

## APPENDIX B TO BYLAWS OPTN

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

#### I. Organ Procurement Organizations.

- A.** **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 in writing within 10 business days, when an adverse action has been taken against it by the regulatory agency of its respective jurisdiction or the regulatory agency's designee.
- B.** **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.
- C.** **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.
- D.** **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.
- E.** **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.

F. Performance: The Membership and Professional Standards Committee (MPSC) will evaluate all OPOs to determine if the difference in observed and expected organ yield can be accounted for by some unique aspect of the Donation Service Area and/or OPO in question. The evaluation may include a peer visit to the OPO at the OPO's expense.

Those OPOs whose observed organ yield rates fall below the expected rates by more than a specified 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 after distribution to the transplant community and subsequent Board approval.

The initial criteria used to identify OPOs with lower than expected organ yield, for all organs as well as for each organ type, will include all of the following:

A difference of at least ~~11~~ More than 10 fewer observed organs per 100 donors than expected yield (Observed per 100 donors-Expected per 100 donors < -10)

- A ratio of observed to expected yield less than 0.90.
- A two-sided p-value is less than 0.05.

All three criteria must be met for an OPO to be identified for MPSC review.

If an OPO's organ yield rate cannot be explained by donor mix or some other unique clinical aspect of the OPO or Donation Service Area in question, the Member, in cooperation with the MPSC, will adopt and promptly implement a plan for performance improvement. The Member's failure to do so will constitute a violation of OPTN requirements.

*NOTE: The amendments and new language to OPTN Appendix B, Section I (Organ Procurement Organizations), shall be effective pending notice to the membership. (Approved at the June 28-29, 2011 Board of Directors Meeting)*

## **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. A Transplant Hospital shall fully inform the OPTN Contractor in writing within 10 business days, when an adverse action an adverse action has been taken against or may impact any of its transplant programs by the regulatory agency of its respective jurisdiction or the regulatory agency's designee.
- 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 improvement. The MPSC may also require, at its discretion, that the Member participate in a discussion regarding a performance review. The discussion may be with the MPSC, a subcommittee or work group, as the MPSC may direct. The discussion referenced above will be conducted according to the principles of confidential medical peer review, as described in Section 2.07A of Appendix A to the OPTN Bylaws. The discussion is not an adverse action or an element of due process. A Member who participates in a discussion with the MPSC is entitled to receive a summary of the discussion.

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.

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.

**C. Functional Inactivity, Inactive Transplant Program Status, Relinquishment of Designated Transplant Program Status and Termination of Designated Transplant Program Status.**

For the purposes of these bylaws, a candidate is defined as an individual who has been added to the waiting list. A potential candidate is defined as an individual who is under evaluation for transplant by the transplant program. Each reference to a candidate includes potential candidates if and as applicable.

1. **Functional Inactivity.** Transplant programs must remain functionally active. Transplant program functional activity will be reviewed periodically by the Membership and Professional Standards Committee (MPSC).

For purposes of these Bylaws, "Functional Inactivity" is defined as any or all of the items below:

- (a) The inability to serve potential candidates, candidates, or recipients, for a period of 15 days or more consecutively;
- (b) failure to perform a transplant during the following stated periods of time:
  - i. In the case of kidney, liver, and heart transplant programs, within three consecutive months;
  - ii. In the case of pancreas and lung programs, within six consecutive months;
  - iii. In the case of stand-alone pediatric transplant hospitals, within twelve consecutive months.
- (c) waiting list inactivation of 15 or more consecutive days and/or 28 cumulative days or more over any 365 consecutive day period.
- (d) given their experimental and evolving nature, functional inactivity thresholds and waiting list notification requirements regarding functional inactivity have not been established for pancreatic islet and intestinal transplant programs.

Any program identified to be functionally inactive shall be provided the opportunity to explain its inactivity through reports requested by the MPSC.

A transplant program must provide written notice to candidates when the transplant program:

- (a) Inactivates its waiting list or is unable to perform transplants for 15 consecutive days or more;
- (b) Inactivates its waiting list or is unable to perform transplants for 28 cumulative days or more over any 365 consecutive day period;

The MPSC may also require, at its discretion, that the Member participate in an informal discussion regarding a performance review. The informal discussion may be with the MPSC, a subcommittee or work group, as the MPSC may direct.

The discussion referenced above will be conducted according to the principles of confidential medical peer review, as described in Section 2.07A of Appendix A to the Bylaws. The discussion is not an adverse action or an element of due process. A Member who participates in an informal discussion with the MPSC is entitled to receive a summary of the discussion.

A functionally inactive transplant program should voluntarily inactivate for a period of up to twelve months by providing written notice to the Executive Director. If the transplant program expects to be inactive for more than twelve months, the Member should relinquish designated transplant program status for the program in accordance with these bylaws.

The MPSC may recommend that a program inactivate or relinquish its designated transplant program status due to the program's functional inactivity. If the program fails to inactivate or relinquish its designated transplant status upon the MPSC's recommendation to do so, the MPSC may recommend the Board of Directors take appropriate action in accordance with Appendix A of these Bylaws. Potential adverse actions are defined under Section 3.01A of the bylaws. Additionally, the Board of Directors may notify the Secretary of HHS of the situation.

**2. Inactive Transplant Program Status.** For the purposes of these bylaws, inactive transplant program status is defined as:

- an inactive transplant program waiting list status in UNet<sup>SM</sup> (short-term inactivation), or
- an inactive transplant program waiting list status in UNet<sup>SM</sup> and an inactive membership status (long-term inactivation).

A Member may voluntarily inactivate a transplant program, on a short-term or long-term basis, for reasons including but not limited to:

- inability to meet functional activity requirements;
- temporarily lacking required physician and/or surgeon coverage;
- substantial change in operations that require temporary cessation of transplantation.

**a. Short-Term Inactivation**

Short-term inactivation means that a transplant program may be inactive for up to 14 consecutive days. A Member may voluntarily inactivate a transplant program for a period not to exceed 14 days by changing the program's waiting list status in UNet<sup>SM</sup>.

- i. **Notice to the OPTN Contractor.** When a Member intends to voluntarily inactivate a transplant program on a short-term basis, the Member is not required to notify the OPTN contractor.
- ii. **Notice to Patients.** In accordance with Attachment I to Appendix B, Section VII each transplant program must provide potential candidates, candidates, and recipients with a written summary of its Program

Coverage Plan at the time of listing or when there are any substantial changes in program or personnel.

**b. Long-Term Inactivation**

Long-term inactivation means inactivation of a transplant program for 15 or more days consecutively. Members should voluntarily inactivate programs that are not able to serve potential candidates, candidates, or recipients, for a period of 15 or more days consecutively. Voluntary inactivation may extend for a period of up to 12 months.

**i. Notice to the OPTN Contractor.** When a Member intends to voluntarily inactivate a transplant program for 15 or more days consecutively, it must provide written notice, including the reason(s) for inactivation, to the OPTN Executive Director upon deciding to inactivate the transplant program.

**ii. Notice to the Patients.** When a Member intends to inactivate a transplant program for 15 or more days consecutively, it must provide:

a) written notice to the transplant program's potential candidates, candidates, recipients, and living donors currently being followed by the transplant program. Written notice should be provided at least 30 days prior to the anticipated inactivation date 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). Written notice must be provided no later than seven days following inactivation and include:

- 1) the reason(s) for inactivating the transplant program;
- 2) notice that while still on the waiting list of the inactive program the candidate cannot receive an organ offer through this member program;
- 3) options for potential candidates, candidates, recipients, and living donors to transfer to an alternative designated transplant program with the phone number of the administrative office of the inactivating program to help with potential candidate, candidate, recipient, and living donor transfers.

The Member must provide a representative copy of the patient notice to the OPTN contractor along with a list of potential candidates, candidates, recipients, and living donors who received the notice.

In the event of a natural disaster that adversely affects a transplant program, the patient notification requirements shall be applied reasonably and flexibly.

**3. Transition Plan.** When the Member inactivates a transplant program for 15 or more days consecutively, it must:

- a) promptly suspend organ implantation for that transplant program;
- b) assist potential candidates and candidates in identifying designated transplant programs to which they can transfer;

- c) provide a list to the OPTN contractor of all of the transplant program's candidates at the time of inactivation and update it throughout this process;
- d) indicate on the list provided the decision of each potential candidate and each candidate to transfer, with the following additional information:
  - i) if a candidate or potential candidate chooses not to transfer to an alternative transplant program, provide the reason and indicate whether the candidate has been completely informed of the implications of this decision; or
  - ii) if a candidate or potential candidate chooses to transfer, indicate the transplant program to which the candidate is transferring. Periodic updates will be required as to the status of each candidate's transfer progress until the candidate is evaluated by the accepting program and an official decision is made regarding the candidate's listing status.
- e) expedite removal of all candidates from the inactive transplant program's waiting list, or, if the candidate requests, transfer the candidate to another OPTN Member transplant hospital;
- f) initiate transfer of all active candidates or potential candidates hospitalized at the inactive transplant program to an accepting transplant hospital within seven days of inactivation of the transplant program. The inactive transplant program must complete the transfer process within 14 days unless transfer would be unsafe or discharge is anticipated within that time; or circumstances outside of the program's control exist that prevent transfer within 14 days. The program must document and submit to the OPTN contractor all efforts for transfer of its hospitalized candidates or potential candidates if it is unable to meet the time periods within this section.
- g) provide a priority list of the most urgent candidates or potential candidates at the inactive transplant program with an individualized plan of transfer, potential alternative transplant programs, and a timeline for transferring these candidates according to the following priorities:
  - i) for liver candidates, all Status 1A and 1B candidates must be transferred within seven days of program inactivation, followed by all active candidates in descending MELD/PELD score order, with all candidates whose MELD/PELD score exceeds 25 to be transferred within 30 days, followed by all inactive candidates;
  - ii) for lung candidates, active candidates should be transferred according to descending Lung Allocation Scores followed by inactive candidates;
  - iii) for kidney candidates, those whose PRA(measured or calculated) is over 80% should be transferred first, followed by all other active candidates in order of waiting time, then transfer of all inactive candidates;
  - iv) for heart candidates, all Status 1A and 1B must be transferred within seven days of inactivation;
  - v) for multivisceral organ transplant candidates, transfer must be completed within 30 days of inactivation; and
  - vi) notwithstanding these guidelines, all active candidates who choose to transfer should be transferred within 60 days of inactivation.
  - vii) The program must document and submit to the OPTN contractor all efforts for transfer of its candidates if it is unable to meet the time periods within this section.
- h) document all efforts to transfer candidates to an alternative designated transplant program including all contacts made to facilitate the transfer of candidates; and

- i) remove every transplant candidate from the inactive transplant program's waiting list within 12 months of the program's inactivation date in the cases when a program does not intend to reactivate.

Transplant programs that inactivate for 15 or more days consecutively may still have the ability to provide care to transplant candidates, recipients and living donors. Should the transplant program continue to provide follow-up care to transplant recipients and living donors, the program must continue to submit OPTN follow-up forms via UNet<sup>SM</sup>. Alternatively, transplant recipients may transfer care to another institution.

4. **Extension of Voluntary Inactive Program Status Beyond Twelve Months.** A Member transplant hospital may request an extension of voluntary inactive program status beyond twelve months by making a request to the MPSC. The request must demonstrate to the MPSC's satisfaction the benefit of such an extension, and be accompanied by a comprehensive plan with a timeline for re-starting transplantation at the program. This demonstration must include assurance that all membership criteria will be met at the time of re-starting transplantation.
5. **Reactivation After Voluntary Long Term Inactivation.** A Member transplant hospital may reactivate its program after long term voluntary inactivation by submitting application materials deemed appropriate by the MPSC that establishes that the program has again become active in organ transplantation and that all criteria for 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.
6. **Relinquishment or Termination of Designated Transplant Program Status.** Relinquishment of Designated Transplant Program Status means that a Member may voluntarily give up its designated transplant program status upon written notice to the OPTN. Members that relinquish designated transplant program status are voluntarily closing the transplant program.

Termination of Designated Transplant Program Status means that a Member's designated program status is terminated by the Secretary of the Department of Health and Human Services ("Secretary"). 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 and/or the Executive Committee request approval from the Secretary to terminate a Member's designated transplant program status in accordance with Appendix A Section 2.06A of these Bylaws. The Board of Directors and/or the Executive Committee may, on its own accord, request such approval from the Secretary.

Once a Member relinquishes a designated transplant program status or it is terminated by the Secretary of HHS, that transplant program may no longer perform organ transplants. The Member must facilitate the transfer of the subject transplant program's candidates to another transplant program.

- a. **Notice to the OPTN Contractor.** A Member transplant hospital must provide written notice to the OPTN contractor within 30 days of the intent to relinquish its designated transplant program status and the reasons therefor upon deciding to relinquish designated transplant program status.
- b. **Notice to the Patients.** When a Member transplant hospital intends to relinquish its designated transplant program status, or its designated transplant program status is terminated, it must provide:
  - i) written notice to the transplant program's potential candidates, candidates, recipients, and living donors currently being followed by

the transplant program. Written notice should be provided at least 30 days prior to the anticipated date of relinquishment or termination 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) Written notice must be provided no later than seven days following relinquishment/termination and include:

1. the reason(s) for loss of designated transplant program status;
2. notice that while still on the waiting list of the inactive program the candidate cannot receive an organ offer through this member program;
3. options for potential candidates, candidates, recipients, and living donors to transfer to an alternative designated transplant program with the phone number of the administrative office of the inactivating program to help with potential candidate, candidate, and recipient transfers; and

The Member transplant hospital must provide a representative copy of the patient notice to the OPTN contractor along with a list of potential candidate, candidate, and recipient names who received the notice.

**c. Transition Plan.** When a Member transplant hospital relinquishes a transplant program's designated program status or its designated program status is terminated, it must:

- i. promptly suspend organ implantation for the transplant program;
- ii. assist potential candidates and candidates in identifying designated transplant programs to which they can transfer;
- iii. provide a list to the OPTN contractor of all of the transplant program's candidates on the waiting list at the time of relinquishment or termination and update it throughout this process;
- iv. indicate on the list provided the decision of each potential candidate and each candidate to transfer, with the following additional information:
  1. if a candidate or potential candidate chooses not to transfer to an alternative transplant program, provide the reason and indicate whether the candidate has been completely informed of the implications of this decision; or
  2. if a candidate or potential candidate chooses to transfer, indicate the transplant program to which the candidate is transferring. Periodic updates will be required as to the status of each candidate's transfer progress until the candidate is evaluated by the accepting program and an official decision is made regarding the candidate's listing status.
- v. expedite removal of all candidates from the transplant program's waiting list, or, if the patient requests, transfer the candidate to another OPTN Member transplant hospital;
- vi. initiate transfer of all active candidates hospitalized at the transplant program to an accepting transplant hospital within seven days of relinquishment of the transplant program. The transplant program must complete the transfer process within 14 days unless transfer would be unsafe or discharge is anticipated within that time; or circumstances outside of the program's control exist that prevent transfer within 14

- days. The program must document and submit to the OPTN contractor all efforts to transfer its hospitalized candidates if it is unable to meet the time periods within this section.
- vii. provide a priority list of the most urgent candidates listed at the transplant program with an individualized plan of transfer, potential alternative transplant programs, and a timeline for transferring these candidates according to the following priorities:
    1. for liver candidates, all Status 1A and 1B candidates must be transferred within seven days of relinquishment, followed by all active candidates in descending MELD/PELD score order, with all candidates whose MELD/PELD score exceeds 25 to be transferred within 30 days, followed by all inactive candidates;
    2. for lung candidates, active candidates should be transferred according to descending Lung Allocation Scores with highest scores first, followed by inactive candidates;
    3. for kidney candidates, those whose PRA (measured or calculated) is over 80% should be transferred first, followed by all other active candidates in order of waiting time, then transfer of all inactive candidates;
    4. for heart candidates, all Status 1A and 1B must be transferred within seven days of relinquishment;
    5. for multivisceral organ transplant candidates, transfer must be completed within 30 days of relinquishment; and
    6. notwithstanding these guidelines, all active candidates should be transferred within 60 days of relinquishment; and;
    7. The program must document and submit to the OPTN contractor all efforts for transfer of its candidates if it is unable to meet the time periods within this section.
  - viii. document all efforts to transfer candidates to an alternative designated transplant program including all contacts made to facilitate the transfer of candidates; and
  - ix. remove every transplant candidate from the transplant program's waiting list within 12 months of the program's relinquishment date.

A Member that relinquishes or terminates a designated transplant program may still have the ability to temporarily provide care to transplant candidates and provide follow-up care to transplant recipients and living donors. Should the transplant program continue to provide follow-up care to transplant recipients and living donors, the program must continue to submit OPTN follow up forms via UNet<sup>SM</sup>. Alternatively, transplant recipients may transfer care to another institution.

- 6. **Waiting time on waiting list.** To assure equity in waiting times, and facilitate smooth transfer of candidates from the waiting list affected programs (i.e. programs that voluntarily inactivate, relinquish or lose designated transplant program status), candidates on the waiting list in such instances may retain existing waiting time and continue to accrue waiting time appropriate to their status on the waiting list at the time of the programs' inactivation, relinquishment, or loss of designated status. This total acquired waiting time will be transferred to the candidate's credit when s(he) is listed with a new program.

7. **Laboratory Tests.** The inactivated program remains responsible for evaluating its candidates. This includes, but is not limited to performing laboratory tests and evaluations required to maintain the candidate's appropriate status on the waiting list until the time of transfer.
- 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.** For each designated organ transplant program, the Transplant Hospital must identify a primary transplant surgeon and primary transplant physician and demonstrate that they meet the requirements set forth in the Bylaws, Appendix B, Attachment I. Where applicable these individuals must be the same individuals reported to the Center for Medicaid and Medicare Services (CMS) as serving in this capacity.
- 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 such written notification must reference and include the OPTN contractor's "Patient Information Letter," which provides 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 in writing within 10 business days, when an adverse action has been taken against it by the regulatory agency of its respective jurisdiction or the regulatory agency's designee.