

At-a-Glance

- **OPTN Bylaws Substantive Rewrite of Appendix A: *Application and Hearing Procedures for Members and Designated Transplant Programs***

- **Affected/Proposed Policy:** This is a substantive rewrite of the current *Appendix A: Application and Hearing Procedures for Members and Designated Transplant Programs*. This rewrite will become the new Appendix L: Reviews, Actions, and Due Process, to fit with the new organization of the OPTN Bylaws Plain Language Rewrite that went to public comment starting December 2, 2011.

- **Membership and Professional Standards Committee (MPSC)**

This rewrite affects the current *Appendix A: Application and Hearing Procedures for Members and Designated Transplant Programs*. This represents a substantive rewrite of the process and procedures for reviewing potential violations of and non-compliance with OPTN obligations. All content of the former Appendix A also underwent a plain language rewrite and reorganization for clarity and usability, and will be presented as the new *Appendix L: Reviews, Actions, and Due Process*.

- **Affected Groups:**

Directors of Organ Procurement
Hospital Administrators
Lab Directors/Supervisors
OPO Executive Directors
OPO Medical Directors
OPO Coordinators
Transplant Administrators
Transplant Data Coordinators
Transplant Physicians/Surgeons
PR/Public Education Staff
Transplant Program Directors
Transplant Social Workers
Organ Recipients
Organ Candidates
Living Donors
Donor Family Members
General Public

- **Number of Potential Candidates Affected:**

All potential candidates

- **Compliance with OPTN Key Goals and Final Rule:**

Because the OPTN Bylaws are the guiding document that includes the requirements for all OPTN Members, including Transplant Hospitals, OPOs, and Histocompatibility Laboratories, the OPTN Bylaws Substantive Rewrite of Appendix A could impact all of the following OPTN Key Goals and related strategic plan goals through increased understanding of membership requirements and adherence to OPTN requirements:

- Patient health and public safety
- Equitable access to organs
- Improvement of post-transplant survival
- Increased living donor safety
- Operational effectiveness of the OPTN

- **Specific Requests for Comment:**

Please comment on the entire new Appendix L, including the reorganization, usability, and clarity. Please comment specifically on any or all of the following updates to Appendix L:

- Review pathways
- Special secretarial reviews
- Deferred Disposition
- Notification Requirements

OPTN Bylaws Substantive Rewrite of Appendix A: *Application and Hearing Procedures for Members and Designated Transplant Programs*

Affected/Proposed Policy: Entire current *Appendix A: Application and Hearing Procedures for Members and Designated Transplant Programs*. The current Appendix A is being rewritten with substantive changes and in plain language as the new *Appendix L: Reviews, Actions, and Due Process*. The new Appendix L will be integrated into the new OPTN Bylaws after the OPTN Bylaws Plain Language Rewrite that went to public comment starting December 2, 2011 is approved by the Board of Directors.

Membership and Professional Standards Committee (MPSC)

Summary and Goals of the Proposal:

The OPTN Bylaws Substantive Rewrite of Appendix A accomplishes the following objectives:

- Outlines the three possible review pathways for potential violations of OPTN obligations and requirements.
- Clarifies the role of Secretary of the U.S. Department of Health and Human Services (HHS) in reviewing and acting on potential violations, particularly those that may pose a threat to patient health and public safety.
- Clarifies when the Secretary may request that the OPTN Contractor perform special reviews of a Member for non-compliance.
- Adds a new monitoring tool to aid Members who may need time and assistance from the OPTN to come into compliance.
- Clarifies notice requirements after an adverse action is taken by the OPTN.
- Provides information to Members about their rights in plain language with logical organization.

Background and Significance of the Proposal:

The OPTN Bylaws Substantive Rewrite of Appendix A was undertaken to offer enhanced review pathways and clarification of the due process provisions and Members' rights. This rewrite represents a collaboration with all the following stakeholders:

- *HRSA representatives*
- *MPSC Bylaws Due Process Substantive Rewrite Workgroup*
- *UNOS staff, including subject matter experts from OPTN/UNOS Committees who reviewed relevant sections*

The strengths of this proposal are that the OPTN and UNOS will have vastly improved Bylaws and due process provisions that are easier to read and understand. The reorganization enables the transplant community to more quickly and easily find the information needed.

Supporting Evidence and/or Modeling:

This proposal does not require supporting evidence or modeling.

Expected Impact on Living Donors or Living Donation:

This proposal is not expected to have any direct impact on living donors or living donation.

Expected Impact on Specific Patient Populations:

This proposal is not expected to have any impact on any specific patient population.

Compliance with OPTN Key Goals and the Final Rule:

Because the OPTN Bylaws is the guiding document that includes the requirements for all OPTN Members, including Transplant Hospitals, OPOs, and Histocompatibility Laboratories, the OPTN Bylaws Substantive Rewrite of Appendix A could impact all of the following OPTN Key Goals and related strategic plan goals through increased understanding of Membership requirements and due process rights:

- Patient health and public safety
- Equitable access to organs
- Improvement of post-transplant survival
- Increased living donor safety
- Operation effectiveness of the OPTN

Membership and Professional Standards Committee’s Plan for Evaluating the Proposal:

Input from the public comment period and any comments sent to the bylawsrewrite@unos.org email will be evaluated by the MPSC initially at its March 2012 meeting, and then at a special meeting in April. The MPSC will address any concerns about the rewrite before presenting it to the Board of Directors at its June 2012 meeting.

Additional Data Collection:

This proposal does not require additional data collection.

Expected Implementation Plan:

This proposal will not require programming in UNETsm.

Communication and Education Plan:

Communication Activities			
Type of Communication	Audience(s)	Deliver Method(s)	Timeframe
E-newsletter	OPTN Members	Mass email	March-April 2012
Q&A Interview Video about the OPTN Bylaws Substantive Appendix A Rewrite	Members, general public, transplant community, staff	Video posted on UNOS website	March-April 2012
FAQ sheet	Members, general public, transplant community, staff	Posted on UNOS website	March 2012

Education/Training Activities			
Education/Training Description	Audience(s)	Deliver Method(s)	Timeframe and Frequency
2 scheduled Live Meetings	OPTN Regions	Live Meeting with question and answer session following	Feb-March 2012
Short presentation at regional meetings	Regional councillors	MPSC regional representative speaks about the OPTN Bylaws Plain Language Rewrite	During public comment period

Compliance Monitoring:

The monitoring and evaluation of Member obligations will not be affected by the OPTN Bylaws Substantive Rewrite of Appendix A. However, the review of Members who are non-compliant with OPTN obligations is changed.

The review of potential violations and non-compliance with OPTN obligations will be affected in the following ways:

- A new Expedited Review pathway enables potential violations to be reviewed in an expedited period.
- Enhanced notification to the Secretary of HHS in instances where a potential violation may pose an urgent and severe risk to patient health and public safety.
- A new Deferred Disposition provides time to the Member to demonstrate the ability and willingness to come into compliance.
- Streamlined notification requirements required by a Member receiving the adverse action of Probation or Member Not in Good Standing.

Bylaws Proposal

The proposed changes to Appendix A involve substantive changes and new formatting that would typically be presented with underlines and strikeouts. For your convenience and ease in reading, the proposed substantive changes are presented intact within the new proposed Appendix L.

Appendix L: Reviews, Actions, and Due Process

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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 Executive Director 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 Executive Director. 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. Executive Director Authority

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 authorities and 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 Executive Director 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 Executive Director 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.

Records of and documents associated with the review activity, deliberations, and actions of the OPTN Contractor, any OPTN Committee, the Executive Committee, and the Board will, as appropriate and to the extent permitted by law, be confidential and protected by the medical peer review privilege. 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 Executive Director, the OPTN Board of Directors, the MPSC, or any standing subcommittee of the MPSC 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 Executive Director 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 to assist the Executive Director in conducting the preliminary investigation of any potential violation, the Member must respond to requests from the Executive Director. 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 risk to patient health or public safety is urgent and severe, the Executive Director will refer the matter to the MPSC Chair within 24 hours.

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

B. Notice to the Secretary after Preliminary Investigation

If the Executive Director refers the potential violation 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 Executive Director 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 Executive Director 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 Executive Director’s 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 Executive Director 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 Executive Director 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 Executive Director 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 Executive Director 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 completion of the imminent threat review investigation, 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*. 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 approved and issued by the Hearing Panel 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 Executive Director 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 recommendations and, if the recommendation is for an adverse action, then the OPTN Executive Director will:

- a) Provide notice to the Member of the Expedited Review Committee's recommendation within 24 hours by an approved method as described in *Section L.4*.
- b) 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, a special in-person meeting may be required, or at the discretion of the MPSC Chair, 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 approved by the Hearing Panel and 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 Executive Director will complete a routine review investigation of the matter within 21 days of the initial determination that the potential violation will proceed through the Routine Review pathway.

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.A: Requesting an Interview* following notice of the Routine Review Committee's determination. If the Member waives its rights to an interview, the MPSC may proceed to issue its recommendation for an adverse action or Letter of Reprimand.

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 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 approved by the Hearing Panel and 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 *Section L.1*.
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 Executive Director 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 submitted 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:

- a) 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.

- b) Any recent changes in the Member's staffing, including changes in those responsible for oversight of the Member.
- c) 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

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 Executive Director that documents correction of the non-compliant activity throughout the period of Probation.

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.

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

- i. 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.

3. Notification Requirements of Probation and 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 patients at the Transplant Hospital as defined in these Bylaws.
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.

The Member must send the notice to each new patient as defined in these Bylaws during the entire effective period of the adverse action. The notice to patients must be provided in writing, in each patient's spoken language, and as specified by the Executive Committee or Board of Directors. The Board may impose additional requirements regarding the form and timing of the notification.

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 actions 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.

1. *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.

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 an Interview

A Member who fails to request an interview within the specified time waives any right to an interview. The Member must submit its written interview request to the Executive Director using one of the approved methods described in *Section L.4*.

The failure to request 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.

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 a Hearing

The Member must submit its written hearing request to the Executive Director using one of the approved methods described in *Section L.4*. A Member who fails to request a hearing within the specified time waives any right to a hearing.

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.

The failure to request 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.

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*.

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

A member of the MPSC or Board 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 Executive Director 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:

1. Call and examine witnesses.

2. Introduce exhibits.
3. Cross-examine any witness on any matter relevant to the issue.
4. Impeach any witness.
5. 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 Executive Director or 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:

1. Issue a recommendation for an adverse action.
2. Issue a lesser action.
3. 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 MPSC Chair 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*. 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*. 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*.

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*, 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 and the hearing will be held at the Member’s expense, as outlined in *Section L.24: 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*. 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.10.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.

Additions to *Appendix M: Definitions*:

Patient

In these Bylaws, patient is defined to include *all* of the following:

1. Potential candidates and donors undergoing the cited Hospital's or Designated Transplant Program's evaluation process.
2. Candidates on the waiting list of the cited Hospital or Designated Transplant Program.
3. Potential living donors undergoing the cited Transplant Hospital's or Designated Transplant Program's evaluation process and awaiting donation.
4. Living donors being followed by the cited Transplant Program.
5. Recipients being followed by the cited Transplant Hospital or Designated Transplant Program.

Corrective Action Plan (CAP)

Corrective Action is an action taken to correct noncompliance or other violations of OPTN obligations. A CAP is a plan that includes changes that must be made to bring expected future performance of a Member in compliance with OPTN obligations and to correct the cause of the detected error or deficiency.

Plan for Quality Improvement (PQI)

A Plan for Quality Improvement (PQI) establishes measurable objectives based on priorities identified through the use of established criteria for improving quality and safety of clinical services provided by OPTN Members.