, and the Hearing Panel may be represented by an attorney.

H. Presiding Officer

The Chair of the MPSC or the Chair's designee will be the presiding officer. The presiding officer will manage the hearing to ensure that all participants in the hearing have the opportunity to present relevant evidence and to conduct any necessary cross-examination required for a full disclosure of the facts.

The presiding officer will determine the order of procedure during the hearing and make all rulings on interpretation or construction of the OPTN Obligations, relevant documents, OPTN requirements on procedure, and on the admissibility of evidence. The presiding officer makes all decisions regarding the exclusion of irrelevant, immaterial, redundant, or repetitive evidence.

I. Rights of Hearing Participants

During a hearing, the member and the Hearing Panel will have the right, subject to the presiding officer's rulings, to:

- Call and examine witnesses.
- Introduce exhibits.
- Cross-examine any witness on any matter relevant to the issue.
- Impeach any witness.
- Refute any evidence.

The Hearing Panel may call and question any member representatives who are present at the hearing, even if they do not testify as witnesses for the member or the member chooses not to testify on its own behalf.

J. Procedure and Evidence

The hearing need not be conducted strictly according to rules of law relating to the examination of witnesses or presentation of evidence. The presiding officer may permit admission of any relevant information, regardless of whether such evidence would be admitted in a court of law.

Each party will, before or during the hearing, be entitled to submit documents concerning any relevant issue, and these documents will become part of the hearing record. The presiding officer may, but is not required to, order that oral evidence is taken only on oath or affirmation. The oath or affirmation may be administered by any person designated by the presiding officer and who is authorized to notarize documents in the state where the hearing is held.

K. Official Notice

In reaching a decision, the Hearing Panel may take official notice at any time during the hearing of any generally accepted technical, scientific, or medical information relating to the issues under consideration.

When the Hearing Panel takes official notice of any information, participants will be informed of the information considered and that information will be noted in the hearing record. Any participant may request that information be given official notice. Hearing participants may challenge any information given official notice, either by providing evidence or expert witness testimony.

L. Burden of Proof

The body whose adverse recommendation or action resulted in the hearing must present

evidence to support the adverse recommendation or action, including an explanation of the action or recommendation, and the reason it was taken. The member will then have the burden of proving and persuading, by clear and convincing evidence, that the adverse recommendation or action lacks substantial basis or that such basis or the conclusions drawn are arbitrary, unreasonable, or capricious.

M. — Hearing Record

The Hearing Panel will keep a record of the hearing that includes a hearing transcript and any documents reviewed during the hearing. A court reporter will prepare the written transcript. All exhibits admitted into evidence at the hearing and all documents submitted to the Hearing Panel will be incorporated in the record until the hearing is declared adjourned.

N. — Postponement

Request for postponement of a hearing will be granted by the MPSC Chair only for good cause and only if the request is made as soon as is reasonably possible.

O. — Presence of Hearing Panel

The Hearing Panel must be present throughout the hearing and deliberations. If a Panel member is absent from any part of the proceedings, the Panel member will not be permitted to participate in the Panel's deliberations or the decision.

P. — Recesses and Adjournment

The Chair of the Hearing Panel may recess the hearing and reconvene within 60 days or when reasonably practical for the convenience of the participants, to obtain material new or additional information, or to consult with experts.

When the presentation of oral and written evidence is concluded, the hearing will be closed. The Hearing Panel will then, at a time convenient to the Panel, conduct its deliberations away from the parties. When the Hearing Panel completes its deliberations, the hearing will be declared finally adjourned.

Q. — Action after Hearing

At the conclusion of their deliberations, the Hearing Panel will do *one* of the following:

- Issue a recommendation for an adverse action.
- Issue a lesser action.
- Recommend that the MPSC close the review of the potential violation without issuing any action.

A hearing cannot remain open or be re-opened after the hearing panel has taken an action.

R. — Hearing Panel Report

Following preparation of the hearing record, the Hearing Panel will make a written report of its findings and recommendations and will forward it, together with the hearing record, to the Board of Directors. At the same time, a copy of the Hearing Panel report will be forwarded to the member. The Hearing Panel report will be approved by the presiding officer before it is provided to the Board of Directors and member.

All findings and recommendations by the Hearing Panel will be supported by references to the

hearing record. The presiding officer may extend the time for making the Hearing Panel's written report at his or her discretion by giving written notice to the participants.

S. — Notice after Hearing

The Executive Director will promptly send a copy of the result of the Hearing to the member by an approved method as described in *Section L.4: Methods for Correspondence and Providing Notice*. A copy of the result also will be provided to the Board of Directors.

T. — Effect of Favorable Result

If the Hearing Panel closes the matter without recommending an adverse action, then no further due process is required.

U. — Effect of Adverse Result

If the result of the hearing continues to be adverse to the member, the adverse recommendation will be forwarded to the Board of Directors to make a final decision. The member will have the right to request to appear before the Board of Directors before a final action is taken by the Board.

L.19. — Final Decision of the Board of Directors

A. — Right to Appear before the Board

Before the Board of Directors takes final action regarding any recommendation for adverse action, the member has the right to appear before the Board and submit a written statement and provide oral statement that details any disagreement with the findings of fact, conclusions, or procedural issues raised at any step in the review process.

The member requesting to appear before the Board must submit a written request to the OPTN Executive Director using one of the approved methods as described in *Section L.4: Methods for Correspondence and Providing Notice*. Members must provide to the Executive Director any written statements that will be submitted to the Board at least 15 days before the scheduled appearance.

At least 25 days before the member is scheduled to appear before the Board, the Executive Director will provide notice to the member of the time, place, and date.

B. — Board of Directors Action

After the conclusion of appropriate due process proceedings and after the MPSC forwards a recommendation to the Board of Directors, the Board will make its final decision in the matter. At this time, the Board will send written notice of its decision to the member and to the Secretary of HHS within 3 business days of the final decision. Written notice will be sent by an approved method as described in *Section L.4: Methods for Correspondence and Providing Notice*.

The Board may take longer than 3 days to provide notice of its decision for good reason, as determined by the Secretary. A majority vote by a quorum is required for the Board to take any action permitted by these Bylaws.

1. — Terms of Probation

A Board action placing a member on Probation will be effective only after hearing proceedings have been concluded, or the member has waived its right to a hearing, and final Board action is taken.

~~Probation may also be made effective at any time the Board finds, based on available information, that the potential violation of OPTN Obligations may pose an urgent and severe risk to patient health or public safety.~~

~~2. Terms of Member Not in Good Standing~~

~~When the Board takes the adverse action of Member Not in Good Standing, the action will be effective only after hearing proceedings have been concluded, or the member has waived its right to a hearing, and final Board action is taken.~~

~~Member Not in Good Standing may also be made effective at any time the Board finds, based on available information, that the potential violation of OPTN Obligations may pose an urgent and severe risk to patient health or public safety.~~

~~3. Board Recommendations to the Secretary~~

~~A Board of Directors' recommendation that the Secretary take action against a member will not become effective until after applicable hearing proceedings have been concluded or the member has waived its right to a hearing, unless the Board finds, at any time, based on available information, that the potential violation of OPTN Obligations may pose an urgent and severe risk to patient health or public safety.~~

~~The action that the Board recommends the Secretary take will not become effective until the Secretary of HHS accepts the Board's recommendation, or takes other action that the Secretary determines is appropriate.~~

~~C. Notice~~

~~Notice of a final decision by the Board of Directors that the member has been placed on Probation or declared a Member Not in Good Standing will be circulated to all members as described in *Section L.15: OPTN Determinations and Actions*. OPTN membership will be notified of final decisions by the Board to recommend to the Secretary of HHS Suspension or Termination of membership only after the Secretary approves the recommendation.~~

~~L.20. Restoration of Unrestricted Membership Privileges~~

~~If a member that is given Probation or declared a Member Not in Good Standing has presented evidence to the MPSC that it has fully complied with OPTN Obligations, including completion of any actions prescribed as a result of the adverse action, the MPSC may recommend that the Board of Directors restore unrestricted membership privileges.~~

~~If Secretarial Action has been taken against a member as described in *Section L.16: Secretarial Actions*, only the Secretary of HHS can restore its unrestricted membership privileges. The MPSC may recommend that the Secretary of HHS restore unrestricted membership privileges if Secretarial Action has been taken against a member if the member has presented evidence to the MPSC that it has fully complied with OPTN Obligations, including completion of any actions prescribed as a result of the adverse action.~~

~~If a membership was suspended or terminated by the Secretary, the member must complete and submit an application for OPTN membership, as described in *Appendix A: Membership Application and Review*.~~

~~A. Request for Restoration of Membership Privileges~~

~~A member may request restoration of membership privileges after it demonstrates to the satisfaction of the MPSC that:~~

- ~~1. The member is in compliance with OPTN Obligations.~~

- ~~2. The member has fully implemented any corrective action plan or a plan for quality improvement previously required by the MPSC.~~
- ~~3. The member has demonstrated that the underlying cause for the adverse action has been corrected, or eliminated.~~
- ~~4. The type of violation that resulted in the adverse action is not likely to recur.~~
- ~~5. There are no pending compliance issues that may lead to a potential violation or non-compliance that would require an Imminent Threat Review.~~

~~The burden is on the member at all times to demonstrate that restoration of membership privileges is appropriate.~~

~~B. Minimum Requirements to Request Restoration of Membership Privileges~~

~~The MPSC will only consider requests for restoration of membership privileges during its regularly scheduled meetings and the member may not request restoration of membership privileges until both occur:~~

- ~~1. At least twelve months have passed since the approval and implementation of the MPSC prescribed corrective action plan.~~
- ~~2. At least twelve months have passed since the approval of the final action by the Board of Directors or the Secretary of HHS.~~

~~If the MPSC denies the member's request for restoration of membership privileges, the member may renew its request 6 months from the date the MPSC denied the request.~~

~~C. Additional Requirements~~

~~At its discretion, the MPSC may require any of the following before it considers a request for restoration of privileges:~~

- ~~1. An unannounced OPTN Contractor on-site review.~~
- ~~2. An unannounced peer on-site review.~~
- ~~3. Data and document review.~~
- ~~4. A presentation to the MPSC by the member.~~

~~D. Hearing~~

~~If the MPSC denies the member's request for restoration of privileges and the member has met the conditions identified above, then the member will be entitled to a hearing at the next regularly scheduled MPSC meeting. The member must submit a written hearing request using one of the approved methods described in *Section L.4: Methods for Correspondence and Providing Notice*. The hearing will be held at the member's expense, as outlined in *Section L.23: Costs and Expenses*.~~

~~E. Restoration of Privileges after Violation of Mandatory Policies under Section 121.10(c) of the OPTN Final Rule~~

~~If the member presents evidence to the MPSC's satisfaction that a member found to be in violation of a mandatory policy under Section 121.10(c) of the OPTN Final Rule has fully complied with OPTN Obligations, including completing any corrective actions prescribed, the MPSC will recommend to the Board of Directors that full membership privileges be restored.~~

~~L.21. Lesser Adverse Actions~~

~~The MPSC may consider a lesser adverse action if a member requests either restoration of unrestricted membership or a lesser adverse action. The MPSC may recommend to the Board of Directors the lesser adverse actions of Probation or, if the existing action is Probation, a trial restoration period.~~

~~The MPSC may consider the recommendation if the member has demonstrated to the MPSC's satisfaction all of the following:~~

- ~~1. The member is now in compliance with OPTN Obligations.~~
- ~~2. The underlying cause for the adverse action is corrected.~~
- ~~3. The corrective action plan or plan for quality improvement has been implemented.~~
- ~~4. The type of violation that resulted in the adverse action is not likely to recur.~~
- ~~5. There are no pending compliance issues that may lead to a potential violation or non-compliance that would require an Imminent Threat Review.~~

~~The burden is on the member at all times to demonstrate that a lesser adverse action is appropriate.~~

~~A. Requesting a Lesser Adverse Action~~

~~The burden is on the member at all times to demonstrate that a lesser adverse action is appropriate. However, the MPSC will only consider requests during its regularly scheduled meetings.~~

~~The member may not request a lesser adverse action until *both* occur:~~

- ~~1. At least twelve months have passed since the approval and implementation of the MPSC prescribed corrective action plan.~~
- ~~2. At least twelve months have passed since the approval of the final action by the Board of Directors or the Secretary of HHS.~~

~~In its discretion, the MPSC may require an unannounced on-site review or peer on-site review before considering the request.~~

~~B. Considering Requests for Lesser Adverse Actions~~

~~The consideration of lesser adverse actions does not entitle the member to an interview or hearing under these Bylaws. If the MPSC denies the request by the member and the member believes that the MPSC acted arbitrarily and capriciously, the member will be entitled to a hearing regarding the recommendation for the action of Probation or trial reinstatement period at the next regularly scheduled meeting of the MPSC. The hearing will be held at the member's expense.~~

~~If the MPSC denies the member's request for a lesser adverse action, the member may renew its request 6 months after the MPSC denies the request.~~

~~L.22. Rejected Membership Applications~~

~~If an application for membership, designated transplant program status, or a Change in Key Personnel is rejected the applicant has the same due process rights given to a member as outlined in this *Appendix L*.~~

~~An applicant for membership or designated transplant program status has the right to appeal to the Secretary of HHS decisions of the MPSC, MPSC subcommittees, or the Board of Directors regarding these applications according to Section 121.10(c) of the OPTN Final Rule.~~

~~If an applicant exercises this right of appeal before exhausting the procedural rights granted in these Bylaws, the applicant will provide written notice to the Executive Director by an approved method as described in *Section L.4: Methods for Correspondence and Providing Notice*. When the Executive Director receives notice, it will notify the Secretary of the appeal within 3 business days, or a longer period if necessary, as determined by the Secretary. Pending a decision on the appeal, due process procedures will continue unless the Secretary directs otherwise.~~

~~If the appeal to the Secretary is denied, the rejection process may continue, according to *Appendix A: Membership Application and Review* of these Bylaws. Any other decision by the Secretary on the appeal will be submitted to the MPSC or Board for action consistent with the Secretary's decision.~~

~~L.23. Costs and Expenses~~

~~A. Reimbursement of OPTN Contractor Costs and Expenses~~

~~Reasonable costs and expenses of conducting interviews and hearings as described in these Bylaws will be paid by the member. Costs and expenses may include, but are not be limited to:~~

- ~~1. Travel and lodging expenses of member, volunteers, and OPTN Contractor representatives.~~
- ~~2. Compensation of OPTN Contractor representatives.~~
- ~~3. Court reporter fees.~~
- ~~4. The costs of preparing copies of the hearing record.~~
- ~~5. The member's costs of preparing for and attending the interview or hearing.~~
- ~~6. The OPTN's costs of obtaining and compiling evidence and exhibits.~~

~~OPTN Contractor representatives may include:~~

- ~~▪ OPTN Contractor staff~~
- ~~▪ Outside counsel~~
- ~~▪ Consultants~~
- ~~▪ Volunteers~~
- ~~▪ Expert witnesses~~

~~The presiding officer, after consultation with the Executive Director, will decide the nature and amount of expenses to be reimbursed. Reasonable costs and expenses may be estimated and billed, wholly or partially, to the member in advance or may be billed, wholly or partially, to the member as the matter is reviewed. If actual costs and expenses otherwise reimbursable by the member for the entire matter before the MPSC are less than \$500.00, or if member is not determined to be in violation of OPTN Obligations, no reimbursement will be due from the member. In addition, any amounts previously reimbursed or deposited will be returned. If the member has multiple matters before the MPSC within any 12-month period, the \$500.00 amount will apply to all such matters cumulatively.~~

~~B. Reasonable Costs and Expenses~~

~~Reasonable costs and expenses resulting from enforcement of OPTN Obligations will be reimbursed by the member, including any of the following:~~

- ~~1. Conducting other than routine on-site reviews.~~
- ~~2. Reviewing and monitoring corrective action plans or plans for quality improvement.~~
- ~~3. Conducting due process proceedings.~~
- ~~4. Monitoring and conducting evaluations of transplant programs with lower than expected survival rates as described in *Section D.12.A: Transplant Program Survival*~~

~~Rates of these Bylaws, including on-site visits and monitoring plans for quality improvement.~~

~~C. Advanced Deposit for Reimbursable Costs and Expenses~~

~~The Executive Director may require that the member make and maintain a deposit with the OPTN Contractor in an amount equal to the currently projected costs and expenses of any of the following:~~

- ~~1. OPTN Contractor on-site reviews~~
- ~~2. OPTN member Peer on-site reviews~~
- ~~3. The interview~~
- ~~4. The hearing~~

~~The failure to make the required deposit within 10 days after the Executive Director requests an advance deposit will be considered a waiver of the member's interview or hearing rights. Following such a waiver, the MPSC and the Board of Directors may impose any actions, including adverse actions.~~

~~D. Default in Payment of Reimbursable Cost and Expenses~~

~~Any member who fails to reimburse costs and expenses within 30 days after receiving notice may be referred to the Secretary for Termination of OPTN membership.~~

Appendix L: Reviews and Actions

By accepting membership in the OPTN, each member agrees to comply with all OPTN Obligations according to Article 1.1: Member Requirements. This Appendix outlines how the OPTN reviews potential noncompliance with OPTN Obligations, the process for other reviews as specified in OPTN Policies and Bylaws, and the actions the OPTN may take in response. The Appendix also describes a member's rights during OPTN reviews.

L.1. Methods for Correspondence

All correspondence between members and the OPTN required by this Appendix L must be sent by a method that can be tracked and provides proof of receipt.

L.2. Representative Terminology Used throughout Appendix L

A. References to the OPTN

Throughout this Appendix L, references to the OPTN include the Board of Directors, OPTN committees and subcommittees, OPTN committee members, the OPTN Executive Director, and the OPTN Contractor. Bylaws requirements that are specific to any of these groups or individuals explicitly name the group or individual.

B. References to the MPSC Chair

References to the MPSC Chair in this Appendix L necessarily include the possibility of an MPSC Chair designee. If the MPSC Chair cannot fulfill a duty as required in these Bylaws for any reason, such as unavailability or potential conflicts of interest, then these duties will be delegated to another individual. Selection of an MPSC Chair designee will proceed in the following order until a designee is identified:

1. MPSC Vice Chair
2. MPSC regional representatives, as selected by the OPTN President

L.3. Medical Peer Review

The OPTN will conduct all deliberations and take all actions according to applicable medical peer review laws. Consistent with applicable laws, all inquiries, deliberations, recommendations, and actions during member reviews by the OPTN will be kept confidential. All proceedings and records within the scope of these OPTN quality review activities are confidential. Members of any OPTN Committee attending the meeting in which a peer review is conducted, serving as a peer reviewer, working for or on behalf of the OPTN, or providing information to the OPTN for peer review activities, are entitled to confidentiality.

The OPTN will keep all materials, information, and correspondences to and from members and directly related to the OPTN peer review process confidential to promote quality improvement and full disclosure by OPTN members. Materials, information, and correspondences created by or for the peer review body are considered “directly related.”

The OPTN will not disclose any materials provided to the OPTN by the member, except as required by law. Materials prepared by members independent of the OPTN medical peer review process may be shared by members in their discretion.

L.4. Conflicts of Interests

The OPTN's Conflict of Interest Policy applies to all OPTN inquiries, deliberations, recommendations and actions during member reviews.

L.5. Investigation of Potential Noncompliance with OPTN Obligations

When the OPTN becomes aware of a member's potential noncompliance with OPTN Obligations, the OPTN will conduct an investigation. This investigation will evaluate whether a potential noncompliance exists. The investigation will also consider whether the potential noncompliance suggests a risk to patient health or public safety, and the urgency and severity of the risk.

Members must respond to all investigation requests within the specified period. A member may provide any information that it believes is relevant to the investigation. The OPTN will notify the member of the date by which the member must submit the requested or additional information.

L.6. Requests to Mitigate Risks

If an OPTN review suggests a potentially urgent or severe risk exists to patient health or public safety, the OPTN may ask that the member take appropriate actions to mitigate the urgency and severity of the risk. A member's failure to sufficiently mitigate the risk in the period requested will be considered a separate potential noncompliance with OPTN Obligations.

L.7. Scheduling MPSC and Member Interactions

Members currently under MPSC review may be offered specific opportunities, in the form of informal discussions, interviews, and hearings, to interact with the MPSC. The MPSC Chair will determine when these interactions will be scheduled. Factors that will influence the scheduling of these MPSC and member interactions include, but are not limited to, any of the following:

- The urgency and severity of the issue
- Whether the member has taken appropriate actions that mitigate the urgency and severity of the risk
- Adequate time for members to demonstrate the results and sustainability of their containment and corrective action plans
- The MPSC's meeting schedule

The OPTN will notify the member when the MPSC is offering an informal discussion, interview, or hearing. The OPTN's offer notice will include all of the following:

1. The reasons the MPSC is offering the member an interaction
2. The date by which the member must accept or decline the MPSC's offer
3. A list of any information the OPTN would like the member to submit in advance of the interaction
4. A summary of what the member should address during the interaction

L.8. Informal Discussions

An informal discussion is a direct conversation between a group of MPSC members and a member currently under MPSC review. Informal discussions are intended to provide the MPSC and member an opportunity to openly discuss the review and seek feedback. Informal discussions are information gathering activities that may lead to a more efficient and effective review than written correspondence and document reviews alone.

A. Member Informal Discussion Requests

A member currently under review by the MPSC may request an informal discussion at any time. Members requesting an informal discussion must submit all of the following:

1. The reasons the member is requesting an informal discussion, including the applicable OPTN Policy or Bylaw
2. A summary of what the member would like to present to the MPSC, or what the member would like the MPSC to address during the informal discussion
3. Any information the member would like the MPSC to consider in advance of the informal discussion

The MPSC Chair will accept or decline a member's request for an informal discussion with the MPSC within 14 days of receiving the member's request. The OPTN will notify the member of the MPSC Chair's decision.

B. MPSC Informal Discussion Requests

The MPSC or MPSC Chair may offer members currently under review one or more informal discussions at any time. A transplant program is entitled to an informal discussion before the MPSC recommends that the program inactivate or withdraw its designated transplant program status due to functional inactivity or transplant program performance reviews according to *Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs*.

C. Waiving an Informal Discussion

Members that decline the MPSC's informal discussion request may submit additional written information for the MPSC's review. The MPSC Chair will set a date by which the member must provide any additional written information.

Members that decline an MPSC informal discussion request do not waive their right to future interactions with the MPSC, including interviews and hearings.

D. Informal Discussion Format

Informal discussions will be conducted by teleconference and will include:

1. At least 10 minutes for the member to present information
2. At least 15 minutes for the member to respond to questions from the MPSC
3. At least 4 MPSC members

E. Informal Discussion Outcome

Within 21 days, the OPTN will provide the member with a written summary of the informal discussion.

The group that conducted the informal discussion may request that the member submit additional information for the MPSC's review after the informal discussion, but will not take an action as outlined in *Section L.12: OPTN Actions*. The group will report its findings to the MPSC, along with any additional materials requested, no later than the MPSC's next in-person meeting. Following this report, the MPSC will continue its review and will notify the member of any decisions or actions, including the reasons for the MPSC's decision.

L.9. Interviews

An interview is an opportunity for the MPSC and member to discuss an ongoing review. During an interview, the member has the opportunity to present information, including any steps the member has taken to correct the issue and to address any concerns the MPSC shared with the member prior to the interview. The MPSC will ask the member questions and will determine an appropriate action based on the interview findings.

A. Right to an Interview

The MPSC or MPSC Chair may offer a member currently under MPSC review one or more interviews at any time.

The member has the right to an interview:

1. Before the MPSC recommends that the Board of Directors places a member on Probation or declares a member Not in Good Standing
2. If the MPSC rejects a member's request for release from Probation or Member Not in Good Standing
3. If the MPSC recommends that the Board of Directors rejects a membership application as outlined in *Appendix A: Membership Application and Review*
4. If the MPSC rejects a key personnel change application as outlined in *Appendix C: Membership Requirements for Histocompatibility Laboratories* or *Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs*

B. Waiving an Interview

Members that do not respond to the interview offer by the specified date waive their right to an interview.

Members that waive their right to an interview with the MPSC also:

- Waive their right to a hearing
- Waive their right to appear before the Board of Directors

Members that waive their right to an interview must still respond to any MPSC requests for written information and may provide additional written information for the MPSC to review. The MPSC Chair will set a date by which the member must provide any additional written information.

C. Interview Format

Interviews may be conducted by teleconference or at an in-person MPSC meeting, as determined by the MPSC Chair. Interviews will include:

1. At least 15 minutes for the member to present information
2. At least 30 minutes for the member to respond to questions from the MPSC
3. At least 10 MPSC members, which shall constitute a quorum for the purpose of any actions resulting from the interview.

At least 2 of the 10 MPSC members must have expertise in the organ system or specific issue that is the subject of the review. If there are not at least 2 subject matter experts available from the MPSC, the MPSC Chair will select individuals with the appropriate expertise from other OPTN committees. These individuals may participate in all aspects of the interview process, but they serve in an advisory role and do not have a vote.

D. Possible Interview Outcomes

Following the interview, the MPSC will determine an appropriate action and notify the member of the interview outcome. Within 21 days of the interview, the OPTN will provide the member with documentation of the reasons for the MPSC's decision and a written summary of the interview.

If the MPSC considers recommending an adverse action, then the member will be entitled to a hearing with the MPSC before the MPSC forwards its recommendation to the Board of Directors.

L.10. Hearings

The MPSC will offer hearings to members when the MPSC is considering recommending that the Board of Directors takes certain actions. Hearings are formal procedures during which the OPTN presents information explaining the rationale for its recommendation. Hearings are the final opportunity for the member to present information for the MPSC to consider before the MPSC makes its recommendation to the Board of Directors.

A. Right to a Hearing

The member has the right to a hearing if the member participated in an interview and:

1. Before the MPSC recommends that the Board of Directors places a member on Probation or declares a member Not in Good Standing
2. The MPSC rejects a member's request for release from Probation or Member Not in Good Standing
3. The MPSC recommends that the Board of Directors rejects a membership application as outlined in *Appendix A: Membership Application and Review*
4. The MPSC rejects a key personnel change application as outlined in *Appendix C: Membership Requirements for Histocompatibility Laboratories* or *Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs*

B. Waiving a Hearing

Members that do not respond to the hearing offer by the specified date waive their right to a hearing.

Members that waive their right to a hearing with the MPSC also:

- Accept the MPSC's recommendation
- Waive their right to appear before the Board of Directors

Members that waive their right to a hearing must still respond to any MPSC requests for written information and may provide any additional written information for the MPSC to consider. The MPSC Chair will set a date by which the member must provide any additional written information.

C. Hearing Format

Hearings will be conducted during an in-person MPSC meeting. The member and the OPTN have the right to be represented by an attorney during a hearing.

Hearings include all of the following:

1. Equal time for the member and the OPTN to present information
2. At least 60 minutes for the member to present information
3. At least 60 minutes for the OPTN to present information
4. At least 60 minutes for the MPSC to question any member and OPTN representatives present at the hearing
5. At least 10 MPSC members, which shall constitute a quorum for the purpose of any actions resulting from the hearing.

At least 2 of the 10 MPSC members must have expertise in the organ system or specific issue that is the subject of the review. If there are not at least 2 subject matter experts available from the MPSC, the MPSC Chair will select individuals with the appropriate expertise from other OPTN committees. These individuals may participate in all aspects of the hearing process, but they serve in an advisory role and do not have a vote.

D. Possible Hearing Outcomes

Following the hearing, the MPSC will determine an appropriate action and notify the member of the hearing outcome. Within 21 days of the hearing, the OPTN will provide the member with documentation of the reasons for the MPSC's decision and a transcript of the hearing.

If the MPSC recommends an adverse action, then the member will be entitled to appear before the Board of Directors.

If the MPSC determines the matter represents a potentially urgent and severe risk to patient health or public safety, the MPSC may recommend to the OPTN President that the OPTN Executive Committee considers the MPSC's recommendation to allow for a more timely resolution of the matter. The OPTN will notify the member following the hearing if the MPSC's recommendation also includes a recommendation that the OPTN Executive Committee considers the recommendation.

L.11. Appearances before the Board of Directors

Members and the MPSC Chair may appear before the Board of Directors prior to the Board of Directors taking a final action on an MPSC recommendation. Appearances before the Board of Directors are formal procedures that provide an opportunity for the MPSC Chair to explain the MPSC's recommendation and for a member to present specific reasons as to why the Board of Directors should not support the MPSC's recommendation.

If the OPTN President determines that an urgent and severe risk to patient health or public safety exists and that allowing the OPTN Executive Committee to consider the recommendation will allow for a more timely resolution of the matter, the OPTN President may permit the appearance to take place before the OPTN Executive Committee instead of the Board of Directors. In these instances, all requirements, considerations, and actions described in the sections that follow that pertain to appearances before the Board of Directors will apply to appearances before the OPTN Executive Committee.

A. Right to Appear before the Board of Directors

A member has the right to appear before the Board of Directors if the member has participated in a hearing and afterwards *one* of the following conditions is met:

- The MPSC recommended that the Board of Directors places the member on Probation or declares a member Not in Good Standing
- The MPSC rejected a member's request to be released from Probation or Member Not in Good Standing
- The MPSC recommended that the Board of Directors rejects a membership application as outlined in *Appendix A: Membership Application and Review*
- The MPSC rejected a key personnel change application as outlined in *Appendix C: Membership Requirements for Histocompatibility Laboratories* or *Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs*

B. Accepting or Waiving a Board of Directors Appearance

Members must accept or waive their right to appear before the Board of Directors within the period specified. Members that fail to respond to the offer of a Board of Directors appearance within the specified period waive their right to appear.

At the same time the member accepts its right to appear before the Board of Directors, the member must also provide its specific disagreements with the OPTN's findings of fact, conclusions, or procedural issues that the member plans to contest before the Board of Directors.

Members that waive their right to appear accept the MPSC's adverse action recommendation. Members that waive their right to appear may provide additional written information for the Board of Directors to consider. The OPTN President will set a date by which the member must provide any additional written information.

C. Scheduling a Board of Directors Appearance

The OPTN President will determine when a member's appearance before the Board of Directors will occur. Factors that will influence the scheduling of a member's Board of Directors appearance include, but are not limited to, *any* of the following:

- The urgency and severity of the issue

- Whether the member has taken appropriate actions that mitigate the urgency and severity of the risk
- The Board of Directors' meeting schedule

The OPTN will notify the member when the member is entitled to an appearance before the Board of Directors. The OPTN's offer notice will include all of the following:

1. The reason the member is entitled to an appearance before the Board of Directors
2. The reasons for the MPSC's recommendation to the Board of Directors
3. The date by which the member must accept or decline the offer
4. A summary of what the member should address during the interaction

D. Board of Directors Appearance Format

A member's appearance before the Board of Directors may be by teleconference or at an in-person Board of Directors meeting, as determined by the OPTN President.

The member and the OPTN have the right to be represented by an attorney during a Board of Directors appearance.

Board of Directors appearances include all of the following:

1. Equal time for the member and the MPSC Chair to present
2. At least 10 minutes for the member to present information to the Board of Directors
3. At least 10 minutes for the MPSC Chair to present information to the Board of Directors
4. At least 15 minutes for the Board of Directors to ask questions of the member and MPSC Chair

A majority vote of the Directors present at any meeting at which a quorum is present is required to approve an adverse action.

E. Burden of Proof

Appearances before the Board of Directors are to address specific disagreements with the findings of fact, conclusions, or procedural issues raised at any step in the review process. The member will have the burden of proving that the MPSC's recommendation lacks substantial basis or that such basis or the conclusions drawn are arbitrary, unreasonable, or capricious.

F. Possible Board of Directors Appearance Outcomes

At the conclusion of the Board of Directors appearance, the Board of Directors will approve the MPSC's recommendation or issue a lesser action and will notify the member of the outcome. Within 21 days of the Board of Directors appearance, the OPTN will provide the member with a written summary of the Board of Directors appearance.

If the Board of Directors approves an adverse action, the OPTN will issue a public notice and the member must provide additional notice within 30 days of receiving the Board of Directors appearance summary as required according to *Section L.12.D: OPTN Adverse Actions*.

L.12. OPTN Actions

The OPTN may impose actions based on a member's failure to comply with OPTN Obligations. The OPTN may impose a separate action for each noncompliance or may choose to impose a single action

for all related instances of noncompliance. The OPTN may also require a member to perform specific activities to address a noncompliance. The OPTN will document all actions in the member's compliance history.

A. Deferred Disposition

Deferred Disposition is a period to allow the member additional time to demonstrate improvement and its ability and willingness to meet OPTN Obligations. Only the MPSC may offer a member a Deferred Disposition period. The MPSC may offer a Deferred Disposition period at any time before a hearing and may offer a member more than one Deferred Disposition period during a review. Deferred Disposition does not apply to rejected membership applications.

During this period, the member must demonstrate compliance with OPTN Obligations, including implementation of and adherence to the member's corrective action plan or plan for quality improvement. The MPSC will specify the length of the Deferred Disposition period, and may end the Deferred Disposition period at any time if the MPSC determines, at its discretion, the member is not demonstrating sufficient improvement or is not adhering to the member's corrective action plan or plan for quality improvement. After the Deferred Disposition period, the MPSC will evaluate whether the member has demonstrated improvement and implemented sustainable corrective actions and will determine an appropriate action.

The member is not entitled to an informal discussion, interview, hearing or Board of Directors appearance to challenge the MPSC's decision not to offer, or to end, a Deferred Disposition period.

B. Types of Actions

The OPTN may offer Deferred Disposition or take any of the following actions:

- Close with No Action
- Issue a Notice of Noncompliance
- Issue a Letter of Warning
- Place a member on Probation
- Declare a member Not in Good Standing

These actions represent a range, from Close with No Action to Member Not in Good Standing. Close with No Action, Issuing a Notice of Noncompliance, and Issuing a Letter of Warning are non-adverse actions. Non-adverse actions do not require approval by the Board of Directors and are not made public. Probation and Member Not in Good Standing are adverse actions. Adverse actions are further described in *Section L.12.D: OPTN Adverse Actions*.

C. Determining Appropriate Action

Factors considered when determining the appropriate action include, but are not limited to, the extent to which:

- The member has demonstrated an awareness of and accountability for the noncompliance, including:
 - whether the member self-reported the noncompliance
 - whether the member took corrective action when learning of the noncompliance
- The noncompliance poses an urgent and severe risk to patient health or public safety
- The noncompliance poses or fails to avoid a substantial risk to the integrity of or trust in the OPTN

- Patient medical records or other documentation provide sufficient detail to determine the presence of mitigating factors at the time the noncompliance occurred
- The noncompliance demonstrates lack of stewardship of donated organs
- The noncompliance is likely to recur
- The member has demonstrated previous and ongoing compliance with OPTN Obligations

D. OPTN Adverse Actions

Probation and Member Not in Good Standing are the two OPTN adverse actions. Adverse actions are OPTN membership designations that must be approved by the Board of Directors and require public notice.

A member’s ongoing failure to comply with OPTN Obligations or a member’s failure to promptly address a potentially urgent and severe risk to patient health or public safety may result in the MPSC recommending that the Board of Directors takes an adverse action against the member.

Before the Board of Directors approves an adverse action, members have the right to an interview and a hearing with the MPSC and an appearance with the Board of Directors.

The Executive Committee will consider MPSC recommendations to release a member from an adverse action.

1. Probation

a. Loss of OPTN Privileges

Members placed on Probation do not lose any OPTN membership privileges.

b. Probation Notification Requirements

When the Board of Directors places a member on Probation, the OPTN will provide notice to the public. This may include but is not limited to communication using the OPTN website. The OPTN may issue other public notices about the Probation as determined by the Board of Directors.

At its discretion, and based on the circumstances surrounding the noncompliance, the MPSC may recommend that the Board of Directors suspends, modifies, or adds to the requirements regarding the notice that members on Probation must provide. After the OPTN notifies the member that it has been placed on Probation, the member must provide notice within 30 days as instructed by the Board of Directors, if the Board of Directors acted on an MPSC recommendation regarding providing notice. If the MPSC did not provide, or the Board of Directors did not act on, recommendations for providing notice, then the member must provide notice within 30 days according to Table L-1 below.

Table L-1: Probation Notification Requirements

<u>If the member is a...</u>	<u>Then the member must provide notice to ...</u>
<u>Transplant hospital</u>	<u>All patients, as defined in these Bylaws, of the designated transplant program receiving Probation, including any new transplant program patients, during the entire Probation period. The notices must be provided in writing in each patient’s spoken language, and as specified by the Executive Committee or Board of Directors. The transplant program must retain a copy of the notification letter it provided to each individual patient.</u>

<u>If the member is a...</u>	<u>Then the member must provide notice to ...</u>
<u>OPO</u>	<u>All hospitals that have a contractual agreement with the OPO in the OPO's Donation Service Area (DSA).</u>
<u>Histocompatibility laboratory</u>	<u>All members that have a contractual agreement with the laboratory.</u>

These notices must communicate that the Board of Directors has placed the member on Probation and must also refer to the public notice about this action distributed by the OPTN.

The member must provide the OPTN Contractor a list of each patient and organization to whom it sent notice, along with an example of the notice it sent, by the date specified by the OPTN Contractor.

c. Probation Monitoring Requirements

The MPSC will monitor members throughout the Probation period.

2. Member Not in Good Standing

a. Loss of OPTN Privileges

Members Not in Good Standing are prohibited from voting in OPTN matters and any personnel associated with the member are prohibited from serving on OPTN Committees and the Board of Directors. However, members designated Members Not in Good Standing must continue to comply with their OPTN member responsibilities.

b. Member Not in Good Standing Notification Requirements

When the Board of Directors declares a member Not in Good Standing, the OPTN will provide notice to the public. This may include but is not limited to communication using the OPTN website. The OPTN may issue other public notices about the Member Not in Good Standing designation as determined by the Board of Directors.

After the OPTN notifies the member that it has been declared Not in Good Standing, the member must provide notice within 30 days according to Table L-2 below.

Table L-2: Member Not in Good Standing Notification Requirements

<u>If the member is a...</u>	<u>Then the member must provide notice to ...</u>
<u>Transplant hospital</u>	<u>All transplant hospital patients as defined in these Bylaws, including any new transplant hospital patients, during the entire effective period of the Member Not in Good Standing designation. The notices must be provided in writing, in each patient's spoken language, and as specified by the Executive Committee or Board of Directors. The transplant program must retain a copy of the notification letter it provided to each individual patient.</u>
<u>OPO</u>	<u>All hospitals that have a contractual agreement with the OPO in the OPO's Donation Service Area (DSA).</u>
<u>Histocompatibility laboratory</u>	<u>All members that have a contractual agreement with the laboratory.</u>

These notices must communicate that the Board of Directors has declared the member Not in Good Standing and must also refer to the public notice about this action distributed by the OPTN.

The member must provide the OPTN Contractor a list of each patient and organization to whom it sent notice, along with an example of the notice it sent, by the date specified by the OPTN Contractor.

c. Member Not in Good Standing Monitoring Requirements

The MPSC will monitor members throughout the Member Not in Good Standing period, which will include the following:

- One or more unannounced on-site reviews
- One or more presentations by the member before the MPSC to provide an update on the member's corrective action plan and ongoing compliance with OPTN Obligations

3. Release from Probation or Member Not in Good Standing

a. Request for Release

A member on Probation or a Member Not in Good Standing must submit a written request to the OPTN requesting release from the adverse action. The MPSC will consider the member's request and will forward any recommendations to release a member from an adverse action to the Executive Committee for approval.

A member on Probation or a Member Not in Good Standing may request release from the adverse action when at least nine months have passed since *both* of the following occurred:

1. The MPSC approved the member's corrective action plan
2. The Board of Directors approved the adverse action

The MPSC may consider member requests to be released from an adverse action at any MPSC meeting where a quorum is present.

b. Burden of Proof for Release

When determining whether to release a member from Probation or a Member Not in Good Standing, the MPSC will consider whether the member can demonstrate *all* of the following:

1. It has implemented and adhered to its corrective action plan
2. Its corrective action plan is effective and sustainable
3. Its ongoing compliance with OPTN Obligations

The burden is on the member at all times to demonstrate that release from Probation or Member Not in Good Standing is appropriate.

c. Possible MPSC Review Outcomes

If the MPSC approves the member's request for release from Probation or Member Not in Good Standing, the MPSC will forward its recommendation to the OPTN Executive Committee. The OPTN President will determine the time and format for the OPTN Executive Committee to consider the MPSC's request.

If the MPSC rejects the member's request for release from Probation or Member

Not in Good Standing, the MPSC must offer the member an interview.

d. Possible OPTN Executive Committee Review Outcomes

The OPTN President will determine the time and format, either in person or by teleconference, of the review. The OPTN Executive Committee will act on the MPSC's recommendation within 45 days of the date that the MPSC recommends the action.

If the OPTN Executive Committee approves the MPSC's recommendation and releases the member from Probation or Member Not in Good Standing, the OPTN will provide notice to the public. This may include, but is not limited to, communication using the OPTN website. The MPSC may still require ongoing monitoring of the member even after the OPTN Executive Committee has released the member from Probation or Member Not in Good Standing.

If the OPTN Executive Committee rejects the MPSC's recommendation to release the member from Probation or Member Not in Good Standing, the OPTN will provide the member with a written summary of the reasons for declining the MPSC's recommendation. The member may submit another request to be released from Probation or Member Not in Good Standing to the MPSC only after it has addressed all of the reasons that the OPTN Executive Committee declined the MPSC's recommendation.

4. Downgrading Member Not in Good Standing

At its discretion, the MPSC may recommend that the Board of Directors downgrades a Member Not in Good Standing designation to Probation. The OPTN President will determine the time and format for the OPTN Board of Directors to consider the MPSC's request.

The burden is on the member at all times to demonstrate that the lesser adverse action is appropriate. The member is not entitled to an informal discussion, an interview, a hearing or a Board of Directors appearance if the MPSC or the Board of Directors does not support downgrading the Member Not in Good Standing to Probation.

If the Board of Directors downgrades a Member Not in Good Standing to Probation, the OPTN will provide notice to the public. This may include, but is not limited to, communication using the OPTN website. After the OPTN notifies the member that it has been downgraded to Probation, the member:

1. Will regain the ability to vote in OPTN matters
2. Will regain the ability for any personnel associated with the member to serve on OPTN committees and the OPTN Board of Directors
3. Must comply with all Probation notification requirements
4. May request release from Probation when at least 3 months have passed since the Board of Directors downgraded the member to Probation

L.13. Secretary of HHS Notice and Actions

A. Secretary's Access to Information

The medical peer review privilege will not be extended to withhold any document from the Secretary of HHS, or the Secretary's designee. The OPTN Contractor is required to provide the Secretary with any information acquired or produced under the OPTN Contract, including information that would otherwise be protected by the medical peer review privilege. As specified

in the OPTN Final Rule, the OPTN Contractor will provide any data or documentation to the Secretary that the Secretary requests, in the format requested by the Secretary.

B. Health Resources and Services Administration (HRSA) Representation

The Project Officer for the OPTN Contract and the Director of the Division of Transplantation within the Health Resources and Services Administration (HRSA) of HHS, serve as *ex-officio*, non-voting members of the OPTN Executive Committee and Board of Directors. As non-voting members of the Executive Committee and Board of Directors, they, or their designees, are granted full access to all deliberations, determinations, and actions. Representatives of HRSA are also *ex-officio*, non-voting members of the Membership and Professional Standards Committee (MPSC) and granted full access to all MPSC deliberations, determinations, and actions as well. Other designees of the Secretary may also attend OPTN meetings.

C. Special Secretarial Reviews

At the request of the Secretary of HHS, the OPTN will conduct special reviews of members when the Secretary has reason to believe that the member may not be in compliance with the OPTN Final Rule or may be acting in a way that poses a risk to patient health or public safety. A Special Review is a review of the member in the manner and within the period specified by the Secretary. This may include, but is not limited to, requests for root cause analysis, corrective action, and due process proceedings completed in the period and as specified by the Secretary. Members must fully comply with all OPTN Contractor requests as part of a Special Review.

D. OPTN Recommendations and Requests to the Secretary

The OPTN Board of Directors will advise the Secretary of the results of any ongoing or periodic reviews and evaluations, or Secretarial-directed reviews, of member OPOs and transplant hospitals which, in the opinion of the Board of Directors, indicate noncompliance with OPTN Obligations or indicate a risk to the health of patients or to the public safety, and will provide any recommendations for appropriate action by the Secretary. Appropriate actions include, but are not limited to, those described in the OPTN Final Rule, as described in Section *L.13.E Secretarial Actions* that follows.

At any time, the Board of Directors may make recommendations to the Secretary for specific actions, on its own or after receiving a recommendation from the MPSC.

A member's failure to come into compliance with OPTN Obligations while designated as a Member Not in Good Standing may result in the Board of Directors recommending that the Secretary take action against the member.

If the Board of Directors finds, based on available evidence, that the member's potential violation poses a severe and urgent risk to patient health or public safety, the Board of Directors may recommend that a Secretarial action be made effective immediately, before completing any required interview or hearing.

E. Secretarial Actions

The Secretary may impose sanctions or take other appropriate action at any time when a member poses a risk to the health of patients or to the public safety.

Consistent with the OPTN Final Rule, the Secretary can take action if an OPTN member:

1. Violates the National Organ Transplant Act (NOTA).
2. Violates the OPTN Final Rule, 42 CFR Part 121.

3. Violates OPTN policies that have been approved by the Secretary as mandatory. For more information on mandatory policies, see *Section L.13.F: OPTN Policies Approved by the Secretary as Mandatory.*
4. Engages in behavior that poses a risk to patient health or public safety.

Termination of membership requires Secretarial approval. Membership can only be terminated if the OPTN member no longer meets the requirements for membership as described in the OPTN Final Rule.

In addition to termination of membership in the OPTN described above, the Secretary may take appropriate actions, which include, but are not limited to:

1. Removal of one or more of the member's designated transplant programs. After designated transplant program status is removed, the program will no longer be eligible to receive organs for transplantation within the OPTN.
2. Termination of the member's reimbursement under Medicare or Medicaid.
3. Termination of a transplant hospital's participation in Medicare or Medicaid.
4. Request for information from the OPTN.
5. Any other action that the Secretary considers necessary.

If Secretarial action has been taken against a member, only the Secretary of HHS can restore its unrestricted membership privileges. If Secretarial action has been taken against a member and the member has presented evidence to the MPSC that it has fully complied with OPTN Obligations, including completion of any actions prescribed as a result of the adverse action, the MPSC may recommend that the Secretary of HHS restore unrestricted membership privileges. If a membership was suspended or terminated by the Secretary, the member must complete and submit an application for OPTN membership.

Actions recommended by the OPTN Board of Directors and taken by the Secretary for noncompliance with mandatory policies will not become effective until the member has waived its right to a hearing or the applicable hearing proceedings have been concluded.

F. OPTN Policies Approved by the Secretary as Mandatory

When and if the Secretary approves any OPTN policies as mandatory, the U.S. Department of HHS will publish lists of OPTN Policies in the Federal Register, indicating which policies are enforceable under Sec. 121.10 of the OPTN Final Rule or are subject to potential sanctions of Section 1138 of the Social Security Act. Violations of such policies can result in sanctions or other actions by the Secretary.

Section 121.11(b)(2) of the OPTN Final Rule requires OPTN members that are OPOs and transplant hospitals to submit to the OPTN, to the Scientific Registry, as appropriate, and to the Secretary certain information in the form required and in accordance with the schedule prescribed.

Data specified by the Secretary under this authority includes all data requested on forms approved by the Office of Management and Budget (OMB), including all applications reviewed by the OPTN. The Secretary may take an action described above for failure of a member to submit accurate and complete data as required by the Secretary (including on OMB-approved forms). Failure to submit accurate and complete data may also result in civil or criminal penalties.

L.14. Costs and Expenses

A. Reimbursement of OPTN Contractor Costs and Expenses

Reasonable costs and expenses of conducting interviews and hearings as described in these Bylaws will be paid by the member. Costs and expenses may include, but are not be limited to all of the following:

1. Travel and lodging expenses of member, volunteers, and OPTN Contractor representatives
2. Compensation of OPTN Contractor representatives
3. Court reporter fees
4. The costs of preparing copies of the hearing record
5. The member's costs of preparing for and attending the interview or hearing
6. The OPTN's costs of obtaining and compiling evidence and exhibits

OPTN Contractor representatives may include:

- OPTN Contractor staff
- Outside counsel
- Consultants
- Volunteers
- Expert witnesses

The OPTN will decide the nature and amount of expenses to be reimbursed. Reasonable costs and expenses may be estimated and billed, wholly or partially, to the member in advance or may be billed, wholly or partially, to the member as the matter is reviewed. If actual costs and expenses otherwise reimbursable by the member for the entire matter before the MPSC are less than \$500.00, or if member is not determined to be in violation of OPTN Obligations, no reimbursement will be due from the member. In addition, any amounts previously reimbursed or deposited will be returned. If the member has multiple matters before the MPSC within any 12-month period, the \$500.00 amount will apply to all such matters cumulatively.

B. Reasonable Costs and Expenses

Reasonable costs and expenses resulting from enforcement of OPTN Obligations will be reimbursed by the member, including any of the following:

1. Conducting other than routine on-site reviews
2. Reviewing and monitoring corrective action plans or plans for quality improvement
3. Conducting due process proceedings
4. Monitoring and conducting evaluations of transplant programs with lower than expected survival rates as described in *Section D.12.A: Transplant Program Performance* of these Bylaws, including on-site visits and monitoring plans for quality improvement

C. Advanced Deposit for Reimbursable Costs and Expenses

The Executive Director may require that the member make and maintain a deposit with the OPTN Contractor in an amount equal to the currently projected costs and expenses of any of the following:

1. OPTN Contractor on-site reviews
2. OPTN member peer on-site reviews
3. The interview
4. The hearing

The failure to make the required deposit within 10 days after the Executive Director requests an advance deposit will be considered a waiver of the member's interview or hearing rights. Following such a waiver, the MPSC and the Board of Directors may impose any actions, including adverse actions.

D. Default in Payment of Reimbursable Cost and Expenses

Any member who fails to reimburse costs and expenses within 30 days after receiving notice may be referred to the Secretary for termination of OPTN membership.

Appendix M: Definitions

Informal Discussion

~~An informal discussion is not an adverse action or an element of due process. An informal discussion is conducted according to the principles of confidential medical peer review, as described in *Appendix L* of these Bylaws. An informal discussion may be with the MPSC, a subcommittee, or a work group, as determined by the MPSC. An informal discussion may be held with a member regarding performance reviews, or when a transplant program is seeking approval for a transplant surgeon through the predominantly pediatric pathway.~~

[Subsequent heading numbers, and any table captions and cross-references, affected by the re-numbering of this policy will also be changed as necessary.]

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