MEMBERSHIP CRITERIA AND EVALUATION OF APPLICATIONS*

An area that overlaps with adopting policies and programming them is the evaluation of applications for Membership, status as a designated transplant program, and changes in key personnel. How policies are established and programmed on the UNet^{SM} computer system has been illustrated. This section describes criteria for OPTN Membership and designation as a transplant program, which is required to enable receipt of organs for transplantation, as well as the applicable application processes. Reviewing applications to ensure that they meet Membership criteria is one of the first "compliance" procedures a Member undergoes. **Chart 1, Application and Hearing Procedures for Members and Designated Transplant Programs,** outlines the Membership application process.

a. Organ Procurement Organizations

i. General Requirements. An OPO must be designated as an organ procurement organization by the Secretary of HHS under Section 1138(b) of the Social Security Act. OPOs may have independent membership or they may be approved as a hospital based OPO under the membership of the transplant hospital. In addition, OPOs must meet the following requirements:

ii. Key Personnel. OPOs must identify and maintain key personnel. These include an Executive Director and, if the OPO chooses, a Medical Director. Changes in key personnel must be reported to the OPTN at least 30 days (if possible) in advance, along with the name of the individual's replacement and credentials.

iii. Plan for Public Education. OPOs must submit to the OPTN written descriptions of their activities regarding public education about organ donation.

iv. Communication of Information. OPOs are responsible for equitable organ allocation within their respective service areas according to OPTN Policies. OPOs 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 their responsibilities regarding organ allocation.

v. Definition of Independence. While not a condition of Membership in the OPTN, OPOs must be independent of the Transplant Hospitals they serve in order to vote on OPTN affairs. An OPO is independent if it has a distinct governing body separate and not under the direct or indirect control of the governing body of any of its Transplant Hospitals or of the governing body of a commonly controlled group of its Transplant Hospitals.

b. Transplant Hospitals.

vi. General. A Transplant Hospital must perform organ transplants or have submitted an active application for designated transplant program status for at least one organ type, and participate in the Medicare or Medicaid programs. In addition, in order to receive organs for transplantation, transplant hospitals must be an OPTN Member Transplant Hospital and shall

* In an effort to assist readers easily identify updates to the Evaluation Plan within the "Membership Criteria and Evaluation of Applications" section, updates to the section will be highlighted in blue. Information that no longer applies will be removed from the section and will not appear in any form.

abide by applicable provisions of the National Organ Transplant Act, the OPTN Final Rule, and OPTN Bylaws and Policies, and shall meet the following:

- Approved as a transplant program by the Secretary of HHS for reimbursement under Medicare,
- A transplant program in a Department of Veterans Affairs, Department of Defense, or other Federal hospital, or
- Qualified as a transplant program in accordance with the following requirements:

    - Facilities and Resources. The program's Transplant Hospital must allocate sufficient operating and recovery room resources, intensive care resources, and surgical beds and personnel to the transplant program.
    - Remain functionally active. See "Inactive Programs" under Transplant Hospitals below.
    - OPO Affiliation. The program must have letters of agreement or contracts with an OPO.
    - Histocompatibility Laboratory Affiliation. The program must use, for its histocompatibility testing, a laboratory that is approved for OPTN Membership and meets the standards for histocompatibility testing described under Histocompatibility Laboratories. The laboratory may be either a member of the OPTN itself, or have approval as a hospital based lab under the transplant center's membership.
    - Key Personnel: Transplant Surgeon and Physician. See "Key Personnel" under Transplant Hospitals below.
    - Report Changes in Key Personnel. See "Key Personnel" under Transplant Hospitals below.
    - Collaborative Support. The program must show evidence of collaborative involvement with experts in the field of radiology, infectious disease, pathology, immunology, anesthesiology, physical therapy and rehabilitation medicine, histocompatibility and immunogenetics, and, as appropriate, hepatology, pediatrics, nephrology with dialysis capability, and pulmonary medicine with respiratory therapy support.
    - Ancillary Services. The program must have immediate access to sophisticated microbiology, clinical chemistry, histocompatibility testing, and radiology services, as well as facilities required or capacity for monitoring immunosuppressive drugs.
    - Blood Bank Support. The program must have extensive blood bank support, including access to large quantities of blood.
    - Social Support. The program must have access to mental health and social support services.
    - Pancreatic Islet Transplantation. To receive pancreata for islet transplantation, programs must meet separate facility, reporting, ancillary personnel, collaborative support, and regulatory compliance requirements in addition to meeting the above criteria.

vii. Survival Rates. The OPTN, through the Membership and Professional Standards Committee, evaluates Transplant Hospitals according to a defined algorithm to identify institutions that have experienced low one-year transplant survival rates compared to the expected survival rates for that program. The Data Subcommittee requested that the Scientific Registry of Transplant Recipients identify a method that could be used to analyze a

program's one-year graft and/or patient survival rates, with adjustments made for the case mix of the patient population. The Scientific Registry of Transplant Recipients provides the Membership and Professional Standards Committee with a report detailing outcomes for all transplant programs for each Committee meeting (four times a year). This report provides organ specific information on the number of transplants performed during the evaluation period; the number of patients who have undergone transplantation; the observed number of graft failures and deaths; the expected number of graft failures and deaths; actual and expected survival rates; and a measure of statistical significance (p-value). Programs identified for further review by the Membership and Professional Standards Committee must meet all of the following criteria: (1) p-value less than 0.05, (2) observed minus expected events greater than three, and (3) observed divided by expected events greater than 1.5. If a transplant program is identified as meeting all three criteria during a two-and-a-half year period, either for graft survival, patient survival, or both, the Membership and Professional Standards Committee will send an inquiry to the center.

Using the Scientific Registry of Transplant Recipients methodology, transplant programs that have a small volume of activity (performing nine or fewer transplants in a two-and-a-half-year interval) are rarely identified as having outcomes that are significantly below expected. Therefore, the Data Subcommittee must systematically review these small volume programs. To do so, the Scientific Registry of Transplant Recipients provides the Membership and Professional Standards Committee with a report listing all small volume programs that experienced at least one death and/or graft failure within one year of transplant during a specified time period for evaluation. The Data Subcommittee then reviews the raw data on patient outcomes using blinded transplant data the program has entered into UNet^{sm}. These data included transplant volume summaries, causes for death/and or graft failure, comparisons to national survival statistics, and performance in years subsequent to the initial period of review.

The graft and patient survival rates of all transplant programs, both large and small volume, are reviewed by the Membership and Professional Standards Committee at each Committee meeting. The review of these hospitals determines whether their outcomes are accounted for by candidate mix or some other unique clinical aspect of the transplant program in question. Programs that are identified for further review will be requested to provide information regarding the program staff as well as a synopsis of the graft failures and/or deaths. Programs will continue to be reviewed by the Membership and Professional Standards Committee until improvements in one-year survival rates have been demonstrated in subsequent years.

viii. Inactive Programs. Transplant Hospitals are expected to inform their candidates on the waiting list if there will be an extended period of time when a designated transplant program will be unable to perform transplants. Transplant Hospitals that fail to remain functionally active with respect to any designated transplant program have the option of (i) voluntarily inactivating that transplant program for up to 12 months, or (ii) relinquishing designated transplant program status for the program. "Functionally inactive" (for the purposes of this provision) 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.

ix. Functional Inactivity Review. The Membership and Professional Standards Committee reviews program activity rates for all Transplant Hospitals. Programs are considered to be functionally inactive if a transplant has not been performed during a specified interval. The

period of review for kidney, liver, and heart programs is three months. Pancreas and lung programs are reviewed on a six-month basis. Stand-alone pediatric hospitals are reviewed on a yearly basis. The Membership and Professional Standards Committee is concerned that such programs may not meet requirements for being active in the field of organ transplantation, which may result in the members of the transplant team not maintaining a current working knowledge. The audit is conducted in a blinded manner and requests that the program identify how the staff is maintaining a current working knowledge in organ transplantation and the reasons for inactivity. The Membership and Professional Standards Committee will review the center's response to determine if further inquiry is required. Transplant programs identified to be functionally inactive may be encouraged to either voluntarily inactivate or relinquish designated transplant program status for the program until the circumstances affecting the status of the program have been resolved.

x. Program Inactivation/Relinquishment of Active Status. Upon inactivating a transplant program or relinquishing the program's status as a designated transplant program, the program must (i) promptly suspend transplantation, (ii) notify its candidates in writing, providing a copy to the OPTN, of the need for inactivation and removal of candidates from the program's waiting list or, if a candidate desires, transfer to the list of another OPTN Member Transplant Hospital, and (iii) assist its candidates in identifying designated transplant programs to which they can transfer.

xi. Key Personnel. Key personnel requirements differ to some degree depending upon the pathway by which a transplant program qualifies to receive organs for transplantation. For any designated transplant program qualified to receive organs by virtue of (i) approval of the program by the Secretary of HHS for reimbursement under Medicare, or (ii) location of the program in a Federal Hospital, the Transplant Hospital must identify 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 for primary surgeon and primary physician by the OPTN for designated transplant programs that do not qualify as a transplant program by virtue of the criteria listed under (i) or (ii) above (*i.e.*, approval for reimbursement under Medicare or location in a Federal Hospital).

For any designated transplant program that does not qualify to receive organs by virtue of approval for reimbursement under Medicare or location in a Federal Hospital, Transplant Hospitals must have key personnel who meet certain minimum levels of commitment to and knowledge of organ procurement and transplantation. Such key personnel include a primary surgeon and primary physician. Qualifications for these individuals include, but are not limited to:

- Completed Transplant Hospital credentialing process; individual is a current Member of the hospital in good standing.
- Licensed to practice medicine in his/her state; individual is accepted onto the medical staff of and on-site at the applicant Transplant Hospital.
- Certified (or achieved eligibility if applicable) by applicable surgery/medical Boards or their foreign (or other applicable) equivalent.
- Meets applicable requirements for training and/or experience, including without limitation, demonstration of competence and currency by performance of sufficient numbers of transplant procedures in the case of primary surgeon, and involvement with the primary care of sufficient numbers of transplant patients, in the case of primary physician.

Changes in key personnel must be reported to the OPTN at least 30 days (if possible) in advance of the effective date, along with the name of the individual's replacement, Curriculum Vitae, and information demonstrating and documenting compliance with OPTN criteria for a designated transplant program. This information should be submitted in the form of an application for Change in Key Personnel.

xii. Candidate Notification. Transplant Hospitals are expected to notify candidates in writing (i) that they either have been placed or have not been placed on the waiting list following their evaluation as a candidate for transplantation, and (ii) that they have been removed from the waiting list when removed for reasons other than transplantation or death. Documentation of the notifications is to be maintained and made available to the OPTN upon request. The notification must also include information about the Patient Services Hotline.

xiii. Clinical Transplant Coordinators. A Transplant Hospital's transplant program(s) are encouraged to identify one or more Members of the transplant team who will be responsible for coordinating clinical aspects of candidate care. The coordinator works with candidates and their families beginning with the evaluation for transplantation and continuing through and after transplantation, in a compassionate and tactful manner to help facilitate access to and provide continuity of care. The coordinator also works with other members of the transplant team, including physicians, surgeons, nurses, social workers, financial coordinators, and administrative personnel. It is recommended that the transplant coordinator be a registered nurse or other licensed clinician who performs or oversees a team of other healthcare personnel and support staff in performing functions related to the evaluation of candidates for transplantation, and care of candidates accepted for and following transplantation.

xiv. Financial Coordinator. Transplant Hospitals are encouraged to identify one or more Members of the transplant team who will be responsible for coordinating and clarifying candidate-specific financial aspects of care. The coordinator works with candidates and their families beginning with the evaluation for transplantation and continuing through and after transplantation, in a compassionate and tactful manner to help facilitate access to and provide continuity of care. The coordinator also works with other members of the transplant team, insurers, and administrative personnel at the Transplant Hospital. It is recommended that responsibilities of the coordinator include, for example, obtaining detailed candidate insurance benefit information for all aspects of the transplant process, serving as a resource for candidates and their families on financial matters, obtaining payor authorizations, and facilitating resolution of billing issues.

x. Transplant Mental Health and Social Support Services. Mental health and social support services are essential for the total care of transplant recipients, living donors and their families. Such services must be available. All transplant programs should identify appropriately trained individuals who are designated members of the transplant team and have primary responsibility for coordinating the psychosocial needs of transplant candidates, recipients, living donors and families. They will work with patients and families in a compassionate, culturally competent and tactful manner in order to facilitate access and provide continuity of care.

xi. **Routine Referral Procedures.** Transplant Hospitals are expected to implement and practice appropriate routine referral procedures for all potential donors, and demonstrate

compliance based upon an annual medical record review performed in collaboration with their OPOs.

c. Histocompatibility Laboratories.

i. General. To be a classified as a member a Histocompatibility Laboratory must be independent of the Transplant Hospitals it serves, which must include at least one Transplant Hospital active in the field of organ transplantation. Alternatively, a laboratory may be hospital based, in which case approval was granted under that of the transplant hospital. Histocompatibility Laboratories also must meet requirements for accuracy and completeness of testing as established from time to time by the OPTN/UNOS Board of Directors, as well as criteria for testing itself, including, for example, performing tests only at the written or electronic request of an authorized person or upon oral request followed by written authorization within 30 days and maintaining procedures in a manual with annual review. In addition, Histocompatibility Laboratories must meet the following requirements:

ii. Definition of Independence. A Histocompatibility Laboratory is independent if it has a distinct governing body separate and not under the direct or indirect control of the governing body of any of its Transplant Hospitals or of the governing body of a commonly controlled group of its Transplant Hospitals.

iii. Key Personnel. A Histocompatibility Laboratory must have a Director, a Technical Supervisor, and a Clinical Consultant. It is possible that one individual may serve more than one or all three positions. The Director/Technical Supervisor must meet specified education/training and experience requirements. The Director also must meet competency standards and be on-site commensurate with the Histocompatibility Laboratory's workload. The Clinical Consultant must be qualified to consult with and render opinions to the Laboratory's clients concerning the appropriateness of human histocompatibility and/or transplantation immunology tests ordered and the interpretation of test results in relation to candidate diagnosis and management. All personnel must be licensed or meet standards required by federal, state, and local laws. Changes in these key personnel must be reported to the OPTN at least 30 days (if possible) in advance, along with the name of the individual's replacement, Curriculum Vitae, and information demonstrating and documenting compliance with OPTN criteria for a Histocompatibility Laboratory.