

# Membership Requirements for Pediatric Components for Kidney, Liver, Pancreas, Heart and Lung Transplant Programs

## ***Appendix E: Membership and Personnel Requirements for Kidney Transplant Programs***

This appendix describes the information and documentation transplant hospitals must provide when:

- Submitting a completed membership application to apply for approval as a designated kidney transplant program.
- Completing a Personnel Change Application for a change in key personnel at a designated kidney transplant program.
- Performing living donor kidney recoveries and transplants, if applicable.

All transplant programs must also meet general membership requirements, which are described in *Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs* of these Bylaws.

For more information on the application and review process, see *Appendix A: Membership Application and Review* of these Bylaws.

### **E.1 Program Director, Primary Transplant Surgeon and Primary Transplant Physician**

A kidney transplant program must identify at least one designated staff member to act as the transplant program director. The director must be a physician or surgeon who is a member of the transplant hospital staff.

The program must also identify a qualified primary transplant surgeon and primary transplant physician, as described below. The primary surgeon and primary physician, along with the program director, must submit a detailed Program Coverage Plan to the OPTN Contractor. For detailed information about the Program Coverage Plan, see *Appendix D, Section D.7.B: Surgeon and Physician Coverage (Program Coverage Plan)* of these Bylaws.

### **E.2 Primary Kidney Transplant Surgeon Requirements**

A designated kidney transplant program must have a primary surgeon who meets *all* the following requirements:

1. The surgeon must have an M.D., D.O., or equivalent degree from another country, with a current license to practice medicine in the hospital's state or jurisdiction.

2. The surgeon must be accepted onto the hospital's medical staff, and be on site at this hospital.
3. The surgeon must have documentation from the hospital credentialing committee that it has verified the surgeon's state license, board certification, training, and transplant continuing medical education, and that the surgeon is currently a member in good standing of the hospital's medical staff.
4. The surgeon must have current certification by the American Board of Surgery, the American Board of Urology, the American Board of Osteopathic Surgery, or the Royal College of Physicians and Surgeons of Canada. In the case of a surgeon who has just completed training and whose American Board of Urology certification is pending, the Membership and Professional Standards Committee (MPSC) may grant conditional approval for 16 months to allow time for the surgeon to complete board certification, with the possibility of one additional 16-month extension.

In place of current certification by the American Board of Surgery, the American Board of Urology, the American Board of Osteopathic Surgery, the Royal College of Physicians and Surgeons of Canada, or pending certification by the American Board of Urology, the surgeon must:

- a. Be ineligible for American board certification.
- b. Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that the surgeon obtains 60 hours of Category I continuing medical education (CME) credits with self-assessment that are relevant to the individual's practice every three years. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program. A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve an acceptable self-assessment score are allowed. The transplant hospital must document completion of this continuing education.
- c. Provide to the OPTN Contractor two letters of recommendation from directors of designated transplant programs not employed by the applying hospital. These letters must address:
  - i. Why an exception is reasonable.
  - ii. The surgeon's overall qualifications to act as a primary kidney transplant surgeon.
  - iii. The surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
  - iv. Any other matters judged appropriate.

If the surgeon has not adhered to the plan for maintaining continuing education or has not obtained the necessary CME credits with self-assessment, the transplant program will have a six-month grace period to address these deficiencies. If the surgeon has not fulfilled the requirements after the six-month grace period, and a key personnel change application has not been submitted, then the transplant program will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws. If the OPTN Contractor becomes aware that a primary surgeon has not been compliant for 12 months or more and deficiencies still exist, then the transplant program will not be given any grace period and will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws.

5. The surgeon must have completed at least one of the pathways listed below:
  - a. The formal 2-year transplant fellowship pathway, as described in *Section E.2.A: Formal 2-year Transplant Fellowship Pathway* below.
  - b. The kidney transplant program clinical experience pathway, as described in *Section E.2.B: Clinical Experience Pathway* below.

### **A. Formal 2-year Transplant Fellowship Pathway**

Surgeons can meet the training requirements for primary kidney transplant surgeon by completing a formal 2-year surgical transplant fellowship if the following conditions are met:

1. The surgeon performed at least 30 kidney transplants as the primary surgeon or first assistant during the 2-year fellowship period. These transplants must be documented in the

- surgeon's fellowship operative log. The date of transplant, the role of the surgeon in the procedure, the medical record number or other unique identifier that can be verified by the OPTN Contractor, and the fellowship director's signature must be provided with this log.
2. The surgeon performed at least 15 kidney procurements as primary surgeon or first assistant. At least 10 of these procurements must be from deceased donors. These procurements must have been performed anytime during the surgeon's fellowship and the two years immediately following fellowship completion. These procedures must be documented in the surgeon's fellowship operative log. The date of procurement and Donor ID must be provided with this log.
  3. The surgeon has maintained a current working knowledge of kidney transplantation, defined as direct involvement in kidney transplant patient care in the last 2 years. This includes the management of patients with end stage renal disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, performing the transplant operation, immediate postoperative and continuing inpatient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long term outpatient care.
  4. This training was completed at a hospital with a kidney transplant training program approved by the American Society of Transplant Surgeons, the Royal College of Physicians and Surgeons of Canada, or another recognized surgical fellowship training program accepted by the OPTN Contractor as described in the *Section E.4: Approved Kidney Transplant Surgeon and Physician Fellowship Training Programs* that follows.
  5. The following letters are submitted directly to the OPTN Contractor:
    - a. A letter from the director of the training program and chairman of the department or hospital credentialing committee verifying that the surgeon has met the above requirements and is qualified to direct a kidney transplant program.
    - b. A letter of recommendation from the fellowship training program's primary surgeon and transplant program director outlining the surgeon's overall qualifications to act as a primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
    - c. A letter from the surgeon that details the training and experience the surgeon has gained in kidney transplantation.

## **B. Clinical Experience Pathway**

Surgeons can meet the requirements for primary kidney transplant surgeon through clinical experience gained post-fellowship if the following conditions are met:

1. The surgeon has performed 45 or more kidney transplants over a 2 to 5-year period as primary surgeon, co-surgeon, or first assistant at a designated kidney transplant program. Of these 45 kidney transplants, 23 or more must have been performed as primary surgeon or co-surgeon. The transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and medical record number or other unique identifier that can be verified by the OPTN Contractor. The log should be signed by the program director, division chief, or department chair from the program where the

- experience was gained. Each year of the surgeon's experience must be substantive and relevant and include pre-operative assessment of kidney transplant candidates, performance of transplants as primary surgeon or first assistant, and post-operative care of kidney recipients.
2. The surgeon has performed at least 15 kidney procurements as primary surgeon, co-surgeon, or first assistant. Of these 15 kidney procurements, at least 8 must have been performed as primary surgeon or co-surgeon. At least 10 of these procurements must be from deceased donors. These cases must be documented in a log that includes the date of procurement and Donor ID.
  3. The surgeon has maintained a current working knowledge of kidney transplantation, defined as direct involvement in kidney transplant patient care in the last 2 years. This includes the management of patients with end stage renal disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, performing the transplant operation, immediate postoperative and continuing inpatient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long term outpatient care.
  4. The following letters are submitted directly to the OPTN Contractor:
    - a. A letter from the director of the transplant program and Chairman of the department or hospital credentialing committee verifying that the surgeon has met the above qualifications and is qualified to direct a kidney transplant program.
    - b. A letter of recommendation from the primary surgeon and transplant program director at the transplant program last served by the surgeon outlining the surgeon's overall qualifications to act as a primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
    - c. A letter from the surgeon that details the training and experience the surgeon has gained in kidney transplantation.

### **E.3 Primary Kidney Transplant Physician Requirements**

A designated kidney transplant program must have a primary physician who meets *all* the following requirements:

1. The physician must have an M.D., D.O., or equivalent degree from another country, with a current license to practice medicine in the hospital's state or jurisdiction.
2. The physician must be accepted onto the hospital's medical staff, and be on site at this hospital.
3. The physician must have documentation from the hospital credentialing committee that it has verified the physician's state license, board certification, training, and transplant continuing medical education and that the physician is currently a member in good standing of the hospital's medical staff.
4. The physician must have current certification in nephrology by the American Board of Internal Medicine, the American Board of Pediatrics, or the Royal College of Physicians and Surgeons of Canada.

In place of current certification in nephrology by the American Board of Internal Medicine, the American Board of Pediatrics, or the Royal College of Physicians and Surgeons of Canada, the physician must:

- a. Be ineligible for American board certification.
- b. Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that the physician obtains 60 hours of Category I continuing medical education (CME) credits with self-assessment that are relevant to the individual's practice every three years. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program. A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve an acceptable self-assessment score are allowed. The transplant hospital must document completion of this continuing education.
- c. Provide to the OPTN Contractor two letters of recommendation from directors of designated transplant programs not employed by the applying hospital. These letters must address:
  - i. Why an exception is reasonable.
  - ii. The physician's overall qualifications to act as a primary kidney transplant physician.
  - iii. The physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
  - iv. Any other matters judged appropriate.

If the physician has not adhered to the plan for maintaining continuing education or has not obtained the necessary CME credits with self-assessment, the transplant program will have a six-month grace period to address these deficiencies. If the physician has not fulfilled the requirements after the six-month grace period, and a key personnel change application has not been submitted, then the transplant program will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws. If the OPTN Contractor becomes aware that a primary physician has not been compliant for 12 months or more and deficiencies still exist, then the transplant program will not be given any grace period and will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws.

5. The physician must have completed at least one of the pathways listed below:
  - a. The transplant nephrology fellowship pathway, as described in *Section E.3.A: Transplant Nephrology Fellowship Pathway* below.
  - b. The clinical experience pathway, as described in *Section E.3.B: Clinical Experience Pathway* below.
  - c. The 3-year pediatric nephrology fellowship pathway, as described in *Section E.3.C: Three-year Pediatric Nephrology Fellowship Pathway* below.
  - d. The 12-month pediatric transplant nephrology fellowship pathway, as described in *Section E.3.D. Twelve-month Pediatric Transplant Nephrology Fellowship Pathway* below.
  - e. The combined pediatric nephrology training and experience pathway, as described in *Section E.3.E. Combined Pediatric Nephrology Training and Experience Pathway* below.
  - f. The conditional approval pathway, as described in *Section E.3.F: Conditional Approval for Primary Transplant Physician* below, if the primary kidney transplant physician changes at an approved kidney transplant program.

### **A. Transplant Nephrology Fellowship Pathway**

Physicians can meet the training requirements for a primary kidney transplant physician during a separate transplant nephrology fellowship if the following conditions are met:

1. The physician completed at least 12 consecutive months of specialized training in transplantation under the direct supervision of a qualified kidney transplant physician and along with a kidney transplant surgeon at a kidney transplant program that performs 50 or more transplants each year. The training must have included at least 6 months of clinical inpatient transplant service. The remaining time must have consisted of transplant-related

- experience, such as experience in a tissue typing laboratory, on another solid organ transplant service, or conducting basic or clinical transplant research.
2. During the fellowship period, the physician was directly involved in the primary care of 30 or more newly transplanted kidney recipients and continued the outpatient follow-up of these recipients for a minimum of 3 months from the time of transplant. If the physician's fellowship was longer than 12 months, the physician also must have been directly involved in the outpatient follow-up of at least 30 kidney recipients for an additional period of 3 consecutive months. The care must be documented in a log that includes the date of transplant and the recipient medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log must be signed by the director of the training program or the transplant program's primary transplant physician.
  3. During the fellowship period, the physician was directly involved in the evaluation of 25 potential kidney recipients, including participation in selection committee meetings. These potential kidney recipient evaluations must be documented in a log that includes each evaluation date and is signed by the director of the training program or the transplant program's primary transplant physician.
  4. During the fellowship period, the physician was directly involved in the evaluation of 10 potential living kidney donors, including participation in selection committee meetings. These potential living kidney donor evaluations must be documented in a log that includes each evaluation date and the potential living kidney donor's medical record number or other unique identifier than can be verified by the OPTN Contractor. This potential living kidney donor evaluation log must be signed by the director of the training program or the transplant program's primary transplant physician.
  5. The physician has maintained a current working knowledge of kidney transplantation, defined as direct involvement in kidney transplant care in the last 2 years. This includes the management of patients with end stage renal disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate postoperative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long term outpatient care.
  6. The physician must have observed at least 3 kidney procurements, including at least 1 deceased donor and 1 living donor. The physician must have observed the evaluation, donation process, and management of these donors. These observations must be documented in a log that includes the date of procurement and Donor ID.
  7. The physician must have observed at least 3 kidney transplants. The observation of these transplants must be documented in a log that includes the transplant date, donor type, and medical record number or other unique identifier that can be verified by the OPTN Contractor.
  8. The following letters are submitted directly to the OPTN Contractor:
    - a. A letter from the director of the training program and the supervising qualified kidney transplant physician verifying that the physician has met the above requirements and is qualified to direct a kidney transplant program.
    - b. A letter of recommendation from the fellowship training program's primary physician and transplant program director outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.

- c. A letter from the physician that details the training and experience the physician has gained in kidney transplantation.

The training requirements outlined above are in addition to other clinical requirements for general nephrology training.

## **B. Clinical Experience Pathway**

A physician can meet the requirements for a primary kidney transplant physician through acquired clinical experience if the following conditions are met:

1. The physician has been directly involved in the primary care of 45 or more newly transplanted kidney recipients and continued the outpatient follow-up of these recipients for a minimum of 3 months from the time of transplant. This patient care must have been provided over a 2 to 5-year period on an active kidney transplant service as the primary kidney transplant physician or under the direct supervision of a qualified transplant physician and in conjunction with a kidney transplant surgeon at a designated kidney transplant program. The care must be documented in a log that includes the date of transplant and recipient medical record number or other unique identifier that can be verified by the OPTN Contractor. The recipient log should be signed by the program director, division Chief, or department Chair from the program where the physician gained this experience.
2. The physician was directly involved in the evaluation of 25 potential kidney recipients, including participation in selection committee meetings. These potential kidney recipient evaluations must be documented in a log that includes each evaluation date and is signed by the program director, division Chief, or department Chair from the program where the physician gained this experience.
3. The physician was directly involved in the evaluation of 10 potential living kidney donors, including participation in selection committee meetings. These potential living kidney donor evaluations must be documented in a log that includes each evaluation date and the potential living kidney donor's medical record number or other unique identifier than can be verified by the OPTN Contractor. This potential living kidney donor evaluation log must be signed by the program director, division Chief, or department Chair from the program where the physician gained this experience.
4. The physician has maintained a current working knowledge of kidney transplantation, defined as direct involvement in kidney transplant patient care over the last 2 years. This includes the management of patients with end stage renal disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate postoperative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long term outpatient care.
5. The physician must have observed at least 3 kidney procurements, including at least 1 deceased donor and 1 living donor. The physician must have observed the evaluation, donation process, and management of these donors. These observations must be documented in a log that includes the date of procurement and Donor ID.
6. The physician must have observed at least 3 kidney transplants. The observation of these transplants must be documented in a log that includes the transplant date, donor type, and medical record number or other unique identifier that can be verified by the OPTN Contractor.
7. The following letters are submitted directly to the OPTN Contractor:

- a. A letter from the qualified transplant physician or the kidney transplant surgeon who has been directly involved with the proposed physician documenting the physician's experience and competence.
- b. A letter of recommendation from the primary physician and transplant program director at the transplant program last served by the physician outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
- c. A letter from the physician that details the training and experience the physician has gained in kidney transplantation.

### **C. Three-year Pediatric Nephrology Fellowship Pathway**

A physician can meet the requirements for primary kidney transplant physician by completion of 3 years of pediatric nephrology fellowship training as required by the American Board of Pediatrics in a program accredited by the Residency Review Committee for Pediatrics (RRC-Ped) of the ACGME. The training must contain at least 6 months of clinical care for transplant patients, and the following conditions must be met:

1. During the 3-year training period the physician was directly involved in the primary care of 10 or more newly transplanted kidney recipients for at least 6 months from the time of transplant and followed 30 transplanted kidney recipients for at least 6 months, under the direct supervision of a qualified kidney transplant physician and in conjunction with a qualified kidney transplant surgeon. The pediatric nephrology program director may elect to have a portion of the transplant experience completed at another kidney transplant program in order to meet these requirements. This care must be documented in a log that includes the date of transplant, and the recipient medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log must be signed by the training program's director or the primary physician of the transplant program.
2. The experience caring for pediatric patients occurred with a qualified kidney transplant physician and surgeon at a kidney transplant program that performs an average of at least 10 pediatric kidney transplants a year.
3. During the fellowship period, the physician was directly involved in the evaluation of 25 potential kidney recipients, including participation in selection committee meetings. These potential kidney recipient evaluations must be documented in a log that includes each evaluation date and is signed by the director of the training program or the transplant program's primary transplant physician.
4. The physician has maintained a current working knowledge of kidney transplantation, defined as direct involvement in kidney transplant patient care over the last 2 years. This includes the management of pediatric patients with end-stage renal disease, the selection of appropriate pediatric recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative care including those issues of management unique to the pediatric recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the pediatric recipient including side-effects of drugs and complications of immunosuppression, the effects of transplantation and immunosuppressive agents on growth and development, differential diagnosis of renal dysfunction in the allograft recipient, manifestation of rejection in the pediatric patient, histological interpretation of allograft biopsies, interpretation of



ancillary tests for renal dysfunction, and long-term outpatient care of pediatric allograft recipients including management of hypertension, nutritional support, and drug dosage, including antibiotics, in the pediatric patient.

5. The physician must have observed at least 3 kidney procurements, including at least 1 deceased donor and 1 living donor. The physician must have observed the evaluation, donation process and management of these donors. These observations must be documented in a log that includes the date of procurement and Donor ID.
6. The physician must have observed at least 3 kidney transplants involving a pediatric recipient. The observation of these transplants must be documented in a log that includes the transplant date, donor type, and medical record number or other unique identifier that can be verified by the OPTN Contractor.
7. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the director and the supervising qualified transplant physician and surgeon of the fellowship training program verifying that the physician has met the above requirements and is qualified to direct a kidney transplant program.
  - b. A letter of recommendation from the fellowship training program's primary physician and transplant program director outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
  - c. A letter from the physician that details the training and experience the physician has gained in kidney transplantation.

#### **D. Twelve-month Pediatric Transplant Nephrology Fellowship Pathway**

The requirements for the primary kidney transplant physician can be met during a separate pediatric transplant nephrology fellowship if the following conditions are met:

1. The physician has current board certification in pediatric nephrology by the American Board of Pediatrics, the Royal College of Physicians and Surgeons of Canada, or is approved by the American Board of Pediatrics to take the certifying exam.
2. During the fellowship, the physician was directly involved in the primary care of 10 or more newly transplanted kidney recipients for at least 6 months from the time of transplant and followed 30 transplanted kidney recipients for at least 6 months, under the direct supervision of a qualified kidney transplant physician and in conjunction with a qualified kidney transplant surgeon. The pediatric nephrology program director may elect to have a portion of the transplant experience completed at another kidney transplant program in order to meet these requirements. This care must be documented in a recipient log that includes the date of transplant, and the recipient medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the training program director or the primary physician of the transplant program.
3. The experience in caring for pediatric patients occurred at a kidney transplant program with a qualified kidney transplant physician and surgeon that performs an average of at least 10 pediatric kidney transplants a year.
4. During the four years that include the physician's three-year pediatric nephrology fellowship and twelve-month pediatric transplant nephrology fellowship, the physician was directly involved in the evaluation of 25 potential kidney recipients, including participation in selection

committee meetings. These potential kidney recipient evaluations must be documented in a log that includes each evaluation date and is signed by the director of the training program or the transplant program's primary transplant physician.

5. The physician has maintained a current working knowledge of kidney transplantation, defined as direct involvement in kidney transplant patient care in the past 2 years. This includes the management of pediatric patients with end-stage renal disease, the selection of appropriate pediatric recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative care including those issues of management unique to the pediatric recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the pediatric recipient including side-effects of drugs and complications of immunosuppression, the effects of transplantation and immunosuppressive agents on growth and development, differential diagnosis of renal dysfunction in the allograft recipient, manifestation of rejection in the pediatric patient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long-term outpatient care of pediatric allograft recipients including management of hypertension, nutritional support, and drug dosage, including antibiotics, in the pediatric patient.
6. The physician must have observed at least 3 kidney procurements, including at least 1 deceased donor and 1 living donor. The physician must have observed the evaluation, donation process, and management of these donors. These observations must be documented in a log that includes the date of procurement and Donor ID.
7. The physician must have observed at least 3 kidney transplants involving a pediatric recipient. The observation of these transplants must be documented in a log that includes the transplant date, donor type, and medical record number or other unique identifier that can be verified by the OPTN Contractor.
8. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the director and the supervising qualified transplant physician and surgeon of the fellowship training program verifying that the physician has met the above requirements and is qualified to become the primary transplant physician of a designated kidney transplant program.
  - b. A letter of recommendation from the fellowship training program's primary physician and transplant program director outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
  - c. A letter from the physician that details the training and experience the physician has gained in kidney transplantation.

## **E. Combined Pediatric Nephrology Training and Experience Pathway**

A physician can meet the requirements for primary kidney transplant physician if the following conditions are met:

1. The physician has current board certification in pediatric nephrology by the American Board of Pediatrics, the Royal College of Physicians and Surgeons of Canada, or is approved by the American Board of Pediatrics to take the certifying exam.
2. The physician gained a minimum of 2 years of experience during or after fellowship, or accumulated during both periods, at a kidney transplant program.

3. During the 2 or more years of accumulated experience, the physician was directly involved in the primary care of 10 or more newly transplanted kidney recipients for at least 6 months from the time of transplant and followed 30 transplanted kidney recipients for at least 6 months, under the direct supervision of a qualified kidney transplant physician, along with a qualified kidney transplant surgeon. This care must be documented in a recipient log that includes the date of transplant, and the recipient medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the training program director or the primary physician of the transplant program.
4. The physician was directly involved in the evaluation of 25 potential kidney recipients, including participation in selection committee meetings. These potential kidney recipient evaluations must be documented in a log that includes each evaluation date and be signed by the program director, division Chief, or department Chair from the program where the physician gained this experience.
5. The physician has maintained a current working knowledge of kidney transplantation, defined as direct involvement in kidney transplant patient care during the past 2 years. This includes the management of pediatric patients with end-stage renal disease, the selection of appropriate pediatric recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative care including those issues of management unique to the pediatric recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the pediatric recipient including side-effects of drugs and complications of immunosuppression, the effects of transplantation and immunosuppressive agents on growth and development, differential diagnosis of renal dysfunction in the allograft recipient, manifestation of rejection in the pediatric patient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long-term outpatient care of pediatric allograft recipients including management of hypertension, nutritional support, and drug dosage, including antibiotics, in the pediatric patient.
6. The physician must have observed at least 3 kidney procurements, including at least 1 deceased donor and 1 living donor. The physician must have observed the evaluation, donation process, and management of these donors. These observations must be documented in a log that includes the date of procurement and Donor ID.
7. The physician must have observed at least 3 kidney transplants involving a pediatric recipient. The observation of these transplants must be documented in a log that includes the transplant date, donor type, and medical record number or other unique identifier that can be verified by the OPTN Contractor.
8. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the supervising qualified transplant physician and surgeon who were directly involved with the physician documenting the physician's experience and competence.
  - b. A letter of recommendation from the fellowship training program's primary physician and transplant program director outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, Director, or others affiliated with any transplant program previously served by the physician, at its discretion.
  - c. A letter from the physician that details the training and experience the physician has gained in kidney transplantation.

## **F. Conditional Approval for Primary Transplant Physician**

If the primary kidney transplant physician changes at an approved Kidney transplant program, a physician can serve as the primary kidney transplant physician for a maximum of 12 months if the following conditions are met:

1. The physician has been involved in the primary care of 23 or more newly transplanted kidney recipients, and has continued the outpatient follow-up of these patients for at least 3 months from the time of their transplant. This care must be documented in a recipient log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair from the transplant program where the experience was gained.
2. The physician was directly involved in the evaluation of 25 potential kidney recipients, including participation in selection committee meetings. These potential kidney recipient evaluations must be documented in a log that includes each evaluation date and is signed by the program director, division Chief, or department Chair from the program where the physician gained this experience.
3. The physician was directly involved in the evaluation of 10 potential living kidney donors, including participation in selection committee meetings. These potential living kidney donor evaluations must be documented in a log that includes each evaluation date and the potential living kidney donor's medical record number or other unique identifier than can be verified by the OPTN Contractor. This potential living kidney donor log must and be signed by program director, division Chief, or department Chair from the program where the physician gained this experience.
4. The physician has maintained a current working knowledge of kidney transplantation, defined as direct involvement in kidney transplant patient care during the last 2 years. This includes the management of patients with end stage renal disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate postoperative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long-term outpatient care.
5. The physician has 12 months experience on an active kidney transplant service as the primary kidney transplant physician or under the direct supervision of a qualified kidney transplant physician and in conjunction with a kidney transplant surgeon at a designated kidney transplant program. These 12 months of experience must be acquired within a 2-year period.
6. The physician must have observed at least 3 kidney procurements, including at least 1 deceased donor and 1 living donor. The physician must have observed the evaluation, donation process, and management of these donors. These observations must be documented in a log that includes the date of procurement and Donor ID.
7. The physician must have observed at least 3 kidney transplants. The observation of these transplants must be documented in a log that includes the transplant date, donor type, and medical record number or other unique identifier that can be verified by the OPTN Contractor.
8. The program has established and documented a consulting relationship with counterparts at another kidney transplant program.
9. The transplant program submits activity reports to the OPTN Contractor every 2 months describing the transplant activity, transplant outcomes, physician recruitment efforts, and

other operating conditions as required by the MPSC to demonstrate the ongoing quality and efficient patient care at the program. The activity reports must also demonstrate that the physician is making sufficient progress to meet the required involvement in the primary care of 45 or more kidney transplant recipients, or that the program is making sufficient progress in recruiting a physician who meets all requirements for primary kidney transplant physician and who will be on site and approved by the MPSC to assume the role of primary physician by the end of the 12 month conditional approval period.

10. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the supervising qualified transplant physician and surgeon who were directly involved with the physician documenting the physician's experience and competence.
  - b. A letter of recommendation from the primary physician and director at the transplant program last served by the physician outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
  - c. A letter from the physician that details the training and experience the physician has gained in kidney transplantation.

The 12-month conditional approval period begins on the initial approval date granted to the personnel change application, whether it is interim approval granted by the MPSC subcommittee, or approval granted by the full MPSC. The conditional approval period ends 12 months after the first approval date of the personnel change application.

The MPSC may consider on a case-by-case basis and grant a 6-month extension to a transplant program that provides substantial evidence of progress toward fulfilling the requirements but is unable to complete the requirements within one year.

If the program is unable to demonstrate that it has an individual on site who can meet the requirements as described in *Sections E.3.A through E.3.F* above at the end of the conditional approval period, it must inactivate. The requirements for program inactivation are described in *Appendix K: Transplant Program Inactivity, Withdrawal, and Termination* of these Bylaws.

## **E.4 Approved Kidney Transplant Surgeon and Physician Fellowship Training Programs**

### **A. Transplant Surgeon Fellowship Training Programs**

Surgeons qualifying as primary transplant surgeon based on completion of a formal 2-year surgical transplant fellowship must complete their training at a fellowship program approved by the American Society of Transplant Surgeons, the Royal College of Physicians and Surgeons of Canada, or another recognized fellowship training program accepted by the OPTN Contractor that meets the following criteria:

1. The program is at a transplant hospital that transplants one or more organs, including kidneys.
2. The program is at an institution that has ACGME approved training in general
3. The program performs at least 60 kidney transplants during each year of the fellowship training.

## **B. Transplant Physician Fellowship Training Programs**

Physicians qualifying as primary transplant physician based on completion of a formal transplant fellowship must complete their training at a fellowship program approved by the American Society of Transplantation Adult Transplant Nephrology Fellowship Training Program, the Royal College of Physicians and Surgeons of Canada, or another recognized fellowship training program accepted by the OPTN Contractor that meets the following criteria:

1. The program is at a transplant hospital that transplants one or more organs, including kidneys.
2. The program is at a hospital that has an ACGME approved nephrology program.
3. The program performs at least 50 kidney transplants per year if the program is training one transplant nephrology fellow, and performs at least 30 additional kidney transplants per year for each additional fellow it trains.
4. The program's curriculum must include training and experience in end-stage renal disease, training in the selection of appropriate transplant recipients and donors, experience in the immediate and long term care of the transplant recipient, and training in the performance of kidney transplant biopsies. Additionally there must be an emphasis on the management of immunosuppressive agents and the evaluation of kidney transplant dysfunction.
5. The program must provide patient co-management responsibility with transplant surgeons from the peri-operative through the outpatient period. The kidney trainee must primarily manage the transplant recipient's medical care including hypertension, diabetes, and dialytic problems. Trainees must also serve as a primary member of the transplant team and participate in making decisions about immunosuppression.

## **E.5 Kidney Transplant Programs that Register Candidates Less than 18 Years Old**

A designated kidney transplant program that registers candidates less than 18 years old must have an approved pediatric component. To be approved for a pediatric component, the designated kidney transplant program must identify a qualified primary pediatric kidney transplant surgeon and a qualified primary pediatric kidney transplant physician, as described below.

### **A. Primary Pediatric Kidney Transplant Surgeon Requirements**

A pediatric component at a designated kidney transplant program must have a primary pediatric surgeon who meets *all* of the following requirements:

1. The surgeon meets all of the requirements described in Section E.2: Primary Kidney Transplant Surgeon Requirements, including completion of at least one of the following training or experience pathways:
  - The formal 2-year transplant fellowship pathway as described in *Section E.2.A: Formal 2-year Transplant Fellowship Pathway*
  - The kidney transplant program clinical experience pathway, as described in *Section E.2.B: Clinical Experience Pathway*
2. The surgeon has performed at least 10 kidney transplants, as the primary surgeon or first assistant, in recipients less than 18 years old at the time of transplant. At least 3 of these kidney transplants must have been in recipients less than 6 years old or weighing less than 25 kilograms at the time of transplant. These transplants must have been performed during or after fellowship, or across both periods. These transplants must be documented in a log that includes the date of transplant, the recipient's date of birth, the recipient's weight at transplant if less than 25 kilograms, the role of the surgeon in the procedure, and the medical record number or other unique identifier that can be verified by the OPTN Contractor.

3. The surgeon has maintained a current working knowledge of pediatric kidney transplantation, defined as direct involvement in pediatric kidney transplant patient care within the last 2 years. This includes the management of pediatric patients with end stage renal disease, the selection of appropriate pediatric recipients for transplantation, donor selection, HLA typing, performing the transplant operation, immediate postoperative and continuing inpatient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long term outpatient care.

## **B. Primary Pediatric Kidney Transplant Physician Requirements**

A pediatric component at a designated kidney transplant program must have a primary pediatric physician who meets all of the requirements described in Section E.3: Primary Kidney Transplant Physician Requirements. In addition, the primary pediatric transplant physician must have completed at least one of the training or experience pathways listed below:

- The 3-year pediatric nephrology fellowship pathway, as described in Section E.3.C: Three-year Pediatric Nephrology Fellowship Pathway
- The 12-month pediatric transplant nephrology fellowship pathway, as described in Section E.3.D: Twelve-month Pediatric Transplant Nephrology Fellowship Pathway
- The combined pediatric nephrology training and experience pathway, as described in Section E.3.E: Combined Pediatric Nephrology Training and Experience Pathway

## **C. Conditional Approval for a Pediatric Component**

A designated kidney transplant program can obtain conditional approval for a pediatric component if either of the following conditions is met:

1. The program has a qualified primary pediatric kidney physician who meets all of the requirements described in Section E.5.B: Primary Pediatric Kidney Transplant Physician Requirements and a surgeon who meets all of the following requirements:
  - a. The surgeon meets all of the requirements described in Section E.2: Primary Kidney Transplant Surgeon Requirements, including completion of at least one of the following training or experience pathways:
    - The formal 2-year transplant fellowship pathway as described in Section E.2.A: Formal 2-year Transplant Fellowship Pathway
    - The kidney transplant program clinical experience pathway, as described in Section E.2.B: Clinical Experience Pathway
  - b. The surgeon has performed at least 5 kidney transplants, as the primary surgeon or first assistant, in recipients less than 18 years old at the time of transplant. At least 1 of these kidney transplants must have been in recipients less than 6 years old or weighing less than 25 kilograms at the time of transplant. These transplants must have been performed during or after fellowship, or across both periods. These transplants must be documented in a log that includes the date of transplant, the recipient's date of birth, the recipient's weight at transplant if less than 25 kilograms, the role of the surgeon in the procedure, and the medical record number or other unique identifier that can be verified by the OPTN Contractor.
  - c. The surgeon has maintained a current working knowledge of pediatric kidney transplantation, defined as direct involvement in pediatric kidney transplant patient care in the last 2 years. This includes the management of pediatric patients with end stage renal disease, the selection of appropriate pediatric recipients for transplantation, donor selection, histocompatibility and HLA typing, performing the pediatric transplant

operation, immediate postoperative and continuing inpatient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long term outpatient care.

2. The program has a qualified primary pediatric kidney surgeon who meets all of the requirements described in Section E.5.A: Primary Pediatric Kidney Transplant Surgeon Requirements and a physician who meets all of the following requirements:
  - a. The physician has current board certification in pediatric nephrology by the American Board of Pediatrics or the foreign equivalent, or is approved by the American Board of Pediatrics to take the certifying exam.
  - b. The physician gained a minimum of 2 years of experience during or after fellowship, or accumulated during both periods, at a kidney transplant program.
  - c. During the 2 or more years of accumulated experience, the physician was directly involved in the primary care of 5 or more newly transplanted kidney recipients and followed 15 newly transplanted kidney recipients for at least 6 months from the time of transplant, under the direct supervision of a qualified kidney transplant physician, along with a qualified kidney transplant surgeon. This care must be documented in a recipient log that includes the date of transplant and the recipient medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the training program director or the primary physician of the transplant program.
  - d. The physician has maintained a current working knowledge of pediatric kidney transplantation, defined as direct involvement in kidney transplant patient care during the past 2 years. This includes the management of pediatric patients with end-stage renal disease, the selection of appropriate pediatric recipients for transplantation, donor selection, histocompatibility and HLA typing, immediate post-operative care including those issues of management unique to the pediatric recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the pediatric recipients including side-effects of drugs and complications of immunosuppression, the effects of transplantation and immunosuppressive agents on growth and development, differential diagnosis of renal dysfunction in the allograft recipient, manifestation of rejection in the pediatric patient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long-term outpatient care of pediatric allograft recipients including management of hypertension, nutritional support, and drug dosage, including antibiotics, in the pediatric patient.
  - e. The physician should have observed at least 3 organ procurements and 3 pediatric kidney transplants. The physician should also have observed the evaluation, the donation process, and management of at least 3 multiple organ donors who donated a kidney. If the physician has completed these observations, they must be documented in a log that includes the date of procurement and Donor ID.
  - f. The following letters are submitted directly to the OPTN Contractor:
    - i. A letter from the supervising qualified transplant physician and surgeon who were directly involved with the physician documenting the physician's experience and competence.
    - ii. A letter of recommendation from the fellowship training program's primary physician and transplant program director outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary pediatric surgeon, Director, or others affiliated with any transplant program previously served by the physician, at its discretion.
    - iii. A letter from the physician that details the training and experience the physician has gained in kidney transplantation.



A designated kidney transplant program's conditional approval for a pediatric component is valid for a maximum of 24 months.

#### **D. Full Approval for a Pediatric Component following Conditional Approval**

The conditional approval period begins on the first approval date granted to the pediatric component application, whether it is interim approval granted by the MPSC subcommittee, or approval granted by the full MPSC. The conditional approval period ends 24 months after first approval date of the pediatric component application.

The MPSC can consider granting a 24-month conditional approval extension to the designated kidney transplant for its pediatric component if the program provides substantial evidence of progress toward fulfilling the requirements, but is unable to complete *all* of the requirements within the initial 24-month period.

Once the designated kidney transplant program has met the full approval requirements for the pediatric component, the program may petition the OPTN Contractor for full approval.

If the designated kidney transplant program is unable to demonstrate that it has both a pediatric primary kidney surgeon onsite that meets *all* of the requirements as described in *Section E.5.A: Primary Pediatric Kidney Transplant Surgeon Requirements* and a pediatric primary kidney physician onsite that meets *all* of the requirements as described in *Section E.5.B: Primary Pediatric Kidney Transplant Physician Requirements* at the end of the 24-month conditional approval period, it must inactivate its pediatric component as described in *Appendix K: Transplant Program Inactivity, Withdrawal, and Termination*.

### **E.6 Kidney Transplant Programs that Perform Living Donor Recovery**

A kidney recovery hospital is a designated kidney transplant program that performs the surgery to recover kidneys from living donors for transplantation. Kidney recovery hospitals must meet all the requirements of a designated kidney transplant program as outlined above and must also have:

1. Protocols and resources in place for performing living donor evaluations.
2. Surgical resources on site for open or laparoscopic living donor kidney recoveries.

Some pediatric living donor or kidney paired donation transplants may require that the living organ donation occurs at a hospital that is separate from the approved transplant hospital.

#### **A. Living Donor Medical Evaluation**

The kidney recovery hospital must have the clinical resources available to assess the medical condition of and specific risks to the living donor.

#### **B. Living Donor Psychological Evaluation**

The kidney recovery hospital must have the clinical resources to perform a psychosocial evaluation of the living donor.

### **C. Independent Living Donor Advocate (ILDA)**

The kidney recovery hospital must have an independent living donor advocate (ILDA) who is not involved with the evaluation or treatment decisions of the potential recipient, and is a knowledgeable advocate for the living donor. The ILDA must be independent of the decision to transplant the potential recipient and follow the protocols that outline the duties and responsibilities of the ILDA according to OPTN *Policy 14.2: Independent Living Donor Advocate (ILDA) Requirements*.

### **D. Primary Open Living Donor Kidney Surgeon**

A kidney donor surgeon who performs open living donor nephrectomies must be on site and must meet *one* of the following criteria:

- Completion of a formal 2-year surgical transplant fellowship in kidney at a fellowship program approved by the American Society of Transplant Surgeons, the Royal College of Physicians and Surgeons of Canada, or other recognized fellowship training program accepted by the OPTN Contractor as described in *Section E.4.A: Transplant Surgeon Fellowship Training Programs*.
- Completion of at least 10 open nephrectomies, including deceased donor nephrectomies or the removal of diseased kidneys, as primary surgeon, co-surgeon, or first assistant. At least 5 of these open nephrectomies must have been performed as the primary surgeon or co-surgeon. The open nephrectomies must be documented in a log that includes the date of recovery, the role of the surgeon in the procedure, the type of procedure (open or laparoscopic), and the medical record number or Donor ID.

### **E. Primary Laparoscopic Living Donor Kidney Surgeon**

A surgeon who performs laparoscopic living donor kidney recoveries must be on site and must have completed at least 15 laparoscopic nephrectomies in the last 5 years as primary surgeon, co-surgeon, or first assistant. Seven of these nephrectomies must have been performed as primary surgeon or co-surgeon, and this role should be documented by a letter from the fellowship program director, program director, division chief, or department chair from the program where the surgeon gained this experience. The laparoscopic nephrectomies must be documented in a log that includes the date of the surgery, the role of the surgeon in the procedure, the type of procedure (open or laparoscopic), and the medical record number or Donor ID.

### **F. Kidney Paired Donation (KPD)**

Transplant hospitals that choose to participate in the OPTN KPD program must do *all* of the following:

1. Meet all the requirements of *Section E.5: Kidney Transplant Programs that Perform Living Donor Recovery* above.
2. Notify the OPTN Contractor in writing if the transplant hospital decides to participate in the OPTN KPD program. A transplant hospital must notify the OPTN Contractor in writing if it decides to quit its participation in the OPTN KPD program.

3. Provide to the OPTN Contractor a primary KPD contact that is available to facilitate the KPD match offer and transplant, and provide at least one alternate KPD contact that is a member of the hospital's staff and can fulfill the responsibilities required by policy.

The requirements for the OPTN KPD Program are described in detail in *OPTN Policy 13*.

# **Appendix F: Membership and Personnel Requirements for Liver Transplant Programs and Intestine Transplant Programs**

## **F.1 Membership and Personnel Requirements for Liver Transplant Programs**

This appendix describes the information and documentation transplant hospitals must provide when:

- Submitting a completed membership application to apply for approval as a designated liver transplant program.
- Completing a Personnel Change Application for a change in key personnel at a designated liver transplant program.
- Performing living donor liver recoveries and transplants, if applicable.

All transplant programs must also meet general membership requirements, which are described in *Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs* of these Bylaws.

For more information on the application and review process, see *Appendix A: Membership Application and Review* of these Bylaws.

## **F.2 Liver Program Director, Primary Liver Transplant Surgeon and Primary Liver Transplant Physician**

A liver transplant program must identify at least one designated staff member to act as the transplant program director. The director must be a physician or surgeon who is a member of the transplant hospital staff.

The program must also identify a qualified primary transplant surgeon and primary transplant physician, as described below. The primary surgeon and primary physician, along with the program director, must submit a detailed Program Coverage Plan to the OPTN Contractor. For detailed information about the Program Coverage Plan, see *Section D.7.B: Surgeon and Physician Coverage (Program Coverage Plan)* of these Bylaws.

## **F.3 Primary Liver Transplant Surgeon Requirements**

A designated liver transplant program must have a primary surgeon who meets *all* of the following requirements:

1. The surgeon must have an M.D., D.O., or equivalent degree from another country, with a current license to practice medicine in the hospital's state or jurisdiction.
2. The surgeon must be accepted onto the hospital's medical staff, and be on site at this hospital.
3. The surgeon must have documentation from the hospital credentialing committee that it has verified the surgeon's state license, board certification, training, and transplant continuing medical education, and that the surgeon is currently a member in good standing of the hospital's medical staff.

4. The surgeon must have current certification by the American Board of Surgery, the American Board of Urology, the American Board of Osteopathic Surgery, or the Royal College of Physicians and Surgeons of Canada. In the case of a surgeon who has just completed training and whose American Board of Urology certification is pending, the Membership and Professional Standards Committee (MPSC) may grant conditional approval for 16 months to allow time for the surgeon to complete board certification, with the possibility of one additional 16-month extension.

In place of current certification by the American Board of Surgery, the American Board of Urology, the American Board of Osteopathic Surgery, the Royal College of Physicians and Surgeons of Canada, or pending certification by the American Board of Urology, the surgeon must:

- a. Be ineligible for American board certification.
- b. Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that the surgeon obtains 60 hours of Category I continuing medical education (CME) credits with self-assessment that are relevant to the individual's practice every three years. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program. A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve an acceptable self-assessment score are allowed. The transplant hospital must document completion of this continuing education.
- c. Provide to the OPTN Contractor two letters of recommendation from directors of designated transplant programs not employed by the applying hospital. These letters must address:
  - i. Why an exception is reasonable.
  - ii. The surgeon's overall qualifications to act as a primary liver transplant surgeon.
  - iii. The surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
  - iv. Any other matters judged appropriate.

If the surgeon has not adhered to the plan for maintaining continuing education or has not obtained the necessary CME credits with self-assessment, the transplant program will have a six-month grace period to address these deficiencies. If the surgeon has not fulfilled the requirements after the six-month grace period, and a key personnel change application has not been submitted, then the transplant program will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws. If the OPTN Contractor becomes aware that a primary surgeon has not been compliant for 12 months or more and deficiencies still exist, then the transplant program will not be given any grace period and will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws.

5. The surgeon must have completed at least one of the pathways listed below:
  - a. The formal 2-year transplant fellowship pathway, as described in *Section F.3.A: Formal 2-year Transplant Fellowship Pathway* below.
  - b. The liver transplant program clinical experience pathway, as described in *Section F.3.B: Clinical Experience Pathway* below.

### **A. Formal 2-year Transplant Fellowship Pathway**

Surgeons can meet the training requirements for primary liver transplant surgeon by completing a formal 2-year surgical transplant fellowship if the following conditions are met:

1. The surgeon performed at least 45 liver transplants as primary surgeon or first assistant during the 2-year fellowship period. These transplants must be documented in the surgeon's fellowship operative log. The date of transplant, the role of the surgeon in the procedure, the

- medical record number or other unique identifier that can be verified by the OPTN Contractor, and the fellowship director's signature must be provided with this log.
2. The surgeon performed at least 20 liver procurements as primary surgeon or first assistant. These procurements must have been performed anytime during the surgeon's fellowship and the two years immediately following fellowship completion. These procedures must be documented in the surgeon's fellowship operative log. The date of procurement and Donor ID must be provided with this log.
  3. The surgeon has maintained a current working knowledge of liver transplantation, defined as direct involvement in liver transplant patient care within the last 2 years. This includes the management of patients with end stage liver disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, performing the transplant operation, immediate postoperative and continuing inpatient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of liver allograft dysfunction, histologic interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long term outpatient care.
  4. The training was completed at a hospital with a liver transplant training program approved by the American Society of Transplant Surgeons, the Royal College of Physicians and Surgeons of Canada, or another recognized fellowship training program accepted by the OPTN Contractor as described in *Section F.6: Approved Liver Surgeon Transplant Fellowship Programs* that follows.
  5. The following letters are submitted directly to the OPTN Contractor:
    - a. A letter from the director of the training program verifying that the surgeon has met the above requirements, and is qualified to direct a liver transplant program.
    - b. A letter of recommendation from the fellowship training program's primary surgeon and transplant program director outlining the surgeon's overall qualifications to act as primary transplant surgeon, as well as the surgeon's personal integrity, honesty, familiarity with and experience in adhering to OPTN obligations, and other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
    - c. A letter from the surgeon that details his or her training and experience in liver transplantation.

## **B. Clinical Experience Pathway**

Surgeons can meet the requirements for primary liver transplant surgeon through clinical experience gained post-fellowship, if the following conditions are met:

1. The surgeon has performed 60 or more liver transplants over a 2 to 5-year period as primary surgeon, co-surgeon, or first assistant at a designated liver transplant program. Of these 60 liver transplants, 30 or more must have been performed as primary surgeon or co-surgeon. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and medical record number or other unique identifier that can be verified by the OPTN Contractor. This log should be signed by the program director, division chief, or department chair from the program where the experience was gained. Each year of the surgeon's experience must be substantive and relevant and include pre-operative assessment of liver transplant candidates, transplants performed as primary surgeon or first assistant, and post-operative management of liver recipients.

2. The surgeon has performed at least 30 liver procurements as primary surgeon, co-surgeon, or first assistant. Of these 30 liver procurements, at least 15 must have been performed as primary surgeon or co-surgeon. These procedures must be documented in a log that includes the date of procurement and Donor ID.
3. The surgeon has maintained a current working knowledge of liver transplantation, defined as direct involvement in liver transplant patient care within the last 2 years. This includes the management of patients with end stage liver disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, performing the transplant operation, immediate postoperative and continuing inpatient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of liver dysfunction in the allograft recipient, histologic interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long term outpatient care.
4. The following letters are sent directly to the OPTN Contractor:
  - a. A letter from the director of the transplant program and chairman of the department or hospital credentialing committee verifying that the surgeon has met the above requirements, and is qualified to direct a liver transplant program.
  - b. A letter of recommendation from the primary surgeon and transplant program director at the transplant program last served by the surgeon outlining the surgeon's overall qualifications to act as primary transplant surgeon, as well as the surgeon's personal integrity, honesty, familiarity with and experience in adhering to OPTN obligations, and other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
  - c. A letter from the surgeon that details the training and experience the surgeon gained in liver transplantation.

#### **F.4 Primary Liver Transplant Physician Requirements**

A designated liver transplant program must have a primary physician who meets *all* the following requirements:

1. The physician must have an M.D., D.O., or equivalent degree from another country, with a current license to practice medicine in the hospital's state or jurisdiction.
2. The physician must be accepted onto the hospital's medical staff, and be on site at this hospital.
3. The physician must have documentation from the hospital credentialing committee that it has verified the physician's state license, board certification, training, and transplant continuing medical education and that the physician is currently a member in good standing of the hospital's medical staff.
4. The physician must have current board certification in gastroenterology, current board certification in transplant hepatology, or a current pediatric transplant hepatology certification of added qualification by the American Board of Internal Medicine, the American Board of Pediatrics, or the Royal College of Physicians and Surgeons of Canada.

In place of current certification by the American Board of Internal Medicine, the American Board of Pediatrics, or the Royal College of Physicians and Surgeons of Canada, the physician must:

- a. Be ineligible for American board certification.
- b. Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that the physician obtains 60 hours of Category I continuing medical education (CME) credits with self-assessment that are relevant to the

individual's practice every three years. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program. A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve an acceptable self-assessment score are allowed. The transplant hospital must document completion of this continuing education.

- c. Provide to the OPTN Contractor two letters of recommendation from directors of designated transplant programs not employed by the applying hospital. These letters must address:
  - i. Why an exception is reasonable.
  - ii. The physician's overall qualifications to act as a primary liver transplant physician.
  - iii. The physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
  - iv. Any other matters judged appropriate.

If the physician has not adhered to the plan for maintaining continuing education or has not obtained the necessary CME credits with self-assessment, the transplant program will have a six-month grace period to address these deficiencies. If the physician has not fulfilled the requirements after the six-month grace period, and a key personnel change application has not been submitted, then the transplant program will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws. If the OPTN Contractor becomes aware that a primary physician has not been compliant for 12 months or more and deficiencies still exist, then the transplant program will not be given any grace period and will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws.

5. The physician must have completed at least one of pathways listed below:
  - a. The 12-month transplant hepatology fellowship pathway, as described in *Section F.4.A: 12-month Transplant Hepatology Fellowship Pathway* below.
  - b. The clinical experience pathway, as described in *Section F.4.B: Clinical Experience Pathway* below.
  - c. The 3-year pediatric gastroenterology fellowship pathway, as described in *Section F.4.C: Three-year Pediatric Gastroenterology Fellowship Pathway* below.
  - d. The 12-month pediatric transplant hepatology fellowship pathway, as described in *Section F.4.D: Pediatric Transplant Hepatology Fellowship Pathway* below.
  - e. The combined pediatric gastroenterology or transplant hepatology training and experience pathway, as described in *Section F.4.E: Combined Pediatric Gastroenterology/Transplant Hepatology Training and Experience Pathway* below.
  - f. The conditional approval pathway, as described in *Section F.3.F: Conditional Approval for Primary Transplant Physician* below, if the primary liver transplant physician changes at an approved liver transplant program.

### **A. 12-month Transplant Hepatology Fellowship Pathway**

Physicians can meet the training requirements for a primary liver transplant physician during a separate 12-month transplant hepatology fellowship if the following conditions are met:

1. The physician completed 12 consecutive months of specialized training in transplantation under the direct supervision of a qualified liver transplant physician and in conjunction with a liver transplant surgeon at a liver transplant program. The training must have included at least 3 months of clinical transplant service. The remaining time must have consisted of transplant-related experience, such as experience in a tissue typing laboratory, on another solid organ transplant service, or conducting basic or clinical transplant research.
2. During the fellowship period, the physician was directly involved in the primary care of 30 or more newly transplanted liver recipients, and continued to follow these recipients for a minimum of 3 months from the time of transplant. The care must be documented in a log that includes the date of transplant and the medical record number or other unique identifier that



- can be verified by the OPTN Contractor. This log must be signed by the director of the training program or the transplant program's primary transplant physician.
3. The physician has maintained a current working knowledge of liver transplantation, defined as direct involvement in liver transplant patient care within the last 2 years. This includes the management of patients with end stage liver disease, acute liver failure, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of liver allograft dysfunction, histologic interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long term outpatient care.
  4. The physician must have observed at least 3 liver procurements. The physician must have observed the evaluation, donation process, and management of these donors. These observations must be documented in a log that includes the date of procurement and Donor ID.
  5. The physician must have observed at least 3 liver transplants. The observation of these transplants must be documented in a log that includes the transplant date, donor type, and medical record number or other unique identifier that can be verified by the OPTN Contractor.
  6. The following letters are submitted directly to the OPTN Contractor:
    - a. A letter from the director of the training program and the supervising liver transplant physician verifying that the physician has met the above requirements and is qualified to direct a liver transplant program.
    - b. A letter of recommendation from the fellowship training program's primary physician and transplant program director outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
    - c. A letter from the physician writes that details the training and experience the physician gained in liver transplantation.

The training requirements outlines above are in addition to other clinical requirements for general gastroenterology training.

## **B. Clinical Experience Pathway**

A physician can meet the requirements for a primary liver transplant physician through acquired clinical experience if the following conditions are met:

1. The physician has been directly involved in the primary care of 50 or more newly transplanted liver recipients and continued to follow these recipients for a minimum of 3 months from the time of transplant. This patient care must have been provided over a 2 to 5-year period on an active liver transplant service as the primary liver transplant physician or under the direct supervision of a qualified liver transplant physician and in conjunction with a liver transplant surgeon at a designated liver transplant program. This care must be documented in a log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log should be signed by the program director, division chief, or department chair from the program where the physician gained this experience.

2. The physician has maintained a current working knowledge of liver transplantation, defined as direct involvement in liver transplant patient care within the last 2 years. This includes the management of patients with end stage liver disease, acute liver failure, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of liver allograft dysfunction, histologic interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long term outpatient care.
3. The physician must have observed at least 3 liver procurements. The physician must have observed the evaluation, donation process, and management of these donors. These observations must be documented in a log that includes the date of procurement and Donor ID.
4. The physician must have observed at least 3 liver transplants. The observation of these transplants must be documented in a log that includes the transplant date, donor type, and medical record number or other unique identifier that can be verified by the OPTN Contractor.
5. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the qualified transplant physician or the liver transplant surgeon who has been directly involved with the proposed physician documenting the physician's experience and competence.
  - b. A letter of recommendation from the primary physician and transplant program director at the transplant program last served by the physician outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
  - c. A letter from the physician that details the training and experience the physician gained in liver transplantation.

### **C. Three-year Pediatric Gastroenterology Fellowship Pathway**

A physician can meet the requirements for primary liver transplant physician by completion of 3 years of pediatric gastroenterology fellowship training as required by the American Board of Pediatrics in a program accredited by the Residency Review Committee for Pediatrics (RRC-Ped) of the Accreditation Council for Graduate Medical Education (ACGME). The training must contain at least 6 months of clinical care for transplant patients, and meet the following conditions:

1. The physician has current board certification in pediatric gastroenterology or a pediatric transplant hepatology certification or added qualification by the American Board of Pediatrics or the Royal College of Physicians and Surgeons of Canada.
2. During the 3-year training period the physician was directly involved in the primary care of 10 or more newly transplanted pediatric liver recipients and followed 20 newly transplanted liver recipients for a minimum of 3 months from the time of transplant, under the direct supervision of a qualified liver transplant physician along with a qualified liver transplant surgeon. The physician was also directly involved in the preoperative, peri-operative and post-operative care of 10 or more liver transplants in pediatric patients. The pediatric gastroenterology program director may elect to have a portion of the transplant experience carried out at another transplant service, to meet these requirements. This care must be documented in a log that includes the date of transplant, the medical record number or other unique identifier

- that can be verified by the OPTN Contractor. This recipient log must be signed by the training program director or the transplant program's primary transplant physician.
3. The experience caring for pediatric patients occurred at a liver transplant program with a qualified liver transplant physician and a qualified liver transplant surgeon that performs an average of at least 10 liver transplants on pediatric patients per year.
  4. The physician must have observed at least 3 liver procurements. The physician must have observed the evaluation, donation process, and management of these donors. These observations must be documented in a log that includes the date of procurement and Donor ID.
  5. The physician must have observed at least 3 liver transplants. The observation of these transplants must be documented in a log that includes the transplant date, donor type, and medical record number or other unique identifier that can be verified by the OPTN Contractor.
  6. The physician has maintained a current working knowledge of liver transplantation, defined as direct involvement in liver transplant patient care within the last 2 years. This includes the management of pediatric patients with end-stage liver disease acute liver failure, the selection of appropriate pediatric recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate postoperative care including those issues of management unique to the pediatric recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the pediatric recipient including side-effects of drugs and complications of immunosuppression, the effects of transplantation and immunosuppressive agents on growth and development, differential diagnosis of liver dysfunction in the allograft recipient, manifestation of rejection in the pediatric patient, histological interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long-term outpatient care of pediatric allograft recipients including management of hypertension, nutritional support, and drug dosage, including antibiotics, in the pediatric patient.
  7. The following letters are submitted directly to the OPTN Contractor:
    - a. A letter from the director of the pediatric gastroenterology training program, and the qualified liver transplant physician and surgeon of the fellowship training program verifying that the physician has met the above requirements, and is qualified to act as a liver transplant physician and direct a liver transplant program.
    - b. A letter of recommendation from the fellowship training program's primary physician and transplant program director outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
    - c. A letter from the physician that details the training and experience the physician gained in liver transplantation.

#### **D. Pediatric Transplant Hepatology Fellowship Pathway**

The requirements for primary liver transplant physician can be met during a separate pediatric transplant hepatology fellowship if the following conditions are met:

1. The physician has current board certification in pediatric gastroenterology or a current pediatric transplant hepatology certification or added qualification by the American Board of Pediatrics, the Royal College of Physicians and Surgeons of Canada, or is approved by the American Board of Pediatrics to take the certifying exam.

2. During the fellowship, the physician was directly involved in the primary care of 10 or more newly transplanted pediatric liver recipients and followed 20 newly transplanted liver recipients for at least 3 months from the time of transplant, under the direct supervision of a qualified liver transplant physician and in conjunction with a qualified liver transplant surgeon. The physician must have been directly involved in the pre-operative, peri-operative and post-operative care of 10 or more liver transplants in pediatric patients. The pediatric gastroenterology program director may elect to have a portion of the transplant experience completed at another liver transplant program in order to meet these requirements. This care must be documented in a log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log must be signed by the training program director or the transplant program primary transplant physician.
3. The experience in caring for pediatric liver patients occurred at a liver transplant program with a qualified liver transplant physician and surgeon that performs an average of at least 10 pediatric liver transplants a year.
4. The physician has maintained a current working knowledge of liver transplantation, defined as direct involvement in liver transplant patient care within the last 2 years. This includes the management of pediatric patients with end-stage liver disease, acute liver failure, the selection of appropriate pediatric recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate postoperative care including those issues of management unique to the pediatric recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the pediatric recipient including side-effects of drugs and complications of immunosuppression, the effects of transplantation and immunosuppressive agents on growth and development, differential diagnosis of liver dysfunction in the allograft recipient, manifestation of rejection in the pediatric patient, histological interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long-term outpatient care of pediatric allograft recipients including management of hypertension, nutritional support, and drug dosage, including antibiotics, in the pediatric patient.
5. The physician must have observed at least 3 liver procurements. The physician must have observed the evaluation, donation process, and management of these donors. These observations must be documented in a log that includes the date of procurement and Donor ID.
6. The physician must have observed at least 3 liver transplants. The observation of these transplants must be documented in a log that includes the transplant date, donor type, and medical record number or other unique identifier that can be verified by the OPTN Contractor.
7. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the director of the pediatric transplant hepatology training program, and the qualified liver transplant physician and surgeon of the fellowship training program verifying that the physician has met the above requirements, and is qualified to act as a liver transplant physician and direct a liver transplant program.
  - b. A letter of recommendation from the fellowship training program's primary physician and transplant program director outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
  - c. A letter from the physician that details the training and experience the physician gained in liver transplantation.

## **E. Combined Pediatric Gastroenterology/Transplant Hepatology Training and Experience Pathway**

A physician can meet the requirements for primary liver transplant physician if the following conditions are met:

1. The physician has current board certification in pediatric gastroenterology or a current pediatric transplant hepatology certification or added qualification by the American Board of Pediatrics, the Royal College of Physicians and Surgeons of Canada, or is approved by the American Board of Pediatrics to take the certifying exam.
2. The physician gained a minimum of 2 years of experience during or after fellowship, or accumulated during both periods, at a liver transplant program.
3. During the 2 or more years of accumulated experience, the physician was directly involved in the primary care of 10 or more newly transplanted pediatric liver recipients and followed 20 newly transplanted liver recipients for a minimum of 6 months from the time of transplant, under the direct supervision of a qualified liver transplant physician and along with a qualified liver transplant surgeon. The physician must have been directly involved in the pre-operative, peri-operative and post-operative care of 10 or more pediatric liver transplant recipients. This care must be documented in a log that includes at the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log must be signed by the training program director or the transplant program primary transplant physician.
4. The individual has maintained a current working knowledge of liver transplantation, defined as direct involvement in liver transplant patient care within the last 2 years. This includes the management of pediatric patients with end-stage liver disease, the selection of appropriate pediatric recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative care including those issues of management unique to the pediatric recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the pediatric recipient including side-effects of drugs and complications of immunosuppression, the effects of transplantation and immunosuppressive agents on growth and development, differential diagnosis of liver dysfunction in the allograft recipient, manifestation of rejection in the pediatric patient, histological interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long-term outpatient care of pediatric allograft recipients including management of hypertension, nutritional support, and drug dosage, including antibiotics, in the pediatric patient.
5. The physician must have observed at least 3 liver procurements. The physician must have observed the evaluation, the donation process, and the management of these donors. These observations must be documented in a log that includes the date of procurement and Donor ID.
6. The physician must have observed at least 3 liver transplants. The observation of these transplants must be documented in a log that includes the transplant date, donor type, and medical record number or other unique identifier that can be verified by the OPTN Contractor.
7. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the qualified liver transplant physician and surgeon who have been directly involved with the physician documenting the physician's experience and competence.
  - b. A letter of recommendation from the primary physician and transplant program director at the fellowship training program or transplant program last served by the physician outlining the physician's overall qualifications to act as a primary transplant physician, as

well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.

- c. A letter from the physician that details the training and experience the physician gained in liver transplantation.

## **F. Conditional Approval for Primary Transplant Physician**

If the primary liver transplant physician changes at an approved liver transplant program, a physician can serve as the primary liver transplant physician for a maximum of 12 months if the following conditions are met:

1. The physician has been involved in the primary care of 25 or more newly transplanted liver recipients, and has followed these patients for at least 3 months from the time of their transplant. This care must be documented in a recipient log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair from the transplant program where the experience was gained.
2. The physician has maintained a current working knowledge of liver transplantation, defined as direct involvement in liver transplant patient care during the last 2 years. This includes the management of patients with end stage liver disease, acute liver failure, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of liver allograft dysfunction, histologic interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long term outpatient care.
3. The physician has 12 months experience on an active liver transplant service as the primary liver transplant physician or under the direct supervision of a qualified liver transplant physician along with a liver transplant surgeon at a designated liver transplant program. These 12 months of experience must be acquired within a 2-year period.
4. The physician must have observed at least 3 liver procurements. The physician must have observed the evaluation, donation process, and management of these donors. These observations must be documented in a log that includes the date of procurement and Donor ID.
5. The physician must have observed at least 3 liver transplants. The observation of these transplants must be documented in a log that includes the transplant date, donor type, and medical record number or other unique identifier that can be verified by the OPTN Contractor.
6. The transplant program submits activity reports to the OPTN Contractor every 2 months describing the transplant activity, transplant outcomes, physician recruitment efforts, and other operating conditions as required by the MPSC to demonstrate the ongoing quality and efficient patient care at the program. The activity reports must also demonstrate that the physician is making sufficient progress to meet the required involvement in the primary care of 50 or more liver transplant recipients, or that the program is making sufficient progress in recruiting a physician who meets all requirements for primary liver transplant physician and who will be on site and approved by the MPSC to assume the role of primary physician by the end of the 12 month conditional approval period.

7. The program has established and documented a consulting relationship with counterparts at another liver transplant program.
8. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the qualified liver transplant physician and surgeon who were directly involved with the physician verifying that the physician has satisfactorily met the above requirements to become the primary transplant physician of a liver transplant program.
  - b. A letter of recommendation from the primary physician and transplant program director at the transplant program last served by the physician outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
  - c. A letter from the physician sends that details the training and experience the physician gained in liver transplantation.

The 12-month conditional approval period begins on the first approval date granted to the personnel change application, whether it is interim approval granted by the MPSC subcommittee, or approval granted by the full MPSC. The conditional approval period ends 12 months after the first approval date of the personnel change application.

The MPSC may consider on a case-by-case basis and grant a 6-month extension to a transplant program that provides substantial evidence of progress toward fulfilling the requirements but is unable to complete the requirements within one year.

If the program is unable to demonstrate that it has an individual on site who can meet the requirements as described in *Sections F.4.A through F.4.F* above at the end of the conditional approval period, it must inactivate. The requirements for program inactivation are described in *Appendix K: Transplant Program Inactivity, Withdrawal, and Termination* of these Bylaws.

## **F.5 Requirements for Director of Liver Transplant Anesthesia**

Liver transplant programs must designate a director of liver transplant anesthesia who has expertise in the area of peri-operative care of liver transplant patients and can serve as an advisor to other members of the team.

1. The director of liver transplant anesthesia must be a Diplomate of the American Board of Anesthesiology.
2. In place of current certification by the American Board of Anesthesiology, the director of liver transplant anesthesia must provide to the OPTN Contractor two letters of recommendation from current directors of liver transplant anesthesia at a designated liver program who are not employed by the applying member. These letters must address:
  - a. Why an exception is reasonable.
  - b. The anesthesiologist's overall qualifications to act as a director of liver transplant anesthesiology.
  - c. Any other matters judged appropriate.

### **A. Director of Liver Transplant Anesthesia Administrative Responsibilities**

The director of liver transplant anesthesia should be a designated member of the transplant team and will be responsible for establishing internal policies for anesthesiology participation in the

peri-operative care of liver transplant patients. These policies will be developed in the context of the institutional needs, transplant volume, and quality improvement initiatives.

## **B. Required Policies for Anesthesiology Participation**

The policy for anesthesiology participation must establish a clear communication channel between the transplant anesthesiology service and services from other disciplines that participate in the care of liver transplant patients. The types of activities to consider include:

- Peri-operative consults
- Participation in candidate selection
- Participation in morbidity and mortality conferences (M&M Conferences)
- Development of intra-operative guidelines based on existing and published knowledge

## **C. Director of Liver Transplant Anesthesia Clinical Responsibilities**

The director of liver transplant anesthesia has clinical responsibilities that include but are not limited to the following:

- Pre-operative assessment of transplant candidates
- Participation in candidate selection
- Intra-operative management
- Post-operative visits
- Participation on the Selection Committee
- Consultation pre-operatively with subspecialists as needed
- Participation in morbidity and mortality (M&M) conferences

## **D. Director of Liver Transplant Anesthesia Qualifications**

The director of liver transplant anesthesia should have *one* of the following:

- Fellowship training in Critical Care Medicine, Cardiac Anesthesiology, or a Liver Transplant Fellowship, that includes the peri-operative care of at least 10 liver transplant recipients.
- Experience in the peri-operative care of at least 20 liver transplant recipients in the operating room, within the last 5 years. Experience acquired during postgraduate residency training does not count for this purpose.

The director of Liver Transplant Anesthesia should also earn a minimum of 8 hours of credit in transplant related educational activities from the Accreditation Council for Continuing Medical Education (ACCME) Category I Continuing Medical Education (CME) within the most recent 3-year period.

## **F.6 Approved Liver Surgeon Transplant Fellowship Programs**

Surgeons qualifying as primary transplant surgeon based on completion of a formal 2-year surgical transplant fellowship must complete their training at a fellowship program approved by the MPSC. Any program approved for training by the Fellowship Training Committee of the American Society of Transplant Surgeons is automatically accepted by the American Society of Transplant Surgeons, the



Royal College of Physicians and Surgeons of Canada, or another recognized fellowship training program accepted by the OPTN Contractor that meets the following criteria:

1. The program is at a transplant hospital that transplants one or more organs, including livers.
2. The program is at an institution that has ACGME approved training in general surgery.
3. The program performs at least 50 liver transplants during each year of the fellowship training.

## **F.7 Liver Transplant Programs that Register Candidates Less than 18 Years Old**

A designated liver transplant program that registers candidates less than 18 years old must have an approved pediatric component. To be approved for a pediatric component, the designated liver transplant program must identify a qualified primary pediatric liver transplant surgeon and a qualified primary pediatric liver transplant physician, as described below.

### **A. Primary Pediatric Liver Transplant Surgeon Requirements**

A pediatric component at a designated liver transplant program must have a primary pediatric surgeon who meets all of the following requirements:

1. The surgeon meets all of the requirements described in *Section F.3: Primary Liver Transplant Surgeon Requirements*, including completion of at least one of the following training or experience pathways:
  - The formal 2-year transplant fellowship pathway as described in *Section F.3.A: Formal 2-year Transplant Fellowship Pathway*
  - The liver transplant program clinical experience pathway, as described in *Section F.3.B: Clinical Experience Pathway*
2. The surgeon has performed at least 15 liver transplants, as the primary surgeon or first assistant, in recipients less than 18 years old at the time of transplant. At least 8 of these liver transplants must have been in recipients less than 6 years old or weighing less than 25 kilograms at the time of transplant. These transplants must have been performed during or after fellowship, or across both periods. These transplants must be documented in a log that includes the date of transplant, the recipient's date of birth, the recipient's weight at transplant if less than 25 kilograms, the role of the surgeon in the procedure, and the medical record number or other unique identifier that can be verified by the OPTN Contractor.
3. The surgeon has maintained a current working knowledge of pediatric liver transplantation, defined as direct involvement in pediatric liver transplant patient care within the last 2 years. This includes the management of pediatric patients with end stage liver disease, the selection of appropriate pediatric recipients for transplantation, donor selection, histocompatibility and HLA typing, performing the pediatric transplant operation, immediate postoperative and continuing inpatient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of liver allograft dysfunction, histologic interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long term outpatient care.

### **B. Primary Pediatric Liver Transplant Physician Requirements**

A pediatric component at a designated liver transplant program must have a primary pediatric physician who meets *all* of the requirements described in *Section F.4: Primary Liver Transplant Physician Requirements*. In addition, the primary pediatric transplant physician must have completed at least *one* of the training or experience pathways listed below:

- The 3-year pediatric gastroenterology fellowship pathway, as described in *Section F.4.C:*

Three-year Pediatric Gastroenterology Fellowship Pathway

- The 12-month pediatric transplant hepatology fellowship pathway, as described in Section F.4.D: Pediatric Transplant Hepatology Fellowship Pathway
- The combined pediatric gastroenterology or transplant hepatology training and experience pathway, as described in Section F.4.E: Combined Pediatric Gastroenterology/Transplant Hepatology Training and Experience Pathway

### **C. Conditional Approval for a Pediatric Component**

A designated liver transplant program can obtain conditional approval for a pediatric component if either of the following conditions is met:

1. The program has a qualified primary pediatric liver physician who meets all of the requirements described in Section F.7.B: Primary Pediatric Liver Transplant Physician Requirements and a surgeon who meets all of the following requirements:
  - a. The surgeon meets all of the requirements described in Section F.3: Primary Liver Transplant Surgeon Requirements, including completion of at least one of the following training or experience pathways:
    - The formal 2-year transplant fellowship pathway as described in Section F.3.A: Formal 2-year Transplant Fellowship Pathway
    - The liver transplant program clinical experience pathway, as described in Section F.3.B: Clinical Experience Pathway
  - b. The surgeon has performed at least 7 liver transplants, as the primary surgeon or first assistant, in recipients less than 18 years old at the time of transplant. At least 2 of these liver transplants must have been in recipients less than 6 years old or weighing less than 25 kilograms at the time of transplant. These transplants must have been performed during or after fellowship, or across both periods. These transplants must be documented in a log that includes the date of transplant, the recipient's date of birth, the recipient's weight at transplant if less than 25 kilograms, the role of the surgeon in the procedure, and the medical record number or other unique identifier that can be verified by the OPTN Contractor.
  - c. The surgeon has maintained a current working knowledge of pediatric liver transplantation, defined as direct involvement in pediatric liver transplant patient care within the last 2 years. This includes the management of pediatric patients with end stage liver disease, the selection of appropriate pediatric recipients for transplantation, donor selection, histocompatibility and HLA typing, performing the transplant operation, immediate postoperative and continuing inpatient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of liver allograft dysfunction, histologic interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long term outpatient care.
2. The program has a qualified primary pediatric liver surgeon who meets all of the requirements described in Section F.7.A: Primary Pediatric Liver Transplant Surgeon Requirements and a physician who meets all of the following requirements:
  - a. The physician has current board certification in pediatric gastroenterology by the American Board of Pediatrics or the foreign equivalent, or is approved by the American Board of Pediatrics to take the certifying exam.
  - b. The physician gained a minimum of 2 years of experience during or after fellowship, or accumulated during both periods, at a liver transplant program.
  - c. During the 2 or more years of accumulated experience, the physician was directly involved in the primary care of 5 or more newly transplanted pediatric liver recipients and followed 10 newly transplanted liver recipients for a minimum of 6 months from the time of transplant, under the direct supervision of a qualified liver transplant physician along

with a qualified liver transplant surgeon. The physician must have been directly involved in the pre-operative, peri-operative and post-operative care of 10 or more pediatric liver transplants recipients. This care must be documented in a log that includes at the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log must be signed by the training program director or the transplant program primary transplant physician.

- d. The individual has maintained a current working knowledge of pediatric liver transplantation, defined as direct involvement in pediatric liver transplant patient care within the last 2 years. This includes the management of pediatric patients with end-stage liver disease, the selection of appropriate pediatric recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative care including those issues of management unique to the pediatric recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the pediatric recipient including side-effects of drugs and complications of immunosuppression, the effects of transplantation and immunosuppressive agents on growth and development, differential diagnosis of liver dysfunction in the allograft recipient, manifestation of rejection in the pediatric patient, histological interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long-term outpatient care of pediatric allograft recipients including management of hypertension, nutritional support, and drug dosage, including antibiotics, in the pediatric patient.
- e. The physician should have observed at least 3 organ procurements and 3 liver transplants. In addition, the physician should have observed the evaluation of donor, the donation process, and the management of at least 3 multiple organ donors who donated a liver. If the physician has completed these observations, they must be documented in a log that includes the date of procurement and Donor ID.
- f. The following letters are submitted directly to the OPTN Contractor:
  - i. A letter from the qualified liver transplant physician and surgeon who have been directly involved with the physician documenting the physician's experience and competence.
  - ii. A letter of recommendation from the primary physician and transplant program director at the fellowship training program or transplant program last served by the physician outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
  - iii. A letter from the physician that details the training and experience the physician gained in liver transplantation.

A designated liver transplant program's conditional approval for a pediatric component is valid for a maximum of 24 months.

#### **D. Full Approval for a Pediatric Component following Conditional Approval**

The conditional approval period begins on the first approval date granted to the pediatric component application, whether it is interim approval granted by the MPSC subcommittee, or approval granted by the full MPSC. The conditional approval period ends 24 months after first approval date of the pediatric component application.

The MPSC may consider granting a 24-month conditional approval extension to the designated liver transplant for its pediatric component if the program provides substantial evidence of progress toward fulfilling the requirements, but is unable to complete *all* of the requirements within the initial 24-month period.

Once the designated liver transplant program has met the full approval requirements for the pediatric component, the program may petition the OPTN Contractor for full approval.

If the designated liver transplant program is unable to demonstrate that it has both a pediatric primary liver surgeon onsite that meets all of the requirements as described in *Section F.7.A: Primary Pediatric Liver Transplant Surgeon Requirements* and a pediatric primary liver physician onsite that meets all of the requirements as described in *Section F.7.B: Primary Pediatric Liver Transplant Physician Requirements* at the end of the 24-month conditional approval period, it must inactivate its pediatric component as described in *Appendix K: Transplant Program Inactivity, Withdrawal, and Termination*.

## **E. Emergency Membership Exceptions for Candidates Less than 18 Years Old**

A designated liver transplant program that does not have an approved pediatric component may register a patient less than 18 years old on the waiting list if *both* of the following conditions are met:

1. The patient meets the requirements for pediatric status 1A according to OPTN *Policy 9.1.B: Pediatric Status 1A Requirements*. This does not include a patient who meets the status 1A requirements by exception according to OPTN *Policy 9.3: Score and Status Exceptions*.
2. The primary pediatric physician or primary pediatric surgeon at an approved pediatric liver component confirms that it is not medically advisable to transport this patient to a liver transplant program with an approved pediatric component. The transplant program that registers the candidate must document this confirmation.

If at any time the candidate no longer meets these criteria, the transplant program must remove the candidate from their waiting list within 24 hours, and may not transplant the candidate. The transplant program must assist candidates in transferring to other designated transplant programs.

Registration of a candidate less than 18 years old through an emergency exception does not grant the transplant program pediatric component approval.

## **F.8 Liver Transplant Programs that Perform Living Donor Recovery**

A liver recovery hospital is a designated liver transplant program that performs the surgery to recover livers for transplantation from living donors. Liver recovery hospitals must meet all the requirements of a designated liver transplant program as outlined above and must also have:

1. At least 2 surgeons on site who have demonstrated experience as described below.
2. Procedures and resources in place for performing living donor assessments.

### **A. Living Donor Surgeon Requirements**

A liver recovery hospital must have on site *at least* 2 surgeons who:

1. Meet the primary liver transplant surgeon requirements as outlined in *Section F.3* above.
2. Have demonstrated experience as the primary surgeon, co-surgeon, or first assistant by completion of at least 20 major liver resection surgeries, including living donor procedures, splits, reductions, and resections, within the past 5 years. Of these 20 major liver resection surgeries, 7 must have been live donor procedures, and at least 10 must have been performed as the primary surgeon or co-surgeon. These procedures must be documented in a log that includes the date of the surgery, the role of the surgeon in the procedure, and the

medical record number or other unique identifier that can be verified by the OPTN Contractor.

In the case of pediatric living donor transplantation, it may be necessary that the live organ recovery occurs at a hospital that is distinct from the approved liver transplant program.

## **B. Living Donor Medical Evaluations**

The liver recovery hospital must have the clinical resources available to assess the medical condition of and specific risks to the living donor.

## **C. Living Donor Psychosocial Evaluation**

The liver recovery hospital must have the clinical resources to perform a psychosocial evaluation of the living donor.

## **D. Independent Living Donor Advocate (ILDA)**

The liver recovery hospital must have an independent living donor advocate (ILDA) who is not involved with the evaluation or treatment decisions of the potential recipient, and is a knowledgeable advocate for the living donor. The ILDA must be independent of the decision to transplant the potential recipient and follow the protocols that outline the duties and responsibilities of the ILDA according to OPTN *Policy 14.2: Independent Living Donor Advocate (ILDA) Requirements*.

## **E. Conditional Program Approval Status**

If the program does not have a second surgeon on site who has performed at least 7 living donor liver recoveries within the past 5-years, the program may be eligible for conditional approval status if the surgeon:

1. Has completed the requirement for obtaining experience in 20 major liver resection surgeries as described in *Section F.7.A* above.
2. Meets all other requirements of a primary liver transplant surgeon.

The transplant program may be granted one year to fully comply with applicable membership criteria with a possible one year extension. This option will be available to new programs as well as previously approved programs that experience a change in key personnel. During this period of conditional approval, both of the designated surgeons must be present at all living donor liver recoveries.

The program must comply with interim operating policies and procedures as required by the MPSC. This may include submitting reports describing the surgeon's progress towards meeting the requirements, and any other operating conditions as requested by the MPSC to demonstrate ongoing quality and efficient patient care. The program must provide a report prior to the end of the first year of conditional approval documenting that the surgeon has met or is making sufficient progress toward performing 7 living donor liver recoveries or that the program is making sufficient progress in employing a transplant surgeon who meets this as well as all other criteria for a qualified live donor liver surgeon.

Should the surgeon meet the requirements before the conditional approval period ends, the program may submit a progress report and request review by the MPSC. The program's approval status will be made available to the public.

## **F. Rejection of Conditional Approval**

If the program is unable to demonstrate that it has 2 designated surgeons on site who can fully

meet the primary living donor liver surgeon requirements as described above at the end of the conditional approval period, it must stop performing living donor liver recoveries by *either*:

1. Inactivating the living donor component of the program for a period up to 12 months.
2. Relinquishing the living donor component of the liver transplant program until it can meet the requirements for full approval.

## **F.9 Membership and Personnel Requirements for Intestine Transplant Programs**

This appendix describes the information and documentation transplant hospitals must provide when:

- Submitting a completed membership application to apply for approval as a designated intestine transplant program.
- Completing a Personnel Change Application for a change in key personnel at a designated intestine transplant program.

All intestine transplant programs must also meet general membership requirements, which are described in *Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs* of these Bylaws.

For more information on the application and review process, see *Appendix A: Membership Application and Review* of these Bylaws.

## **F.10 Intestine Program Director, Primary Intestine Transplant Surgeon, and Primary Intestine Transplant Physician**

An intestine transplant program must identify at least one designated staff member to act as the transplant program director. The director must be a surgeon or physician who is a member of the transplant hospital staff.

The program must also identify a qualified primary transplant surgeon and primary transplant physician, as described below. The primary surgeon and primary physician, along with the program director, must submit a detailed Program Coverage Plan to the OPTN Contractor. For detailed information about the Program Coverage Plan, see *Appendix D, Section D.7.B: Surgeon and Physician Coverage* of these Bylaws.

## **F.11 Primary Intestine Transplant Surgeon Requirements**

A designated intestine transplant program must have a primary surgeon who meets *all* of the following requirements:

1. The surgeon must have an M.D., D.O., or equivalent degree from another country, with a current license to practice medicine in the hospital's state or jurisdiction.
2. The surgeon must be accepted onto the hospital's medical staff, and be on site at this hospital.
3. The surgeon must have documentation from the hospital credentialing committee that it has verified the surgeon's state license, board certification, training, and transplant continuing medical education, and that the surgeon is currently a member in good standing on the hospital's medical staff.
4. The surgeon must have current certification by the American Board of Surgery, the American Board of Osteopathic Surgery, or the Royal College of Physicians and Surgeons of Canada.

In place of current certification by the American Board of Surgery, the American Board of Osteopathic Surgery, or the Royal College of Physicians and Surgeons of Canada, the surgeon must:

- a. Be ineligible for American board certification.

- b. Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that the surgeon obtains 60 hours of Category I continuing medical education (CME) credits with self-assessment that are relevant to the individual's practice every three years. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program. A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve an acceptable self-assessment score are allowed. The transplant hospital must document completion of this continuing education.
- c. Provide to the OPTN Contractor two letters of recommendation from directors of designated transplant programs not employed by the applying hospital. These letters must address:
  - i. Why an exception is reasonable.
  - ii. The surgeon's overall qualifications to act as a primary intestine transplant surgeon.
  - iii. The surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
  - iv. Any other matters judged appropriate.

If the surgeon has not adhered to the plan for maintaining continuing education or has not obtained the necessary CME credits with self-assessment, the transplant program will have a six-month grace period to address these deficiencies. If the surgeon has not fulfilled the requirements after the six-month grace period, and a key personnel change application has not been submitted, then the transplant program will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws. If the OPTN Contractor becomes aware that a primary surgeon has not been compliant for 12 months or more and deficiencies still exist, then the transplant program will not be given any grace period and will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws.

5. The surgeon must have completed at least *one* of the pathways listed below:
  - a. The primary intestine transplant surgeon full approval pathway, as described in *Section F.11.A* below.
  - b. The primary intestine transplant surgeon conditional pathway, as described in *Section F.11.B* below.

### **A. Full Intestine Surgeon Approval Pathway**

Surgeons can be fully approved as a primary intestine transplant surgeon by completing a formal surgical transplant fellowship or by completing clinical experience at an intestine transplant program if *all* of the following conditions are met:

1. The surgeon performed 7 or more intestine transplants at a designated intestine transplant program, to include the isolated bowel and composite grafts, as primary surgeon or first assistant within the last 10 years. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair from the program where the experience or training was gained.
2. The surgeon performed 3 or more intestine procurements as primary surgeon or first assistant. These procurements must include 1 or more organ recovery that includes a liver. These procedures must be documented in a log that includes the date of procurement and Donor ID. This log must be signed by the program director, division chief, or department chair from the program where the experience or training was gained.
3. The surgeon has maintained a current working knowledge of intestine transplantation, defined as direct involvement in intestine transplant patient care within the last 5 years. This includes the management of patients with short bowel syndrome or intestinal failure, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, performing the transplant operation, immediate postoperative and continuing

- inpatient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of intestine allograft dysfunction, histologic interpretation of allograft biopsies, interpretation of ancillary tests for intestine dysfunction, and long term outpatient care.
4. The training was completed at a hospital with an intestinal transplant training program approved by the American Society of Transplant Surgeons or the Royal College of Physicians and Surgeons of Canada, or another recognized fellowship training program accepted by the OPTN Contractor as described in *Section F.14: Approved Intestine Transplant Surgeon Fellowship Training Programs* that follows.
  5. The following letters are submitted to the OPTN Contractor:
    - a. A letter from the qualified intestine transplant physician and surgeon who have been directly involved with the surgeon documenting the surgeon's experience and competence.
    - b. A letter of recommendation from the primary surgeon and transplant program director at the fellowship training program or transplant program last served by the surgeon outlining the surgeon's overall qualifications to act as a primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary surgeon, primary physician surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
    - c. A letter from the surgeon that details the training and experience the surgeon gained in intestine transplantation.

## **B. Conditional Intestine Surgeon Approval Pathway**

Surgeons can meet the requirements for conditional approval as primary intestine transplant surgeon through experience gained during or post-fellowship, if *all* of the following conditions are met:

1. The surgeon has performed at least 4 intestine transplants that include the isolated bowel and composite grafts and must perform 3 or more intestine transplants over the next 3 consecutive years as primary surgeon or first assistant at a designated intestine transplant program. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair from the program where the experience or training was gained. Each year of the surgeon's experience must be substantive and relevant and include pre-operative assessment of intestine transplant candidates, transplants performed as primary surgeon or first assistant and post-operative management of intestine recipients.
2. The surgeon has performed at least 3 intestine procurements as primary surgeon or first assistant. These procurements must include at least 1 procurement of a graft that includes a liver. This procedure must be documented in a log that includes the date of procurement and Donor ID.
3. The surgeon has maintained a current working knowledge of intestine transplantation, defined as direct involvement in intestine transplant patient care within the last 5 years. This includes the management of patients with short bowel syndrome or intestinal failure, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, performing the transplant operation, immediate postoperative and continuing inpatient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of intestine dysfunction in the allograft recipient, histologic interpretation of allograft biopsies, interpretation of ancillary tests for intestine dysfunction, and long term outpatient care.
4. The surgeon develops a formal mentor relationship with a primary intestine transplant surgeon at another approved intestine transplant program. The mentor will discuss program



requirements, patient and donor selection, recipient management, and be available for consultation as required until full approval conditions are all met.

5. The following letters are sent to the OPTN Contractor:
  - a. A letter from the director of the transplant program and chair of the department or hospital credentialing committee verifying that the surgeon has met the above requirements and is qualified to direct an intestine transplant program.
  - b. A letter of recommendation from the primary surgeon and transplant program director at the transplant program last served by the surgeon, outlining the surgeon's overall qualifications to act as primary transplant surgeon, as well as the surgeon's personal integrity, honesty, familiarity with and experience in adhering to OPTN obligations, and other matters judged appropriate. The MPSC may request additional recommendation letters from the primary surgeon, primary physician, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
  - c. A letter from the surgeon that details the training and experience the surgeon gained in intestine transplantation as well as detailing the plan for obtaining full approval within the 3-year conditional approval period.
  - d. A letter of commitment from the surgeon's mentor supporting the detailed plan developed by the surgeon to obtain full approval.

## **F.12 Primary Intestine Transplant Physician Requirements**

A designated intestine transplant program must have a primary physician who meets *all* the following requirements:

1. The physician must have an M.D., D.O., or the equivalent degree from another country, with a current license to practice medicine in the hospital's state or jurisdiction.
2. The physician must be accepted onto the hospital's medical staff, and be on site at this hospital.
3. The physician must have documentation from the hospital credentialing committee that it has verified the physician's state license, board certification, training, and transplant continuing medical education, and that the physician is currently a member in good standing on the hospital's medical staff.
4. The physician must have current board certification in gastroenterology by the American Board of Internal Medicine, the American Board of Pediatrics, or the Royal College of Physicians and Surgeons of Canada.

In place of current certification in gastroenterology by the American Board of Internal Medicine, the American Board of Pediatrics, or the Royal College of Physicians and Surgeons of Canada, the physician must:

- a. Be ineligible for American board certification.
- b. Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that the physician obtains 60 hours of Category I continuing medical education (CME) credits with self-assessment that are relevant to the individual's practice every three years. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program. A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve an acceptable self-assessment score are allowed. The transplant hospital must document completion of this continuing education.
- c. Provide to the OPTN Contractor two letters of recommendation from directors of designated transplant programs not employed by the applying hospital. These letters must address:
  - i. Why an exception is reasonable.
  - ii. The physician's overall qualifications to act as a primary intestine transplant physician.
  - iii. The physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
  - iv. Any other matters judged appropriate.

If the physician has not adhered to the plan for maintaining continuing education or has not obtained the necessary CME credits with self-assessment, the transplant program will have a six-month grace period to address these deficiencies. If the physician has not fulfilled the requirements after the six-month grace period, and a key personnel change application has not been submitted, then the transplant program will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws. If the OPTN Contractor becomes aware that a primary physician has not been compliant for 12 months or more and deficiencies still exist, then the transplant program will not be given any grace period and will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws.

5. The physician must have completed at least *one* of the pathways listed below:
  - a. The primary intestine transplant physician full approval pathway, as described in *Section F.12.A* below.
  - b. The primary intestine transplant physician conditional pathway, as described in *Section F.12.B* below.

Any physician who meets the criteria as a primary intestine transplant physician can function as the primary intestine transplant physician for a program that serves predominantly pediatric patients, if a pediatric gastroenterologist is also involved in the care of the transplant recipients.

#### **A. Full Intestine Physician Approval Pathway**

Physicians can meet the requirements for a primary intestine transplant physician during the physician's adult gastroenterology fellowship, pediatric gastroenterology fellowship, or through acquired clinical experience (including accumulated training during any fellowships) if all of the following conditions are met:

1. The physician has been directly involved within the last 10 years in the primary care of 7 or more newly transplanted intestine recipients and continued to follow these recipients for a minimum of 3 months from the time of transplant. This clinical experience must be gained as the primary intestine transplant physician or under the direct supervision of a intestine transplant physician and in conjunction with an intestine transplant surgeon at a designated intestine transplant program. This care must be documented in a log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair from the program where the experience or training was gained.
2. The physician has maintained a current working knowledge of intestine transplantation, defined as direct involvement in intestine transplant patient care within the last 5 years. This includes the management of patients with intestinal failure, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of intestine allograft dysfunction, histologic interpretation of allograft biopsies, interpretation of ancillary tests for intestine dysfunction, and long term outpatient care.
3. The physician must have observed at least 1 isolated intestine transplant and at least 1 combined liver-intestine or multi-visceral transplant.
4. The following letters are submitted to the OPTN Contractor:
  - a. A letter from the transplant program director documenting the physician's experience and training.
  - b. A letter of recommendation from the primary physician and transplant program director at the fellowship training program or transplant program last served by the physician outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary

- surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
- c. A letter from the physician that details the training and experience the physician gained in intestine transplantation.

## **B. Conditional Intestine Physician Approval Pathway**

Physicians can meet the requirements for approval as primary intestine transplant physician through a conditional approval pathway if *all* of the following conditions are met:

1. The physician has been involved in the primary care of at least 4 newly transplanted intestine recipients, and has followed these patients for at least 3 months from the time of their transplant. Additionally, the physician must become involved in the care of 3 or more intestine recipients over the next 3 consecutive years. This clinical experience must be gained as the primary intestine transplant physician or under the direct supervision of an intestine transplant physician and in conjunction with an intestine transplant surgeon at a designated intestine transplant program. This care must be documented in a recipient log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair from the program where the experience or training was gained.
2. The physician has maintained a current working knowledge of intestine transplantation, defined as direct involvement in intestine transplant patient care within the last 5 years. This includes the management of patients with intestine failure, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of intestine allograft dysfunction, histologic interpretation of allograft biopsies, interpretation of ancillary tests for intestine dysfunction, and long term outpatient care.
3. The physician has 12 months experience as the primary intestine transplant physician or under the direct supervision of a qualified intestine transplant physician along with an intestine transplant surgeon at a designated intestine transplant program. These 12 months of experience must be acquired within a 2-year period.
4. The physician develops a formal mentor relationship with a primary intestine transplant physician at another approved designated intestine transplant program. The mentor will discuss program requirements, patient and donor selection, recipient management, and be available for consultation as required.
5. The following letters are submitted to the OPTN Contractor:
  - a. A letter from the qualified intestine transplant physician and surgeon who were directly involved with the physician verifying that the physician has satisfactorily met the above requirements to become the primary transplant physician of an intestine transplant program.
  - b. A letter of recommendation from the primary physician and transplant program director at the transplant program last served by the physician outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
  - c. A letter from the physician that details the training and experience the physician gained in intestine transplantation as well as a detailed plan for obtaining full approval.
  - d. A letter of commitment from the physician's mentor supporting the detailed plan developed by the physician to obtain full approval.

## **F.13 Conditional Intestine Program Approval**

Either the primary surgeon or primary physician must qualify through one of the full approval pathways described above in sections *F.11.A* or *F.12.A* for the program to be eligible for conditional approval status. If either the primary surgeon or primary physician qualify through one of the conditional pathways described above in sections *F.11.B* or *F.12.B*, the program must meet the requirements as described below to obtain full approval:

- The transplant program is granted 36 months to fully comply with all membership requirements. This option is available to new programs as well as previously approved programs that experience a change in key personnel.
- The program must comply with all policies and procedures as required by the MPSC. This includes submitting reports describing the surgeon or physician's progress towards meeting the requirements, and any other conditions as requested by the MPSC to demonstrate ongoing quality and efficient patient care.
- During this 36-month period of conditional approval, the surgeon must be present at all intestine transplant surgeries.
- During this 36-month period, the physician must be directly involved in the primary care of all intestine patients, including new recipients.

Prior to the end of each year of conditional approval, the program must provide an annual report documenting at least *one* of the following:

- The designated surgeon has met or is making sufficient progress toward performing 3 or more intestine transplants
- The designated physician has met or is making sufficient progress toward the direct involvement in the primary care of 3 or more intestine transplant patients
- The program is making sufficient progress in employing a transplant surgeon or physician who meets this, as well as all other criteria, for a primary intestinal transplant surgeon or physician

Should the surgeon or physician meet the requirements before the conditional approval period ends, the program may submit a progress report and request a review by the MPSC.

### **A. Full Approval Following Conditional Approval**

The conditional approval period begins on the first approval date granted to the application, whether it is interim approval granted by the MPSC subcommittee, the MPSC or approval granted by the full Board of Directors. The conditional approval period ends 36 months after the first approval date of the application.

The MPSC may consider on a case-by-case basis granting a 12-month extension to a transplant program that provides substantial evidence of progress toward fulfilling the requirements, but is unable to complete the requirements within the 36-month approval period.

Once the program has met the full approval requirements for both primary surgeon and primary physician, the program may petition the OPTN Contactor in writing for full approval.

### **B. Rejection of Conditional Approval**

If the program is unable to demonstrate that it has a designated surgeon and physician on site who can fully meet the primary surgeon and primary physician requirements as described above at the end of the conditional approval period, it must stop performing intestine transplants and *either*:

- Inactivate the intestine transplant program for a period up to 12 months
- Withdraw the intestine transplant program until it can meet the requirements for full approval

The requirements for program inactivation and withdrawal are described in *Appendix K: Transplant Program Inactivity, Withdrawal, and Termination* of these Bylaws.

#### **F.14 Approved Intestine Surgeon Transplant Fellowship Programs**

Surgeons qualifying as primary transplant surgeon based on completion of a formal transplant fellowship must complete their training at a fellowship program approved by the American Society of Transplant Surgeons, the Royal College of Physicians and Surgeons of Canada, or another recognized fellowship training program accepted by the OPTN Contractor that meets *all* of the following criteria:

1. The program is at a transplant hospital that transplants two or more organs, including liver and intestines.
2. The program is at an institution that has ACGME approved training in general surgery.
3. The program performs at least 10 intestine transplants during each year of the fellowship training.

# **Appendix G: Membership and Personnel Requirements for Pancreas and Pancreatic Islet Transplant Programs**

This appendix describes the information and documentation transplant hospitals are required to provide when:

- Submitting a completed membership application for approval as a designated pancreas or pancreatic islet transplant program.
- Completing a Personnel Change Application for a change in key personnel at a designated pancreas or pancreatic islet transplant program.

It does not include the general membership requirements that all transplant programs must meet, which are described in *Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs* of these Bylaws.

For more information on the application and review process, see *Appendix A: Membership Application and Review* of these Bylaws.

## **G.1 Pancreas Program Director, Primary Transplant Surgeon and Primary Transplant Physician**

A pancreas transplant program must identify at least one designated staff member to act as the transplant program director. The director must be a physician or surgeon who is a member of the transplant hospital staff.

The program must also identify a qualified primary transplant surgeon and primary transplant physician, as described below. The primary surgeon and primary physician, along with the program director, must submit a detailed Program Coverage Plan to the OPTN Contractor. For detailed information about the Program Coverage Plan, see *Section D.7.B: Surgeon and Physician Coverage (Program Coverage Plan)* of these Bylaws.

## **G.2 Primary Pancreas Transplant Surgeon Requirements**

A designated pancreas transplant program must have a primary surgeon who meets *all* the following requirements:

1. The surgeon must have an M.D., D.O., or equivalent degree from another country, with a current license to practice medicine in the hospital's state or jurisdiction.
2. The surgeon must be accepted onto the hospital's medical staff, and be on site at this hospital.
3. The surgeon must have documentation from the hospital credentialing committee that it has verified the surgeon's state license, board certification, training, and transplant continuing medical education, and that the surgeon is currently a member in good standing of the hospital's medical staff.
4. The surgeon must have current certification by the American Board of Surgery, the American Board of Urology, the American Board of Osteopathic Surgery, or the Royal College of Physicians and Surgeons of Canada. In the case of a surgeon who has just completed training and whose American Board of Urology certification is pending, the Membership and Professional Standards Committee

(MPSC) may grant conditional approval for 16 months to allow time for the surgeon to complete board certification, with the possibility of one additional 16-month extension.

In place of current certification by the American Board of Surgery, the American Board of Urology, the American Board of Osteopathic Surgery, the Royal College of Physicians and Surgeons of Canada, or pending certification by the American Board of Urology, the surgeon must:

- a. Be ineligible for American board certification.
- b. Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that the surgeon obtains 60 hours of Category I continuing medical education (CME) credits with self-assessment that are relevant to the individual's practice every three years. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program. A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve an acceptable self-assessment score are allowed. The transplant hospital must document completion of this continuing education.
- c. Provide to the OPTN Contractor two letters of recommendation from directors of designated transplant programs not employed by the applying hospital. These letters must address:
  - i. Why an exception is reasonable.
  - ii. The surgeon's overall qualifications to act as a primary pancreas transplant surgeon.
  - iii. The surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
  - iv. Any other matters judged appropriate.

If the surgeon has not adhered to the plan for maintaining continuing education or has not obtained the necessary CME credits with self-assessment, the transplant program will have a six-month grace period to address these deficiencies. If the surgeon has not fulfilled the requirements after the six-month grace period, and a key personnel change application has not been submitted, then the transplant program will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws. If the OPTN Contractor becomes aware that a primary surgeon has not been compliant for 12 months or more and deficiencies still exist, then the transplant program will not be given any grace period and will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws.

5. The surgeon must have completed at least one of the pathways listed below:
  - a. The formal 2-year transplant fellowship pathway, as described in *Section G.2.A: Formal 2-year Transplant Fellowship Pathway* below.
  - b. The pancreas transplant program clinical experience pathway, as described in *Section G.2.B: Clinical Experience Pathway* below.
  - c. The alternative pathway for predominantly pediatric programs, as described in *Section G.2.C: Alternate Pathway for Predominantly Pediatric Programs* below.

### **A. Formal 2-year Transplant Fellowship Pathway**

Surgeons can meet the training requirements for primary pancreas transplant surgeon by completing a formal 2-year surgical transplant fellowship if the following conditions are met:

1. The surgeon performed at least 15 pancreas transplants as primary surgeon or first assistant. These transplants must be documented in the surgeon's fellowship operative log. The date of transplant, the role of the surgeon in the procedure, the medical record number or other unique identifier that can be verified by the OPTN Contractor, and the fellowship director's signature must be provided with this log.
2. The surgeon performed at least 10 pancreas procurements as primary surgeon or first assistant. These procurements must have been performed anytime during the surgeon's fellowship and the two years immediately following fellowship completion. These cases must

- be documented in the surgeon's fellowship operative log. The date of procurement, Donor ID, and the fellowship director's signature must be provided with this log.
3. The surgeon has maintained a current working knowledge of pancreas transplantation, defined as direct involvement in patient care within the last 2 years. This includes the management of patients with diabetes mellitus, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, performing the transplant operation, immediate postoperative and continuing inpatient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of pancreas dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for pancreatic dysfunction, and long term outpatient care.
  4. The training was completed at a hospital with a pancreas transplant training program approved by the American Society of Transplant Surgeons, the Royal College of Physicians and Surgeons of Canada, or another recognized fellowship training program accepted by the OPTN Contractor as described in *Section G.7: Approved Pancreas Transplant Surgeon Fellowship Training Programs* that follows.
  5. The following letters are submitted directly to the OPTN Contractor:
    - a. A letter from the director of the training program and chairman of the department or hospital credentialing committee verifying that the fellow has met the above requirements and is qualified to direct a pancreas transplant program.
    - b. A letter of recommendation from the fellowship training program's primary surgeon and transplant program director outlining the surgeon's overall qualifications to act as primary transplant surgeon as well as the surgeon's personal integrity, honesty, familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request similar letters of recommendation from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
    - c. A letter from the surgeon that details the training and experience the surgeon has gained in pancreas transplantation.

## **B. Clinical Experience Pathway**

Surgeons can meet the requirements for primary pancreas transplant surgeon through clinical experience gained post-fellowship if the following conditions are met:

1. The surgeon has performed 20 or more pancreas transplants over a 2 to 5-year period as primary surgeon, co-surgeon, or first assistant, at a designated pancreas transplant program. Of these 20 pancreas transplants, 10 or more must have been performed as primary surgeon or co-surgeon. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and medical record number or other unique identifier that can be verified by the OPTN Contractor. This log should be signed by the program director, division chief, or department chair from the program where the experience was gained. Each year of the surgeon's experience must be substantive and relevant and include pre-operative assessment of pancreas transplant candidates, transplants performed as primary surgeon or first assistant, and post-operative care of pancreas recipients.
2. The surgeon has performed at least 10 pancreas procurements as primary surgeon, co-surgeon, or first assistant. Of these 10 pancreas procurements, at least 5 must have been



- performed as primary surgeon or co-surgeon. These procurements must be documented in a log that includes the date of procurement and Donor ID.
3. The surgeon has maintained a current working knowledge of pancreas transplantation, defined as direct involvement in pancreas transplant patient care within the last 2 years. This includes the management of patients with diabetes mellitus, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, performing the transplant operation, immediate postoperative and continuing inpatient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of pancreatic dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for pancreatic dysfunction, and long term outpatient care.
  4. The following letters are submitted directly to the OPTN Contractor:
    - a. A letter from the director of the transplant program and chairman of the department or hospital credentialing committee verifying that the surgeon has met the above requirements and is qualified to direct a pancreas transplant program.
    - b. A letter of recommendation from the primary surgeon and director at the transplant program last served by the surgeon outlining the surgeon's overall qualifications to act as primary transplant surgeon as well as the surgeon's personal integrity, honesty, familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request similar letters of recommendation from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the individual, at its discretion.
    - c. A letter from the surgeon that details the training and experience the surgeon has gained in pancreas transplantation.

### **C. Alternate Pathway for Predominantly Pediatric Programs**

If a surgeon does not meet the requirements for primary pancreas transplant surgeon through either the 2-year transplant fellowship pathway or clinical experience pathway as described above, transplant programs that serve predominantly pediatric patients may petition the MPSC in writing to consider the surgeon for primary transplant surgeon if the program can demonstrate that the following conditions are met:

1. The surgeon's pancreas transplant training or experience is equivalent to the fellowship or clinical experience pathways as described in *Sections G.2.A or G.2.B* above.
2. The surgeon has maintained a current working knowledge of all aspects of pancreas transplantation and patient care, defined as direct involvement in pancreas transplant patient care within the last 2 years.
3. The surgeon submits a letter of recommendation from the training program's primary surgeon and director at the fellowship training program or transplant program last served by the surgeon outlining the surgeon's overall qualifications to act as a primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
4. The hospital participates in an informal discussion with the MPSC.

The MPSC or an Ad Hoc Subcommittee of at least 4 MPSC members appointed by the MPSC Chair is authorized to conduct the informal discussion and make an interim determination. Interim determinations are:

- Advisory to the MPSC, Board of Directors, or both, who have the final authority to grant approval of a designated transplant program.
- Effective temporarily, pending final decision by the MPSC or Board.

The MPSC must offer the member an interview if the MPSC recommends that the Board of Directors rejects a membership application. The member may also be entitled to a hearing with the MPSC and an appearance before the Board of Directors prior to the Board of Directors taking a final action on any MPSC recommendation. Any interviews, hearings, or Board of Directors appearances that occur as a part of a membership application process will be held according to *Appendix L: Reviews and Actions*.

### **G.3 Primary Pancreas Transplant Physician Requirements**

A designated pancreas transplant program must have a primary physician who meets *all* the following requirements:

1. The physician must have an M.D., D.O., or equivalent degree from another country, with a current license to practice medicine in the hospital's state or jurisdiction.
2. The physician must be accepted onto the hospital's medical staff, and be on site at this hospital.
3. The physician must have documentation from the hospital credentialing committee that it has verified the physician's state license, board certification, training, and transplant continuing medical education and that the physician is currently a member in good standing of the hospital's medical staff.
4. The physician must have current board certification in nephrology, endocrinology, or diabetology by the American Board of Internal Medicine, the American Board of Pediatrics, or the Royal College of Physicians and Surgeons of Canada.

In place of current certification in nephrology, endocrinology, or diabetology by the American Board of Internal Medicine, the American Board of Pediatrics, or the Royal College of Physicians and Surgeons of Canada, the physician must:

- a. Be ineligible for American board certification.
- b. Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that the physician obtains 60 hours of Category I continuing medical education (CME) credits with self-assessment that are relevant to the individual's practice every three years. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program. A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve an acceptable self-assessment score are allowed. The transplant hospital must document completion of this continuing education.
- c. Provide to the OPTN Contractor two letters of recommendation from directors of designated transplant programs not employed by the applying hospital. These letters must address:
  - i. Why an exception is reasonable.
  - ii. The physician's overall qualifications to act as a primary pancreas transplant physician.
  - iii. The physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
  - iv. Any other matters judged appropriate.

If the physician has not adhered to the plan for maintaining continuing education or has not obtained the necessary CME credits with self-assessment, the transplant program will have a six-month grace period to address these deficiencies. If the physician has not fulfilled the requirements after the six-month grace period, and a key personnel change application has not been submitted, then the transplant program will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws. If the OPTN Contractor becomes aware that a primary physician has not been compliant for 12 months or more and deficiencies still exist, then the transplant program will not be given any grace period and will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws.

5. The physician must have completed at least one of the pathways listed below:
  - a. The 12-month pancreas transplant fellowship pathway, as described in *Section G.3.A: Twelve-month Transplant Medicine Fellowship Pathway* below.
  - b. The clinical experience pathway, as described in *Section G.3.B: Clinical Experience Pathway* below.
  - c. The alternative pathway for predominantly pediatric programs, as described in *Section G.3.C: Alternative Pathway for Predominantly Pediatric Programs* below.
  - d. The conditional approval pathway, as described in *Section G.3.D: Conditional Approval for Primary Transplant Physician* below, if the primary pancreas transplant physician changes at an approved pancreas transplant program.

#### **A. Twelve-month Transplant Medicine Fellowship Pathway**

Physicians can meet the training requirements for a primary pancreas transplant physician during a separate 12-month transplant medicine fellowship if the following conditions are met:

1. The physician completed 12 consecutive months of specialized training in pancreas transplantation at a pancreas transplant program under the direct supervision of a qualified pancreas transplant physician along with a pancreas transplant surgeon. The training must have included at least 6 months on the clinical transplant service. The remaining time must have consisted of transplant-related experience, such as experience in a tissue typing laboratory, on another solid organ transplant service, or conducting basic or clinical transplant research.
2. During the fellowship period, the physician was directly involved in the primary care of 8 or more newly transplanted pancreas recipients and followed these recipients for a minimum of 3 months from the time of transplant. The care must be documented in a log that includes the date of transplant and medical record number or other unique identifier that can be identified by the OPTN Contractor. This recipient log must be signed by the director of the training program or the transplant program's primary transplant physician.
3. The physician has maintained a current working knowledge of pancreas transplantation, defined as direct involvement in pancreas transplant patient care within the last 2 years. This includes the management of patients with end stage pancreas disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of pancreas dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for pancreas dysfunction, and long term outpatient care.
4. The physician must have observed at least 3 pancreas procurements. The physician must have also observed the evaluation, donation process, and management of these donors. These observations must be documented in a log that includes the date of procurement and Donor ID.

5. The physician must have observed at least 3 pancreas transplants. The observation of these transplants must be documented in a log that includes the transplant date and medical record number or other unique identifier that can be verified by the OPTN Contractor.
6. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from director of the training program and supervising qualified pancreas transplant physician send a letter directly to the OPTN Contractor verifying that the fellow has met the above requirements and is qualified to direct a pancreas transplant program.
  - b. A letter of recommendation from the fellowship training program's primary physician and transplant program director outlining the physician's overall qualifications to act as primary transplant physician as well as the physician's personal integrity, honesty, familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request similar letters of recommendation from the primary physician, primary surgeon, director, or others affiliated with any transplant program that the physician previously served, at its discretion.
  - c. A letter from the physician that details the training and experience the physician has gained in pancreas transplantation.

The above training is in addition to other clinical requirements for general nephrology, endocrinology, or diabetology training.

## **B. Clinical Experience Pathway**

A physician can meet the requirements for a primary transplant physician through acquired clinical experience if the following conditions are met:

1. The physician has been directly involved in the primary care of 15 or more newly transplanted pancreas recipients and continued to follow these recipients for a minimum of 3 months from the time of transplant. This patient care must have been provided over a 2 to 5-year period on an active pancreas transplant service as the primary pancreas transplant physician or under the direct supervision of a qualified pancreas transplant physician along with a pancreas transplant surgeon at a designated pancreas transplant program. The care must be documented in a log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log should be signed by the program director, division chief, or department chair from the program where the physician gained this experience.
2. The physician has maintained a current working knowledge of pancreas transplantation, defined as direct involvement in pancreas transplant patient care within the last 2 years. This includes the management of patients with end stage pancreas disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of pancreas dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for pancreas dysfunction, and long term outpatient care.
3. The physician must have observed at least 3 pancreas procurements. The physician must have observed the evaluation, donation process, and management of these donors. These observations must be documented in a log that includes the date of procurement and Donor ID.

4. The physician must have observed at least 3 pancreas transplants. The observation of these transplants must be documented in a log that includes the transplant date and medical record number or other unique identifier that can be verified by the OPTN Contractor.
5. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the qualified pancreas transplant physician or surgeon who has been directly involved with the physician documenting the physician's experience and competence.
  - b. A letter of recommendation from the primary physician and director at the transplant program last served by the physician outlining the physician's overall qualifications to act as primary transplant physician as well as the physician's personal integrity, honesty, familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request similar letters of recommendation from the primary physician, primary surgeon, director, or others affiliated with any transplant program the physician previously served, at its discretion.
  - c. A letter from the physician that details the training and experience the physician has gained in pancreas transplantation.

### **C. Alternative Pathway for Predominantly Pediatric Programs**

If a physician does not meet the requirements for primary physician through the transplant fellowship or clinical experience pathways as described above, transplant programs that serve predominantly pediatric patients may petition the MPSC in writing to consider the physician for primary transplant physician if the program can demonstrate that the following conditions are met:

1. That the physician's pancreas transplant training or experience is equivalent to the fellowship or clinical experience pathways as described in *Sections G.3.A and G.3.B* above.
2. The physician has maintained a current working knowledge of all aspects of pancreas transplantation, defined as direct involvement in pancreas transplant patient care within the last 2 years.
3. The physician submits a letter of recommendation from the primary physician and transplant program director at the fellowship program or transplant program last served by the physician outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
4. The hospital participates in an informal discussion with the MPSC.

The MPSC or an Ad Hoc Subcommittee of at least 4 MPSC members appointed by the MPSC Chair is authorized to conduct the informal discussion and make an interim determination. Interim decisions are:

- Advisory to the MPSC, Board of Directors, or both, which has the final authority to grant approval of a designated transplant program.
- Effective temporarily, pending final decision by the MPSC or Board.

The MPSC must offer the member an interview if the MPSC recommends that the Board of Directors rejects a membership application. The member may also be entitled to a hearing with

the MPSC and an appearance before the Board of Directors prior to the Board of Directors taking a final action on any MPSC recommendation. Any interviews, hearings, or Board of Directors appearances that occur as a part of a membership application process will be held according to *Appendix L: Reviews and Actions*.

#### **D. Conditional Approval for Primary Transplant Physician**

If the primary pancreas transplant physician changes at an approved pancreas transplant program, a physician can serve as the primary pancreas transplant physician for a maximum of 12 months if the following conditions are met:

1. The physician has been involved in the primary care of 8 or more newly transplanted pancreas recipients, and has followed these patients for at least 3 months from the time of their transplant. This care must be documented in a recipient log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log should be signed by the program director, division chief, or department chair from the transplant program where the experience was gained.
2. The physician has maintained a current working knowledge of pancreas transplantation, defined as direct involvement in pancreas transplant patient care within the last 2 years. This includes the management of patients with end stage pancreas disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of pancreas dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for pancreas dysfunction, and long term outpatient care.
3. The physician has 12 months experience on an active pancreas transplant service as the primary pancreas transplant physician or under the direct supervision of a qualified pancreas transplant physician along with a pancreas transplant surgeon at a designated pancreas transplant program. This 12-month period of experience on the transplant service must have been acquired over a maximum of 2 years.
4. The physician must have observed at least 3 pancreas procurements. The physician must have observed the evaluation, donation process, and management of these donors. These observations must be documented in a log that includes the date of procurement and Donor ID.
5. The physician must have observed at least 3 pancreas transplants. The observation of these transplants must be documented in a log that includes the transplant date and medical record number or other unique identifier that can be verified by the OPTN Contractor.
6. The program has established and documented a consulting relationship with counterparts at another pancreas transplant program.
7. The transplant program submits activity reports to the OPTN Contractor every 2 months describing the transplant activity, transplant outcomes, physician recruitment efforts, and other operating conditions as required by the MPSC to demonstrate the ongoing quality and efficient patient care at the program. The activity reports must also demonstrate that the physician is making sufficient progress in meeting the required involvement in the primary care of 15 or more pancreas transplant recipients, or that the program is making sufficient progress in recruiting a physician who will be on site and approved by the MPSC to assume the role of Primary Physician by the end of the 12 month conditional approval period.
8. The following letters are submitted directly to the OPTN Contractor:

- a. A letter from the qualified pancreas transplant physician and surgeon who were directly involved with the physician documenting the physician's experience and competence.
- b. A letter of recommendation from the primary physician and director at the transplant program last served by the physician outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
- c. A letter from the physician that details the training and experience the physician has gained in pancreas transplantation.

The 12-month conditional approval period begins on the initial approval date granted to the personnel change application, whether it is interim approval granted by the MPSC subcommittee, or approval granted by the full MPSC. The conditional approval period ends 12 months after the first approval date of the personnel change application.

The MPSC may consider on a case-by-case basis and grant a 6-month extension to a transplant program that provides substantial evidence of progress toward fulfilling the requirements but is unable to complete the requirements within one year.

If the transplant program is unable to demonstrate that it has an individual on site who can meet the requirements as described in *Sections G.3.A through G.3.C* above at the end of the conditional approval period, it must inactivate. The requirements for program inactivation are described in *Appendix K: Transplant Program Inactivity, Withdrawal and Termination* of these Bylaws.

## **G.4 Requirements for Designated Pancreatic Islet Transplant Programs**

All pancreatic islet transplant programs must meet the following criteria:

1. All of the requirements of a designated pancreas transplant program as defined in the sections above or meet the criteria for an exception as detailed in *Section G.4.D: Programs Not Located at an Approved Pancreas Transplant Program* below.
2. Demonstrate that the required resources and facilities are available as described in the sections that follow.

### **A. Transplant Facilities**

The program must document adequate clinical and laboratory facilities for pancreatic islet transplantation as defined by current Food and Drug Administration (FDA) regulations. The program must also document that the required Investigational New Drug (IND) application is in effect as required by the FDA.

### **B. Expert Medical Personnel**

The program must have a collaborative relationship with a physician qualified to perform portal vein cannulation 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

3. A laboratory-based researcher with experience in pancreatic islet isolation and transplantation

Adequate access is defined as having an agreement with another institution for access to employees with the expertise described above.

### **C. Islet Isolation**

Pancreatic islets must be isolated in a facility with an FDA IND application in effect, with documented collaboration between the program and the facility.

### **D. Programs Not Located at an Approved Pancreas Transplant Program**

A program that meets all requirements for a designated pancreatic islet transplant program but is not located at a hospital approved as a designated pancreas transplant program may qualify as a pancreatic islet transplant program if the following additional criteria are met:

1. The program demonstrates a documented affiliation with a designated pancreas transplant program, including on-site admitting privileges for the primary pancreas transplant surgeon and physician.
2. The program provides protocols documenting its commitment and ability to counsel patients about all their options for the medical treatment of diabetes.
3. The program demonstrates availability of qualified personnel to address pre-, peri-, and post-operative care issues regardless of the treatment option ultimately selected. An informal discussion with the MPSC is also required.

## **G.5 Primary Pancreatic Islet Transplant Surgeon Requirements**

The program must have on site a qualified surgeon who is designated as the primary pancreatic islet transplant surgeon and meets the requirements for pancreas transplant surgeon defined in these Bylaws.

## **G.6 Primary Pancreatic Islet Transplant Physician Requirements**

The program must have on site a qualified physician who is designated as the primary pancreatic islet transplant physician and meets the requirements for pancreas transplant physician defined in these Bylaws.

## **G.7 Approved Pancreas Transplant Surgeon Fellowship Training Programs**

Surgeons qualifying as primary transplant surgeons based on completion of a formal 2-year surgical transplant fellowship must complete their training at a fellowship program approved by the American Society of Transplant Surgeons, the Royal College of Physicians and Surgeons of Canada, or another recognized fellowship training program accepted by the OPTN Contractor that meets the following criteria:

1. The program is located at a transplant hospital that transplants one or more organs, including pancreas.
2. The program is at an institution that has ACGME approved training in general surgery.
3. The program performs at least 20 pancreas transplants during each year of fellowship training.



## **G.8 Pancreas Transplant Programs that Register Candidates Less than 18 Years Old**

A designated pancreas transplant program that registers candidates less than 18 years old must have an approved pediatric component. To be approved for a pediatric component, the designated pancreas transplant program must identify a qualified primary pediatric pancreas transplant surgeon and a qualified primary pediatric pancreas transplant physician, as described below.

### **A. Primary Pediatric Pancreas Transplant Surgeon Requirements**

A pediatric component at a designated pancreas transplant program must have a primary pediatric surgeon who meets *all* of the requirements described in *Section G.2: Primary Pancreas Transplant Surgeon Requirements*.

### **B. Primary Pediatric Pancreas Transplant Physician Requirements**

A pediatric component at a designated pancreas transplant program must have a primary pediatric physician who meets *all* of the requirements described in *Section G.3: Primary Pancreas Transplant Physician Requirements*.

# **Appendix H: Membership and Personnel Requirements for Heart Transplant Programs**

This appendix describes the information and documentation transplant hospitals must provide when:

- Submitting a completed membership application to apply for approval as a designated heart transplant program.
- Completing a Personnel Change Application for a change in key personnel at a designated heart transplant program.

This appendix does not include the general membership requirements that all transplant programs must meet, which are described in *Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs* of these Bylaws.

For more information on the application and review process, see *Appendix A: Membership Application and Review* of these Bylaws.

## **H.1 Program Director, Primary Transplant Surgeon, and Primary Transplant Physician**

A heart transplant program must identify at least one designated staff member to act as the transplant program director. The director must be a physician or surgeon who is a member of the transplant hospital staff.

The program must also identify a qualified primary transplant surgeon and primary transplant physician, as described below. The primary surgeon and physician, along with the program director, must submit a detailed program Coverage Plan to the OPTN Contractor. For detailed information about the Program Coverage Plan, see *Section D.7.B: Surgeon and Physician Coverage (Program Coverage Plan)* of these Bylaws.

## **H.2 Primary Heart Transplant Surgeon Requirements**

A designated heart transplant program must have a primary surgeon who meets *all* the following requirements:

1. The surgeon must have an M.D., D.O., or equivalent degree from another country, with a current license to practice medicine in the hospital's state or jurisdiction.
2. The surgeon must be accepted onto the hospital's medical staff, and be on site at this hospital.
3. The surgeon must have documentation from the hospital credentialing committee that it has verified the surgeon's state license, board certification, training, and transplant continuing medical education, and that the surgeon is currently a member in good standing of the hospital's medical staff.
4. The surgeon must have current certification by the American Board of Thoracic Surgery or current certification in thoracic surgery by the Royal College of Physicians and Surgeons of Canada. In the case of a surgeon who has just completed training and whose certification by the American Board of Thoracic Surgery is pending, the Membership and Professional Standards Committee (MPSC) may grant conditional approval for 24 months to allow time for the surgeon to complete board certification, with the possibility of renewal for one additional 24-month period.

In place of current certification by the American Board of Thoracic Surgery, current certification in thoracic surgery by the Royal College of Physicians and Surgeons of Canada, or pending certification by the American Board of Thoracic Surgery, the surgeon must:

- a. Be ineligible for American board certification.
- b. Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that the surgeon obtains 60 hours of Category I continuing medical education (CME) credits with self-assessment that are relevant to the individual's practice every three years. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program. A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve an acceptable self-assessment score are allowed. The transplant hospital must document completion of this continuing education.
- c. Provide to the OPTN Contractor two letters of recommendation from directors of designated transplant programs not employed by the applying hospital. These letters must address:
  - i. Why an exception is reasonable.
  - ii. The surgeon's overall qualifications to act as a primary heart transplant surgeon.
  - iii. The surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
  - iv. Any other matters judged appropriate.

If the surgeon has not adhered to the plan for maintaining continuing education or has not obtained the necessary CME credits with self-assessment, the transplant program will have a six-month grace period to address these deficiencies. If the surgeon has not fulfilled the requirements after the six-month grace period, and a key personnel change application has not been submitted, then the transplant program will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws. If the OPTN Contractor becomes aware that a primary surgeon has not been compliant for 12 months or more and deficiencies still exist, then the transplant program will not be given any grace period and will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws.

6. The surgeon must have completed at least one of the pathways listed below:
  - a. The formal cardiothoracic surgery residency pathway, as described in *Section H.2.A: Cardiothoracic Surgery Residency Pathway* below.
  - b. The 12-month heart transplant fellowship pathway, as described in *Section H.2.B: Twelve-month Heart Transplant Fellowship Pathway* below.
  - c. The heart transplant program clinical experience pathway, as described in *Section H.2.C: Clinical Experience Pathway* below.
  - d. The alternative pathway for predominantly pediatric programs, as described in *Section H.2.D: Alternative Pathway for Predominantly Pediatric Programs* below.

### **A. Cardiothoracic Surgery Residency Pathway**

Surgeons can meet the training requirements for primary heart transplant surgeon by completing a cardiothoracic surgery residency if *all* the following conditions are met:

1. The surgeon performed at least 20 heart or heart/lung transplants as primary surgeon or first assistant during the cardiothoracic surgery residency. These transplants must be documented in the surgeon's cardiothoracic surgery residency operative log. The date of transplant, role of the surgeon in the procedure, medical record number or other unique identifier that can be verified by the OPTN Contractor, and the training program director's signature must be provided with this log.

2. The surgeon performed at least 10 heart or heart/lung procurements as primary surgeon or first assistant under the supervision of a qualified heart transplant surgeon. These procurements must have been performed anytime during the surgeon's cardiothoracic surgery residency and the two years immediately following cardiothoracic surgery residency completion. These procedures must be documented in the surgeon's cardiothoracic surgery residency operative log. The date of procurement, Donor ID, and the training program director's signature must be provided with this log.
3. The surgeon has maintained a current working knowledge of all aspects of heart transplantation, defined as a direct involvement in heart transplant patient care within the last 2 years. This includes performing the transplant operation, donor selection, use of mechanical assist devices, recipient selection, post-operative hemodynamic care, postoperative immunosuppressive therapy, and outpatient follow-up.
4. This training was completed at a hospital with a cardiothoracic surgery training program approved by the American Board of Thoracic Surgery or the Royal College of Physicians and Surgeons of Canada.
5. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the director of the training program verifying that the surgeon has met the above requirements and is qualified to direct a heart transplant program.
  - b. A letter of recommendation from the training program's primary surgeon and transplant program director outlining the individual's overall qualifications to act as primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
  - c. A letter from the surgeon that details the training and experience the surgeon has gained in heart transplantation.

## **B. Twelve-month Heart Transplant Fellowship Pathway**

Surgeons can meet the training requirements for primary heart transplant surgeon by completing a 12-month heart transplant fellowship if the following conditions are met:

1. The surgeon performed at least 20 heart or heart/lung transplants as primary surgeon or first assistant during the 12-month heart transplant fellowship. These transplants must be documented in the surgeon's fellowship operative log. The date of transplant, the role of the surgeon in the procedure, the medical record number or other unique identifier that can be verified by the OPTN Contractor, and the fellowship director's signature must be provided with this log.
2. The surgeon performed at least 10 heart or heart/lung procurements as primary surgeon or first assistant under the supervision of a qualified heart transplant surgeon. These procurements must have been performed anytime during the surgeon's fellowship and the two years immediately following fellowship completion. These procedures must be documented in the surgeon's fellowship operative log. The date of procurement, Donor ID, and the training program director's signature must be provided with this log.
3. The surgeon has maintained a current working knowledge of all aspects of heart transplantation, defined as a direct involvement in heart transplant patient care within the last 2 years. This includes performing the transplant operation, donor selection, the use of

- mechanical circulatory assist devices, recipient selection, post-operative hemodynamic care, postoperative immunosuppressive therapy, and outpatient follow-up.
4. This training was completed at a hospital with a cardiothoracic surgery training program approved by the American Board of Thoracic Surgery or the Royal College of Physicians and Surgeons of Canada.
  5. The following letters are submitted directly to the OPTN Contractor:
    - a. A letter from the director of the training program verifying that the surgeon has met the above requirements and is qualified to direct a heart transplant program.
    - b. A letter of recommendation from the training program's primary surgeon and transplant program director outlining the individual's overall qualifications to act as primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
    - c. A letter from the surgeon that details the training and experience the surgeon has gained in heart transplantation.

### **C. Clinical Experience Pathway**

Surgeons can meet the requirements for primary heart transplant surgeon through clinical experience gained post-fellowship if the following conditions are met:

1. The surgeon has performed 20 or more heart or heart/lung transplants as primary surgeon or first assistant at a designated heart transplant program. These transplants must have been completed over a 2 to 5-year period and include at least 15 of these procedures performed as the primary surgeon. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and medical record number or other unique identifier that can be verified by the OPTN Contractor. This log should be signed by the program director, division chief, or department chair from program where the experience was gained. Transplants performed during board qualifying surgical residency or fellowship do not count.
2. The surgeon has performed at least 10 heart or heart/lung procurements as primary surgeon or first assistant under the supervision of a qualified heart transplant surgeon. These procedures must be documented in a log that includes the date of procurement and Donor ID.
3. The surgeon has maintained a current working knowledge of all aspects of heart transplantation, defined as a direct involvement in heart transplant patient care within the last 2 years. This includes performing the transplant operation, donor selection, the use of mechanical assist devices, recipient selection, post-operative hemodynamic care, postoperative immunosuppressive therapy, and outpatient follow-up.
4. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the director of the program where the surgeon acquired transplant experience verifying that the surgeon has met the above requirements and is qualified to direct a heart transplant program.
  - b. A letter of recommendation from the primary surgeon and transplant program director at the transplant program last served by the surgeon outlining the surgeon's overall qualifications to act as primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations,

and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.

- c. A letter from the surgeon that details the training and experience the surgeon has gained in heart transplantation.

### **H.3 Primary Heart Transplant Physician Requirements**

A designated heart transplant program must have a primary physician who meets *all* the following requirements:

1. The physician must have an M.D., D.O., or equivalent degree from another country, with a current license to practice medicine in the hospital's state or jurisdiction.
2. The physician must be accepted onto the hospital's medical staff, and be practicing on site at this hospital.
3. The physician must have documentation from the hospital credentialing committee that it has verified the physician's state license, board certification, training, and transplant continuing medical education and that the physician is currently a member in good standing of the hospital's medical staff.
4. The physician must have current certification in adult or pediatric cardiology or current board certification in advanced heart failure and transplant cardiology by the American Board of Internal Medicine, the American Board of Pediatrics, or the Royal College of Physicians and Surgeons of Canada.

In place of current board certification by the American Board of Internal Medicine, the American Board of Pediatrics, or the Royal College of Physicians and Surgeons of Canada, the physician must:

- a. Be ineligible for American board certification.
- b. Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that the physician obtains 60 hours of Category I continuing medical education (CME) credits with self-assessment that are relevant to the individual's practice every three years. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program. A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve an acceptable self-assessment score are allowed. The transplant hospital must document completion of this continuing education.
- c. Provide to the OPTN Contractor two letters of recommendation from directors of designated transplant programs not employed by the applying hospital. These letters must address:
  - i. Why an exception is reasonable.
  - ii. The physician's overall qualifications to act as a primary heart transplant physician.
  - iii. The physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
  - iv. Any other matters judged appropriate.

If the physician has not adhered to the plan for maintaining continuing education or has not obtained the necessary CME credits with self-assessment, the transplant program will have a six-month grace period to address these deficiencies. If the physician has not fulfilled the requirements after the six-month grace period, and a key personnel change application has not been submitted, then the transplant program will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws. If the OPTN Contractor becomes aware that a primary physician has not been compliant for 12 months or more and deficiencies still exist, then the transplant program will not be given any grace period and will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws.

The physician must have completed at least *one* of the pathways listed below:

- a. The 12-month transplant cardiology fellowship pathway, as described in *Section H.3.A: Twelve-month Transplant Cardiology Fellowship Pathway* below.
- b. The clinical experience pathway, as described in *Section H.3.B: Clinical Experience Pathway* below.
- c. The conditional approval pathway, as described in *Section H.3.C: Conditional Approval for Primary Transplant Physician* below, if the primary heart transplant physician changes at an approved heart transplant program.

## **A. Twelve-month Transplant Cardiology Fellowship Pathway**

Physicians can meet the training requirements for primary heart transplant physician during a 12-month transplant cardiology fellowship if the following conditions are met:

1. During the fellowship period, the physician was directly involved in the primary care of at least 20 newly transplanted heart or heart/lung recipients. This training will have been under the direct supervision of a qualified heart transplant physician and in conjunction with a heart transplant surgeon. This care must be documented in a log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log must be signed by the director of the training program or the primary transplant physician at the transplant program.
2. The physician has maintained a current working knowledge of heart transplantation, defined as direct involvement in heart transplant patient care within the last 2 years. This includes the care of acute and chronic heart failure, donor selection, the use of mechanical circulatory support devices, recipient selection, pre- and post-operative hemodynamic care, post-operative immunosuppressive therapy, histological interpretation and grading of myocardial biopsies for rejection, and long-term outpatient follow-up.
3. The physician must have observed at least 3 heart procurements. The physician must have observed the evaluation, donation process, and management of these donors. These observations must be documented in a log that includes the date of procurement and Donor ID.
4. The physician must have observed at least 3 heart transplants. The observation of these transplants must be documented in a log that includes the transplant date and medical record number or other unique identifier that can be verified by the OPTN Contractor.
5. This training was completed at a hospital with an American Board of Internal Medicine certified fellowship training program in adult cardiology, an American Board of Pediatrics certified fellowship training program in pediatric cardiology, or a cardiology training program approved by the Royal College of Physicians and Surgeons of Canada.
6. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the director of the training program and the supervising qualified heart transplant physician verifying that the physician has met the above requirements and is qualified to direct a heart transplant program.
  - b. A letter of recommendation from the training program's primary physician and transplant program director outlining the physician's overall qualifications to act as primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the Primary Physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
  - c. A letter from the physician that details the training and experience the physician has gained in heart transplantation.

## **B. Clinical Experience Pathway**

A physician can meet the requirements for primary heart transplant physician through acquired clinical experience if the following conditions are met.

1. The physician has been directly involved in the primary care of 20 or more newly transplanted heart or heart/lung recipients and continued to follow these recipients for a minimum of 3 months from transplant. This patient care must have been provided over a 2 to 5-year period on an active heart transplant service as the primary heart transplant physician or under the direct supervision of a qualified heart transplant physician and in conjunction with a heart transplant surgeon at a heart transplant program. This care must be documented in a log that includes the date of transplant and medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log should be signed by the director or the primary transplant physician at the transplant program where the physician gained this experience.
2. The physician has maintained a current working knowledge of heart transplantation, defined as direct involvement in heart transplant patient care within the last 2 years. This includes the care of acute and chronic heart failure, donor selection, use of mechanical circulatory support devices, recipient selection, pre- and post-operative hemodynamic care, post-operative immunosuppressive therapy, histological interpretation and grading of myocardial biopsies for rejection, and long-term outpatient follow-up.
3. The physician must have observed at least 3 heart procurements. The physician must have observed the evaluation, donation process, and management of these donors. These observations must be documented in a log that includes the date of procurement and Donor ID.
4. The physician must have observed at least 3 heart transplants. The observation of these transplants must be documented in a log that includes the transplant date and medical record number or other unique identifier that can be verified by the OPTN Contractor.
5. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the heart transplant physician or the heart transplant surgeon who has been directly involved with the physician at the transplant program verifying the physician's competence.
  - b. A letter of recommendation from the primary physician and transplant program director at the transplant program last served by the physician outlining the physician's overall qualifications to act as primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
  - c. A letter from the physician that details the training and experience the physician has gained in heart transplantation.

## **C. Conditional Approval for Primary Transplant Physician**

If the primary heart transplant physician changes at an approved heart transplant program, a physician can serve as the primary heart transplant physician for a maximum of 12 months if the following conditions are met:



1. The physician has 12 months experience on an active heart transplant service as the primary heart transplant physician or under the direct supervision of a qualified heart transplant physician and in conjunction with a heart transplant surgeon at a designated heart transplant program. These 12 months of experience must be acquired within a 2-year period.
2. The physician has maintained a current working knowledge of heart transplantation, defined as direct involvement in heart transplant patient care within the last 2 years. This includes knowledge of acute and chronic heart failure, donor selection, the use of mechanical circulatory support devices, recipient selection, pre- and post-operative hemodynamic care, post-operative immunosuppressive therapy, histological interpretation in grading of myocardial biopsies for rejection, and long-term outpatient follow-up.
3. The physician has been involved in the primary care of 10 or more newly transplanted heart or heart/lung transplant recipients as the heart transplant physician or under the direct supervision of a qualified heart transplant physician or in conjunction with a heart transplant surgeon at a designated heart transplant program. The physician will have followed these patients for a minimum of 3 months from the time of transplant. This care must be documented in a log that includes the date of transplant and medical record or other unique identifier that can be verified by the OPTN Contractor. This recipient log should be signed by the program director or the primary transplant physician at the transplant program where the physician gained experience.
4. The physician must have observed at least 3 heart procurements. The physician must have observed the evaluation, donation process, and management of these donors. These observations must be documented in a log that includes the date of procurement and Donor ID.
5. The physician must have observed at least 3 heart transplants. The observation of these transplants must be documented in a log that includes the transplant date and medical record number or other unique identifier that can be verified by the OPTN Contractor.
6. The program has established and documented a consulting relationship with counterparts at another heart transplant program.
7. The transplant program submits activity reports to the OPTN Contractor every 2 months describing the transplant activity, transplant outcomes, physician recruitment efforts, and other operating conditions as required by the MPSC to demonstrate the ongoing quality and efficient patient care at the program. The activity reports must also demonstrate that the physician is making sufficient progress to meet the required involvement in the primary care of 20 or more heart transplant recipients, or that the program is making sufficient progress in recruiting a physician who meets all requirements for primary heart transplant physician by the end of the 12 month conditional approval period.
8. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the heart transplant physician or the heart transplant surgeon who has been directly involved with the physician at the transplant program verifying the physician's competence.
  - b. A letter of recommendation from the primary physician and director at the transplant program last served by the physician outlining the physician's overall qualifications to act as primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
  - c. A letter from the physician that details the training and experience the physician has gained in heart transplantation.

The 12-month conditional approval period begins on the first approval date granted to the personnel change application, whether it is an interim approval granted by the MPSC subcommittee, or an approval granted by the full MPSC. The conditional approval period ends exactly 12 months after this first approval date of the personnel change application.

The MPSC may consider on a case-by-case basis and grant a 6-month extension to a transplant program that provides substantial evidence of progress toward fulfilling the requirements but is unable to complete the requirements within one year.

If the program is unable to demonstrate that it has an individual on site who can meet the requirements as described in *Sections H.3.A through H.3.B* above at the end of the conditional approval period, it must inactivate. The requirements for program inactivation are described in *Appendix K: Transplant Program Inactivity, Withdrawal, and Termination* of these Bylaws.

#### **H.4 Heart Transplant Programs that Register Candidates Less than 18 Years Old**

A designated heart transplant program that registers candidates less than 18 years old must have an approved pediatric component. To be approved for a pediatric component, the designated heart transplant program must identify a qualified primary pediatric heart transplant surgeon and a qualified primary pediatric heart transplant physician, as described below.

##### **A. Primary Pediatric Heart Transplant Surgeon Requirements**

A pediatric component at a designated heart transplant program must have a primary pediatric surgeon who meets all of the following requirements:

1. The surgeon meets all of the requirements described in *Section H.2: Primary Heart Transplant Surgeon Requirements*.
2. The surgeon has performed at least 8 heart transplants, as the primary surgeon or first assistant, in recipients less than 18 years old at the time of transplant. At least 4 of these heart transplants must have been in recipients less than 6 years old or weighing less than 25 kilograms at the time of transplant. These transplants must have been performed during or after fellowship, or across both periods. These transplants must be documented in a log that includes the date of transplant, the recipient's date of birth, the recipient's weight at transplant if less than 25 kilograms, the role of the surgeon in the procedure, and the medical record number or other unique identifier that can be verified by the OPTN Contractor.
3. The surgeon has maintained a current working knowledge of pediatric heart transplantation, defined as a direct involvement in pediatric heart transplant patient care within the last 2 years. This includes performing the pediatric transplant operation, donor selection, use of mechanical assist devices, pediatric recipient selection, post-operative hemodynamic care, post-operative immunosuppressive therapy, and outpatient follow up.

##### **B. Primary Pediatric Heart Transplant Physician Requirements**

A pediatric component at a designated heart transplant program must have a primary pediatric physician who meets all of the following requirements:

1. The physician meets all of the requirements described in *Section H.3: Primary Heart Transplant Physician Requirements* and has current certification in pediatric cardiology by the American Board of Pediatrics.
2. The physician has been directly involved in the primary care of at least 8 heart transplant recipients less than 18 years old at the time of transplant. At least 4 of these heart transplants must have been in recipients less than 6 years old or weighing less than 25 kilograms at the time of transplant. These transplants must have been performed during or after fellowship, or

- across both periods. This care must be documented in a log that includes the date of transplant, the recipient's date of birth, the recipient's weight at transplant if less than 25 kilograms, and medical record number or other unique identifier that can be verified by the OPTN Contractor.
3. The physician has maintained a current working knowledge of pediatric heart transplantation, defined as direct involvement in pediatric heart transplant patient care within the last 2 years. This includes the care of acute and chronic heart failure, donor selection, the use of mechanical circulatory support devices, recipient selection, pre- and post-operative hemodynamic care, post-operative immunosuppressive therapy, histological interpretation and grading of myocardial biopsies for rejection, and long-term outpatient follow up.

### **C. Conditional Approval for a Pediatric Component**

A designated heart transplant program can obtain conditional approval for a pediatric component if *either* of the following conditions is met:

1. The program has a qualified primary pediatric heart physician who meets *all* of the requirements described in *Section H.4.B: Primary Pediatric Heart Transplant Physician Requirements* and a surgeon who meets *all* of the following requirements:
  - a. The surgeon meets *all* of the requirements described in *Section H.2: Primary Heart Transplant Surgeon Requirements*, including completion of at least *one* of the following training or experience pathways:
    - The formal cardiothoracic surgery residency pathway, as described in *Section H.2.A: Cardiothoracic Surgery Residency Pathway*
    - The 12-month heart transplant fellowship pathway, as described in *Section H.2.B: Twelve-month Heart Transplant Fellowship Pathway*
    - The heart transplant program clinical experience pathway, as described in *Section H.2.C: Clinical Experience Pathway*
  - b. The surgeon has performed at least 4 heart transplants, as the primary surgeon or first assistant, in recipients less than 18 years old at the time of transplant. At least 1 of these heart transplants must have been in recipients less than 6 years old or weighing less than 25 kilograms at the time of transplant. These transplants must have been performed during or after fellowship, or across both periods. These transplants must be documented in a log that includes the date of transplant, the recipient's date of birth, the recipient's weight at transplant if less than 25 kilograms, the role of the surgeon in the procedure, and the medical record number or other unique identifier that can be verified by the OPTN Contractor.
  - c. The surgeon maintained a current working knowledge of pediatric heart transplantation, defined as a direct involvement in pediatric heart transplant patient care within the last 2 years. This includes performing the transplant operation, donor selection, use of mechanical assist devices, pediatric recipient selection, post-operative hemodynamic care, post-operative immunosuppressive therapy, and outpatient follow up.
2. The program has a qualified primary pediatric heart surgeon who meets *all* of the requirements described in *Section H.4.A: Primary Pediatric Heart Transplant Surgeon Requirements* and a physician who meets *all* of the following requirements:
  - a. The physician meets *all* of the requirements described in *Section H.3: Primary Heart Transplant Physician Requirements* and has current certification in pediatric cardiology by the American Board of Pediatrics.
  - b. The physician has been directly involved in the primary care of at least 4 heart transplant recipients less than 18 years old at the time of transplant. At least 1 of these heart

transplants must have been in recipients less than 6 years old or weighing less than 25 kilograms at the time of transplant. These transplants must have been performed during or after fellowship, or across both periods. This care must be documented in a log that includes the date of transplant, the recipient's date of birth, the recipient's weight at transplant if less than 25 kilograms, and medical record number or other unique identifier that can be verified by the OPTN Contractor.

- c. The physician has maintained a current working knowledge of pediatric heart transplantation, defined as direct involvement in pediatric heart transplant patient care within the last 2 years. This includes the care of acute and chronic heart failure, donor selection, the use of mechanical circulatory support devices, recipient selection, pre- and post-operative hemodynamic care, post-operative immunosuppressive therapy, histological interpretation and grading of myocardial biopsies for rejection, and long-term outpatient follow up.

A designated heart transplant program's conditional approval for a pediatric component is valid for a maximum of 24 months.

#### **D. Full Approval for a Pediatric Component following Conditional Approval**

The conditional approval period begins on the first approval date granted to the pediatric component application, whether it is interim approval granted by the MPSC subcommittee, or approval granted by the full MPSC. The conditional approval period ends 24 months after first approval date of the pediatric component application.

The MPSC may consider granting a 24-month conditional approval extension to the designated heart transplant for its pediatric component if the program provides substantial evidence of progress toward fulfilling the requirements, but is unable to complete *all* of the requirements within the initial 24-month period.

Once the designated heart transplant program has met the full approval requirements for the pediatric component, the program may petition the OPTN Contractor for full approval.

If the designated heart transplant program is unable to demonstrate that it has both a primary pediatric heart surgeon onsite that meets *all* of the requirements as described in *Section H.4.A: Primary Pediatric Heart Transplant Surgeon Requirements* and a primary pediatric heart physician onsite that meets *all* of the requirements as described in *Section H.4.B: Primary Pediatric Heart Transplant Physician Requirements* at the end of the 24-month conditional approval period, it must inactivate its pediatric component as described in *Appendix K: Transplant Program Inactivity, Withdrawal, and Termination*.

#### **E. Emergency Membership Exceptions for Candidates Less than 18 Years Old**

A designated heart transplant program that does not have an approved pediatric component may register a patient less than 18 years old on the waiting list if *all* of the following conditions are met:

1. The patient has one of the following conditions:
  - a. Is admitted to the transplant hospital and is supported by a surgically implanted, non-endovascular ventricular assist device (VAD) that is not FDA-approved for out of hospital use for any age group.
  - b. Is admitted to the transplant hospital and is supported by veno-arterial extracorporeal membrane oxygenator (VA ECMO).
2. The patient meets the requirements for pediatric status 1A according to *OPTN Policy 6.1.D: Pediatric Heart Status 1A Requirements*.
3. The primary pediatric physician or primary pediatric surgeon at an approved pediatric heart

component confirms that it is not medically advisable to transport this patient to a heart transplant program with an approved pediatric component. The transplant program that registers the candidate must document this confirmation.

If at any time the candidate no longer meets these criteria, the transplant program must remove the candidate from their waiting list within 24 hours, and may not transplant the candidate. The transplant program must assist candidates in transferring to other designated transplant programs.

Registration of a candidate less than 18 years old through an emergency exception does not grant the transplant program pediatric component approval.

# ***Appendix I: Membership and Personnel Requirements for Lung Transplant Programs***

This appendix describes the information and documentation transplant hospitals must provide when:

- Submitting a completed membership application to apply for approval as a designated lung transplant program.
- Completing a Personnel Change Application for a change in key personnel at a designated lung transplant program.

This appendix does not include the general membership requirements that all transplant programs must meet, which are described in *Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs* of these Bylaws.

For more information on the application and review process, see *Appendix A: Membership Application and Review* of these Bylaws.

## **I.1 Program Director, Primary Transplant Surgeon, and Primary Transplant Physician**

A lung transplant program must identify at least one designated staff member to act as the transplant program director. The director must be a physician or surgeon who is a member of the transplant hospital staff.

The program must also identify a qualified primary transplant surgeon and primary transplant physician, as described below. The primary surgeon and physician, along with the program director, must submit a detailed Program Coverage Plan to the OPTN Contractor. For detailed information about the Program Coverage Plan, see *Section D.7.B: Surgeon and Physician Coverage (Program Coverage Plan)* of these Bylaws.

## **I.2 Primary Lung Transplant Surgeon Requirements**

A designated lung transplant program must have a primary surgeon who meets *all* the following requirements:

1. The surgeon must have an M.D., D.O., or equivalent degree from another country, with a current license to practice medicine in the hospital's state or jurisdiction.
2. The surgeon must be accepted onto the hospital's medical staff, and be practicing on site at this hospital.
3. The surgeon must have documentation from the hospital credentialing committee that it has verified the surgeon's state license, board certification, training, and transplant continuing medical education, and that the surgeon is currently a member in good standing of the hospital's medical staff.
4. The surgeon must have current certification by the American Board of Thoracic Surgery or current certification in thoracic surgery by the Royal College of Physicians and Surgeons of Canada. In the case of a surgeon who has just completed training and whose certification by the American Board of

Thoracic Surgery is pending, the Membership and Professional Standards Committee (MPSC) may grant conditional approval for 24 months to allow time for the surgeon to complete board certification, with the possibility of renewal for one additional 24-month period.

In place of current certification by the American Board of Thoracic Surgery, current certification in thoracic surgery by the Royal College of Physicians and Surgeons of Canada, or pending board certification by the American Board of Thoracic Surgery, the surgeon must:

- a. Be ineligible for American board certification.
- b. Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that the surgeon obtains 60 hours of Category I continuing medical education (CME) credits with self-assessment that are relevant to the individual's practice every three years. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program. A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve an acceptable self-assessment score are allowed. The transplant hospital must document completion of this continuing education.
- c. Provide to the OPTN Contractor two letters of recommendation from directors of designated transplant programs not employed by the applying hospital. These letters must address:
  - i. Why an exception is reasonable.
  - ii. The surgeon's overall qualifications to act as a primary lung transplant surgeon.
  - iii. The surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
  - iv. Any other matters judged appropriate.

If the surgeon has not adhered to the plan for maintaining continuing education or has not obtained the necessary CME credits with self-assessment, the transplant program will have a six-month grace period to address these deficiencies. If the surgeon has not fulfilled the requirements after the six-month grace period, and a key personnel change application has not been submitted, then the transplant program will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws. If the OPTN Contractor becomes aware that a primary surgeon has not been compliant for 12 months or more and deficiencies still exist, then the transplant program will not be given any grace period and will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws.

5. The surgeon must have completed at least one of the pathways listed below:
  - a. The formal cardiothoracic surgery residency pathway, as described in *Section 1.2.A: Cardiothoracic Surgery Residency Pathway* below.
  - b. The 12-month lung transplant fellowship pathway, as described in *Section 1.2.B: Twelve-month Lung Transplant Fellowship Pathway* below.
  - c. The lung transplant program clinical experience pathway, as described in *Section 1.2.C: Clinical Experience Pathway* below.
  - d. The alternative pathway for predominantly pediatric programs, as described in *Section 1.2.D: Alternative Pathway for Predominantly Pediatric Programs* below.

### **A. Cardiothoracic Surgery Residency Pathway**

Surgeons can meet the training requirements for primary lung transplant surgeon by completing a cardiothoracic surgery residency if the following conditions are met:

1. During the cardiothoracic surgery residency, the surgeon has performed at least 15 lung or heart/lung transplants as primary surgeon or first assistant under the direct supervision of a qualified lung transplant surgeon and in conjunction with a lung transplant physician at a lung transplant program. At least half of these transplants must be lung procedures. These transplants must be documented in the surgeon's cardiothoracic surgery residency operative

- log. The date of transplant, role of the surgeon in the procedure, medical record number or other unique identifier that can be verified by the OPTN Contractor, and the training program director's signature must be provided with this log.
2. The surgeon performed at least 10 lung procurements as primary surgeon or first assistant under the supervision of a qualified lung transplant surgeon. These procurements must have been performed anytime during the surgeon's cardiothoracic surgery residency and the two years immediately following cardiothoracic surgery residency completion. These procedures must be documented in the surgeon's cardiothoracic surgery residency operative log. The date of procurement and Donor ID must be provided with this log.
  3. The surgeon has maintained a current working knowledge of all aspects of lung transplantation, defined as a direct involvement in lung transplant patient care within the last 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass, donor selection, recipient selection, pre- and postoperative ventilator care, postoperative immunosuppressive therapy, histological interpretation and grading of lung biopsies for rejection, and long-term outpatient follow-up. This training must also include the other clinical requirements for thoracic surgery
  4. This training was completed at a hospital with a cardiothoracic training program approved by the American Board of Thoracic Surgery, or the Royal College of Physicians and Surgeons of Canada.
  5. The following letters are submitted directly to the OPTN Contractor:
    - a. A letter from the director of the training program verifying that the surgeon has met the above requirements and is qualified to direct a lung transplant program.
    - b. A letter of recommendation from the program's primary surgeon and transplant program director outlining the individual's overall qualifications to act as primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
    - c. A letter from the surgeon that details the training and experience the surgeon has gained in lung transplantation.

## **B. Twelve-month Lung Transplant Fellowship Pathway**

Surgeons can meet the training requirements for primary lung transplant surgeon by completing a 12-month lung transplant fellowship if the following conditions are met:

1. The surgeon has performed at least 15 lung or heart/lung transplants under the direct supervision of a qualified lung transplant surgeon and in conjunction with a qualified lung transplant physician as primary surgeon or first assistant during the 12-month lung transplant fellowship. At least half of these transplants must be lung procedures. These transplants must be documented in the surgeon's fellowship operative log. The date of transplant, the role of the surgeon in the procedure, the medical record number or other unique identifier that can be verified by the OPTN Contractor, and the fellowship director's signature must be provided with this log.
2. The surgeon has performed at least 10 lung procurements as primary surgeon or first assistant under the supervision of a qualified lung transplant surgeon. These procurements must have been performed anytime during the surgeon's fellowship and the two years immediately following fellowship completion. These procedures must be documented in the



- surgeon's fellowship operative log. The date of procurement and Donor ID must be provided with this log.
3. The surgeon has maintained a current working knowledge of all aspects of lung transplantation, defined as a direct involvement in lung transplant patient care within the last 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass, donor selection, recipient selection, pre- and postoperative ventilator care, postoperative immunosuppressive therapy, histological interpretation and grading of lung biopsies for rejection, and long-term outpatient follow-up.
  4. This training was completed at a hospital with a cardiothoracic training program approved by the American Board of Thoracic Surgery, or the Royal College of Physicians and Surgeons of Canada.
  5. The following letters are submitted directly to the OPTN Contractor:
    - a. A letter from the director of the training program verifying that the surgeon has met the above requirements and is qualified to direct a lung transplant program.
    - b. A letter of recommendation from the training program's primary surgeon and transplant program director outlining the individual's overall qualifications to act as primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
    - c. A letter from the surgeon that details the training and experience the surgeon has gained in lung transplantation.

### **C. Clinical Experience Pathway**

Surgeons can meet the requirements for primary lung transplant surgeon through clinical experience gained post-fellowship if the following conditions are met:

1. The surgeon has performed 15 or more lung or heart/lung transplants over a 2 to 5-year period as primary surgeon or first assistant at a designated lung transplant program. At least half of these transplants must be lung procedures, and at least 10 must be performed as the primary surgeon. The surgeon must also have been actively involved with cardiothoracic surgery. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log should be signed by the program director, division chief, or department chair from program where the experience was gained.
2. The surgeon has performed at least 10 lung procurements. These procedures must be documented in a log that includes the date of procurement and Donor ID.
3. The surgeon has maintained a current working knowledge of all aspects of lung transplantation, defined as a direct involvement in lung transplant patient care within the last 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass, donor selection, recipient selection, pre- and postoperative ventilator care, postoperative immunosuppressive therapy, histological interpretation and grading of lung biopsies for rejection, and long-term outpatient follow-up.
4. The following letters are submitted directly to the OPTN Contractor:

- a. A letter from the director of the program where the surgeon gained experience verifying that the surgeon has met the above requirements and is qualified to direct a lung transplant program.
- b. A letter of recommendation from the primary surgeon and director at the transplant program last served by the surgeon outlining the surgeon's overall qualifications to act as primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
- c. A letter from the surgeon that details the training and experience the surgeon has gained in lung transplantation.

#### **D. Alternative Pathway for Predominantly Pediatric Programs**

If a surgeon does not meet the requirements for primary lung transplant surgeon through either the training or clinical experience pathways described above, hospitals that serve predominantly pediatric patients may petition the MPSC in writing to consider the surgeon for primary transplant surgeon if the program can demonstrate that the following conditions are met:

1. The surgeon's lung transplant training or experience is equivalent to the residency, fellowship, or clinical experience pathways as described in *Sections 1.2.A through 1.2.C* above.
2. The surgeon has maintained a current working knowledge of all aspects of lung transplantation and patient care, defined as direct involvement in lung transplant patient care within the last 2 years.
3. The surgeon submits a letter of recommendation from the primary surgeon and transplant program director of the fellowship training program or transplant program last served by the surgeon outlining the surgeon's overall qualifications to act as a primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
4. The hospital participates in an informal discussion with the MPSC.

The MPSC or an Ad Hoc Subcommittee of at least 4 MPSC members appointed by the MPSC Chair is authorized to conduct the informal discussion and make an interim determination. Interim determinations are:

- Advisory to the MPSC, Board of Directors, or both, who have the final authority to grant approval of a designated transplant program.
- Effective temporarily, pending final decision by the MPSC or Board.

The MPSC must offer the member an interview if the MPSC recommends that the Board of Directors rejects a membership application. The member may also be entitled to a hearing with the MPSC and an appearance before the Board of Directors prior to the Board of Directors taking a final action on any MPSC recommendation. Any interviews, hearings, or Board of Directors appearances that occur as a part of a membership application process will be held according to *Appendix L: Reviews and Actions*.

### I.3 Primary Lung Transplant Physician Requirements

A designated lung transplant program must have a primary physician who meets *all* the following requirements:

1. The physician must have an M.D., D.O., or equivalent degree from another country, with a current license to practice medicine in the hospital's state or jurisdiction.
2. The physician must be accepted onto the hospital's medical staff, and be practicing on site at this hospital.
3. The physician must have documentation from the hospital credentialing committee that it has verified the physician's state license, board certification, training, and transplant continuing medical education and that the physician is currently a member in good standing of the hospital's medical staff.
4. The lung transplant physician must have current board certification or have achieved eligibility in adult or pediatric pulmonary medicine by the American Board of Internal Medicine, the American Board of Pediatrics, or the Royal College of Physicians and Surgeons of Canada.

In place of current board certification or achieved eligibility in adult or pediatric pulmonary medicine by the American Board of Internal Medicine, the American Board of Pediatrics, or the Royal College of Physicians and Surgeons of Canada, the physician must:

- a. Be ineligible for American board certification.
- b. Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that the physician obtains 60 hours of Category I continuing medical education (CME) credits with self-assessment that are relevant to the individual's practice every three years. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program. A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve an acceptable self-assessment score are allowed. The hospital must document completion of this continuing education.
- c. Provide to the OPTN Contractor two letters of recommendation from directors of designated transplant programs not employed by the applying hospital. These letters must address:
  - i. Why an exception is reasonable.
  - ii. The physician's overall qualifications to act as a primary lung transplant physician.
  - iii. The physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
  - iv. Any other matters judged appropriate.

If the physician has not adhered to the plan for maintaining continuing education or has not obtained the necessary CME credits with self-assessment, the transplant program will have a six-month grace period to address these deficiencies. If the physician has not fulfilled the requirements after the six-month grace period, and a key personnel change application has not been submitted, then the transplant program will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws. If the OPTN Contractor becomes aware that a primary physician has not been compliant for 12 months or more and deficiencies still exist, then the transplant program will not be given any grace period and will be referred to the MPSC for appropriate action according to *Appendix L* of these Bylaws.

5. The physician must have completed at least one of the pathways listed below:
  - a. The 12-month transplant pulmonary fellowship pathway, as described in Section I.3.A: Twelve-month Transplant Pulmonary Fellowship Pathway below.
  - b. The clinical experience pathway, as described in Section I.3.B: Clinical Experience Pathway below.
  - c. The alternative pathway for predominantly pediatric programs, as described in *Section I.3.C*:

*Alternative Pathway for Predominantly Pediatric Programs below.*

- d. The conditional approval pathway, as described in *Section I.3.D: Conditional Approval for Primary Transplant Physician* below, if the primary lung transplant physician changes at an approved lung transplant program.

### **A. Twelve-month Transplant Pulmonary Fellowship Pathway**

Physicians can meet the training requirements for primary lung transplant physician during a 12-month transplant pulmonary fellowship if the following conditions are met:

1. The physician was directly involved in the primary and follow-up care of at least 15 newly transplanted lung or heart/lung recipients. This training will have been under the direct supervision of a qualified lung transplant physician and in conjunction with a lung transplant surgeon. At least half of these patients must be single or double-lung transplant recipients. This care must be documented in a log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log must be signed by the director of the training program or the primary transplant physician at the transplant program.
2. The physician has maintained a current working knowledge of all aspects of lung transplantation, defined as a direct involvement in lung transplant patient care within the last 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass, donor selection, recipient selection, pre- and postoperative ventilator care, postoperative immunosuppressive therapy, histological interpretation and grading of lung biopsies for rejection, and long-term outpatient follow-up.
3. The physician must have observed at least 3 lung or heart/lung procurements. The physician must have observed the evaluation, donation process, and management of these donors. These observations must be documented in a log that includes the date of procurement and Donor ID.
4. The physician must have observed at least 3 lung transplants. The observation of these transplants must be documented in a log that includes the transplant date and medical record number or other unique identifier that can be verified by the OPTN Contractor.
5. This training was completed at a hospital with an American Board of Internal Medicine certified fellowship training program in adult pulmonary medicine, an American Board of Pediatrics-certified fellowship training program in pediatric medicine, or a pulmonary medicine training program approved by the Royal College of Physicians and Surgeons of Canada.
6. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the director of the training program verifying that the physician has met the above requirements and is qualified to direct a lung transplant program.
  - b. A letter of recommendation from the training program's primary physician and transplant program director outlining the physician's overall qualifications to act as primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
  - c. A letter from the physician that details the training and experience the physician has gained in lung transplantation.

## **B. Clinical Experience Pathway**

A physician can meet the requirements for primary lung transplant physician through acquired clinical experience if the following conditions are met.

1. The physician has been directly involved in the primary care of 15 or more newly transplanted lung or heart/lung recipients and continued to follow these recipients for a minimum of 3 months from the time of transplant. At least half of these transplant must be lung transplants. This patient care must have been provided over a 2 to 5-year period at a designated lung transplant program. This care must have been provided as the lung transplant physician or directly supervised by a qualified lung transplant physician along with a lung transplant surgeon. This care must be documented in a log that includes the date of transplant and medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log should be signed by the director or the primary transplant physician at the transplant program where the physician gained this experience.
2. The physician has maintained a current working knowledge of all aspects of lung transplantation, defined as a direct involvement in lung transplant patient care within the last 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass, donor selection, recipient selection, pre- and postoperative ventilator care, postoperative immunosuppressive therapy, histological interpretation and grading of lung biopsies for rejection, and long-term outpatient follow-up.
3. The physician must observe at least 3 lung or heart/lung procurements. The physician must have observed the evaluation, donation process, and management of these donors. These observations must be documented in a log that includes the date of procurement and Donor ID.
4. The physician must have observed at least 3 lung transplants. The observation of these transplants must be documented in a log that includes the transplant date and medical record number or other unique identifier that can be verified by the OPTN Contractor.
5. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the lung transplant physician or surgeon of the training program who has been directly involved with the physician documenting the physician's competence.
  - b. A letter of recommendation from the primary physician and transplant program director at the transplant program last served by the physician outlining the physician's overall qualifications to act as primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
  - c. A letter from the physician that details the training and experience the physician has gained in lung transplantation.

## **C. Alternative Pathway for Predominantly Pediatric Programs**

If a physician does not meet the requirements for primary physician through any of the transplant fellowship or clinical experience pathways as described above, hospitals that serve predominantly pediatric patients may petition the MPSC in writing to consider the physician for primary transplant physician if the program can demonstrate that the following conditions are met:

1. That the physician's lung transplant training or experience is equivalent to the fellowship or clinical experience pathways as described in *Sections 1.3.A and 1.3.B* above.

2. The physician has maintained a current working knowledge of all aspects of lung transplantation, defined as direct involvement in lung transplant patient care within the last 2 years.
3. The physician submits a letter of recommendation from the primary physician and transplant program director of the fellowship training program or transplant program last served by the physician outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
4. The hospital participates in an informal discussion with the MPSC.

The MPSC or an Ad Hoc Subcommittee of at least 4 MPSC members appointed by the MPSC Chair is authorized to conduct the informal discussion and make an interim determination. Interim decisions are:

- Advisory to the MPSC, Board of Directors, or both, which has the final authority to grant approval of a designated transplant program.
- Effective temporarily, pending final decision by the MPSC or Board of Directors.

The MPSC must offer the member an interview if the MPSC recommends that the Board of Directors rejects a membership application. The member may also be entitled to a hearing with the MPSC and an appearance before the Board of Directors prior to the Board of Directors taking a final action on any MPSC recommendation. Any interviews, hearings, or Board of Directors appearances that occur as a part of a membership application process will be held according to *Appendix L: Reviews and Actions*.

#### **D. Conditional Approval for Primary Transplant Physician**

If the primary lung transplant physician changes at an approved lung transplant program, a physician can serve as the primary lung transplant physician for a maximum of 12 months if the following conditions are met:

1. The physician has 12 months of experience on an active lung transplant service as the primary lung transplant physician or under the direct supervision of a qualified lung transplant physician and in conjunction with a lung transplant surgeon at a designated lung transplant program. These 12 months of experience must be acquired within a 2-year period.
2. The physician has been involved in the primary care of 8 or more newly transplanted lung or heart/lung transplant recipients as the lung transplant physician or under the direct supervision of a qualified lung transplant physician and in conjunction with a lung transplant surgeon. At least half of these patients must be lung transplant recipients. This care must be documented in a recipient log that includes the date of transplant and medical record or other unique identifier that can be verified by the OPTN Contractor. This log should be signed by the program director or the primary transplant physician at the transplant program where the physician gained experience.
3. The physician has maintained a current working knowledge of all aspects of lung transplantation, defined as a direct involvement in lung transplant patient care within the last 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass, donor selection, recipient selection, pre- and postoperative ventilator care, postoperative

- immunosuppressive therapy, histological interpretation and grading of lung biopsies for rejection, and long-term outpatient follow-up.
4. The physician must have observed at least 3 lung or heart/lung procurements. The physician must have observed the evaluation, donation process, and management of these donors. These observations must be documented in a log that includes the date of procurement and Donor ID.
  5. The physician must have observed at least 3 lung transplants. The observation of these transplants must be documented in a log that includes the transplant date and medical record number or other unique identifier that can be verified by the OPTN Contractor.
  6. The program has established and documented a consulting relationship with counterparts at another lung transplant program.
  7. The transplant program submits activity reports to the OPTN Contractor every 2 months describing the transplant activity, transplant outcomes, physician recruitment efforts, and other operating conditions as required by the MPSC to demonstrate the ongoing quality and efficient patient care at the program. The activity reports must also demonstrate that the physician is making sufficient progress to meet the required involvement in the primary care of 20 or more lung transplant recipients, or that the program is making sufficient progress in recruiting a physician who meets all requirements for primary lung transplant physician by the end of the 12 month conditional approval period.
  8. The following letters are submitted directly to the OPTN Contractor:
    - a. A letter from the supervising lung transplant physician or surgeon of the training program documenting the physician's competence.
    - b. A letter of recommendation from the training program's primary physician and director outlining the physician's overall qualifications to act as primary transplant physician of the transplant program last served by the physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
    - c. A letter from the physician that details the training and experience the physician has gained in lung transplantation.

The 12-month conditional approval period begins on the first approval date granted to the personnel change application, whether it is an interim approval granted by the MPSC subcommittee, or approval granted by the full MPSC. The conditional approval period ends exactly 12 months after this first approval date of the personnel change application.

The MPSC may consider on a case-by-case basis and grant a 6-month extension to a transplant program that provides substantial evidence of progress toward fulfilling the requirements but is unable to complete the requirements within one year.

If the program is unable to demonstrate that it has an individual practicing on site who can meet the requirements as described in *Sections 1.3.A through 1.3.C* above at the end of the conditional approval period, it must inactivate. The requirements for transplant program inactivation are described in *Appendix K: Transplant Program Inactivity, Withdrawal, and Termination* of these Bylaws.

#### **I.4 Lung Transplant Programs that Register Candidates Less than 18 Years Old**

A designated lung transplant program that registers candidates less than 18 years old must have an approved pediatric component. To be approved for a pediatric component, the designated lung transplant program must identify a qualified primary pediatric lung transplant surgeon and a qualified primary pediatric lung transplant physician, as described below.

##### **A. Primary Pediatric Lung Transplant Surgeon Requirements**

A pediatric component at a designated lung transplant program must have a primary pediatric surgeon who meets *all* of the requirements described in *Section I.2: Primary Lung Transplant Surgeon Requirements*.

##### **B. Primary Pediatric Lung Transplant Physician Requirements**

A pediatric component at a designated lung transplant program must have a primary pediatric physician who meets *all* of the requirements described in *Section I.3: Primary Lung Transplant Physician Requirements*.