

## APPENDIX B TO BYLAWS

### UNITED NETWORK FOR ORGAN SHARING

#### Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership

##### II. Transplant Hospitals.

**General.** A hospital (i) that aspires to perform organ transplants, as evidenced by submission of an active application for designated transplant program status for at least one organ type, or in which organ transplantation is performed, and (ii) that participates in the Medicare or Medicaid programs (Transplant Hospital) is eligible for membership in UNOS. Transplant Hospitals shall abide by applicable provisions of the National Organ Transplant Act, as amended, 42 U.S.C. 273 *et seq.*; the requirements set forth in the OPTN Final Rule, 42 CFR Part 121; these Bylaws, Appendices, and Attachments; and UNOS policies. Transplant Hospitals shall also submit to reviews (including on-site reviews) and requests for information as may be necessary to determine compliance with the OPTN Final Rule, 42 CFR Part 121; these Bylaws; and UNOS policies. Failure to conform with such requirements shall be cause for corrective action described in Appendix A of these Bylaws.

**Survival Rates.** In the distribution of survival rates of all Members a center with a low (as defined below) survival rate would be subject to evaluation to determine if the low survival rate may be accounted for by patient mix or some other unique clinical aspect of the transplant program in question.

Those programs whose actual observed patient and/or graft survival rates fall below their expected rates by more than a threshold will be reviewed. The absolute values of relevant parameters in the formula may be different for different organs, and may be reviewed and modified by the Membership and Professional Standards Committee, subject to Board approval.

While the precise numerical criteria may be selected by the MPSC, the initial criteria employed to identify programs with low patient and/or graft survival rates will include the finding that observed events minus expected events is  $>3$  and the observed events divided by expected events is greater than 1.5; and there exists an one sided p value of  $<0.05$ .

Observed events represent deaths or graft loss as reported in the UNOS database. Expected events represent deaths or grafts as calculated utilizing organ specific transplant models. Incomplete follow-up data will be treated as a graft loss or patient deaths in the context of this analysis.

If a program's performance cannot be explained by patient mix or some other unique clinical aspect of the transplant program in question, it will be considered for appropriate action in accordance with Appendix A of these Bylaws.

**Inactive Membership Status.** A Member Transplant Hospital that fails to remain functionally active with respect to any designated transplant program (as defined below) may voluntarily inactivate that transplant program for a period of up to twelve months by notice to the Executive Director, or may relinquish designated transplant program status for the program. For purposes of these Bylaws, "functionally inactive" is defined as the inability to serve patients, as a group, for a sustained and significant time period. A period of 15 days or more is presumed to be sustained and significant. If the Member fails to take either action voluntarily, the Membership and Professional Standards Committee may recommend that the Board of Directors take appropriate action in accordance with Appendix A of these Bylaws in all other cases. Program inactivation or relinquishment of designated transplant program status involves (i) prompt suspension of transplantation, (ii) notice to patients of the need to inactivate, removal of these patients from the program's waiting list, or - if the patient desires - transfer of the patient to the list of another Member Transplant Hospital, and (iii) assistance for patients in identifying the designated transplant programs to

which they can transfer. Upon submission and review of information establishing that the Member has again become active in human organ transplantation and that all other criteria for membership are met, the Membership and Professional Standards Committee shall recommend to the Board of Directors that the Member be designated as an active member.

To assure equity in waiting times, and facilitate smooth transfer of patients from the waiting list of a program that is inactivated or relinquishes designated transplant status, patients on the waiting list of a designated transplant program at the time of inactivation or relinquishment of designated status may retain existing waiting time and continue to accrue waiting time appropriate to their status on the waiting list at the time of inactivation or relinquishment of designated status of their program for a maximum of 90 days following that program's inactivation or relinquishment of designated status. This total acquired waiting time may be, with agreement of the accepting center, transferred to the patient's credit when s(he) is listed with a new program.

It is expected that all Transplant Hospitals will duly inform their patients on the waiting list if there will be an extended period of time when a designated transplant program will be unable to perform transplants. Programs that are not able to serve patients, as a group, for a period of 15 consecutive days or more are further expected to notify UNOS and their patients as described above.

**Key Personnel.** The Transplant Hospital must identify for any designated transplant program (as defined below) qualified as a transplant program by other than the requirements set forth in Attachment I and sub-attachments to Appendix B the primary surgeon and primary physician reported to the Center for Medicaid and Medicare Services (CMS) and demonstrate whether these individuals meet the requirements specified in this Appendix B, Attachment I, Section VI, and applicable sub-attachments. When the Transplant Hospital learns that one or more of these individuals plan to leave, UNOS must be notified immediately. At least 30 days (if possible) prior to the departure of the individual, the Transplant Hospital shall submit to UNOS the name of the replacement physician or surgeon, Curriculum Vitae, and information documenting whether the individual meets the requirements specified in this Appendix B, Attachment I, Section VI, and applicable sub-attachments. Failure to inform UNOS of changes in primary physician and surgeon shall result in recommendation to the Board of Directors that the Board take appropriate action.

**Patient Notification.** Transplant Hospitals are expected to notify patients in writing: (i) within ten business days (a) of the patient's being placed on the Patient Waiting List including the date the patient was listed, or (b) of completion of the patient's evaluation as a candidate for transplantation, that the evaluation has been completed and that the patient will not be placed on the Patient Waiting List at this time, which ever is applicable; and (ii) within ten business days of removal from the Patient Waiting List as a transplant candidate for reasons other than transplantation or death that the patient has been removed from the Waiting List. Transplant Hospitals are further expected to maintain documentation of these notifications and make it available to UNOS upon request for purposes of monitoring compliance with this provision. If the Member fails voluntarily to comply with this provision, the Membership and Professional Standards Committee may recommend that the Board of Directors take appropriate action in accordance with Appendix A of these Bylaws in all other cases.

**Clinical Transplant Coordinator.** All transplant programs should identify one or more staff members who will be responsible for coordinating clinical aspects of patient care. The clinical transplant coordinator shall be a designated member of the transplant team and will be assigned primary responsibility for coordinating clinical aspects of care. The coordinator will work with patients and their families beginning with the evaluation for transplantation and continuing through and after transplantation, in a compassionate and tactful manner in order to help facilitate access to and provide continuity of care. The coordinator will also work with other members of the transplant team, including physicians, surgeons, nurses, social workers, financial coordinators and administrative personnel at the transplant program. The coordinator should be a registered nurse or other licensed clinician who performs or oversees a team of other healthcare personnel and support staff in performing the functions (listed below).

Specific responsibilities should include, but are not limited, to:

Candidate Phase:

1. Assures the performance of necessary studies to determine a patient's candidacy;
2. Participates in both patient and family education;
3. Assists in the evaluation and selection of potential living donors;
4. Maintains appropriate monitoring of patients' status throughout work-up and while on the deceased donor organ transplant waiting list.

Transplant/Inpatient Phase:

1. Assumes lead in directing responsibility of all patient and family education;
2. Maintains communication with patients' referring physicians;
3. Contributes to the education and acts as the resource person regarding transplantation for all staff nurses;
4. Acts as liaison between patients' families and other health care team members;
5. Prepares patients for discharge and outpatient follow-up.

Recipient Phase:

1. Monitors and follows all diagnostic studies;
2. Evaluates patient health status on a regular basis;
3. Communicates all patient issues and concerns to appropriate transplant physicians;
4. Coordinates comprehensive care with other team members (i.e. financial coordinator, social worker, dietician, etc).

Additional responsibilities may include but are not limited to clinical research studies, public and professional education and completion of all required data as established by UNOS. Coordinators may also be involved with the organ procurement process by taking organ offer calls, dispatching the organ procurement team, and arranging for potential organ recipients to be admitted to the hospital.

**Financial Coordinator.** All Transplant Hospitals should identify one or more staff members who will be responsible for coordinating and clarifying patient-specific financial aspects of care. The Financial Coordinator shall be a designated member of the transplant team and will be assigned primary responsibility for coordinating financial aspects of care. The Coordinator will work with patients and their families beginning with the evaluation for transplantation and continuing through and after transplantation, in a compassionate and tactful manner in order to help facilitate access to and provide continuity of care. The Coordinator will also work with other members of the transplant team, insurers and administrative personnel at the Transplant Center.

Specific responsibilities should include, but are not limited, to:

1. Obtaining detailed patient insurance benefit information for all aspects of the transplant process, including, but not limited to, outpatient prescription drugs, organ acquisition, follow-up clinic visits, and travel and housing if necessary.
2. Discussing benefits and other transplant financial issues with patients and/or family members during initial evaluation.
3. Advising patients on insurance and billing issues and options. Serving as a resource for patients and their family members on financial matters.
4. Obtaining all necessary payor authorizations. Verifying transplant coverage and other medical benefits and acquiring necessary referrals and authorizations.
5. Monitoring and updating information regarding insurance data, physicians, authorizations, and preferred providers. Assisting patients with questions concerning insurance and other financial

- issues.
6. Identifying and effectively communicating financial information to transplant team members, patients and their families with emphasis on identifying any potential patient out-of-pocket liability.
  7. Working with patients, their families and team members when possible to help address insurance coverage gaps via alternative funding options.
  8. Facilitating resolution of patient billing issues.

**Routine Referral Procedures.** Transplant Hospitals are expected to implement and practice appropriate routine referral procedures for all potential donors. Transplant Hospitals are further expected to demonstrate compliance based upon an annual medical record review, performed in collaboration with the OPO. Centers found to be out of compliance will be reviewed by the Membership and Professional Standards Committee.

**Designated Transplant Program Status.** In order to receive organs for transplantation, a transplant program in a Transplant Hospital that is a Member shall abide by the requirements set forth in applicable provisions of the National Organ Transplant Act, as amended, 42 U.S.C. 273 *et seq.*; the OPTN Final Rule, 42 CFR Part 121; these Bylaws, and UNOS Policies; and shall meet the criteria of (a), (b), or (c) below.

- a. Approved as a transplant program by the Secretary of HHS for reimbursement under Medicare.
- b. Qualified as a transplant program in accordance with the requirements set forth in Attachment I and the sub-attachments. The evaluation of each applicant for designated transplant program status will be performed in accordance with these Bylaws.
- c. Transplant program in a Department of Veterans Affairs, Department of Defense, or other Federal hospital.