APPENDIX B TO BYLAWS
OPTN

Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership

I. Organ Procurement Organizations.

General. An organization designated as an organ procurement organization by the Secretary of the Department of Health and Human Services (HHS) under Section 1138(b) of the Social Security Act or an organization that meets all requirements for such designation other than OPTN membership (OPO) is eligible for membership in the OPTN. OPOs 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; and OPTN policies. OPOs 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 OPTN policies. Failure to conform with such requirements shall be cause for corrective action described in Appendix A of these Bylaws. Each OPO shall fully inform the OPTN Contractor within five (5) days, to include copies of all related correspondence or reports, when any of the following events occur:

(1) an adverse action that leads to or threatens material change in the OPO's eligibility to procure organs or be reimbursed for organ procurement costs by Medicare or a state Medicaid program, including but not limited to any threatened or actual termination of Medicare designated status; and (2) any threatened or actual adverse action by a state or federal regulatory agency or its designee that would impose a significant limitation upon the OPO's ability to procure organs.

Key Personnel. The OPO must identify the individual selected to serve as the OPO's Executive Director and, if the OPO maintains a position for Medical Director, the OPO must identify the individual selected to serve as Medical Director, and their respective credentials. The Executive Director, together with other OPO staff, are responsible for effective organ recovery and distribution according to applicable policies. If the OPO has a Medical Director, he/she is responsible for the medical and clinical activities of the OPO. When the OPO learns that one or both of the Executive/Medical Directors plan(s) to leave, the OPTN Contractor must be notified immediately. At least 30 days (if possible) prior to the departure of the individual, the OPO shall submit to the OPTN Contractor the name of the replacement Director and information documenting his/her credentials. Failure to inform the OPTN Contractor of changes in the Executive Director or Medical Director shall result in recommendation to the Board of Directors that the Board so notify the Secretary and/or take appropriate action in accordance with Appendix A of these Bylaws, which action may include those defined as adverse under Section 3.01A. Failure to fill vacant Executive or Medical Director positions for six months shall be reported to the MPSC for possible recommendation to the Board of Directors that the Board so notify the Secretary.

Plan for Public Education on Organ Donation. The OPO shall submit to the OPTN Contractor written descriptions of activities with which it is involved regarding public education about organ donation, including how donor families, transplant patients, and transplant recipients participate. Failure to submit such documentation voluntarily shall result in recommendation to the Board of Directors that the Board so notify the Secretary.

Communication of Information for Organ Distribution. The OPO is responsible for equitable organ allocation within its service area according to OPTN policies and must be able to communicate in a timely manner appropriate information necessary to facilitate equitable organ distribution as well as perform other functions necessary to discharge this responsibility. Failure to comply with these requirements shall be cause for corrective action described in Appendix of these Bylaws, if applicable, or result in recommendation to the Board of Directors that the Board so notify the Secretary.

Donation After Cardiac Death: OPOs must develop, and once developed must comply with, protocols to facilitate the recovery of organs from DCD donors. OPO DCD recovery protocols must address the required model elements set forth in Attachment III.

II. Transplant Hospitals.

A. **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 the OPTN. 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; and OPTN 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 OPTN policies. For each of its organ-specific transplant programs, a Transplant Hospital shall fully inform the OPTN Contractor within five (5) days, to include copies of all related correspondence or reports, when any of the following events occur: (1) an adverse action that leads to or threatens material change in the status of the program's eligibility to perform or be reimbursed for organ transplants for Medicare or state Medicaid beneficiaries, in the status of the program's eligibility to perform or be reimbursed for organ transplants for Medicare or state Medicaid beneficiaries, including but not limited to initial approval of eligibility and any threatened or actual termination of eligibility; and (2) any threatened or actual adverse action by a state or federal regulatory agency or its designee (e.g., the Joint Commission on Accreditation of Healthcare Organizations) which would impose a significant limitation upon the program's ability to serve transplant candidates or recipients.

B. **Survival Rates.** In the distribution of survival rates of all OPTN Members a transplant program with a low (as defined below) survival rate would be subject to evaluation by the Membership and Professional Standards Committee (“MPSC”) 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. The MPSC may conduct a site visit to the program at Member expense and may require the Member to adopt a plan for quality

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 MPSC, 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 losses as reported in UNOS database. Expected events represent deaths or graft losses 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, the Member, in cooperation with the MPSC, shall adopt and promptly implement an appropriate plan for quality improvement. The Member’s failure to do so shall constitute a violation of UNOS requirements. The Member’s failure to do so shall constitute a violation of UNOS requirements

C. **Inactive Membership Status.** An OPTN Member Transplant Hospital that fails to remain functionally active with respect to any designated transplant program (as defined below) may voluntarily stop transplantation at 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. This voluntary action to stop transplantation may be extended beyond twelve months upon request to the MPSC and demonstration to the MPSC's satisfaction of the benefit of such extension, together with a plan and timeline for re-starting transplantation at the program which shall include assurance that all OPTN membership criteria will be met at the time of re-starting transplantation.

For purposes of these Bylaws, "functionally inactive" is defined as:

(1) The inability to serve patients, as a group, for a sustained and significant time period, where a period of 15 days or more is presumed to be sustained and significant, or

(2) No transplant performed for a period of time defined as:

(i) No transplant performed in three months in the case of kidney, liver, and heart transplant programs,
(ii) No transplant performed in six months in the case of pancreas and lung programs, and
(iii) No transplant performed in one year in the case of transplant programs located in stand-alone pediatric transplant hospitals,

with no explanation deemed satisfactory by the MPSC that the program remains qualified pursuant to the criteria defined in this Appendix B to provide transplant services.

If the Member fails to take either action voluntarily, the Membership and Professional Standards Committee may recommend that the Board of Directors notify the Secretary of HHS of the situation in the case of transplant programs approved by the Secretary of HHS for reimbursement under Medicare or transplant programs in Federal hospitals, or take appropriate action in accordance with Appendix A of these Bylaws in all other cases, which action may include those defined as adverse under Section 3.01A. Program inactivation or relinquishment of designated transplant program status involves (i) prompt suspension of transplantation, (ii) notice to patients (with a copy to the entity that operates the OPTN under contract with HHS (OPTN Contractor)) 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 OPTN 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 OPTN membership are met, the Membership and Professional Standards Committee shall recommend to the Board of Directors that the Board so notify the Secretary of HHS.

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 the OPTN Contractor and their patients as described above.

D. **Investigation of Personnel.** At the request of the MPSC, the Transplant Hospital must conduct an investigation, of personnel identified by the MPSC, who are associated with one or more of the Transplant Hospital's designated transplant programs (as defined below) qualified as a transplant program by other than the requirements set forth in Attachment I and sub-attachments to Appendix B, and report to the MPSC upon initiation and conclusion of the inquiry that it has conducted the investigation in accordance with the terms of this provision. The purpose of the investigation would be to examine the individual's or individuals' role(s) in a matter under review or reviewed by the MPSC and would be explained to the Transplant Hospital. The Hospital's investigation must be conducted pursuant to the institution's standard peer review process for conducting inquiries of potential professional misconduct and conclude with appropriate action consistent with this process. Failure to comply with this provision shall result in recommendation to the Board of Directors that the Board so notify the Secretary, and/or take appropriate action in accordance with Appendix A of these Bylaws.

E. **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, the OPTN Contractor must be notified immediately. At least 30 days (if possible) prior to the departure of the individual, the Transplant Hospital shall submit to the OPTN Contractor 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 the OPTN Contractor of changes in primary physician and surgeon shall result in recommendation to the Board of Directors that the Board so notify the Secretary, and/or take appropriate action in accordance with Appendix A of these Bylaws, which action may include those defined as adverse under Section 3.01A.

F. **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 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 Waiting List at this time, which ever is applicable; and (ii) within ten business days of removal from the Waiting List as a transplant candidate for reasons other than transplantation or death that the patient has been removed from the Waiting List. Each notification must include the telephone number that is available to patients and others to report concerns or grievances through the OPTN. All candidates currently on the waiting list should be notified by their listing center about the patient notification hotline, or other information as directed by the Executive Committee. Transplant Hospitals are further expected to maintain documentation of these notifications and make it available to the OPTN Contractor 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 notify the Secretary of HHS of the situation in the case of transplant programs approved by the Secretary of HHS for reimbursement under Medicare or transplant programs in Federal hospitals, or take appropriate action in accordance with Appendix A of these Bylaws in all other cases.

G. **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 the OPTN. 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.

H. **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.

I. **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.

J. **Designated Transplant Program Status.** In order to receive organs for transplantation, a transplant program in a Transplant Hospital that is a Member of the OPTN 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 OPTN 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 the OPTN Bylaws.

c. Transplant program in a Department of Veterans Affairs, Department of Defense, or other Federal hospital.

K. **Donation After Cardiac Death.** Transplant hospitals must develop, and once developed must comply with, protocols to facilitate the recovery of organs from DCD donors. Transplant Hospital DCD recovery protocols must address the required model elements set forth in Attachment III.

III. Histocompatibility Laboratories.

General. An independent histocompatibility laboratory that serves at least one Transplant Hospital that is active in the field of human organ transplantation within its service area (Histocompatibility Laboratory) is eligible for membership in the OPTN. For purposes of the OPTN Charter and Bylaws, independence from Transplant Hospital(s) served shall be defined by demonstration of a distinct governing body for the Histocompatibility Laboratory that is separate and not under the direct or indirect control of the governing body of any of the Histocompatibility Laboratory's Transplant Hospitals or of the governing body of a commonly controlled group of the Histocompatibility Laboratory's Transplant Hospitals. To attain membership in the OPTN, such a laboratory must conform to the Standards for Histocompatibility Testing set forth in Attachment II and applicable sub-attachments. The evaluation of each applicant laboratory will be performed in accordance with the OPTN Bylaws. Additionally, Histocompatibility Laboratories 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; and OPTN policies. Histocompatibility Laboratories 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 OPTN policies. Failure to conform with such requirements shall be cause for corrective action described in Appendix A of these Bylaws. Each Histocompatibility Laboratory shall fully inform the OPTN Contractor within five (5) days, to include copies of all related correspondence or reports, when any of the following events occur:

1) an adverse action that leads to or threatens material change in the laboratory's ability to perform histocompatibility testing or be reimbursed for the costs of such testing by Medicare or a state Medicaid program, including but not limited to any threatened or actual termination of Medicare participation; and

(2) any threatened or actual adverse action by a state or federal regulatory agency or its designee that would impose a significant limitation upon the laboratory's ability to perform histocompatibility testing for the benefit of transplant candidates and recipients.