

ATTACHMENT I TO APPENDIX B OF THE OPTN BYLAWS

A transplant program that meets the following criteria shall be qualified as a designated transplant program to receive organs for transplantation:

- I. **Facilities and Resources.** A successful transplant program requires extensive facilities and commitment of resources. Consequently, institutions must allocate sufficient operating and recovery room resources, intensive care resources, and surgical beds and personnel to the transplant program.
- II. **Reporting Key Personnel Changes:** Designated transplant programs must have key personnel - specifically a primary transplant surgeon and a primary transplant physician- who meet certain minimum levels of commitment to and knowledge of organ procurement and transplantation as specified below. All programs should develop a succession plan that addresses changes in key personnel staffing.

When a designated transplant program is informed of a key personnel change it must notify the OPTN Contractor within 7 business days in writing, as described below in "Reporting Key Personnel Changes". The member must then follow the procedures for applications that are described in the Bylaws, Appendix A, Section 1.03A. Designated programs are also responsible for maintaining Program Coverage Plans as described below in Section VI. The Program Coverage Plan should address instances when key personnel are unavailable to perform their transplant duties for short periods of time.

Reporting Key Personnel Changes:

- A. The primary transplant surgeon and/or primary transplant physician departs from the program and/or is no longer involved with the program:

When the Transplant Hospital is informed that one or more of these individuals plan to leave or otherwise cease their active participation in the transplant program, the OPTN Contractor must be notified within 7 business days in writing. ("OPTN Contractor Notification Date")

No less than 30 days prior to the end of the individual's active participation in the program the Transplant Hospital is required to submit to the OPTN Contractor, a complete Personnel Change Application, which documents that the proposed new primary transplant surgeon or physician meets the requirements specified in this Appendix B, Attachment I, Section VI, and applicable sub-attachments.

If the Transplant Hospital receives less than 60 days advance notice of the key personnel change taking place, then the Transplant Hospital must submit a complete application (see paragraph above) to the OPTN Contractor within 30 days from the OPTN Contractor Notification Date.

If a program is unable to verify or propose through a complete Personnel Change Application that it has on site both a transplant surgeon and a transplant physician who meet the requirements for primary transplant surgeon and physician the Transplant Hospital must inactivate the program's membership, or relinquish or terminate its Designated Transplant Program Status as described in Appendix B, Section II, C of the Bylaws.

- B. The primary transplant surgeon and/or primary transplant physician remains involved in the program as an additional transplant surgeon or /physician:

When the Transplant Hospital plans to change the individual designated as the primary transplant surgeon or primary transplant physician, the OPTN Contractor must be notified within 7 business days in writing.

No less than 30 days prior to the change in the individual's status, the Transplant Hospital is required to submit a complete Personnel Change Application to the OPTN Contractor. This Personnel Change Application documents that the individual meets the requirements specified in the Bylaws, Appendix B, Attachment I, Section VI, and applicable sub-attachments.

The transition to the new designated primary transplant surgeon or physician becomes effective after the application has been reviewed and approved by the Membership and Professional Standards Committee (MPSC) or an Ad hoc Subcommittee of the MPSC, as described below in the Processing Applications section of the bylaws.

- C. The primary transplant surgeon and/or primary transplant physician will not be involved with the program on a temporary basis such as periods of military or medical leave: (Temporary here is defined as greater than 30 days but less than 1 year.) When the Transplant Hospital learns that one or more of these individuals must take a temporary leave of absence or otherwise temporarily cease their active participation in the transplant program, the OPTN Contractor must be notified within 7 business days in writing. At least 30 days prior to the end of the individual's active participation in the program, the Transplant Hospital is required to submit to the OPTN Contractor a complete Personnel Change Application. This application documents compliance with OPTN criteria for a designated transplant program and indicates that the proposed new primary transplant surgeon or physician meets the requirements specified in the Bylaws, Appendix B, Attachment I, Section VI, and applicable sub-attachments. If the Transplant Hospital receives less than 60 days notice of that the key personnel change will take place, the Transplant Hospital must submit a complete application (see paragraph above) to the OPTN Contractor within 30 days from the OPTN Contractor Notification Date.

If a program is unable to verify or propose through a complete Personnel Change Application that it has on site both a transplant surgeon and a transplant physician who meet the requirements for primary transplant surgeon and physician, the Transplant Hospital must inactivate the program's membership, or relinquish or terminate its Designated Transplant Program Status as described in Appendix B, Section II, C of the Bylaws.

- D. Option for Reinstatement: If the previously named primary transplant surgeon or primary transplant physician returns to the same organ transplant program within 1 year of his/her departure date the individual can be considered for reinstatement as the primary transplant surgeon or physician if the Transplant Hospital submits a written reinstatement request to the OPTN Contractor. This written reinstatement request must include the following documentation:
- (1) A letter from the transplant program director, department chair, or chief of the division, attesting to the individual's current working knowledge; and
 - (2) A letter from the individual confirming his/her commitment to the program and on site availability.
 - (3) A current letter from the hospital credentialing committee verifying that the individual meets the requirements and is qualified and able to resume their previous role.

The Membership and Professional Standards Committee (MPSC) or an Ad hoc Subcommittee of the MPSC, as described below under Processing Applications, will review Requests for Reinstatement. In cases where reinstatement of an individual surgeon or physician may affect the program's status, the MPSC will recommend the appropriate new program status and any special conditions as indicated.

- E. **Failure to Provide Notification:**
- (1) Failure to inform the OPTN Contractor of a change in primary transplant surgeon and/or primary transplant physician within the time frames specified above may result in the MPSC imposing a sanction on the member. A sanction may include a Notice of Uncontested Violation, Letter of Warning, or Letter of Reprimand, as described in detail in Appendix A of these Bylaws.
 - (2) Failure to inform the OPTN Contractor of any changes in primary transplant surgeon and/or primary transplant physician or to submit the required Personnel Change Application shall result in a recommendation to the Board of Directors (Board) that the Board take appropriate action in accordance with Appendix A of these Bylaws. Potential adverse actions that the Board may choose to take are defined under Section 3.01A of the Bylaws. Additionally, the Board of Directors may notify the Secretary of HHS of the situation.
- F. **Processing Applications:** For processing of applications to change key personnel, the Membership and Professional Standards Committee (MPSC) Chair is authorized to appoint an Ad hoc Subcommittee of at least two committee members, other than the MPSC chair, to review the credentials of the proposed new key personnel. The Subcommittee is empowered to provide, with the concurrence of the MPSC Chair, interim approval effective until review by the full MPSC as its next meeting. Such interim approval shall not extend beyond the next meeting of the full MPSC and shall automatically expire if the full MPSC does not approve the interim action. Designated transplant programs are responsible for maintaining qualified key personnel for the program, without regard to the status of applications for change in key personnel.
- III. **Investigation of Personnel.** At the request of the MPSC, the designated transplant program must conduct an investigation of personnel identified by the MPSC, who are associated with the program, 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 designated transplant program. The program's investigation must be conducted pursuant to the program's institutional 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 appropriate action in accordance with Appendix A of these Bylaws.
- IV. **OPO Affiliation.** The transplant program must have letters of agreement or contracts with an OPO as defined in Article 1.2 of the Bylaws.
- V. **Histocompatibility Laboratory Affiliation.** The transplant program must use, for its histocompatibility testing, a laboratory that meets the standards for histocompatibility testing, as described in these Bylaws, Appendix B, Attachment II, and is approved by the Board of Directors as meeting these standards.
- VI. **Transplant Surgeon and Physician.** The transplant program must identify a qualified primary surgeon and primary physician, the requirements for whom are specified below, as well as the program director.

- A. The program director, in conjunction with the primary transplant surgeon and primary transplant physician, must submit to the OPTN Contractor in writing documents how 100% surgical and medical coverage is provided by individuals credentialed by the institution to provide transplant service for the program. The Program Coverage Plan must address the following requirements:
- (1) All transplant programs must have transplant surgeon(s) and transplant physician(s) available 365 days a year, 24 hours a day, 7 days a week, to provide program coverage unless a written explanation is provided that justifies the current level of coverage to the satisfaction of the Membership and Professional Standards Committee (MPSC). All transplant programs shall provide patients with a written summary of the Program Coverage Plan at the time of listing or when there are any substantial changes in program or personnel.
 - (2) When “on call” a transplant surgeon and transplant physician may not be on call at two transplant programs more than 30 miles apart unless the specific circumstances of that coverage have been reviewed and approved by the Membership and Professional Standards Committee.
 - (3) A transplant surgeon or transplant physician must be readily available in a timely manner to facilitate organ acceptance, procurement, and implantation, and to address urgent patient issues.
 - (4) Unless exempted by the MPSC for specific causal reasons, the primary transplant surgeon or primary transplant physician cannot be designated as the primary transplant surgeon/primary transplant physician at more than one transplant center unless there are additional transplant surgeons/transplant physicians at each of those facilities.
 - (i) Additional Transplant Surgeons must be credentialed by the institution to provide transplant services and be able to independently manage the care of transplant patients including performing the transplant operation and procurement procedures.
 - (ii) Additional Transplant Physicians must be credentialed by the institution to provide transplant services and be able to independently manage the care of the transplant patients.
- B. The primary surgeon and primary physician, collectively, are further responsible for ensuring the ongoing operation of the program in compliance with the criteria set forth in this Appendix B and notification to the OPTN Contractor if at any time the program deviates from such criteria.

Each primary surgeon or primary physician, listed on the application as a part of the plan for continuing policy compliance, shall submit an assessment, subject to medical peer review confidentiality requirements and which follows guidelines provided in the application and is satisfactory to the MPSC, of all physicians and surgeons participating in the program regarding their involvement in prior transgressions of OPTN requirements and plans to ensure that the improper conduct is not continued. A transplant program served by a single surgeon or physician shall inform its patients of this fact and potential unavailability of one or both of these individuals, as applicable, during the year.

A. Renal Transplantation

1. Transplant Surgeon.

- a. The primary transplant surgeon must have a report from his/her hospital credentialing committee that the committee has reviewed the individual's state licensing, board certification status, and training and transplant CMEs and affirms that he/she is "currently" a member in good standing.
- b. The surgeon must be a physician with an M.D. or D.O. degree or equivalent degree from another country who is licensed to practice medicine in his/her state or political jurisdiction and has been accepted onto the medical staff of the applicant program's hospital. The surgeon must be on site at this hospital.
- c. The surgeon shall have current certification by either the American Board of Surgery, the American Board of Urology, the American Board of Osteopathic Surgery, or their foreign equivalent. If board certification in Urology is pending (as in the case of one just finished training) conditional approval may be granted for a 12-month period, with the possibility of its being renewed for an additional 12-month period to allow time for the completion of certification.
- d. The surgeon shall meet such requirements for training and/or experience, including without limitation, demonstration of competence and currency by performance of sufficient numbers of transplant procedures, as established from time to time by the Board of Directors in accordance with the process set forth in Appendix C of these Bylaws. Pending approval of requirements different from those for membership in the United Network for Organ Sharing (UNOS), the criteria for UNOS membership shall serve as the OPTN criteria for surgeon training and/or experience.

2. Transplant Physician.

- a. The primary transplant physician must have a report from his/her hospital credentialing committee that the committee has reviewed the individual's state licensing, board certification status, and training and affirms that he/she is "currently" a member in good standing.
- b. The physician must be a physician with an M.D. or D.O. degree or equivalent degree from another country who is licensed to practice medicine in his/her state or political jurisdiction and has been accepted onto the medical staff of the applicant program's hospital. The physician must be on site at this hospital.
- c. The kidney transplant physician shall have current board certification in nephrology by the American Board of Internal Medicine, the American Board of Pediatrics, or the foreign equivalent.
- c. The physician shall meet such requirements for training and/or experience, including without limitation, demonstration of competence and currency by involvement with the primary care of sufficient numbers of transplant patients, as established from time to time by the Board of Directors in accordance with the process set forth in Appendix C of these Bylaws. Pending approval of requirements different from those for membership in the United Network for Organ Sharing (UNOS), the criteria for UNOS membership shall serve as the OPTN criteria for physician training and/or experience.

B. Liver Transplantation

1. Transplant Surgeon.

- a. The primary transplant surgeon must have a report from his/her hospital credentialing committee that the committee has reviewed the individual's state licensing, board certification status, and training and affirms that he/she is "currently" a member in good standing.
- b. The surgeon must be a physician with an M.D. or D.O. degree or equivalent degree from another country who is licensed to practice medicine in his/her state or political jurisdiction and has been accepted onto the medical staff of the applicant program's hospital. The surgeon must be on site at this hospital.
- c. The surgeon shall have current certification by either the American Board of Surgery, the American Board of Urology, the American Board of Osteopathic Surgery, or their foreign equivalent. If board certification in Urology is pending (as in the case of one just finished training) conditional approval may be granted for a 12-month period, with the possibility of its being renewed for an additional 12-month period to allow time for the completion of certification.
- d. The surgeon shall meet such requirements for training and/or experience, including without limitation, demonstration of competence and currency by performance of sufficient numbers of transplant procedures, as established from time to time by the Board of Directors in accordance with process set forth in Appendix C of these Bylaws. Pending approval of requirements different from those for membership in the United Network for Organ Sharing (UNOS), the criteria for UNOS membership shall serve as the OPTN criteria for surgeon training and/or experience.

2. Transplant Physician.

- a. The primary transplant physician must have a report from his/her hospital credentialing committee that the committee has reviewed the individual's state licensing, board certification status, and training and affirms that he/she is "currently" a member in good standing.
- b. The physician must be a physician with an M.D. or D.O. degree or equivalent degree from another country who is licensed to practice medicine in his/her state or political jurisdiction and has been accepted onto the medical staff of the applicant program's hospital. The physician must be on site at this hospital.
- c. The liver transplant physician shall have current board certification or have achieved eligibility in gastroenterology or the subspecialty of his/her major area of interest by the American Board of Internal Medicine, the American Board of Pediatrics, or the foreign equivalent.
- d. The physician shall meet such requirements for training and/or experience, including without limitation, demonstration of competence and currency by involvement with the primary care of sufficient numbers of transplant patients, as established from time to time by the Board of Directors in accordance with the process set forth in Appendix C of these Bylaws. Pending approval of requirements different from those for membership in the United Network for Organ Sharing (UNOS), the criteria for UNOS membership shall serve as the OPTN criteria for physician training and/or experience.

C. **Pancreas Transplantation**

1. Transplant Surgeon.

- a. The primary transplant surgeon must have a report from his/her hospital credentialing committee that the committee has reviewed the individual's state licensing, board certification status, and training and affirms that he/she is "currently" a member in good standing.
- b. The surgeon must be a physician with an M.D. or D.O. degree or equivalent degree from another country who is licensed to practice medicine in his/her state or political jurisdiction and has been accepted onto the medical staff of the applicant program's hospital. The surgeon must be on site at this hospital.
- c. The surgeon shall have current certification by either the American Board of Surgery, the American Board of Urology, the American Board of Osteopathic Surgery, or their foreign equivalent. If board certification in Urology is pending (as in the case of one just finished training) conditional approval may be granted for a 12-month period, with the possibility of its being renewed for an additional 12-month period to allow time for the completion of certification.
- d. The surgeon shall meet such requirements for training and/or experience, including without limitation, demonstration of competence and currency by performance of sufficient numbers of transplant procedures, as established from time to time by the Board of Directors in accordance with the process set forth in Appendix C of these Bylaws. Pending approval of requirements different from those for membership in the United Network for Organ Sharing (UNOS), the criteria for UNOS membership shall serve as the OPTN criteria for surgeon training and/or experience.

2. Transplant Physician.

- a. The primary transplant physician must have a report from his/her hospital credentialing committee that the committee has reviewed the individual's state licensing, board certification status, and training and affirms that he/she is "currently" a member in good standing.
- b. The physician must be a physician with an M.D. or D.O. degree or equivalent degree from another country who is licensed to practice medicine in his/her state or political jurisdiction and has been accepted onto the medical staff of the applicant program's hospital. The physician must be on site at this hospital.
- c. The transplant physician shall have current certification by either the American Board of Internal Medicine, the American Board of Pediatrics, or their foreign equivalent.
- d. The physician shall meet such requirements for training and/or experience, including without limitation, demonstration of competence and currency by involvement with the primary care of sufficient numbers of transplant patients, as established from time to time by the Board of Directors in accordance with the process set forth in Appendix C of these Bylaws. Pending approval of requirements different from those for membership in the United Network for Organ Sharing (UNOS), the criteria for UNOS membership shall serve as the OPTN criteria for physician training and/or experience.

D. Pancreatic Islet Transplantation

1. Transplant Surgeon. The program must have on site a qualified surgeon who is designated as the primary surgeon for the pancreatic islet transplant program and meets the requirements for pancreas transplant surgeon set forth in these Bylaws, Appendix B, Attachment I, Section VI (C)(1).
2. Transplant Physician. The program must have on site a qualified physician who is designated as the primary physician for the pancreatic islet transplant program and meets the requirements for pancreas transplant physician set forth in these Bylaws, Appendix B, Attachment I, Section VI (C)(2).

E. Heart Transplantation

1. Transplant Surgeon.
 - a. The primary transplant surgeon must have a report from his/her hospital credentialing committee that the committee has reviewed the individual's state licensing, board certification status, and training and affirms that he/she is "currently" a member in good standing.
 - b. The surgeon must be a physician with an M.D. or D.O. degree or equivalent degree from another country who is licensed to practice medicine in his/her state or political jurisdiction and has been accepted onto the medical staff of the applicant program's hospital. The surgeon must be on site at this hospital.
 - c. The surgeon shall have current certification by the American Board of Thoracic Surgery or its foreign equivalent. If board certification in thoracic surgery is pending (as in the case of one just finished training) conditional approval may be granted for a 24-month period, with the possibility of its being renewed for an additional 24-month period to allow time for the completion of certification.

If an individual is certified by the American Board of Thoracic Surgery or its foreign equivalent, then the individual must maintain their certification in the American Board or its foreign equivalent.
 - d. The surgeon shall meet such requirements for training and/or experience, including without limitation, demonstration of competence and currency by performance of sufficient numbers of transplant procedures, as established from time to time by the Board of Directors in accordance with the process set forth in Appendix C of these Bylaws. Pending approval of requirements different from those for membership in the United Network for Organ Sharing (UNOS), the criteria for UNOS membership shall serve as the OPTN criteria for surgeon training and/or experience.
2. Transplant Physician.
 - a. The primary transplant physician must have a report from his/her hospital credentialing committee that the committee has reviewed the individual's state licensing, board certification status, and training and affirms that he/she is "currently" a member in good standing.
 - b. The physician must be a physician with an M.D. or D.O. degree or equivalent degree from another country who is licensed to practice medicine in his/her state or political jurisdiction and has been accepted onto the medical staff of the

applicant program's hospital. The physician must be on site at this hospital. If the individual is certified by the American Board and its foreign equivalent, he/she must maintain currency in the American Board.

- c. The cardiac transplant physician shall have current board certification or have achieved eligibility in adult or pediatric cardiology by the American Board of Internal Medicine or American Board of Pediatrics or their foreign equivalent.
- d. The physician shall meet such requirements for training and/or experience, including without limitation, demonstration of competence and currency by involvement with the primary care of sufficient numbers of transplant patients, as established from time to time by the Board of Directors in accordance with the process set forth in Appendix C of these Bylaws. Pending approval of requirements different from those for membership in the United Network for Organ Sharing (UNOS), the criteria for UNOS membership shall serve as the OPTN criteria for physician training and/or experience.

F. Lung Transplantation

1. Transplant Surgeon.

- a. The primary transplant surgeon must have a report from his/her hospital credentialing committee that the committee has reviewed the individual's state licensing, board certification status, and training and affirms that he/she is "currently" a member in good standing.
- b. The surgeon must be a physician with an M.D. or D.O. degree or equivalent degree from another country who is licensed to practice medicine in his/her state or political jurisdiction and has been accepted onto the medical staff of the
- c. The surgeon shall have current certification by the American Board of Thoracic Surgery or its foreign equivalent. If board certification in thoracic surgery is pending (as in the case of where the surgeon has just completed training) conditional approval may be granted for a 24-month period, with the possibility of its being renewed for an additional 24-month period to allow time for completion of certification. If the individual is certified by the American Board of Thoracic Surgery or its foreign equivalent, then the individual must maintain their certification in the American Board or its foreign equivalent.
- d. The surgeon shall meet such requirements for training and/or experience, including without limitation, demonstration of competence and currency by performance of sufficient numbers of transplant procedures, as established from time to time by the Board of Directors in accordance with the process set forth in Appendix C of these Bylaws. Pending approval of requirements different from those for membership in the United Network for Organ Sharing (UNOS), the criteria for UNOS membership shall serve as the OPTN criteria for surgeon training and/or experience.

2. Transplant Physician.

- a. The primary transplant physician must have a report from his/her hospital credentialing committee that the committee has reviewed the individual's state licensing, board certification status, and training and affirms that he/she is "currently" a member in good

- b. The physician must be a physician with an M.D. or D.O. degree or equivalent degree from another country who is licensed to practice medicine in his/her state or political jurisdiction and has been accepted onto the medical staff of the applicant program's hospital. The physician must be on site at this hospital.
- c. The lung transplant physician shall have current board certification or have achieved eligibility in adult or pediatric pulmonary medicine or the subspecialty of his/her major area of interest by the American Board of Internal Medicine, the American Board of Pediatrics or the foreign equivalent. The individual shall provide a letter from the hospital credentialing committee of the applicant hospital stating that the physician continues to meet all requirements to be in good standing. The option for qualifying without having board certification or eligibility in pulmonary medicine or their foreign equivalent will cease to exist for applications received after January 1, 2007.
- d. The physician shall meet such requirements for training and/or experience, including without limitation, demonstration of competence and currency by involvement with the primary care of sufficient numbers of transplant patients, as established from time to time by the Board of Directors in accordance with the process set forth in Appendix C of these Bylaws. Pending approval of requirements different from those for membership in the United Network for Organ Sharing (UNOS), the criteria for UNOS membership shall serve as the OPTN criteria for physician training and/or experience.

G. Heart/Lung Transplantation

1. Transplant Surgeon.

- a. The primary transplant surgeon must have a report from his/her hospital credentialing committee that the committee has reviewed the individual's state licensing, board certification status, and training and affirms that he/she is "currently" a member in good standing.
- b. The surgeon must be a physician with an M.D. or D.O. degree or equivalent degree from another country who is licensed to practice medicine in his/her state or political jurisdiction and has been accepted onto the medical staff of the applicant program's hospital. The surgeon must be on site at this hospital.
- c. The surgeon shall have current certification by the American Board of Thoracic Surgery or its foreign equivalent. If board certification in thoracic surgery is pending (as in the case of where the surgeon has just completed training) conditional approval may be granted for a 24-month period, with the possibility of its being renewed for an additional 24-month period to allow time for completion of certification.

If an individual is certified by the American Board of Thoracic Surgery or its foreign equivalent, then the individual must maintain their certification in the American Board or its foreign equivalent.

- d. The surgeon shall meet such requirements for training and/or experience, including without limitation, demonstration of competence and currency by performance of sufficient numbers of transplant procedures, as established from time to time by the Board of Directors in accordance with the process set forth in Appendix C of these Bylaws. Pending approval of requirements different from those for membership in the United Network for Organ Sharing (UNOS),

the criteria for UNOS membership shall serve as the OPTN criteria for surgeon training and/or experience.

2. Transplant Physician.

- a. The primary transplant physician must have a report from his/her hospital credentialing committee that the committee has reviewed the individual's state licensing, board certification status, and training and affirms that he/she is "currently" a member in good standing.
- b. The physician must be a physician with an M.D. or D.O. degree or equivalent degree from another country who is licensed to practice medicine in his/her state or political jurisdiction and has been accepted onto the medical staff of the applicant program's hospital. The physician must be on site at this hospital.
- c. The lung transplant physician shall have current board certification or have achieved eligibility in adult or pediatric pulmonary or cardiac medicine by the American Board of Internal Medicine, the American Board of Pediatrics or the foreign equivalent.
- d. The physician shall meet such requirements for training and/or experience, including without limitation, demonstration of competence and currency by involvement with the primary care of sufficient numbers of transplant patients, as established from time to time by the Board of Directors in accordance with the process set forth in Appendix C of these Bylaws. Pending approval of requirements different from those for membership in the United Network for Organ Sharing (UNOS), the criteria for UNOS membership shall serve as the OPTN criteria for physician training and/or experience.

VII. Collaborative Support. The proper care and management of transplant recipients often requires the assistance of both physicians other than surgeons and ancillary health professionals. The transplant program, therefore, 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.

VIII. Ancillary Services. The matching of transplant recipients and donors, as well as routine evaluation and follow-up of transplant patients requires sophisticated laboratory facilities. Therefore, the transplant program must have immediate access to sophisticated microbiology, clinical chemistry, histocompatibility testing, and radiology services, as well as the facilities required or capacity for monitoring immunosuppressive drugs.

IX. Blood Bank Support. Access to large quantities of blood is necessary, particularly for liver transplant patients. Therefore, it is essential that the transplant program have extensive blood bank support.

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

Direct patient care, including:

Psychosocial evaluation of potential living donors and recipients;
Substance abuse evaluation, treatment, referral, monitoring;
Individual counseling;
Crisis intervention;
Support groups/newsletters;
Patient care conferences;
Advocacy;
Patient and family education;
Referral to community services, e.g., vocational rehabilitation, housing;
Ongoing knowledge of social services available, regulations; and
Death, dying, and bereavement counseling.

Other:

Transplant team building;
Department meetings, e.g., staff, process improvement;
Participation in organ donation awareness initiatives; and
Participation with community advocacy groups, e.g., National Kidney Foundation and the Coalition for Donation.

- XI. Clinical Transplant Pharmacist.** All transplant programs should identify one or more pharmacists who will be responsible for providing pharmaceutical care to solid organ transplant recipients. The clinical transplant pharmacist should be a designated member of the transplant team and will be assigned primary responsibility for providing comprehensive pharmaceutical care to transplant recipients in a culturally competent manner. The transplant pharmacist will work with patients and their families, and members of the transplant team, including physicians, surgeons, nurses, clinical coordinators, social workers, financial coordinators and administrative personnel at the transplant program. The transplant pharmacist should be a licensed pharmacist with experience in transplant pharmacotherapy, 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:

Perioperative Phase:

1. Evaluates, identifies and solves medication related problems for transplant recipients;
2. Educates transplant recipients and their family members on transplant medications and adherence to medication regimen;
3. Acts as liaison (advocate) between patient and patients' families and other health care team members regarding medication issues;
4. Prepares and assists with discharge planning for all transplant recipients; and
5. Provides drug information for all members of the transplant team.

Post Transplant Phase:

1. Evaluates transplant recipient medication regimens on a regular basis;
2. Communicates all transplant recipient medication issues and concerns to appropriate members of the transplant team; and

3. Assists with designing, implementing, and monitoring of comprehensive care plans with other team members (i.e. transplant coordinators, financial coordinator, social worker, dietician, etc.).

Additional responsibilities may include but are not limited to clinical research studies, quality assurance of medication regimens, public and professional education.

XII. Additional Requirements for Pancreatic Islet Transplantation. The following provisions apply to all pancreatic islet transplantation programs. Pancreatic islet transplantation programs approved under any previous criteria must submit an application documenting their compliance with the criteria below. For pancreatic islet transplantation, programs must meet all of the following criteria in addition to the criteria set forth in Sections I - X above:

- A. Approved Pancreas Transplant Program** – The program must be located at a medical center approved under the OPTN Bylaws to perform whole pancreas transplantation, or meet the requirements for an exception to this criterion as set forth in this Section XI(F) below.
- B. Reporting** – The program must submit data to the OPTN through use of standardized forms. Data requirements include submission of information on all deceased and living donors, potential transplant recipients, and actual transplant recipients. Pending development of standardized data forms for pancreatic islet transplantation, the program must provide patient logs to the OPTN every six months and on an annual basis, reporting transplants performed, by patient name, social security number, date of birth, and donor identification number, as well as whether patient is alive or dead, and whether the pancreas was allocated for islet or whole organ transplantation. The logs shall be cumulative. Additionally, for each donor pancreas allocated to the program for islet transplantation, the program must report to the OPTN whether the islets were used for clinical islet transplantation and, if not, why and their ultimate disposition, together with such other information as requested on the Pancreatic Islet Donor Form.
- C. Transplant Facilities** – The program must document adequate clinical and laboratory facilities for pancreatic islet transplantation as defined by current regulations provided by the Food and Drug Administration (FDA). The program also must document the required Investigational New Drug (IND) application as reviewed by the FDA is in effect.
- D. Radiology Expertise/Ancillary Personnel** – The program must have a collaborative relationship with a physician qualified to cannulate the portal system under direction of the transplant surgeon. It is further recommended that the program have on site or adequate access to:
 - (1) A board-certified endocrinologist.
 - (2) A physician, administrator, or technician with experience in compliance with FDA regulations, and
 - (3) A laboratory-based researcher with experience in pancreatic islet isolation and transplantation.

Adequate access is defined by an agreement of affiliation with counterparts at another institution who employ individuals with the expertise described above.

- E. Islet Isolation** – Pancreatic islets must be isolated in a facility with an FDA IND application in effect, with documented collaboration between the program and such facility.

F. Programs Not Located at an Approved Pancreas Transplant Program – A program that meets all requirements for a pancreatic islet transplant program set forth in these Bylaws, including, without limitation, requirements applicable generally for designated transplant program status and without regard to organ specificity, with the sole exception that the program is not located at a medical center approved under the OPTN Bylaws to perform whole pancreas transplantation, may nevertheless qualify as a pancreatic islet transplant program if the following additional criteria are met to the satisfaction of the Membership and Professional Standards Committee and Board of Directors:

- (1) The program demonstrates a documented affiliation relationship with an OPTN approved pancreas transplant program, including on-site admitting privileges for the primary whole pancreas transplant surgeon and physician,
- (2) The program provides written protocols demonstrating its commitment and ability to counsel patients regarding all their options for appropriate medical treatment for diabetes, and
- (3) The program demonstrates availability of qualified personnel to address pre-, peri-, and post-operative care issues regardless of the treatment option ultimately selected.

A preliminary interview with the Membership and Professional Standards Committee shall be required.