

ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK (OPTN)

BYLAWS

APPENDIX A

**APPENDIX A TO BYLAWS
OPTN**

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APPENDIX A TO BYLAWS OPTN

Application and Hearing Procedures for Members and Designated Transplant Programs

1.01A - Nature of Membership/Designated Transplant Program Status

Any organ procurement organization, transplant hospital, independent histocompatibility laboratory, or organization, institution, or individual with an interest in the fields of organ donation or transplantation that demonstrates compliance with all applicable OPTN membership criteria shall be entitled to become a Member upon completion of the prescribed application process and satisfaction of applicable requirements. Additionally, in the case of Transplant Hospital Members that request status as a designated transplant program for one or more organs, the Member shall be entitled to attain such status upon completion of the prescribed application process and satisfaction of applicable requirements. Membership shall be extended only to institutions, agencies, laboratories, entities, and individuals who consistently meet the membership qualifications and requirements established from time to time by the Board of Directors. The rights, privileges, and responsibilities of Members as set forth in the OPTN Charter, Bylaws, and Policies may be amended by the Board of Directors, with approval if and as necessary from the Secretary of the Department of Health and Human Services (HHS), from time to time. See Figure A-1 for a general overview of the application process for membership in the OPTN. OPTN designated transplant program status will not be granted for types of clinical, vascularized organ transplantation for which the OPTN has not yet established criteria. In order to initiate or conduct clinical, vascularized organ transplantation for which there are no established criteria, including but not limited to multi-visceral organ transplants, an institution must be a OPTN member transplant center approved for transplantation of at least one other organ; in the case of abdominal multi-visceral transplants, the approved organ must be liver.

1.02A - Duration of Membership

The term of an OPO, Transplant Hospital, or Histocompatibility Laboratory Member shall be for an indefinite period, provided that a failure to conform to membership requirements (as established from time to time by the Board of Directors with any necessary approval from the Secretary of HHS) shall be cause for corrective action as described in Section 2 of this Appendix A, which may impact OPTN membership status, and a failure to qualify as an OPTN Member shall be cause for removal pursuant to Articles 1.10 and 1.11 of the Bylaws. The term of Medical/Scientific Members; Public Organization Members; Business Members; or Individual Members shall be two years, provided that a failure to qualify as an OPTN Member shall be cause for removal pursuant to Articles 1.10 and 1.11 of the Bylaws. Any of these Members may serve for successive terms upon application and approval for such term. A Medical/Scientific Member; Public Organization Member; Business Member; or Individual Member may resign at any time by written notice to the Executive Director.

1.03A - Procedures upon Application for Membership

- (1) **General Procedure:** The Membership and Professional Standards Committee shall investigate and consider under confidential medical peer review each application for membership and designation as a transplant program and shall adopt and transmit recommendations thereon to the Board of Directors.
- (2) **Application Form:** Each application for membership and designation as a transplant program shall be in writing, submitted on the prescribed form approved by the Membership and Professional Standards Committee, and signed by the applicant.

- (3) **Content:** The application form shall include:
- (a) **Acknowledgment and Agreement:** A statement that the applicant has received and read the current Charter, Bylaws, and Policies and that the applicant agrees: (i) to be bound by the terms thereof, as amended, if the applicant is granted membership and/or designated transplant program status and (ii) to be bound by the terms thereof in all matters relating to consideration of the application without regard to whether or not the applicant is granted membership or designated transplant program status.
 - (b) **Qualifications:** Detailed information and supporting documentation, as may be specified by the Membership and Professional Standards Committee (MPSC) from time to time and described in the application form, concerning the applicant's qualifications, including information in satisfaction of the basic qualifications specified in Article 1 of the Bylaws and the Criteria for Membership (Appendix B) regarding applicable membership requirements. This shall include, by way of example and without in any way limiting information that may be required in the application, submission of a:
 - (1) Plan for Continuing Policy Compliance that reports results from an assessment by the named primary physician and/or surgeon for transplant programs designated to perform organ transplants regarding involvement of any of the program's physicians or surgeons in prior transgressions of UNOS requirements and plans to ensure that the improper conduct is not continued.

NOTE: OPTN Bylaws, Appendix A, Section 1.03A (Procedures upon Application for Membership) shall be effective pending distribution of appropriate notice and programming in UNetsm. (Approved at the March 2007 Board of Directors Meeting)

- (c) **Information on Liability Insurance Coverage:** For OPO, Transplant Hospital, and Histocompatibility Laboratory Members, information as to whether the applicant has currently in force liability insurance with at least \$1,000,000 limits of coverage per occurrence. Coverage must be provided by an insurer that is either licensed or approved by the insurance regulatory agency of the state in which the applicant's principal office is located. In lieu of insurance coverage, evidence of equivalent coverage through a funded self-insurance arrangement shall suffice. At the request of the organization that operates the OPTN under contract with HHS (OPTN Contractor), the applicant or member shall furnish a current certificate of insurance.
- (d) **Administrative Remedies:** A statement whereby the Member agrees that, when an adverse ruling is made with respect to membership or designated transplant program status, the Member will exhaust the administrative remedies afforded by these Bylaws and applicable Federal regulations before resorting to formal legal action.
- (e) **Release of Information to HHS:** A statement whereby the Member authorizes the release of any and all information to HHS (directly or through the OPTN Contractor) regarding applications for membership or designation as a transplant program in the OPTN, and activities for monitoring and enforcing OPTN membership criteria, policies, and Federal regulations as described in these Bylaws.

1.04A - Processing the Application

- (1) **Applicant's Burden:** The applicant shall have the burden of producing adequate information for a proper evaluation of the applicant's qualifications.

- (2) **Statement of Release and Immunity From Liability:** The following are express conditions applicable to any applicant during the period membership is sought and to any Member during the term of membership. By applying for membership an applicant expressly accepts these conditions during the processing and consideration of the application, regardless of whether or not the applicant is granted membership or designation as a transplant program.
- (a) To the fullest extent permitted by law, the applicant or Member extends absolute immunity to, and releases from liability, the OPTN Contractor and its representatives and any third party with respect to any and all civil liability which might arise from any acts, communications reports, recommendations, or disclosures involving an applicant or Member, performed, made, requested, or received by the OPTN Contractor and its representatives, to, from, or by any third party, including other Members concerning activities within the scope of the OPTN Contract relating but not limited to:
- (1) applications for membership or designation as a transplant program;
 - (2) 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;
 - (3) hearings and appellate reviews;
 - (4) other committee activities relating to the membership status or status as a designated transplant program of either an applicant or a Member and concerning statements, investigations, materials provided, or inquiries, oral or written, relating to an applicant's or Member's qualifications, as well as the inspection of all records and documents that may be material to such questions.
- (b) Any act, communication, report, recommendation or disclosure, with respect to any such applicant or Member made in good faith and at the request of an authorized representative of the OPTN Contractor, anywhere at anytime, for the purposes set forth in (a) above shall be privileged as components of OPTN medical peer review to the fullest extent permitted bylaw. Such peer review privilege shall extend to employees of the OPTN Contractor and its authorized representatives, and to any third parties who either supply or are supplied information and to any of the foregoing authorized to receive, release or act upon the same.
- (c) As used in this section, the term "OPTN Contractor and its representatives" means the corporation currently operating the OPTN under contract with HHS, its officers, its Board of Directors, and their appointed representatives or employees, consultants to the OPTN Contractor, the Contractor's attorney and his or her partners, assistants or designees, and all members, organizations or other persons who have any responsibility for obtaining or evaluating the applicant's or Member's qualifications and/or acting upon his or her application or membership or designated transplant program status and any authorized representative of any of the foregoing.
- (d) As used in this section, the term "third parties" 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 or who have requested such information from the OPTN Contractor and its authorized representatives.

- (e) 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.

- (3) **Verification of Information:** The applicant shall deliver a completed application (including the supporting documentation and such other information that may be relevant to consideration of the applicant's qualifications) to the Chairman of the Membership and Professional Standards Committee or Executive Director or the designated representative of either of them, who shall in timely fashion seek to collect or verify the qualification evidence submitted. The Chairman or the Executive Director or the designated representative of either of them shall promptly notify the applicant of any problems in obtaining the information required and it shall then be the applicant's obligation to obtain the required information.

Designated staff representatives will conduct a preliminary review of all applications (including the required support documentation and such other information that may be relevant to consideration of the applicant's qualifications) for the purpose of assessing completeness before presenting it to the Membership and Professional Standards Committee (MPSC) for review. This review will be conducted for all application types. Applications that are not appropriately completed and that are missing the key supporting information and/or documents will not be forwarded to the MPSC for review. Key information and/or documents for applying for changes in key personnel include, without limitation, physician or surgeon Curriculum Vitae, letter of commitment, letter(s) of reference, transplant log, and Board certification, as well as surgeon transplant operative notes, where applicable, and procurement notes and/or log. Key information and/or documents for applications for Membership or designated transplant program status include, without limitation, OPO or Histocompatibility Laboratory contract/letter, where applicable, in addition to the information/documentation associated with key personnel listed above. Applications not completed in the appropriate manner will be deemed "incomplete." The Chair or the Executive Director or the designated representative of the MPSC will notify the applicant of the incomplete status as well as their available options.

- (4) **Membership and Professional Standards Committee (MPSC):** The Membership and Professional Standards Committee shall review the complete application, the supporting documentation, and such other information available to it that may be relevant to consideration of the applicant's qualifications. The Chairman or the Executive Director shall prepare for the Board of Directors on the prescribed form a written report and recommendations as to whether membership and/or designated transplant program status is recommended. The reason for each recommendation shall be stated and supported by references to the completed application and all other documentation considered by the Committee, all of which shall be included with the report. Any minority views shall also be reduced to writing, supported by reasons and references, and included with the majority report.

The MPSC or an Ad Hoc Subcommittee of at least four committee members appointed by the Chairperson of the MPSC at his/her discretion is authorized to make determinations regarding applications for membership or designation as a transplant program. Such determinations shall be advisory to the Board of Directors, which is the body responsible for final decisions with respect to membership and transplant designation applications, and shall be effective on an interim basis pending final decisions by the Board or action as may be directed through due process.

- (a) **Recommendations for Approval.** Upon issuing a recommendation for approval, the applicant is approved on an interim basis. This approval is effective until review by the full MPSC (if not already accomplished) and final determination by the Board of Directors. Such interim approval shall (subject to final action by the full Board) grant the applicant status as a Member or designated transplant program, as

applicable; shall not extend beyond the date of the Board meeting following the meeting of the full MPSC, subsequent to the subcommittee's grant of interim approval or at which the interim approval is granted by the full Committee (as applicable) except as otherwise specified in Section 1.05A below; and shall expire if the Board does not approve the interim action.

- (b) **Recommendations for Rejection.** Upon issuing a recommendation for rejection, the application is rejected on an interim basis. This rejection is effective until review by the full MPSC (if not already accomplished) and final determination by the Board of Directors. Such interim rejection shall (subject to final action by the full Board) result in denial of membership or designated transplant program status pending due process, including any rights of appeal to the Secretary, and a different decision.

1.05A - Effect of Membership and Professional Standards Committee Action

- (a) **Favorable Recommendation:** When the recommendation of the MPSC is favorable to the applicant, the MPSC Chairman shall promptly forward its report and recommendation, together with all supporting documentation, to the Board of Directors. The Board of Directors shall then review the application and act on it at its next regular meeting at which a quorum is present after receipt of the application unless it is not able to do so due to, for example, receipt of the application from the MPSC ten (10) working days or less before a regular meeting, in which case it shall defer review and action until the following regular meeting at which a quorum is present. In the event any such cases involve interim approval determinations by the MPSC, a decision to defer the matter will continue the interim approval until the next regular meeting of the Board of Directors at which a quorum is present. A majority vote of the Board members present at any meeting at which a quorum is present is required to elect a Member.
- (b) **Adverse Recommendation:** When the recommendation of the MPSC (or Ad Hoc Subcommittee of the MPSC) is adverse to the applicant, the MPSC Chairman shall immediately notify the applicant and the applicant shall be entitled to the procedural rights as provided in section 3.01 A and following entitled "Interviews and Hearings." The applicant shall exercise its procedural rights prior to submission of the adverse recommendation to the Board of Directors.

1.06A - Time Periods for Processing

Applications for membership and designated transplant program status shall be considered in a timely and good faith manner by all individuals and groups required by these Bylaws to act thereon and, except for good cause, shall be processed within the time periods specified in this section. The MPSC (or Ad Hoc Subcommittee of the MPSC) shall act on an application with a recommendation for acceptance and grant of interim approval or a recommendation for rejection resulting in disallowance of membership or designated transplant program status on an interim basis pending due process within 90 days after receiving it. The Board of Directors shall then review and act on recommendations for acceptance at its next regular meeting at which a quorum is present after receipt of the application unless it is unable to do so, in which case it shall defer review and action until the following regular meeting at which a quorum is present. Recommendations for rejection resulting in interim rejection of membership or designated transplant program status pending due process shall entitle the applicant to procedural rights as specified in Article 3.01(4) of this Appendix A to the Bylaws, including an appeal to the Secretary, in writing, within 30 days of the recommendation for rejection of the application.

1.07A - Reapplication after Adverse Decision

An applicant who has been denied OPTN membership or designated transplant program status shall be reconsidered for membership or designation for transplantation for the particular organ upon reapplication. The reapplication will be evaluated based on membership or designated transplant program criteria in effect at the time of reapplication. Any such reapplication shall be processed as an initial application and the

applicant shall submit such additional information as the MPSC or the Board of Directors may require to demonstrate that the basis for the earlier adverse action no longer exists.

**Corrective Action and Enforcement of OPTN Requirements
OPO, Transplant Hospital, and Histocompatibility Laboratory Members**

2.01A - Member Responsibilities

A voting or non-voting Member shall be obligated to comply with all applicable provisions of the National Organ Transplant Act, as amended, 42 U.S.C. 273 *et seq.*; OPTN Final Rule, 42 CFR Part 121; these Bylaws; and OPTN Policies, as in effect from time to time (hereafter referred to as "OPTN requirements"). The OPTN will conduct ongoing and periodic reviews and evaluations of each Member OPO and Transplant Hospital for compliance with these Bylaws, the OPTN Final Rule and OPTN policies. All OPTN Members are subject to review and evaluation for compliance with applicable OPTN requirements. All such compliance monitoring is performed using processes and protocols developed by the OPTN Contractor in accordance with the OPTN Contract. The OPTN also is responsible under the Final Rule to conduct reviews at the request of the Secretary of HHS where the Secretary has reason to believe that an OPTN Member Transplant Hospital or OPO is non-compliant with the Final Rule or poses a risk to the health of patients or to public safety. Such reviews may result in recommendations for action entitling the Member to procedural rights as provided in Sections 3.01A – 3.03A and/or recommendations for appropriate action by the Secretary. 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 shall be considered a violation of OPTN requirements. The failure of a Medical/Scientific, Public Organization, Business, or Individual Member to comply with applicable OPTN requirements shall result in rejection of any request to serve for a successive term as OPTN Member unless the deficiencies are shown to be corrected to the satisfaction of the MPSC and Board of Directors. Any person who becomes aware of an alleged violation of OPTN requirements shall inform the Chair of the Board of Directors or the Executive Director. If the Chair of the Board shall be so informed, he/she shall promptly inform the Executive Director.

2.02A - Executive Director

The Executive Director, or his/her designee, is hereby authorized and directed to monitor compliance by all Members with the OPTN requirements and refer incidences of potential non-compliance to the MPSC.

2.03A - Criteria for Initiation

Whenever an OPO, Transplant Hospital, or Histocompatibility Laboratory Member has failed to conform to the applicable OPTN requirements, corrective action to enforce OPTN requirements may be initiated by the Executive Director, the MPSC, or the Board of Directors, in accordance with these Bylaws.

2.04A - Requests

All requests for corrective action to enforce OPTN requirements shall be submitted to the MPSC in writing by the Executive Director or his/her designee, and shall be supported by reference to the specific activities or conduct which constitute the grounds for the request. The Executive Director, or his/her designee, shall promptly give notice of such request for corrective action to the Member by registered or certified mail, return receipt requested.

2.05A - Referral to Membership and Professional Standards Committee

- (1) Upon being informed of or discovery of possible failure of an OPO, Transplant Hospital, or Histocompatibility Laboratory Member to comply in all material respects with applicable OPTN requirements, the Executive Director or his/her designee shall communicate with the Member alleged to be in violation and the Regional Councillor requesting clarification and /or explanation of the alleged violation.

At the same time, the Executive Director, or his/her designee, in consultation with other designated staff shall make a preliminary determination of the seriousness and/or time-sensitivity of the matter, referring the most serious and/or time sensitive for further consultation among the Executive Director, Chairperson of the MPSC, and President. These matters of potential non-compliance with OPTN requirements shall be defined as Category I potential violations involving action or inaction that poses substantial threat to patient health and/or public safety. In the event of agreement by the MPSC Chairperson with the preliminary determination of a Category I potential violation, the Secretary of HHS, or his/her designee, will be notified that the matter is under investigation, and rapid review of the matter will proceed as follows:

- (a) Preliminary investigation of the matter conducted by OPTN Contractor staff, which may include but is not limited to: data and document review, telephone interviews, and on-site reviews.
 - (b) Referral to a subcommittee of the MPSC formed to consider policy compliance issues (MPSC-PCSC), or, at the discretion of the MPSC Chairperson, to an Ad Hoc Subcommittee. The subcommittee shall include at least five members, including two members with expertise in the organ system or specific issue that is the subject of the review.
 - (c) Determination by the subcommittee to continue review of the matter as a Category I potential violation, or to remove the matter from Category I review and refer it for Category II or III (as defined in Section 2.06 of this Appendix A below) review.
 - (d) In the event the matter continues as Category I, a determination by the subcommittee that there exists a time sensitive threat to patient health or public safety shall require immediate referral to the Executive Committee with notice of the subcommittee's determinations. At the same time, notice will be given to the Member with a stated time period within which to respond. The Executive Committee shall then determine whether it or the Board of Directors shall consider the matter and whether the procedural rights provided to the Member in Sections 3.01A and 3.02A shall be conducted by the MPSC, by the Board of Directors, or by the Executive Committee.
- (2) For matters other than Category I potential violations, Members shall be given a period of up to 21 days to respond. If a response, considered satisfactory to the Executive Director and Chairperson of the MPSC, or their respective designees, has not been received within the time period granted, the Executive Director will refer the alleged violation to the MPSC-PCSC or, at the discretion of the Chairperson of the MPSC, to the full MPSC, for confidential medical peer review investigation and consideration. At the same time, the Executive Director will notify the relevant committee(s) of the alleged violation and referral to the MPSC or its subcommittee without identifying the Member. Matters also may be referred initially to the relevant organ-specific committee without identifying the Member to obtain input based upon the committee's expertise in the particular organ system. If the result of the committee deliberations is a recommendation for further action by the MPSC, the committee Chairperson will refer the matter to the MPSC-PCSC, or, at the discretion of the Chairperson of the MPSC, to the full MPSC, for additional investigation. The Member will be notified of the committee's determination, any recommendation for a specific action, and that the matter has been referred to the MPSC/MPSC-PCSC. In cases where the committee recommends an action that would entitle the Member to an interview as discussed in Section 2.06A, Members will be notified of their right to an interview before the MPSC/MPSC-PCSC at the time they are informed of the committee determinations and recommendations.

The Secretary, or his/her designee, will be notified, in writing, within three days of meetings of the MPSC-PCSC or MPSC in which alleged violations by Transplant Hospitals or OPOs are considered. Additionally, upon determination with respect to a particular alleged violation that the Secretary requires written documentation pertaining to the matter, the documentation shall be provided to the Secretary or his/her designee, upon written request therefor to the OPTN Contractor and in the form specified by the Secretary.

The MPSC-PCSC will meet by conference call approximately once monthly, as needed, for the purpose of considering any new and/or ongoing alleged policy violations. In each Category II or III case the MPSC-PCSC, or full MPSC at the discretion of the Chairperson of the MPSC, will:

- (a) Determine that no further investigation is appropriate because no violation occurred, any violation was the result of a good faith mistake or bona fide lack of knowledge of relevant criteria/policies with assurances regarding future behavior satisfactory to the MPSC-PCSC/MPSC, or non-compliant activity was present but has been corrected with assurances regarding future behavior satisfactory to the MPSC-PCSC/MPSC, in which case the affected Member will be notified of the sanctions imposed (if any) to ensure ongoing compliance with membership requirements. These matters generally would be considered as Category III.
- (b) Determine that a violation or activity warranting inquiry may have occurred and that additional investigation is appropriate but that dialogue between the MPSC-PCSC and the Member in accordance with principles of confidential medical peer review is expected to bring the Member into compliance. Responses by the Member that may contribute to such expectations of compliance include, for example, involvement and commitment from institutional leadership in the matter or demonstration of improvement in terms of compliance or an outcome under review. These matters generally would be considered as Category III; or
- (c) Determine that a material breach of OPTN requirements, such as occurrence of a repeat violation of OPTN policy or expectation of such an occurrence in the future based upon the Member's failure to respond and/or develop or agree to a reasonable compliance action plan, may have taken place. The MPSC-PCSC or MPSC will proceed with additional investigation, as appropriate, in accordance with principles of confidential medical peer review in order to bring the Member into compliance. These matters generally would be considered as Category II.

2.06A - Membership and Professional Standards Committee Action

- (a) **Category I, II, and III Potential Violations.** Matters referred to the MPSC, MPSC-PCSC, or a MPSC ad hoc subcommittee will be defined initially by decision of the MPSC Chairperson (with advice from the Executive Director and President) as Category I potential violations according to the process outlined in Section 2.05 above, or by the MPSC, MPSC-PCSC, or MPSC ad hoc subcommittee as either Category II or Category III potential violations. For Category I potential violations, the MPSC-PCSC or ad hoc subcommittee shall report its determination in writing to the Executive Committee and full MPSC.

Category II potential violations generally are of the type described in Section 2.05(2)(c) above, while Category III potential violations generally are of the type described in Section 2.05(2)(a-b) above. Category II and III potential violations are further distinguished by the expectation that Category II potential violations will proceed to formal Hearings and, perhaps, Appellate Reviews. Upon determination of a Category II potential violation, the MPSC shall consider a timeline for review and action to assist in timely resolution of the matter.

- (b) For Category II and III potential violations, the MPSC-PCSC shall report its action in writing to the full MPSC. The MPSC shall report its action in writing to the Board of Directors.

Category I, II, and III potential violations are generally defined as follows. Individual cases may vary depending upon the unique circumstances, and cases may move among the categories as circumstances may change.

- Category I = potential violation of OPTN requirements posing substantial, time sensitive threat to patient health or public safety,
- Category II = material breach of OPTN requirements, and
- Category III = dialogue with MPSC expected to correct any noncompliant behavior and lead to ongoing future compliance.

Actions available for all categories of potential violations may include, without limitation (see Figures A-2a and A2b for a general overview of these actions), the following. Sanctions listed under numbers (1) and (2) below may be imposed directly by action of either the MPSC-PCSC or MPSC. Sanctions listed under numbers (3) – (7) below must be recommended by the MPSC to the Board of Directors and imposed by the Board, or may be imposed by the Executive Committee or the Board without recommendation of the MPSC. Unless specifically noted, the sanctions listed below may be taken in cases of : (i) noncompliance with policies or behavior posing risk to patient health or public safety covered by Section 1138 of the Social Security Act, 42 U.S.C. § 1320-b8, by virtue of (a) recommendation by the OPTN to be mandatory and designation by the Secretary of HHS for coverage, (b) determination by the Secretary of HHS to be mandatory under the OPTN Final Rule, or (c) determination of risk to the health of patients or to the public safety, which is confirmed by the Secretary of HHS, and (ii) noncompliance with all other OPTN requirements. Policies and behavior posing risk to patient health or public safety described under category (i) above are hereinafter referred to collectively as “policies covered by Section 1138 of the Social Security Act,” or individually as “policy covered by Section 1138 of the Social Security Act.”

The MPSC-PCSC or the MPSC may impose the following sanctions without referral to the Board of Directors for approval:

- (1) **Reject Request for Corrective Action.** The MPSC-PCSC or the MPSC may reject the request for corrective action, notice of which shall be provided to the Board of Directors;
- (2) **Notice of Uncontested Violation, Letter of Warning or Letter of Reprimand.** The MPSC-PCSC or the MPSC may issue a Notice of Uncontested Violation, Letter of Warning or a Letter of Reprimand, any of which is not an adverse action under the Bylaws but is meant to inform the Member of the need for the Member to ensure continuing compliance with OPTN requirements. The Board of Directors and the Secretary of HHS shall be notified of final decisions to issue a Notice of Uncontested Violation, Letter of Warning or a Letter of Reprimand. These categories of non-adverse actions are appropriate under the following circumstances:
 - (a) **Notice of Uncontested Violation** – There has been a violation of OPTN requirements with no substantial evidence of mitigating factors based on medical judgment, and there is believed to be no likelihood of recurrence. The Member is not entitled to an interview.
 - (b) **Letter of Warning** – There has been an apparent violation of OPTN requirements under circumstances in which medical judgment is credibly put forth as a partial mitigating factor and there is believed to be no likelihood of recurrence. The Member is not entitled to an interview.
 - (c) **Letter of Reprimand** – There has been an apparent violation of OPTN requirements under circumstances where medical judgment is not a credible mitigating factor and there is believed to be no likelihood of recurrence. The Member shall be entitled to an interview under the procedures described in Section 3.01A prior to any issuance of a Letter of Reprimand by the MPSC/PCSC or the MPSC.

The MPSC may make recommendations to the Board of Directors for the imposition of the following adverse sanctions or the Board of Directors or the Executive Committee may take such action without recommendation by the MSPC:

(3) **Probation.**

- a. **Adverse Action.** The MPSC may recommend that the Board of Directors or the Executive Committee place the Member on Probation, or the Executive Committee or the Board of Directors may do so on its own accord. Such action would be an adverse action under the Bylaws. This adverse action would first entitle the Member to procedural rights as provided in Section 3.01A – 3.03A. The Member is entitled to the procedural rights described in that Section in the case of a recommendation of Probation by the MPSC. The Member is also entitled to those same rights by a final decision of the Board of Directors or the Executive Committee to place the Member on Probation and give notice of that final action to the Secretary of HHS.
- b. **General Requirements.** The OPTN will give notice to all Members that a Member has been placed on Probation. Probation may include one or more of the following or other actions specified by the MPSC-PCSC, the MPSC, the Executive Committee, or the Board of Directors:
 - (1) Required submission of a compliance action plan or plan of correction developed to specifications defined by the MPSC-PCSC, the MPSC, the Executive Committee, or the Board of Directors. The Member must demonstrate to such specifying body that it has adhered to the plan and that it has corrected any non-compliant activity within a period of time as specified.
 - (2) Unscheduled on-site audit(s) performed by the OPTN Contractor audit staff throughout the period of Probation. The Member shall be responsible for reimbursing the reasonable costs and expenses of the audit(s). Such costs and expenses shall include, but not be limited to personal salaries and benefits, administrative overhead, and travel and lodging expenses of OPTN Contractor staff.
 - (3) Specified submission of reports, data, or other evidence to the OPTN Contractor documenting correction of the non-compliant activity throughout the period of Probation.
- c. **Additional Notice Requirements if the Member Placed on Probation is a Transplant Center.** Notice of this adverse action must be given by the Member to all Patients directly associated with the cited transplant program. For purposes of this requirement, “Patients” shall include the following individuals:
 - (1) Patients undergoing the cited transplant program’s evaluation process;
 - (2) Candidates on the waitlist of the cited transplant program;
 - (3) Candidates added to the cited transplant program’s waiting list; and
 - (4) Recipients being followed by the cited transplant program.

If the Member placed on Probation by the OPTN is a Transplant Center, then the Member Transplant Center must notify its patients that the Member received this adverse action. This notice to Patients must be given within 30 days of the Member receiving formal notification from the OPTN that it has been placed on Probation. The notice must be sent by the Member Transplant Center to each Patient as defined above during the time the Member is on Probation.

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 Member shall comply with any additional notification requirements specified by the MPSC-PCSC, MPSC, Executive Committee, or Board of Directors.

(4) **Member Not in Good Standing.**

a. **Adverse Action.** The MPSC may recommend that the Board of Directors or the Executive Committee declare the Member a “Member Not in Good Standing,” or the Executive Committee or the Board of Directors may do so on its own accord. Such action would be an adverse action under the Bylaws. This adverse action would first entitle the Member to procedural rights as provided in Section 3.01A – 3.03A. The Member is entitled to the procedural rights described in that Section in the case of recommendation of declaring a Member a “Member Not in Good Standing” by the MPSC. The Member is also entitled to those same rights by a final decision of the Board of Directors or the Executive Committee to declare the Member a “Member Not in Good Standing” and give notice of that final action to the Secretary of HHS.

b. **General Requirements.** The adverse action of Member Not in Good Standing may include one or more of the following, plus any other action, as specified by the Board of Directors or the Executive Committee:

- (1) Suspension of voting privileges in OPTN affairs.
- (2) During the duration of the adverse action, suspension of the ability for any personnel named in the OPTN Contractor Membership database as associated with the Member to sit on any Committee, hold office, and sit on the Board of Directors.
- (3) Formal notification, along with subsequent changes in such status, to the entire OPTN Membership, including the Chief Executive Officer of each OPTN Institutional Members
- (4) Formal notification, along with subsequent changes in such status, to the Member’s Chief Executive Officer or Administrator and to the state health commissioner or other appropriate state representative with oversight of health care institutions doing business in the Member’s state.
- (5) Notice within reasonable limits and means to the general public in the area of the Member as specified by the Board of Directors or the Executive Committee. Such notice may include, but is not limited to, communication using the OPTN website.
- (6) The actions listed for a Member on Probation.

c. **Additional Notice Requirements for Transplant Centers Declared a Member Not in Good Standing.** Notice of this adverse action must be given by the Member to all Patients directly associated with the Member Transplant Center, including Patients of all of the Member’s transplant programs. For purposes of this requirement, “Patients” shall include the following individuals:

- (1) Patients undergoing the evaluation process at all of the Member’s transplant programs;

- (2) Candidates on the waitlist of all of the Member's transplant programs;
- (3) Candidates added to all of the Member's transplant programs' waiting lists; and
- (4) Recipients being followed by all of the Member's transplant programs.

If the Member declared a Member Not in Good Standing by the OPTN is a Transplant Center, then the Member must notify its Patients that the Member received this adverse action. This notice to Patients must be given within 30 days of the Member receiving formal notification from the OPTN that it has been declared a Member Not in Good Standing. The notice must be sent by the Member to each Patient as defined above during the time the Member is a Member Not in Good Standing of the OPTN.

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 Member shall comply with any additional notification requirements specified by the MPSC-PCSC, MPSC, Executive Committee, or Board of Directors.

(5) **Suspension of Member Privileges.**

- a. **Adverse Action.** In the case of noncompliance with policies covered by Section 1138 of the Social Security Act, the MPSC may recommend that the Board of Directors or the Executive Committee request approval from the Secretary of HHS to suspend the Member's Privileges. The Board of Directors or the Executive Committee may request such approval from the Secretary on its own accord. This adverse action would first entitle the Member to procedural rights as provided in Section 3.01A – 3.03A. The Member is entitled to the procedural rights described in that Section in the case of a recommendation by the MSPC that the Board of Directors or the Executive Committee request approval from the Secretary to suspend the Member's Privileges. The Member is also entitled to those same rights by a final decision of the Board of Directors or the Executive Committee to request such approval from the Secretary.
- b. **General Requirements.** Suspension of membership privileges may include one or more of the following or other actions as specified by the MPSC-PCSC, the MPSC, the Executive Committee, or the Board of Directors. The actions requested to be taken shall be included in the request for approval from the Secretary.
 - (1) Suspension of voting privileges in OPTN affairs.
 - (2) During the duration of the adverse action, suspension of the ability for any personnel named in the OPTN Contractor Membership database as associated with the Member to hold office and/or sit on OPTN Board of Directors or Committees.
 - (3) Suspension of the privilege to receive all organ offers or offers of particular organ types for transplantation and related services.
 - (4) Suspension of the privilege to list all patients or patients in need of particular organ types on the OPTN Waiting List.
 - (5) The actions listed for a Member on Probation and the actions listed for a Member Not in Good Standing

- c. **Additional Notice Requirements if the OPTN Recommends Suspension of Member Privileges for a Transplant Center.** Notice of this adverse action must be given by the Member to all Patients directly associated with the Member Transplant Center, including Patients of all of the Member's transplant programs. For purposes of this requirement, "Patients" shall include the following individuals:
- (1) Patients undergoing the evaluation process at all of the Member's transplant programs;
 - (2) Candidates on the waitlist of all of the Member's transplant programs;
 - (3) Candidates added to all of the Member's transplant programs' waiting lists; and
 - (4) Recipients being followed by all of the Member's transplant programs.

If the Member whose Privileges are suspended is a transplant center, then the Member must notify its Patients that the Member received this adverse action. This notice to Patients must be given within 30 days of the Member receiving formal notification from the OPTN that its Privileges have been suspended. The notice must be sent by the Member to each Patient as defined above during the time the Member's Privileges are suspended.

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 Member shall comply with any additional notification requirements specified by the MPSC-PCSC, MPSC, Executive Committee, or Board of Directors.

(6) **Termination of Membership or Designated Transplant Program Status.**

- a. **Adverse Action.** The MPSC may recommend that the Board of Directors or the Executive Committee request approval from the Secretary of HHS to terminate membership or designated transplant program status for one or more of the Member's organ transplant programs. The Board of Directors or the Executive Committee may request such approval from the Secretary on its own accord. This adverse action would first entitle the Member to procedural rights as provided in Section 3.01A – 3.03A. The Member is entitled to the procedural rights described in that Section in the case of a recommendation of the MPSC that the Board of Directors, or the Executive Committee, request approval from the Secretary to terminate membership or designated transplant program status for one or more of the Member's organ transplant programs. The Member is also entitled to those same procedural rights by a final decision of the Board of Directors or the Executive Committee to request such approval from the Secretary.
- b. **General Requirements.** Termination of Membership or Designated Transplant Program Status may include one or more of the following or other actions as specified by the MPSC-PCSC, the MPSC, the Executive Committee, or the Board of Directors. The actions requested to be taken shall be included in the request for approval from the Secretary.
- (1) Suspension of voting privileges in OPTN affairs.
 - (2) During the duration of the adverse action, suspension of the ability for any personnel named in the OPTN Contractor Membership

database as associated with the Member to hold office and/or sit on OPTN Board of Directors or Committees.

- (3) Suspension of the privilege to receive all organ offers or offers of particular organ types for transplantation and related services.
- (4) Suspension of the privilege to list all patients or patients in need of particular organ types on the OPTN Waiting List.
- (5) The actions listed for a Member on Probation, the actions listed for a Member Not in Good Standing, and/or the actions listed for Suspension of Member Privileges.

c. **Additional Notice Requirements for Transplant Centers if the OPTN Recommends Termination of Membership or Designated Transplant Program Status.** Notice of this adverse action must be given by the Member to all Patients directly associated with the Member Transplant Center, including Patients of all of the Member's transplant programs. For purposes of this requirement, "Patients" shall include the following individuals:

- (1) Patients undergoing the evaluation process at all of the Member's transplant programs;
- (2) Candidates on the waitlist of all of the Member's transplant programs;
- (3) Candidates added to all of the Member's transplant programs' waiting lists; and
- (4) Recipients being followed by all of the Member's transplant programs.

If the Member whose Membership is terminated or whose organ transplant program's Designated Transplant Program Status is terminated must notify its Patients that the Member received this adverse action. This notice to Patients must be given within 30 days of the Member receiving formal notification from the OPTN that its Membership or Designated Transplant Program Status has been terminated.

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 Member shall comply with any additional notification requirements specified by the MPSC-PCSC, MPSC, Executive Committee, or Board of Directors.

(7) **Action Specified in OPTN Final Rule.**

a. **Adverse Action.** In the case of noncompliance with policies covered by Section 1138 of the Social Security Act, the MPSC may recommend that the Board of Directors or the Executive Committee recommend to the Secretary of HHS any action specifically identified in Section 121.10(c) of the OPTN Final Rule. The Board of Directors or the Executive Committee may make such a recommendation to the Secretary on its own accord. This adverse action would first entitle the Member to procedural rights as provided in Section 3.01A – 3.03A. The Member is entitled to the procedural rights described in that Section in the case of a recommendation by the MPSC that the Board of Directors or the Executive Committee recommend that the Secretary take any action specifically identified in Section 121.120(c) of the OPTN Final Rule. The Member is also entitled to those same rights by a final decision of the Board of Directors or the Executive Committee to make such a recommendation to the Secretary of HHS.

- b. **Additional Notice Requirements if the OPTN Recommends an Action Specified in OPTN Final Rule against a Transplant Center.** Notice of this adverse action must be given by the Member to all Patients directly associated with the Member Transplant Center, including Patients of all of the Member's transplant programs. For purposes of this requirement, "Patients" shall include the following individuals:
- (1) Patients undergoing the evaluation process at all of the Member's transplant programs;
 - (2) Candidates on the waitlist of all of the Member's transplant programs;
 - (3) Candidates added to all of the Member's transplant programs' waiting lists; and
 - (4) Recipients being followed by all of the Member's transplant programs.

If the Member against which the adverse action is taken is a transplant center, then the Member must notify its Patients that the Member received this adverse action. This notice to Patients must be given within 30 days of the Member receiving formal notification from the OPTN that the adverse action has been taken.

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 Member shall comply with any additional notification requirements specified by the MPSC-PCSC, MPSC, Executive Committee, or Board of Directors.

2.07A - - Medical Peer Review

Deliberations and actions of the MPSC, the Executive Committee, and the Board of Directors while investigating and considering applications for membership and designation as a transplant program, as well as incidences of potential non-compliance with the OPTN requirements shall be accorded confidentiality as an essential element of OPTN medical peer review. The Project Officer for the OPTN Contract and the Director of the Division of Transplantation within the Health Resources and Services Administration, HHS, or their designee(s) serve as ex-officio, non-voting members of these bodies and, as such, are parties with full access to these deliberations and actions. Records of and documents associated with MPSC, and the Executive Committee, and the Board deliberations and actions shall, to the extent permitted by law, be confidential and protected by the peer review privilege. Peer review privilege shall not be asserted, however, to withhold any document from the Secretary, or his/her designee, upon submission of a request therefor by the Secretary or his/her designee to the OPTN Contractor.

2.08A - Enforcement Period

The failure by an OPO, Transplant Hospital, or Histocompatibility Laboratory Member to comply in all material respects with the OPTN requirements may ultimately result in a recommendation to the Secretary of HHS for expulsion from membership or action as specifically identified in Section 121.10(c) of the OPTN Final Rule, 42 CFR § 121.10(c), including, for example, termination of a Transplant Hospital or OPO Member's reimbursement under Medicare and Medicaid. The nature of the violation will determine the time period allowed to bring the Member into compliance prior to a recommendation to the Secretary of HHS for such action (hereafter referred to as the "enforcement period"). By way of example, and not by way of limitation, the following demonstrate examples of policy violations and potential enforcement periods and actions that may apply:

- (1) Failure to comply with OPTN allocation policy designated as a Category I potential violation, with finding of urgent, time sensitive threat to patient health and/or public safety:

- (a) Recommend to Member that it voluntarily inactivate the applicable program, with recommendation to Secretary of HHS to suspend the Member's ability to list patients on the waiting list, eligibility to receive organ offers for transplant or related services, and other privileges of membership if Member does not take action voluntarily (during this period the Member's patients will be offered the opportunity for transfer to another Member's waiting list pursuant to OPTN requirements); simultaneous declaration that the Member is Not in Good Standing
- (2) Failure to comply with OPTN allocation policy designated as a Category II potential violation:
- (a) Letter from MPSC-PCSC requesting full compliance within 30 days.
 - (b) Placement on probation or declaration that the Member is Not in Good Standing if the violation continues beyond 45 days.
 - (c) Recommendation to the Secretary of HHS for expulsion from membership or action specifically identified under Section 121.10(c) of the OPTN Final Rule only if the violation involves a policy covered by Section 1138 of the Social Security Act and is not corrected within 45 days after the Member has been placed on probation or declared a Member Not in Good Standing.
- (3) Failure to submit data within time periods as may be specified in the OPTN policies:
- (a) Letter from the MPSC or MPSC-PCSC, allowing a 60-day period to correct deficiencies and bring all data current;
 - (b) If the violation is not corrected within 75 days after the issuance of a warning letter, the Member will be placed on probation or declared a Member Not in Good Standing.
 - (c) Only if the violation involves a policy covered by Section 1138 of the Social Security Act and is not corrected within 30 days after the Member has been placed on probation or declared a Member Not in Good Standing, a request for approval from the Secretary of HHS to suspend the Member's ability to list patients on the waiting list, eligibility to receive organ offers for transplant or related services, and other privileges of membership for 60 days. During this period the Member's patients will be offered the opportunity for transfer to another Member's waiting list;
 - (d) Recommendation to the Secretary of HHS for expulsion from membership or action specifically identified under Section 121.10(c) of the OPTN Final Rule only if the violation involves a policy covered by Section 1138 of the Social Security Act and the Member fails to demonstrate full compliance by end of the 60-day suspension period.
- (4) Failure to pay OPTN registration fees:
- (a) Letter from the MPSC or MPSC-PCSC allowing 10 to 90 days, at the discretion of the Committee, to correct the specified deficiencies.
 - (b) If the violation is not corrected within the specified time period, the Member will be placed on probation or declared a Member Not in Good Standing.
 - (c) Only if the violation involves a policy covered by Section 1138 of the Social Security Act and is not corrected within 30 days after the Member has been placed on probation or declared a Member Not in Good Standing, a request for approval from the Secretary of HHS to suspend the Member's ability to list patients on the waiting list, eligibility to receive organ offers for transplant or related services, and other privileges of membership

for 60 days. During this period the Member's patients will be offered the opportunity for transfer to another Member's waiting list.

- (d) Recommendation to the Secretary of HHS for expulsion from membership or action specifically identified under Section 121.10(c) of the OPTN Final Rule only if the violation involves a policy covered by Section 1138 of the Social Security Act and the Member fails to demonstrate full compliance by end of the 60-day suspension period.

2.09A - Restoration of Membership Privileges

An OPO, Transplant Hospital, or Histocompatibility Laboratory Member that is declared a Member Not in Good Standing or placed on probation shall be entitled to full restoration of membership privileges at any time prior to recommendation for expulsion, if the Member demonstrates to the Board of Directors full compliance with OPTN requirements, including completion of actions prescribed as a result of the imposition of sanctions. An OPO, Transplant Hospital, or Histocompatibility Laboratory Member that is placed on suspension shall, with prior approval from the Board and Secretary of HHS, be entitled to full restoration of membership privileges at any time prior to recommendation for expulsion, if the Member demonstrates to the Board of Directors full compliance with OPTN requirements, including completion of actions prescribed as a result of the imposition of sanctions. After expulsion, the Member must submit a new complete application for OPTN membership.

2.10A - Notice

All OPTN Members and OPOs and Histocompatibility Laboratories with whom the Member has affiliation known to the OPTN Contractor shall be notified by the Executive Director when an OPO, Transplant Hospital, or Histocompatibility Laboratory Member has been finally placed on probation, declared Not in Good Standing, suspended or expelled, as well as when there is a subsequent change in such status.

2.11A - Procedural Rights

Procedural rights, including "interviews and hearings," are further described in Section 3.01A – 3.03A of the Bylaws. If the Member does not deliver a written request for an interview to the chairperson of the MPSC or the Executive Director either in person or by certified or registered mail within 14 days following his receipt of such notice, the Member waives it rights to an interview and the MPSC may proceed to implement its proposed action.

2.12A - Time Period for Action

To the extent practicable, the MPSC-PCSC or full MPSC shall initiate investigation of a request for corrective action within 45 days of receipt by the OPTN Contractor of the request.

Interviews and Hearings

3.01A - Definition of "Adverse"

- (1) **Recommendations or Actions:** Subject to Section 3.01a (4) below, the following recommendations or actions shall, if deemed adverse pursuant to Section 3.01a (2) below, entitle the applicant or Member affected thereby to a hearing:
 - (a) Rejection of initial membership or rejection of designation as a transplant program;
 - (b) Probation;
 - (c) Initial declaration of Member Not in Good Standing and subsequent determinations not to restore the Member to unrestricted membership status;
 - (d) Suspension of membership privileges either directly or after a period of probation;
 - (e) Termination of membership, either directly or after a period of probation or suspension.
 - (f) Any other action specified in Section 121.10(c) of the OPTN Final Rule, 42 CFR § 121.10(c), including, by way of example and not limitation, removal of designation as a transplant program.

- (2) **When Deemed Adverse:** A recommendation or action listed in section 3.01a (1) above shall be deemed adverse only when it has been:
 - (a) Recommended by the MPSC or, in the case of: (i) rejection of initial membership, (ii) rejection of designation as a transplant program, or (iii) findings with respect to Category I potential violations, recommended by a Subcommittee of the MPSC; or
 - (b) Taken by the Board of Directors or the Executive Committee contrary to a favorable recommendation by the MPSC or subcommittee of the MPSC under circumstances where no right to a hearing existed; or
 - (c) Taken by the Board of Directors or the Executive Committee on its own initiative without benefit of a prior recommendation by the MPSC.

- (3) **Interviews:** Except in the case of Category I potential violations, when the MPSC or MPSC-PCSC is considering making an adverse recommendation concerning an applicant or a Member or issuing a letter of reprimand, or when an organ-specific committee refers a matter to the MPSC/MPSC-PCSC with a recommendation that the MPSC consider such an action under Section 2.05A above, the applicant or Member shall be entitled to an interview before the MPSC or the MPSC-PCSC. The interview shall not constitute a hearing, shall be preliminary in nature, and shall not be conducted according to the procedural rules provided with respect to hearings. The applicant or Member shall be informed of the general nature of the circumstances and may present information relevant thereto. A summary record of such interview shall promptly be made by the MPSC and a copy promptly provided to the applicant or Member who was granted the interview. Notwithstanding the foregoing, upon determination by the Board of Directors based on available evidence that an alleged violation of OPTN requirements poses a substantial and imminent threat to the quality of patient care, the Board may take appropriate action even if the Member has not had the opportunity for an interview and/or other procedural rights described below.

Members shall not be entitled to an interview in the case of Category I potential violations.

(4) **Right to a Hearing:**

- (a) An applicant or Member shall have the right to one hearing proceeding, and subsequent appellate review unless the Board of Directors conducts the hearing, with respect to any application for membership, application for designation as a transplant program, and request for corrective action to enforce membership requirements in which an adverse recommendation or action is taken. The hearing may be requested upon the first to occur of the adverse recommendations or actions listed in section 3.01A(1) above or, if waived at such time by the applicant's or member's failure to request a hearing within the time and in the manner specified in section 3.02A below, upon any subsequent adverse recommendation or action arising out of the same application for membership, application for designation as a transplant program, or request for corrective action to enforce membership requirements.
- (b) **Category I Potential Violations.** In the case of a determination of time sensitive threat to patient health or public safety in connection with Category I potential violations, the hearing and any subsequent appellate review will commence together with or follow rather than precede the Executive Committee's or the Board's decision regarding and action upon the MPSC subcommittee's recommendation, as set forth below:
- (i) The MPSC subcommittee recommendation will be referred immediately to the Executive Committee. At the same time, notice will be given to the Member by registered or certified mail, return receipt requested, as well as facsimile transmission. Where the finding continues to be a Category I potential violation with time sensitive threat to patient health or public safety, the MPSC subcommittee action shall include a recommendation for designation of the Member to be Member Not in Good Standing and that the offending transplant program or institution voluntarily inactivate, and, failing acceptance of this recommendation to voluntarily inactivate with immediate action to so inactivate (including notice to and assistance for patients pursuant to OPTN requirements), the MPSC subcommittee shall further recommend approval from the Secretary to suspend member privileges, terminate membership or designated transplant program status, and/or take action specified in the OPTN Final Rule.
- (ii) Following receipt of the MPSC subcommittee recommendation, the Executive Committee shall determine whether it or the Board of Directors shall consider the matter and the Executive Committee or the Board, as the case may be, shall consider the same and affirm, modify, or reverse the recommendation or action in the matter. A concise statement of the result and the reasons therefore, and all documentation considered, shall be transmitted to the Executive Director.
- (iii) The Executive Director, or his/her designee, shall promptly send a copy of the result to the Member by registered or certified mail, return receipt requested (as well as facsimile transmission), and to the Secretary of HHS within three business days or such longer period as may be necessitated for good cause, as determined by the Secretary, if the decision continues to be adverse to the Member. A copy of the result also shall be forwarded to the MPSC or to the Board of Directors, as determined by the Executive Committee, in the event the Member exercises its rights to a hearing under Section 3.02A of the Bylaws. The Member may request that a copy of the supporting documentation be furnished at the Member's expense.
- (iv) Notice of a decision by the Executive Committee or Board that the Member has been placed on probation or declared Not in Good Standing shall be circulated to all Members. The membership shall be notified of decisions by the Executive Committee or Board to recommend to the Secretary of HHS suspension of

membership privileges or termination of membership only upon approval of such recommendation by the Secretary.

- (v) In the event the Member exercises its right to a hearing, the process described in Section 3.02A will be initiated or continued, as applicable, consistent with the timing of delivery and receipt of notices. The hearing will be before the MPSC, the Board or the Executive Committee as determined by the Executive Committee.

Notwithstanding the foregoing, upon determination by the Board of Directors based on available evidence that an alleged violation of OPTN requirements poses a substantial and imminent threat to the quality of patient care, the Board may take other appropriate action using other appropriate process even if the steps noted above for a Category I proceeding have not been completed or the Member otherwise has not had the opportunity for a hearing and/or subsequent appellate review.

- (5) **Right of Appeal to the Secretary.** An applicant for membership or designation as a transplant program shall have the right to appeal decisions of the MPSC, MPSC subcommittees, or the Board of Directors regarding these applications to the Secretary of HHS in accordance with the OPTN Final Rule, 42 CFR Part 121. In the event an applicant exercises this right of appeal prior to exhaustion of the applicant's other procedural rights as described in these Bylaws, the applicant shall notify the OPTN Contractor of this exercise by registered or certified mail, return receipt requested. Upon receiving such notification, the OPTN Contractor shall notify the Secretary of the status of the matter with respect to these procedures within three business days or such longer period as may be necessitated for good cause, as determined by the Secretary. Pending a decision on the appeal, the process defined by these procedures shall continue unless the Secretary directs otherwise. In the event the appeal is denied, the process shall be further continued or reinitiated, as applicable. Any other decision on the appeal by the Secretary shall be submitted to the MPSC or Board of Directors as appropriate for action consistent with the Secretary's decision.

3.02A – Hearings

- (1) **Parties:** The parties to a hearing shall be the applicant or Member against whom an adverse recommendation or action has been taken and the MPSC, the Executive Committee, or the Board of Directors, i.e., the body whose adverse recommendation or action is at issue.
- (2) **Notice of Adverse Recommendation or Action:** An applicant or Member against whom an adverse recommendation or action has been taken shall promptly be given notice of such action by registered or certified mail, return receipt requested. Such notice shall:
 - (a) Briefly advise the applicant or Member of the nature of the adverse recommendation or action and the grounds therefor; and
 - (b) Advise the applicant or Member of the right to a hearing pursuant to the provisions of these Bylaws; and
 - (c) Specify the number of days following the date of receipt of notice within which a request for a hearing must be submitted; and
 - (d) State that the failure to request a hearing within the specified time period shall constitute a waiver of rights to a hearing and to any appellate review of the matter; and
 - (e) State that all materials about the applicant or Member that were generated by or submitted to the MPSC, the Executive Committee, or the Board, as the case may be, prior to that body's adverse recommendation or action, shall be made available to the applicant or Member, upon request, for inspection and copying; and

- (f) State that upon the OPTN Contractor's receipt of the hearing request, the applicant or Member will be notified of the date, time and place of the hearing.
- (3) **Request for Hearing:**
- (a) Except in the case of Category I potential violations, an applicant or Member shall have 14 days following his receipt of a notice to file a written request for a hearing. If the applicant or Member wishes to be represented at the hearing by an attorney, the request for hearing shall include a statement to that effect and identify by name and business address the attorney who will represent the applicant or Member. Such requests shall be delivered to the chair of the MPSC or the Executive Director either in person or by certified or registered mail.
- (b) Category I Potential Violations. In the case of Category I potential violations, an applicant or Member shall have seven days following his receipt of a notice to file a written request for a hearing. If the applicant or Member wishes to be represented at the hearing by an attorney, the request for hearing shall include a statement to that effect and identify by name and business address the attorney who will represent the applicant or Member. Such requests shall be delivered to the chair of the MPSC or the Executive Director either in person or by certified or registered mail.
- (4) **Waiver by Failure to Request a Hearing:** An applicant or Member who fails to request a hearing within the time and in the manner specified waives any right to such a hearing or any appellate review to which he might otherwise have been entitled. Such waiver in connection with:
- (a) An adverse action by the Board of Directors or the Executive committee, shall constitute acceptance of that action, which shall thereupon become effective as the final decision by the Board;
- (b) An adverse recommendation by the MPSC or the Executive committee shall constitute acceptance of that recommendation, which shall thereupon become and remain effective pending the final decision of the Board of Directors.
- (5) **Notice of Hearing:** Upon receipt of a timely request for a hearing, notification of the time, place, and date of the hearing shall be sent to the applicant or Member by certified mail at least 7 days prior to the hearing.
- (6) **Statement of Issues:** The notice of hearing described in Section 3.02A(5) above shall contain a concise statement of the issues raised by the adverse recommendation or action which is the subject of the hearing.
- (7) **Appointment of Hearing Committees:**
- (a) **By MPSC:** A hearing occasioned by an adverse MPSC recommendation shall be conducted by a hearing committee appointed by the chair of the MPSC and composed of three (3) members of the MPSC or in the discretion of the chair, shall be composed of those MPSC members who are in attendance at a regular or special MPSC meeting and are not disqualified under section 3.02A(8) below.
- (b) **By Board of Directors:** A hearing occasioned by an adverse action of the Board of Directors may be conducted by a hearing committee appointed by the chair of the Board of Directors and composed of three (3) directors. One of the appointees shall be designated as chair. Alternatively, in the discretion of the chair of the Board, the hearing shall be conducted by those Board Members who are in attendance at a regular or special meeting of the Board, provided that such Members are not

disqualified under Section 3.02A(8) below and constitute at least a quorum of the full Board.

- (c) **By MPSC-PCSC or Ad Hoc MPSC Subcommittee/Executive Committee or Board in the Case of Category I Potential Violations:** A hearing occasioned by an adverse recommendation from a subcommittee of the MPSC or Executive Committee or Board in the case of Category I potential violations shall be conducted by a hearing committee appointed by the chair and composed of at least three (3) members of the MPSC or, in the discretion of the chair, shall be composed of those members who are in attendance at a regular or special meeting and are not disqualified under section 3.02A(8) below, provided that such members constitute at least a quorum of the full committee or Board.
- (8) **Service on Hearing Committee:** A MPSC or Board of Directors member shall be disqualified from serving on a hearing committee if he/she has been personally and directly involved in compiling evidence for the OPTN Contractor on the matter at issue.
- (9) **Appearance and Representation:** Appearance by the applicant or Member who requested the hearing shall be required. An applicant or Member who fails without good cause to appear and proceed at such hearing shall be deemed to have waived his rights to such a hearing or any appellate review to which it might otherwise have been entitled. The applicant or Member may be represented by an attorney at any hearing or at any appellate review proceeding. The MPSC, MPSC subcommittee, Executive committee, or the Board of Directors shall be allowed representation by an attorney.
- (10) **Presiding Officer:** The chair of the hearing committee shall be the presiding officer. The presiding officer shall regulate the course of the hearing to assure that all participants in the hearing have a reasonable opportunity to present relevant oral and documentary evidence and to conduct such cross-examination as may be required for a full and true disclosure of the facts. He/she shall determine the order of procedure during the hearing and shall make all rulings on interpretation or construction of the OPTN Charter and Bylaws and other relevant documents and OPTN requirements on procedure; and on the admissibility of evidence. He/she shall provide for the exclusion of irrelevant, immaterial, or unduly repetitious evidence.
- (11) **Rights of Parties:** During a hearing, each of the parties shall have the right, subject to the presiding officer's rulings, to:
- (a) Call and examine witnesses;
 - (b) Introduce exhibits;
 - (c) Cross-examine any witness on any matter relevant to the issue;
 - (d) Impeach any witness;
 - (e) Rebut any evidence.

If the applicant or Member who requested the hearing does not testify in its own behalf, representatives of the application who are present may be called and examined as if under cross-examination.

- (12) **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. Any relevant matter upon which responsible persons customarily rely in the conduct of serious affairs shall be admitted, regardless of the admissibility of such evidence in a court of law. Each party shall, prior to or during the hearing, be entitled to submit memoranda concerning any issue, and such memoranda shall become part of the hearing record. The presiding officer may, but shall not be required to,

order that oral evidence be taken only on oath or affirmation administered by any person designated by him/her and entitled to notarize documents in the state where the hearing is held.

- (13) **Official Notice:** In reaching a decision, the hearing committee may take official notice, either before or after submission of the matter for decision, of any generally accepted technical or scientific matter relating to the issues under consideration and of any facts that may be judicially noticed by the courts of the state where the hearing is held. Parties present at the hearing shall be informed of the matters to be thus noticed and those matters shall be noted in the hearing record. Any party shall be given opportunity, on timely request, to request that a matter be officially noticed and to refute the officially noticed matters by evidence or by written or oral presentation of authority, the manner of such refutation to be determined by the hearing committee. The committee shall also be entitled to consider all other information that can be considered, pursuant to these Bylaws, in connection with applications for membership, applications for designation as a transplant program, or requests for corrective action.
- (14) **Burden of Proof:** The body whose adverse recommendation or action occasioned the hearing shall have the initial obligation to present evidence in support thereof, including an explanation of the action or recommendation and why it was taken. The applicant or Member who requested the hearing shall then have the burden of proving and persuading, by clear and convincing evidence, that the adverse recommendation or action lacks any substantial factual basis or that such basis or the conclusions drawn therefrom are arbitrary, unreasonable, or capricious.
- (15) **Record of Hearing:** A record of the hearing shall be kept that is of sufficient accuracy to permit an informed and valid judgment to be made by any group that may later be called upon to review the record and render an appellate recommendation or decision in the matter. The hearing committee and the applicant or Member shall, by mutual agreement, select the method to be used for making the record such as court reporter, electronic recording unit, detailed transcription, or minutes of the proceedings. In the absence of mutual agreement, a court reporter shall be in attendance and shall prepare a written transcript. All exhibits admitted into evidence at the hearing and all memoranda submitted to the hearing committee before, during, or after the hearing, shall be incorporated in the record.
- (16) **Postponement:** Request for postponement of a hearing shall be granted by the hearing committee only upon a showing of good cause and only if the request therefor is made as soon as is reasonably practicable.
- (17) **Presence of Hearing Committee Members and Vote:** A majority of the hearing committee must be present throughout the hearing and deliberations. If a committee member is absent from any part of the proceedings, he/she shall not be permitted to participate in the committee's deliberations or the decision.
- (18) **Recesses and Adjournment:** The hearing committee may recess the hearing and reconvene the same without additional notice for the convenience of the participants or for the purpose of obtaining new or additional evidence or consultation. Upon conclusion of the presentation of oral and written evidence, the hearing shall be closed. The hearing committee shall thereupon, at a time convenient to itself, conduct its deliberations outside the presence of the parties. Upon conclusion of its deliberations, the hearing shall be declared finally adjourned.
- (19) **Hearing Committee Report:** Following preparation of the hearing record, the hearing committee shall make a written report of its findings and recommendations in the matter and shall forward the same, together with the hearing record and all other documentation considered by it, to the body whose adverse recommendation or action occasioned the hearing. At the same time, a copy of the hearing committee report shall be forwarded to the applicant or Member. All findings and recommendations by the hearing committee shall be supported by reference to the hearing record. The presiding officer may extend the time for making the hearing committee's written report in his/her discretion by giving written notice to the participants.

- (20) **Action on Hearing Committee Report:** Following receipt of the report of the hearing committee, the MPSC, MPSC subcommittee, the Executive Committee, or the Board of Directors, as the case may be, shall consider the same and affirm, modify, or reverse its recommendation or action in the matter. It shall transmit a concise statement of the result and the reasons therefor, together with the hearing record, the report of the hearing committee, and all other documentation considered, to the Executive Director.
- (21) **Notice:** The Executive Director, or his/her designee, shall promptly send a copy of the result to the applicant or Member by registered or certified mail, return receipt requested. A copy of the result also shall be forwarded to the MPSC, Executive Committee, and/or to the Board of Directors in the event the applicant or Member exercises its rights to appellate review under Section 3.03A of the Bylaws. The applicant or Member may request that a copy of the hearing record and related documentation be furnished at the applicant's or Member's expense.
- (22) **Effect of Favorable Result:**
- (a) **Adopted by the Board of Directors or Executive Committee:** If the Board of Directors' or Executive Committee's action is favorable to the applicant or Member, such action shall become the final decision of the Board and the matter shall be considered finally closed.
- (b) **Adopted by the MPSC:** If the MPSC's action is favorable to the applicant or Member, the Executive Director shall promptly forward it, together with all supporting documentation, to the Board of Directors for its final action. The Board shall take action thereon by adopting or rejecting the MPSC's action in whole or in part, or by referring the matter back to the MPSC for further consideration. Any such referral back shall state the reasons therefor, set a limit within which a subsequent recommendation to the Board must be made, and may include a directive that an additional hearing be conducted to clarify issues that are in doubt. After receipt of such subsequent recommendation and any new evidence in the matter, the Board shall take final action. The Executive Director shall promptly send the applicant or Member notice by registered or certified mail, return receipt requested, informing him/her of each action taken. Favorable action shall become the final decision of the Board of Directors, and the matter shall be considered finally closed. In the case of favorable action with respect to a Category I potential violation that has resulted in notice to the Secretary of HHS and/or public, the Board of Directors shall remove the designation of Member Not in Good Standing or probation, as applicable, with appropriate notice thereof, and recommend restoration of unrestricted membership privileges to the Secretary of HHS. If the Board's action is adverse, the special notice shall inform the applicant or Member of his right to request an appellate review by the Board of Directors as provided in Section 3.03A below, unless the Board itself has conducted the hearing.
- (23) **Effect of Adverse Result:** If the result of the MPSC or of the Board of Directors or the Executive Committee continues to be adverse to the applicant or Member, the notice sent to him by registered or certified mail, return receipt requested, shall inform him of any applicable right to request an appellate review by the Board of Directors as provided in section 3.03A below.

3.03A - Appellate Review

- (1) **Request for Appellate Review:**
- (a) Except in the case of Category I potential violations, in which the Board of Directors has not been the forum for the Member's exercise of hearing rights, an applicant or Member shall have 14 days following his receipt of notice that a hearing resulted in adverse action

to file a written request for appellate review. Such request shall be delivered to the Executive Director either in person or by certified or registered mail and may include a request for a copy of the report and record of the hearing committee and all other material, favorable or unfavorable, if not previously forwarded, that was considered in making the adverse action or result. The applicant or Member may be represented during the appellate review by an attorney. If the applicant or Member wishes to be so represented, the request for appellate review shall include a statement to that effect and identify by name and business address the attorney who will represent the applicant or Member. Notwithstanding the foregoing, upon determination by the Board of Directors based on available evidence that an alleged violation of OPTN requirements poses a substantial and imminent threat to the quality of patient care, the Board may take appropriate action even if the Member has not had the opportunity for an appellate review.

- (b) **Category I Potential Violations.** In the case of Category I potential violations in which the Board of Directors has not been the forum for the Member's exercise of hearing rights, a Member shall have seven days following his receipt of notice that a hearing resulted in adverse action to file a written request for appellate review. Such request shall be delivered to the Executive Director either in person or by certified or registered mail and may include a request for a copy of the report and record of the hearing committee and all other material, favorable or unfavorable, if not previously forwarded, that was considered in making the adverse action or result. If the Board of Directors is the forum for the exercise of the Member's procedural rights, there is no right to Appellate Review and the decision of the Board is final. The Member may be represented during the appellate review by an attorney. If the Member wishes to be so represented, the request for appellate review shall include a statement to that effect and identify by name and business address the attorney who will represent the Member. Notwithstanding the foregoing, upon determination by the Board of Directors based on available evidence that an alleged violation of OPTN requirements poses a substantial and imminent threat to the quality of patient care, the Board may take appropriate action even if the steps for a Category I proceeding have not been completed or the Member otherwise has not had the opportunity for an appellate review.

- (2) **Waiver by Failure to Request Appellate Review:** An applicant or Member who fails to request an appellate review within the time and manner specified in section 3.03A(1) above waives any right to such review.

- (3) **Notice of Time and Place for Appellate Review:**

- (a) Upon receipt of a timely request for appellate review, the Executive Director shall deliver such request to the Board of Directors. As soon as practicable, the Board shall schedule and arrange for an appellate review which, except in the case of Category I potential violations, shall be not less than 30 days from the date of receipt of the appellate review request. At least 25 days prior to the appellate review, the Executive Director shall send the applicant or Member notice of the time, place, and date of the review by registered or certified mail, return receipt requested. The time for the appellate review may be extended by the appellate review body for good cause and if the request therefor is made as soon as is reasonably practicable.
- (b) **Category I Potential Violations.** In the case of Category I potential violations, the Board shall schedule and arrange for an appellate review not less than seven nor more than 30 days from the date of receipt of the appellate review request. At least five days prior to the appellate review, the Executive Director shall send the applicant or Member notice of the time, place, and date of the review by facsimile or electronic transmission. The time for the appellate review may be extended by the appellate review body for good cause and if the request therefor is made as soon as is reasonably practicable.

- (4) **Appellate Review Body:** The appellate review shall be conducted by the Board as a whole.
- (5) **Nature of Proceedings:** The proceedings by the review body shall be in the nature of an appellate review based upon the record of the hearing before the hearing committee, that committee's report, and all subsequent results and actions thereon. The appellate review body shall also consider any written or oral statements submitted by the applicant or Member, and its representative(s), if any, and any written or oral statements by the MPSC or the Board of Directors and any of their members, individually.
- (6) **Written Statements:** The applicant or Member seeking the review may submit a written statement detailing the findings of fact, conclusions, and procedural matters with which it disagrees, and the reasons for such disagreement. This written statement may cover any matters raised at any step in the hearing process, and legal counsel may assist in its preparation. The statement shall be submitted to the appellate review body through the Executive Director or his/her designee at least 15 days prior to the scheduled date of the appellate review, except if such time limit is waived or modified by the appellate review body. A written statement in reply may be submitted by the MPSC or by the Board of Directors, and if submitted, the Executive Director, or his/her designee, shall provide a copy thereof to the applicant or Member at least 5 days prior to the scheduled date of the appellate review or such shorter time as determined by the appellate review body.
- (7) **Presiding Officer:** The chair of the appellate review body shall be the presiding officer. He/she shall determine the order of procedure during the review, make all required rulings, and maintain decorum.
- (8) **Oral Statement:** The appellate review body, in its sole discretion, may allow the parties or their representatives to personally appear and make oral statements in favor of their positions. Any party or representative so appearing shall be required to answer questions put to him/her by any member of the appellate review body.
- (9) **Consideration of New or Additional Matters:** An applicant or Member may introduce at the appellate review matters or evidence related to steps taken after the conclusion of the original hearing to bring the applicant or Member into full compliance with membership qualifications or requirements. Other new or additional matters or evidence not raised or presented during the original hearing or in the hearing report and not otherwise reflected in the record shall be introduced at the appellate review only in the discretion of the appellate review body, following an explanation by the party requesting the consideration of such matter or evidence as to why it was not presented earlier. In the discretion of the appellate review body, new or additional matters or evidence permitted to be introduced at the appellate review may, but need not, be referred back to the hearing committee in accordance with section 3.03A(13) below.
- (10) **Powers:** The appellate review body shall have all the powers granted to the hearing committee, and such additional powers as are reasonably appropriate to the discharge of its responsibilities.
- (11) **Presence of Members and Vote:** A majority of the appellate review body must be present throughout the review and deliberations. If a member of the review body is absent from any part of the proceedings, he/she shall not be permitted to participate in the deliberations or the decision.
- (12) **Recesses and Adjournment:** The appellate review body may recess the review proceedings and reconvene the same without additional notice for the convenience of the participants or for the purpose of obtaining new or additional evidence or consultation. Upon the conclusion of oral statements, if allowed, the appellate review shall be closed. The appellate review body shall thereupon, at a time convenient to itself, conduct its deliberations outside the presence of the parties. Upon the conclusions of those deliberations, the appellate review shall be declared finally adjourned.

- (13) **Action Taken:** The appellate review body may recommend affirmation, modification, or reversal of the adverse result or action taken by the MPSC, by the Executive Committee or by a committee of the Board or, in its discretion, may refer the matter back to the hearing committee for further review and recommendation to be returned to it in accordance with its instructions. After receipt of such recommendations after referral, the appellate review body shall make its decision as provided in this section. In the case of favorable action, which reverses an adverse result with respect to a Category I potential violation that has resulted in notice to the Secretary of HHS and/or public, the Board of Directors shall remove the designation of Member Not in Good Standing or probation, as applicable, with appropriate notice thereof, and recommend restoration of unrestricted membership privileges to the Secretary of HHS.
- (14) **Conclusion:** The appellate review shall not be deemed to be concluded until all of the procedural steps provided herein have been completed or waived.

Final Decision of the Board of Directors

4.01A - Board of Directors Action

After the MPSC forwards a recommendation to the Board of Directors for which an applicant or Member waives the hearing and appellate review rights or after the conclusion of hearing and appellate review proceedings, the Board shall render its final decision in the matter (which, in the case of an appellate review proceeding, shall be the decision of the Appellate Review Body) in writing and shall send notice thereof to the applicant or Member by certified or registered mail, and to the Secretary of HHS within three business days or such longer period as may be necessitated for good cause, as determined by the Secretary, if the decision continues to be adverse to the applicant or Member. A majority vote by a quorum is required for the Board to take any action permitted by these Bylaws.

If the Board should decide that a more serious sanction than the sanction recommended by the MPSC or Executive Committee is appropriate, the Board shall return the matter to the MPSC or Executive Committee, as the case may be, for its consideration of the imposition of the more serious sanction. If the MPSC or Executive Committee agrees with the Board, the more serious sanction shall be the final decision of the Board. If the MPSC or Executive Committee does not agree that the more serious sanction is appropriate, its initial recommendation to the Board shall be the final decision of the Board.

Notice of a final decision by the Board of Directors or Executive Committee that the Member has been placed on probation or declared Not in Good Standing shall be circulated to all Members. The membership shall be notified of final decisions by the Board or Executive Committee to recommend to the Secretary of HHS suspension of membership privileges or termination of membership only upon approval of such recommendations by the Secretary.

Effect of Board Actions

5.01A - Terms of Probation

A Board action placing a Member on probation shall be effective when taken or at such other time as the Board may direct, and may remain in effect during the period in which hearing and appellate review proceedings are pending. Notice of a Board action placing a Member on probation will not be circulated to all Members until such time as the applicable hearing and appellate review proceedings are waived or concluded.

5.02A - Terms of Member Not in Good Standing

A Board action declaring a Member a Member Not in Good Standing, except as provided in the next sentence, shall be effective when final Board action is taken pursuant to Section 4.01A above after the Member has waived its right to a hearing and appellate review with respect to such Board action or applicable hearing and appellate review proceedings have been concluded. Notwithstanding the foregoing, a Board or Executive Committee action declaring a Member Not in Good Standing may be made effective pursuant to the process for considering Category I potential violations described in this Appendix A of the Bylaws or at any time if the Board shall find based on available evidence that the alleged violation of membership requirements poses a substantial and imminent threat to the quality of patient care.

5.03A - Suspension and Expulsion

A Board action recommending suspension of membership privileges or expelling a Member, except as provided in the next sentence, shall not become effective until final Board action is taken pursuant to Section 4.01A above after the Member has waived its right to a hearing and appellate review with respect to such Board action or applicable hearing and appellate review proceedings have been concluded and acceptance of the Board's recommendation by the Secretary of HHS. Notwithstanding the foregoing, a Board or Executive Committee action recommending suspension of a Member may be made effective pursuant to the process for considering Category I potential violations described in this Appendix A of the Bylaws or at any time, subject to acceptance by the Secretary of HHS, if the Board shall find based on available evidence that the alleged violation of membership requirements poses a substantial and imminent threat to the quality of patient care.

5.04A - Secretarial Approval for Certain Actions

A Board decision recommending suspension of member privileges, termination of OPTN membership, termination of status as designated transplant program, termination of participation in Medicare/Medicaid, or termination of reimbursement under Medicare/Medicaid for violation of mandatory policies except as provided in the next sentence, shall not become effective until (i) final Board action is taken pursuant to Section 4.01A above; (ii) the Member has waived its right to a hearing and appellate review with respect to such Board action or applicable hearing and appellate review proceedings have been concluded; (iii) the Secretary of HHS has accepted the Board's recommendation; and (iv) the Secretary of HHS has authorized the implementation of such action. Notwithstanding the foregoing, a Board or Executive Committee decision recommending such action for violation of mandatory policies may be made effective pursuant to the process for considering Category I potential violations described in this Appendix A of the Bylaws or at any time, subject to acceptance and authorization of implementation by the Secretary of HHS, if the Board shall find, based on available evidence, that the alleged violation of mandatory policies poses a substantial and imminent threat to the quality of patient care.

5.05A - Restoration of Unrestricted Membership

Upon presentation of evidence to the satisfaction of the MPSC that a probationary Member, Member declared Not in Good Standing, or suspended Member has fully complied with OPTN requirements, including completion of actions prescribed as a result of the imposition of sanctions, the MPSC shall recommend that the Board of Directors restore unrestricted membership privileges, in the case of a Member placed on probation or declared Not in Good Standing, or recommend restoration of unrestricted membership privileges to the Secretary of HHS, in the case of suspension of the Member's membership privileges.

5.06A - Restoration Of Privileges After Violation of Mandatory Policies Under Section 121.10(c) Of the OPTN Final Rule

Upon presentation of evidence to the satisfaction of the MPSC that a Member penalized for violation of a mandatory policy under Section 121.10(c) of the OPTN Final Rule, 42 CFR § 121.10(c), has fully complied with OPTN requirements, including completion of actions prescribed as a result of the imposition of sanctions, the MPSC shall recommend that the Board of Directors recommend to the Secretary of HHS that the penalty be removed.

Costs and Expenses

6.01A –Reimbursement of OPTN Contractor Costs and Expenses

Reasonable costs and expenses of (i) conducting other than routine on-site audits, reviewing and monitoring corrective action plans and conducting due process proceedings (“compliance costs and expenses”) resulting from enforcement of OPTN requirements under Section 2.01A and (ii) following and conducting evaluations of transplant programs with low survival rates under Appendix B, Section II, including on-site visits and review and monitoring of plans for quality improvement (“program evaluation costs and expenses”) shall be reimbursed by the applicant or Member. Such costs and expenses shall include, but shall not be limited to, travel and lodging expenses of volunteers and OPTN Contractor representatives; compensation of OPTN Contractor representatives, and costs of preparation of reports. A binding decision as to the nature and amount of costs and expenses charged to be reimbursed by the applicant or Member shall be made by the Treasurer, or his/her designees, after consultation with the Executive Director.

Reasonable costs and expenses of conducting interviews, hearings and appellate reviews under Section 3.01A and following shall be reimbursed by the applicant or Member. Such costs and expenses shall include, but shall not be limited to, travel and lodging expenses of the applicant or Member and of volunteers and OPTN Contractor representatives; compensation of OPTN Contractor representatives; court reporter fees and the cost of preparation of the necessary number of copies of the hearing record; and the costs of preparing for and attending, and of obtaining and compiling evidence and exhibits. A binding decision as to the nature and amount of costs and expenses to be reimbursed shall be made by the Presiding Officer after consultation with the Executive Director.

“OPTN Contractor representatives” shall include staff and outside counsel, consultants and expert witnesses. Reasonable costs and expenses may be estimated and billed, wholly or partially, to the applicant or Member in advance or may be billed, wholly or partially, to the applicant or Member as the matter progresses. If actual costs and expenses otherwise reimbursable by the applicant or Member for the entire matter before the MPSC are less than \$500.00, or if the applicant or Member is not determined to be in violation of OPTN requirements, no reimbursement shall be due from the application or Member and any amounts previously reimbursed or deposited shall be returned. If the applicant or Member has multiple matters before the MPSC within any twelve-month period, the dollar amount in the preceding sentence shall apply to all such matters in the aggregate.

6.02A - Advanced Deposit for Reimbursable Costs and Expenses

As a condition to allowing a compliance or program evaluation site visit, an interview, a hearing or an appellate review to proceed, the Presiding Officer may require that the applicant or Member make and maintain a deposit with the Executive Director in an amount equal to the currently projected compliance costs and expenses, program evaluation costs and expenses or costs and expenses of the interview, hearing or appellate review, as the case may be. The failure to make the required deposit within 10 days after the Presiding Officer requests an advance deposit shall be considered a waiver of the applicant or Member's interview, hearing or appellate review rights. Following such a waiver, the MPSC and the Board of Directors may go forward with the imposition of sanctions.

6.03A - Default in Payment of Reimbursable Cost and Expenses

Any applicant or Member who fails to pay reimbursable costs and expenses assessed pursuant to Section 6.01A within 30 days after having received notice by certified or registered mail, at the applicant or Member's address as shown on the records of the OPTN Contractor, shall be referred to the Secretary for termination of either OPTN membership or further consideration of the application, as appropriate.

Time Periods for Action

7.01 A - Time Periods for Action

To the extent practicable, the following time periods shall apply in scheduling and taking actions with respect to interviews, hearings, and appellate reviews:

- (1) **Interviews:** Interviews will be scheduled within 60 days of the decision of the MPSC-PCSC or full MPSC that entitles the Member to the interview.
- (2) **Initial Determination of Category I Potential Violations:** Determination of Category I potential violation by decision of MPSC Chairperson (with advice from Executive Director and President) will occur within 72 hours of OPTN Contractor receipt of notice of issue, followed by OPTN Contractor staff preliminary investigation within 14 days of determination.
- (3) **Initial Consideration of Category I Potential Violation.** Initial consideration of Category I potential violations by the MPSC-PCSC or ad hoc subcommittee of the MPSC, followed by the action of the Executive Committee or the Board regarding the subcommittee's recommendations and the Executive Committee's determination of the forum for exercise of the Member's procedural rights, will occur within 14 days of referral of the matter to the MPSC subcommittee.
- (4) **Hearings:** In the case of Category II and III potential violations, hearings will be scheduled not less than 7 days nor more than 60 days from the date of the OPTN Contractor's receipt of the request for hearing. In the case of Category I potential violations, hearings will be scheduled not less than 7 days nor more than 30 days from the date of the OPTN Contractor's receipt of the request for hearing.
- (5) **Hearing Committee Report:** In the case of Category II and III potential violations, the Hearing Committee report will be issued within 30 days after preparation of the hearing record. In the case of Category I potential violations, the Hearing Committee report will be issued within seven days after preparation of the hearing record.
- (6) **Action on Hearing Committee Report:** In the case of Category II and III potential violations, the MPSC or Board of Directors, as applicable, will consider and act on the report of the Hearing Committee within 30 days following receipt of the report. In the case of Category I potential violations, the MPSC, Executive Committee or the Board will consider and act on the report of the Hearing Committee within two days following receipt of the report.
- (7) **Appellate Review:** In the case of Category II and III potential violations, appellate reviews will be scheduled not less than 30 days nor more than 90 days from the date of the OPTN Contractor's receipt of the request for appellate review.
 - (a) **Action Taken:** In the event the Appellate Review Body refers a matter back to the Hearing Committee, the Appellate Review Body will make its decision with respect to the matter within 14 days after receipt of any recommendations from the Hearing Committee.

In the case of Category I potential violations, appellate reviews will be scheduled not less than seven days nor more than 30 days from the date of the OPTN Contractor's receipt of the request for appellate review. If the Board of Directors conducts the hearing, there is no right to Appellate Review and the decision of the Board is final.
 - (b) **Action Taken:** In the event the Appellate Review Body refers a matter back to the Hearing Committee, the Appellate Review Body will make its decision with respect to the matter within 14 days after receipt of any recommendations from the Hearing Committee.
- (8) **Board of Directors Action:** The Board of Directors will render its decision within 90 days after the conclusion of applicable hearing and appellate review proceedings.