

APPENDIX A TO BYLAWS

UNITED NETWORK FOR ORGAN SHARING

Corrective Action and Enforcement of UNOS 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 UNOS Policies, as in effect from time to time (hereafter referred to as “UNOS requirements”). UNOS 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 UNOS policies. All UNOS Members are subject to review and evaluation for compliance with applicable UNOS requirements. All such compliance monitoring is performed using processes and protocols developed by UNOS in accordance with the OPTN Contract. In its role as the OPTN Contractor, UNOS, serving as 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 fee, charge, or other monetary obligation to UNOS shall be considered a violation of UNOS membership requirements. The failure of a Medical/Scientific, Public Organization, Business, or Individual Member to comply with applicable UNOS membership requirements shall result in rejection of any request to serve for a successive term as a 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 UNOS 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 UNOS 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 UNOS requirements, corrective action to enforce UNOS 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 membership 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 a method that can be tracked and that provides proof of receipt (for example, commercial overnight delivery service, secure electronic communication or 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 UNOS 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 UNOS 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 UNOS 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; and
 - (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 a subcommittee of 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.
- (3) 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 case Category II or III 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 UNOS requirements, such as occurrence of a repeat violation of UNOS 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; and

- (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 UNOS requirements posing substantial, time sensitive threat to patient health or public safety,
- Category II = material breach of UNOS 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 MSPC. 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 UNOS 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; and
- (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 UNOS requirements. These categories of non-adverse actions are appropriate under the following circumstance.
 - (a) **Notice of Uncontested Violation** –There has been a violation of UNOS 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 UNOS 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; and
 - (c) **Letter of Reprimand** – There has been an apparent violation of UNOS 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.** UNOS 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 UNOS 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 personnel salaries and benefits, administrative overhead, and travel and lodging expenses of UNOS staff.
 - (3) Specified submission of reports, data, or other evidence to UNOS 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 UNOS 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 UNOS 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 UNOS affairs.
 - (2) During the duration of the adverse action, suspension of the ability for any personnel named in the UNOS 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 UNOS Membership, including the Chief Executive Officer of each UNOS Institutional Member
 - (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 UNOS 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 UNOS 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 UNOS 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 UNOS.

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 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 UNOS affairs.
 - (2) During the duration of the adverse action, suspension of the ability for any personnel named in the UNOS Membership database as associated with the Member to hold office and/or sit on OPTN/UNOS 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 UNOS 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 UNOS 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 UNOS 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 UNOS affairs.
 - (2) During the duration of the adverse action, suspension of the ability for any personnel named in the UNOS Membership database as associated with the Member to hold office and/or sit on OPTN/UNOS 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 UNOS 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 UNOS 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 UNOS 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 UNOS 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 UNOS 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 UNOS Bylaws shall be accorded confidentiality as an essential element of medical peer review. Records of and documents associated with MPSC, 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.

2.08A Enforcement Period

The failure by an OPO, Transplant Hospital, or Histocompatibility Laboratory Member to comply in all material respects with the UNOS requirements may ultimately result in 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 (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 UNOS 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 UNOS requirements); simultaneous declaration that the Member is Not in Good Standing.
- (2) Failure to comply with UNOS 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; and
 - (c) Recommendation 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 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 UNOS 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, 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; and

- (d) Recommendation 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 and the Member fails to demonstrate full compliance by end of the 60-day suspension period.
- (4) Failure to pay 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 and is not corrected within 30 days after the Member has been placed on probation or declared a Member Not in Good Standing, 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; and
 - (d) Recommendation for expulsion from membership or action specifically identified under Section 121.10(c) of the OPTN Final Rule if the violation involves a policy and the Member fails to demonstrate full compliance by end of the 60-day suspension period.
- (5) Exportation of organs to foreign countries (except for Canada), other than through the UNOS Organ Center: Recommendation for expulsion upon the first violation.
- (6) Failure to register a donor or a potential recipient (and to submit the applicable recipient registration forms within 14 days):
- (a) Letter from the MPSC-PCSC requesting full compliance with registration requirements within 30 days;
 - (b) Declaration that the Member is "Not in Good Standing" if the violation continues beyond 45 days; and
 - (c) Recommendation for expulsion, if the violation is not corrected within 45 days after the Member has been declared "Not in Good Standing".

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 UNOS 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 UNOS 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 UNOS membership.

2.10A Notice

All UNOS Members and OPOs and Histocompatibility Laboratories with whom the Member has affiliation known to UNOS 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 a method that can be tracked (for example, commercial overnight delivery service, secure electronic communication or registered or certified mail) within 14 days following his receipt of such notice, the Member waives its 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 UNOS of the request.