

## APPENDIX A TO BY-LAWS

### 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 the OPTN Final Rule and UNOS policies. All UNOS Members are subject to review and evaluation for compliance with UNOS policies. 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 registered or certified mail, return receipt requested.

##### **2.05A Referral to Membership and Professional Standards Committee**

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. If a response, considered satisfactory to the Executive Director and Chairperson of the Membership and

Professional Standards Committee, or their respective designees, has not been received within 1 week, the Executive Director will refer the alleged violation to a subcommittee of the Membership and Professional Standards Committee formed to consider policy compliance issues (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 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 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 mistake or 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 determination and any recommended actions to ensure ongoing compliance with membership requirements. After peer review communications with the Member are completed, the Member will be notified that the matter is concluded and what sanction, if any, has been imposed. Cases involving past non-compliant behavior, for example, may result as well in issuance of a Letter of Reprimand following opportunity for an interview and any other procedures described in these Bylaws, as further provided for in Section 2.06A below.
- (b) Determine that a violation 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.
- (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.

## **2.06A Membership And Professional Standards Committee Action**

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. These actions may include, without limitation (see Figure A-2 for a general overview of these actions), the following. Actions listed under numbers (1) and (2) below may be taken directly by either the MPSC-PCSC or MPSC. Actions listed under numbers (3) – (7) below must be approved by the MPSC before the recommendation may be moved on to the Board of Directors. Unless specifically noted, the actions listed below may be taken in cases of noncompliance with (i) policies recommended by UNOS to be mandatory and designated by the Secretary of HHS as covered by Section 1138 of the Social Security Act, 42 U.S.C. § 1320-b8, and (ii) all other policies.

- (1) Reject Request for Corrective Action. Rejecting the request for corrective action notice of which shall be provided to the Board of Directors;

- (2) Warning, Letter of Admonition, or Letter of Reprimand. Issuing a warning, a letter of admonition, or a letter of reprimand, 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 policies monitored by UNOS. This would first entitle the Member to an interview under the procedures described in Section 3.01A(3) followed by final action by the MPSC-PCSC/MPSC and notice to the Board of Directors;
- (3) Probation. Recommending that the Board of Directors place the Member on probation, which would be an adverse action under the Bylaws and would first entitle the Member to an interview and other procedural rights as provided in Section 3.01A – 3.03A followed by a final recommendation to and action by the Board of Directors. Probation may include one or more of the following or other action deemed appropriate by the MPSC-PCSC/MPSC:
  - (a) Required submission of a compliance action plan or plan of correction developed to specifications as may be defined by the MPSC-PCSC/MPSC, with demonstration to the MPSC-PCSC/MPSC of adherence to the plan and correction of any non-compliant activity within some period of time.
  - (b) Unscheduled on-site audit(s) throughout the period of probation, to be performed by UNOS audit staff at the sole reasonable cost and expense of the Member. Such costs and expenses shall include, but not be limited to, travel and lodging expenses of UNOS staff.
  - (c) Required submission of reports, data, or other evidence to UNOS documenting correction of the non-compliant activity throughout the period of probation.
- (4) Member Not in Good Standing. Recommending that the Board of Directors declare the Member a Member “Not in Good Standing” which would be an adverse action under the Bylaws and would first entitle the Member to an interview and other procedural rights as provided in Section 3.01A – 3.03A followed by a final recommendation to and action by the Board of Directors. Member Not in Good Standing includes all of the following plus any other action deemed appropriate by the Board of Directors, unless specifically limited to one or more of such actions by the Board of Directors:
  - (a) Withdrawal of voting privileges in UNOS affairs.
  - (b) Suspension of the ability for any personnel named in the UNOS Membership database as associated with the Member - who are not otherwise eligible to serve by virtue of their association with a member in Good Standing - to sit on any Committee, hold office, and sit on the Board of Directors.
  - (c) Formal notification, along with subsequent changes in such status, of the Membership and OPOs and Histocompatibility Laboratories with whom the Member has affiliations known to UNOS, as well as the Chief Executive Officer of those institutions.
  - (d) 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.
  - (e) Notice, within reasonable limits and means, to patients and the general public in the area of the Member. Such notice may include, but is not limited to, communication using the UNOS website and/or as prescribed by the Board of Directors for distribution by the Member.
- (5) Suspension of Member Privileges. Only in the case of noncompliance with policies recommended by UNOS, operating as the OPTN to be mandatory and designated by the Secretary of HHS as covered by Section 1138 of the Social Security Act, recommending that

the Board of Directors request approval from the Secretary to suspend the Member's ability to list patients on the waiting list, eligibility to receive organ offers for transplants and related services, and other membership privileges, any of which would be an adverse action under the Bylaws and would first entitle the Member to an interview and other procedural rights as provided in Section 3.01A – 3.03A followed by a final recommendation to and action by the Board of Directors and, if the decision is to move the request forward, submission of the request to the Secretary of HHS for consideration. Suspension of membership privileges may include one or more of the following or other action deemed appropriate by the MPSC-PCSC/MPSC:

- (a) Suspension of the privilege to hold office and/or sit on the UNOS Board of Directors or Committees.
  - (b) Suspension of voting privileges in UNOS affairs.
  - (c) Suspension of the privilege to receive all organ offers or offers of particular organ types for transplantation and related services.
  - (d) Suspension of the privilege to list all patients or patients in need of particular organ types on the Patient Waiting List.
- (6) Termination of Membership or Designated Transplant Program Status. Only in the case of noncompliance with policies recommended by UNOS, operating as the OPTN to be mandatory and designated by the Secretary of HHS as covered by Section 1138 of the Social Security Act, recommending that the Board of Directors terminate membership or designated transplant program status for one or more organs, which are adverse actions under the Bylaws and would first entitle the Member to an interview and other procedural rights as provided in Section 3.01A – 3.03A followed by a final recommendation to and action by the Board of Directors; and
- (7) Action Specified in OPTN Final Rule. Only in the case of noncompliance with policies recommended by UNOS, operating as the OPTN, to be mandatory and designated by the Secretary of HHS as covered by Section 1138 of the Social Security Act, recommending that the Board of Directors recommend any action specifically identified in Section 121.10(c) of the OPTN Final Rule, 42 CFR § 121.10(c), which would be an adverse action under the Bylaws and would first entitle the Member to an interview and other procedural rights as provided in Section 3.01A – 3.03A followed by a final recommendation to and action by the Board of Directors.

#### **2.07A Medical Peer Review**

Deliberations and actions of the MPSC and 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 these Bylaws and applicable policies, shall be accorded confidentiality as an essential element of medical peer review. Records of and documents associated with MPSC and 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:

- (a) Warning letter from MPSC or 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 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 recommended by UNOS, to be mandatory and is not corrected within 45 days after the Member has been placed on probation or declared a Member Not in Good Standing.
- (2) Failure to submit data within time periods as may be specified in the UNOS policies:
- (a) Warning 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 recommended by UNOS to be mandatory as 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;
  - (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 recommended by UNOS to be mandatory and the Member fails to demonstrate full compliance by end of the 60-day suspension period.
- (3) Failure to pay registration fees:
- (a) Warning letter from the Membership and Professional Standards Committee 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 recommended by UNOS to be mandatory 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.
  - (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 recommended by UNOS to be mandatory and the Member fails to demonstrate full compliance by end of the 60-day suspension period.
- (4) Exportation of organs to foreign countries (except for Canada), other than through the UNOS Organ Center: Recommendation for expulsion upon the first violation.
- (5) Failure to register a donor or a potential recipient (and to submit the applicable recipient registration forms within 14 days):

- (a) Warning letter from the Membership and Professional Standards Committee or 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;
- (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. An OPO, Transplant Hospital, or Histocompatibility Laboratory Member that is placed on suspension shall, with prior approval from the Board, be entitled to full restoration of membership privileges at any time prior to recommendation for expulsion, if the Member demonstrates full compliance with UNOS requirements. 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, suspended, or expelled, as well as when there is a subsequent change in such status. Such notice shall be applied in the case of a Member declared Not in Good Standing, unless the Board of Directors determines such notice is not appropriate as part of the corrective action.

**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 its rights to an interview and the MPSC may proceed to implement its proposed action.

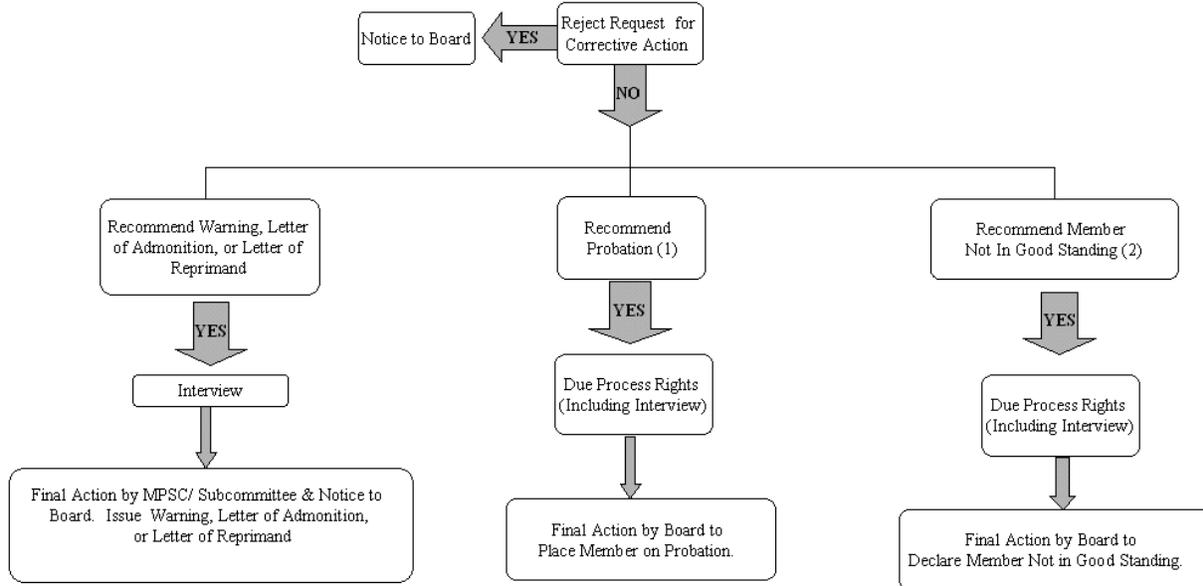
**2.12A Time Period For Action**

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.

Figure A-2

Policy Enforcement Options

Potential Violation of Voluntary Policy/ Referral to MPSC  
(Subcommittee)



(1) Probation might include, for example, one or more of the following: (a) required submission of a compliance action plan or plan of correction developed to specifications as may be defined by the MPSC/MPSC-PCSC, with demonstration to the MPSC/MPSC-PCSC of adherence to the plan and correction of any non-compliant activity within some period of time; (b) unscheduled on-site audit(s) throughout the period of probation, to be performed by UNOS audit staff at the sole reasonable cost and expense of the Member; (c) required submission of reports, data, or other evidence to UNOS documenting correction of the non-compliant activity throughout the period of probation.

(2) Member Not in Good Standing might include, for example, one or more of the following: (a) withdrawal of voting rights in corporate affairs; (b) suspension of ability of affiliated personnel to sit on Committees or Board of Directors or hold office; (c) notification to OPTN/UNOS Membership, State Representatives in Member's state, and/or patients and general public in Member's area.

