Mini-Brief

Clarification to Remove Donor Location from Required Procurement Log Information

OPTN/UNOS Membership and Professional Standards Committee

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Clarification to Remove Donor Location from Required Procurement Log Information


Sponsoring Committee: Membership and Professional Standards

Executive Summary

The Bylaws unnecessarily require primary physician and primary surgeon applicants to include donor location information on procurement logs submitted with their application. Neither UNOS staff nor the MPSC require this information to process or evaluate applications. Removing the requirement from the bylaws will promote efficient management of the OPTN by ensuring the bylaws reflect current requirements and reducing the time members spend compiling information to submit with applications.

Because this clarification does not add any new member burdens, public comment is not required. Typically, policy clarifications are reviewed and approved by the Executive Committee however only the Board may approve changes to the Bylaws.
What problem will this proposal solve?

In response to an MPSC-sponsored public comment proposal to update the key personnel requirements for primary kidney transplant physicians, the American Society of Transplantation (AST) suggested that the MPSC remove the requirement for the “location of the donor” from the procurement log. AST noted that the information is very difficult to obtain once a fellow moves to a different transplant program. During its discussion of public comment responses, the MPSC agreed that the information is difficult to obtain and also noted that the information is not needed for their review of key personnel applications. The Committee supported removing “location of the donor” as it pertains to key personnel procurement logs not only in the applicable kidney physician sections, but also throughout the bylaws, including the applicable sections for the primary heart, liver, lung, intestine and pancreas physicians and surgeons. The MPSC felt that proposing this widespread change as a post public-comment change to the kidney physician proposal would be outside the intended scope of the kidney physician proposal and therefore inappropriate. Instead, the MPSC proposes this clarification for the OPTN/UNOS Board of Directors’ consideration. This clarification would ensure the bylaws do not include unnecessary requirements and would reduce the time and resources required for members to complete the application.

Why should you support this proposal?

During its discussions, the MPSC expressed its support for amending the bylaws through the clarification process. The MPSC Chair reviewed and approved the final language. Removing the requirement from the bylaws will promote efficient management of the OPTN by ensuring the bylaws reflect current requirements and reducing the time members spend compiling information to submit with applications.

How does this proposal impact the OPTN Strategic Plan?

Increase the number of transplants: There is no impact to this goal.
Improve equity in access to transplants: There is no impact to this goal.
Improve waitlisted patient, living donor, and transplant recipient outcomes: There is no impact to this goal.
Promote living donor and transplant recipient safety: There is no impact to this goal.
Promote the efficient management of the OPTN: This proposal will clarify which information members must obtain and submit with key personnel applications and will reduce the amount of time necessary for members to prepare application materials.

How will the OPTN implement this proposal?

Assuming the Board adopts these changes, members will be alerted through a policy notice. Staff will update the Frequently Asked Questions guide available for members completing key personnel applications to note that, for all applications received on or after the March 1, 2017, implementation date, donor location is no longer a required field. Staff will update the application forms to remove the donor location during the next regularly scheduled application form revision and approval process.

This proposal will not require programming in UNetSM.

How will members implement this proposal?

No actions are required of members to implement this proposal. Members that previously spent time researching donor location and including the information with key personnel applications will no longer need to do so.
**Will this proposal require members to submit additional data?**

No, this proposal does not require additional data collection. Instead it lowers future data submission requirements.

**How will members be evaluated for compliance with this proposal?**

Members will not need to take any action to comply with this proposal. Members will be expected to review the applicable bylaws and to submit all information that continues to be required. For example, programs must continue to submit procurement logs containing the donor ID and procurement date for applicable primary physician and primary surgeon applications, even though donor location will no longer be required.
Policy or Bylaws Language


Proposed new language is underlined (example) and language that is proposed for removal is struck through (example).

E.2 Primary Kidney Transplant Surgeon Requirements

A. Formal 2-year Transplant Fellowship Pathway

Surgeons can meet the training requirements for primary kidney transplant surgeon by completing a 2-year 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 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 director of the training program.

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 a log that includes the date of procurement, location of the donor, 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. This training was completed at a hospital with a kidney transplant training program approved by the Fellowship Training Committee of the American Society of Transplant Surgeons, the Royal College of Physicians and Surgeons of Canada, or 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 or first assistant at a designated kidney transplant program. 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 or first assistant. 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, location of the donor, 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. Twelve-month Transplant Nephrology Fellowship Pathway

Physicians can meet the training requirements for a primary kidney transplant physician during a
separate 12-month transplant nephrology 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 kidney transplant physician and along with a kidney
transplant surgeon at a kidney transplant program that performs 30 or more transplants each
year. The training must have included at least 6 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 kidney 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 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. 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. The
curriculum for obtaining this knowledge should be approved by the Residency Review
Committee for Internal Medicine (RRC-IM) of the Accreditation Council for Graduate Medical
Education (ACGME).

4. 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, location of the donor, and Donor
ID.

5. 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.

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 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 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 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 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.

3. 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, location of the donor, and Donor ID.

4. 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.

5. 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 and followed 30 newly transplanted kidney recipients for at least 6 months from the time of transplant, 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. 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. The curriculum for obtaining this knowledge must be approved by the Residency Review Committee (RRC) -Ped of the ACGME.

4. 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, location of the donor, and Donor ID.
5. 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.

6. 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 and followed 30 newly transplanted kidney recipients for at least 6 months from the time of transplant, 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. 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. The curriculum for obtaining this knowledge must be approved by the Residency Review Committee (RRC) -Ped of the ACGME.

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, location of the donor, 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 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 and followed 30 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.

4. 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. The curriculum for obtaining this knowledge must be approved by the Residency Review Committee (RRC) - Ped of the ACGME or a Residency Review Committee.

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, location of the donor, 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 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 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 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.

3. 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.

4. 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, location of the donor, and Donor
ID.

5. 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.

6. The program has established and documented a consulting relationship with counterparts at
another kidney 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 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.

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

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. The curriculum for obtaining this knowledge must be approved by the Residency Review Committee (RRC) – Ped of the ACGME or a Residency Review Committee.

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, location of the donor, 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.
F.3 Primary Liver Transplant Surgeon Requirements

A. Formal 2-year Transplant Fellowship Pathway

Surgeons can meet the training requirements for primary liver transplant surgeon by completing a 2-year 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 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 director of the training program.

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 a log that includes the date of procurement, location of the donor, and Donor ID. This log must be signed by the director of the training program.

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 transplant training program approved by the Fellowship Training Committee of the American Society of Transplant Surgeons, the Royal College of Physicians and Surgeons of Canada, or 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 or first assistant at a designated liver 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 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 or first assistant. These procedures must be documented in a log that includes the date of procurement, location of the donor, 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. 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, location of the donor, 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, the location of the donor, 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 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 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, location of the donor 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 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, location of the donor 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 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, location of the donor, 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, location of the donor, 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.7.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, location of the donor, 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
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.

F.11 Primary Intestine Transplant Surgeon Requirements

A. Full Intestine Surgeon Approval Pathway

Surgeons can be fully approved as a primary intestine transplant surgeon by completing a formal 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, location of the donor, 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 a transplant training program approved by the American Society of Transplant Surgeons (ASTS) or accepted by the OPTN Contractor as described in Section F.13 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, location of the donor, 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.
G.2 Primary Pancreas Transplant Surgeon Requirements

A. Formal 2-year Transplant Fellowship Pathway

Surgeons can meet the training requirements for primary pancreas transplant surgeon by completing a 2-year 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 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 director of the training program.

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 a log that includes the date of procurement, location of the donor, and Donor ID. This log must be signed by the director of the training program.

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 Fellowship Training Committee of the American Society of Transplant Surgeons, the Royal College of Physicians and Surgeons of Canada, or 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 or first assistant, at a designated pancreas 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 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 or first assistant. These procurements must be documented in a log that includes the date of procurement, location of the donor, 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.

G.3 Primary Pancreas Transplant Physician Requirements

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
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, location of the donor, 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 curriculum of this transplant medicine fellowship should be approved by the Residency Review Committee for Internal Medicine (RRC-IM) of the Accreditation Council for Graduate Medical Education (ACGME).

7. 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, location of the donor, 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.

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, location of the donor, 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.

H.2 Primary Heart Transplant Surgeon Requirements

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 a log that includes the date of transplant, 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 director of the training program.

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 a log that includes the date of procurement, location of the donor, and Donor ID. This log must be signed by the director of the training program.

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 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 director of the training program.

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 a log that includes the date of procurement, location of the donor, and Donor ID. This log must be signed by the director of the training program.

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, location of the donor, 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. 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, location of the donor, 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, location of the donor, 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, location of
   the donor, 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.

I.2 Primary Lung Transplant Surgeon Requirements

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 a log that includes the date of transplant, 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 director of the training program.

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 a log that includes the date of procurement, location of the donor, 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. 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 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 director of the program.

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 a log that includes the date of procurement, location of the donor, 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. 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, location of the donor, 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.

1.3 Primary Lung Transplant Physician Requirements

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,
location of the donor, 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, location of the donor, 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.

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, location of the donor, 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 I.3.A through I.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.