OPTN/UNOS Policy Notice
Updating Primary Kidney Transplant Physician Requirements

Sponsoring Committee: Membership and Professional Standards
Policy/Bylaws Affected: E.3 (Primary Kidney Transplant Physician Requirements)
Public Comment: August 2016
Effective Date: Pending implementation and notice to members

Problem Statement
Although fellowship training requirements generally serve as the foundation for key personnel requirements in the OPTN/UNOS Bylaws, the primary transplant kidney physician pathways do not reflect some options and standards currently associated with transplant nephrology fellowships.

Summary of Changes
These Bylaws changes will align primary kidney transplant physician requirements with transplant nephrology fellowship requirements. With the exception of requiring a certain number of kidney biopsies and observing a living donor kidney transplant, the changes incorporate all other relevant requirements that transplant programs must continually meet to be accredited by the Transplant Nephrology Fellowship Training Accreditation Program. The most significant element of these changes is modifying Appendix E.3.A so that it will accommodate transplant nephrology fellows who opt to complete their fellowship through the Transplant Nephrology Fellowship Training Accreditation Program’s alternative pathway.

What Members Need to Do
No immediate action will be required of members when we implement these changes. After implementation, we will evaluate any membership and key personnel change applications we receive from kidney programs based on the changes.

Affected Policy Language:
New language is underlined (example) and language that is removed is struck through (example).

E.3 Primary Kidney Transplant Physician Requirements
A designated kidney transplant program must have a primary physician who meets all the following requirements:

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

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

a. Be ineligible for American board certification.

b. Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that the physician obtains 60 hours of Category I continuing medical education (CME) credits with self-assessment that are relevant to the individual’s practice every three years. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program. A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve an acceptable self-assessment score are allowed. The transplant hospital must document completion of this continuing education.

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

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

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

a. The 12-month transplant nephrology fellowship pathway, as described in Section E.3.A. Twelve-month Transplant Nephrology Fellowship Pathway below.

b. The clinical experience pathway, as described in Section E.3.B. Clinical Experience Pathway below.

c. The 3-year pediatric nephrology fellowship pathway, as described in Section E.3.C. Three-year Pediatric Nephrology Fellowship Pathway below.

d. The 12-month pediatric transplant nephrology fellowship pathway, as described in Section E.3.D. Twelve-month Pediatric Transplant Nephrology Fellowship Pathway below.

e. The combined pediatric nephrology training and experience pathway, as described in Section E.3.E. Combined Pediatric Nephrology Training and Experience Pathway below.

f. The conditional approval pathway, as described in Section E.3.F. Conditional Approval for Primary Transplant Physician below, if the primary kidney transplant physician changes at an approved kidney transplant program.
A. 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 at least 12 consecutive months of specialized training in transplantation under the direct supervision of a qualified kidney transplant physician and along with a kidney transplant surgeon at a kidney transplant program that performs 30 or more transplants each year. The training must have included at least 6 months of clinical inpatient transplant service. The remaining time must have consisted of transplant-related experience, such as experience in a tissue typing laboratory, on another solid organ transplant service, or conducting basic or clinical transplant research.

2. During the fellowship period, the physician was directly involved in the primary care of 30 or more newly transplanted kidney recipients and continued to the outpatient follow-up of these recipients for a minimum of 3 months from the time of transplant. If the physician’s fellowship was longer than 12 months, the physician also must have been directly involved in the outpatient follow-up of at least 30 kidney recipients for an additional period of 3 consecutive months. The care must be documented in a log that includes the date of transplant and the recipient medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log must be signed by the director of the training program or the transplant program’s primary transplant physician.

3. During the fellowship period, the physician was directly involved in the evaluation of 25 potential kidney recipients, including participation in selection committee meetings. These potential kidney recipient evaluations must be documented in a log that includes each evaluation date and is signed by the director of the training program or the transplant program’s primary transplant physician.

4. During the fellowship period, the physician was directly involved in the evaluation of 10 potential living kidney donors, including participation in selection committee meetings. These potential living kidney donor evaluations must be documented in a log that includes each evaluation date and the potential living kidney donor’s medical record number or other unique identifier that can be verified by the OPTN Contractor. This potential living kidney donor evaluation log must be signed by the director of the training program or the transplant program’s primary transplant physician.

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

6. The physician must have observed at least 3 kidney procurements, including at least 1 deceased donor and 1 living donor. The physician must have observed the evaluation, donation process, and management of these donors. These observations must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
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.

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

2. The physician was directly involved in the evaluation of 25 potential kidney recipients, including participation in selection committee meetings. These potential kidney recipient evaluations must be documented in a log that includes each evaluation date and is signed by the program director, division Chief, or department Chair from the program where the physician gained this experience.

3. The physician was directly involved in the evaluation of 10 potential living kidney donors, including participation in selection committee meetings. These potential living kidney donor evaluations must be documented in a log that includes each evaluation date and the potential living kidney donor’s medical record number or other unique identifier than can be verified by the OPTN Contractor. This potential living kidney donor evaluation log must be signed by the program director, division Chief, or department Chair from the program where the physician gained this experience.

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

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.

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.

The following letters are submitted directly to the OPTN Contractor:

a. A letter from the qualified transplant physician or the kidney transplant surgeon who has
been directly involved with the proposed physician documenting the physician's
experience and competence.

b. A letter of recommendation from the primary physician and transplant program director at
the transplant program last served by the physician outlining the physician's overall
qualifications to act as a primary transplant physician, as well as the physician's personal
integrity, honesty, and familiarity with and experience in adhering to OPTN obligations
and compliance protocols, and any other matters judged appropriate. The MPSC may
request additional recommendation letters from the primary physician, primary surgeon,
director, or others affiliated with any transplant program previously served by the
physician, at its discretion.

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

C. Three-year Pediatric Nephrology Fellowship Pathway

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

1. During the 3-year training period the physician was directly involved in the primary care of 10
or more newly transplanted kidney recipients for at least 6 months from the time of transplant
and followed 30 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. During the fellowship period, the physician was directly involved in the evaluation of 25 potential kidney recipients, including participation in selection committee meetings. These potential kidney recipient evaluations must be documented in a log that includes each evaluation date and is signed by the director of the training program or the transplant program’s primary transplant physician.

4. The physician has maintained a current working knowledge of kidney transplantation, defined as direct involvement in kidney transplant patient care over the last 2 years. This includes the management of pediatric patients with end-stage renal disease, the selection of appropriate pediatric recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative care including those issues of management unique to the pediatric recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the pediatric recipient including side-effects of drugs and complications of immunosuppression, the effects of transplantation and immunosuppressive agents on growth and development, differential diagnosis of renal dysfunction in the allograft recipient, manifestation of rejection in the pediatric patient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long-term outpatient care of pediatric allograft recipients including management of hypertension, nutritional support, and drug dosage, including antibiotics, in the pediatric patient. 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.

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

D. Twelve-month Pediatric Transplant Nephrology Fellowship Pathway

The requirements for the primary kidney transplant physician can be met during a separate pediatric transplant nephrology fellowship if the following conditions are met:
1. The physician has current board certification in pediatric nephrology by the American Board of Pediatrics, the Royal College of Physicians and Surgeons of Canada, or is approved by the American Board of Pediatrics to take the certifying exam.

2. During the fellowship, the physician was directly involved in the primary care of 10 or more newly transplanted kidney recipients for at least 6 months from the time of transplant and followed 30 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. During the four years that include the physician's three-year pediatric nephrology fellowship and twelve-month pediatric transplant nephrology fellowship, the physician was directly involved in the evaluation of 25 potential kidney recipients, including participation in selection committee meetings. These potential kidney recipient evaluations must be documented in a log that includes each evaluation date and is signed by the director of the training program or the transplant program's primary transplant physician.

5. The physician has maintained a current working knowledge of kidney transplantation, defined as direct involvement in kidney transplant patient care in the past 2 years. This includes the management of pediatric patients with end-stage renal disease, the selection of appropriate pediatric recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative care including those issues of management unique to the pediatric recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the pediatric recipient including side-effects of drugs and complications of immunosuppression, the effects of transplantation and immunosuppressive agents on growth and development, differential diagnosis of renal dysfunction in the allograft recipient, manifestation of rejection in the pediatric patient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long-term outpatient care of pediatric allograft recipients including management of hypertension, nutritional support, and drug dosage, including antibiotics, in the pediatric patient. The curriculum for obtaining this knowledge must be approved by the Residency Review Committee (RRC) -Ped of the ACGME.

6. The physician must have observed at least 3 kidney procurements, including at least 1 deceased donor and 1 living donor. The physician must have observed the evaluation, donation process, and management of these donors. These observations must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.

7. The physician must have observed at least 3 kidney transplants involving a pediatric recipient. The observation of these transplants must be documented in a log that includes the transplant date, donor type, and medical record number or other unique identifier that can be verified by the OPTN Contractor.

8. The following letters are submitted directly to the OPTN Contractor:
   a. A letter from the director and the supervising qualified transplant physician and surgeon of the fellowship training program verifying that the physician has met the above requirements.
requirements and is qualified to become the primary transplant physician of a designated
kidney transplant program.

b. A letter of recommendation from the fellowship training program’s primary physician and
transplant program director outlining the physician’s overall qualifications to act as a
primary transplant physician, as well as the physician’s personal integrity, honesty, and
familiarity with and experience in adhering to OPTN obligations, and any other matters
judged appropriate. The MPSC may request additional recommendation letters from the
primary physician, primary surgeon, director, or others affiliated with any transplant
program previously served by the physician, at its discretion.

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

E. Combined Pediatric Nephrology Training and Experience Pathway

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

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

2. The physician gained a minimum of 2 years of experience during or after fellowship, or
accumulated during both periods, at a kidney transplant program.

3. During the 2 or more years of accumulated experience, the physician was directly involved in
the primary care of 10 or more newly transplanted kidney recipients for at least 6 months
from the time of transplant and followed 30 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 was directly involved in the evaluation of 25 potential kidney recipients,
including participation in selection committee meetings. These potential kidney recipient
evaluations must be documented in a log that includes each evaluation date and be signed by
the program director, division Chief, or department Chair from the program where the
physician gained this experience.

45. 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.

56. 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.

67. 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.

78. 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 continued the outpatient follow-up of these patients for at least 3
months from the time of their transplant. This care must be documented in a recipient log that
includes the date of transplant and the medical record number or other unique identifier that
can be verified by the OPTN Contractor. This log must be signed by the program director,
division chief, or department chair from the transplant program where the experience was

gained.

2. The physician was directly involved in the evaluation of 25 potential kidney recipients,

including participation in selection committee meetings. These potential kidney recipient
evaluations must be documented in a log that includes each evaluation date and is signed by
the program director, division Chief, or department Chair from the program where the
physician gained this experience.

3. The physician was directly involved in the evaluation of 10 potential living kidney donors,

including participation in selection committee meetings. These potential living kidney donor
evaluations must be documented in a log that includes each evaluation date and the potential
living kidney donor's medical record number or other unique identifier than can be verified by
the OPTN Contractor. This potential living kidney donor log must and be signed by program
director, division Chief, or department Chair from the program where the physician gained
this experience.
24. 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.

25. The physician has 12 months experience on an active kidney inpatient 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.

26. 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.

27. 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.

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

29. 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.

30. 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 12-month 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.