OPTN | UNOS Public Comment Proposal

# Updating Primary Kidney Transplant Physician Requirements

*OPTN/UNOS Membership and Professional Standards Committee*

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# Updating Primary Kidney Transplant Physician Requirements

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| *Affected Policies:* | *Include specific Policy/Bylaw sections with title* |
| *Sponsoring Committee:* | *Membership and Professional Standards* |
| *Public Comment Period:* | *August 14, 2016 – October 14, 2016* |

## Executive Summary

Fellowship training requirements have historically served as the foundation for key personnel requirements in OPTN/UNOS Bylaws. Primary kidney transplant physician requirements in the Bylaws have not evolved with nephrology fellowship training. For example, the Bylaws currently do not accommodate transplant nephrology fellowships longer than 12 months which have been developed for fellows wishing to pursue transplantation research during their training period, nor do they include requirements pertaining to the evaluation of living donors or potential kidney recipients which are now standard fellowship requirements. The goal of this proposal is to update the Bylaws to better align with transplant nephrology fellowship requirements.

# What problem will this proposal solve?

Fellowship training requirements have generally served as the foundation for key personnel requirements in OPTN/UNOS Bylaws; however, primary transplant kidney physician pathways do not reflect some options and standards currently associated with transplant nephrology fellowships. These proposed changes have the potential to impact the OPTN Strategic Plan key goals of promoting the efficient management of the OPTN, promoting living donor and transplant recipient safety, and improving waitlisted patient, living donor, and transplant recipient outcomes.

# Why should you support this proposal?

The changes presented in this proposal stem directly from recommendations developed by a Joint Societies Working Group (JSWG), and are representative of a collaborative effort between the American Society of Transplantation (AST), the American Society of Transplant Surgeons (ASTS), the North American Transplant Coordinators Organization (NATCO), and the MPSC. These proposed changes incorporate requirements into the primary kidney transplant physician pathways that are currently standard for transplant nephrology fellowships and modify other language to accommodate transplant nephrology fellowships longer than 12 months which have been developed for fellows wishing to pursue transplantation research during their training period. By doing so, these proposed changes will address questions confronted by the MPSC about nephrology transplant fellowship longer than 12 months, which will contribute to the OPTN strategic plan key goal of promoting efficient management of the OPTN. Including additional requirements that are now standards of transplant nephrology fellowship training to qualify as the primary kidney transplant physician are intended to increase living donor and transplant recipient safety and improve outcomes.

# How was this proposal developed?

In 2013, the MPSC created a working group to address a number of aspects in the Bylaws key personnel requirements that had repeatedly been noted as ambiguous, unenforceable, or regularly yielding questions from members of the MPSC. As the MPSC Working Group began making progress on possible solutions to clarify these Bylaws, the Joint Societies Policy Steering Committee met in May 2014 and opted for the formation of a Joint Societies Working Group (JSWG) to address the key personnel Bylaws projects being worked on by the MPSC. One of the key personnel topics pertains to questions about approved transplant fellowship programs, and the MPSC's evaluation of these programs. Preliminary discussion of this topic prompted AST representatives to note a number of deficiencies in OPTN Bylaws Appendix E.3 (Primary Kidney Transplant Physician Requirements) relative to current transplant nephrology fellowship requirements. Examples include the Bylaws specificity of a "twelve-month transplant nephrology fellowship" that does not accommodate transplant nephrology fellowships longer than 12-months that had been developed for fellows wishing to pursue transplantation research during their training period, and the lack of requirements pertaining to the evaluation of potential kidney recipients and living donors which are now standard requirements for transplant nephrology fellowships. AST representatives also pointed out that references to fellowship programs approved by AST are outdated. In 2014, The AST recently formed a new limited liability company to accredit institutions that provide specialty transplant nephrology training- Transplant Nephrology Fellowship Training Accreditation Program, LLC.[1]

The JSWG agreed that these Bylaws should be updated and that it would develop recommendations on this topic during its review of the key personnel requirement topics that it had been charged to address. To develop these recommendation, the JSWG compared the requirements currently included in Appendix E.3 against the eligibility criteria that must be continuously satisfied by a transplant nephrology fellowship

[1] "Announcing Transfer of AST Renal Transplant Fellowship Accreditation Program," accessed June 23, 2016, https://www.myast.org/news/announcing-transfer-ast-renal-transplant-fellowship-accreditation-program

training program that is accredited by the Transplant Nephrology Fellowship Training Accreditation Program, LLC. The JSWG commented on the following:

- *Transplant Nephrology Fellowship "Alternative Pathway"*- The Transplant Nephrology Fellowship Training Accreditation Program provides two pathways for transplant nephrology fellowship programs to follow: a standard, one-year transplant nephrology fellowship, and an "alternative pathway." The "alternative pathway" was designed for nephrology fellows who have a more in depth academic interest in transplantation and wish to pursue active research related to transplantation over the span of a two or three year training period. The primary kidney transplant physician fellowship pathway in the OPTN Bylaws only references the standard nephrology fellowship, "Physicians can meet the training requirements for a primary kidney transplant physician during a separate 12-month transplant nephrology fellowship," and is silent on fellowships that last longer than 12 months (i.e., the Program's "alternative pathway").

  The JSWG believes that individuals who complete the transplant nephrology fellowship through the "alternative pathway," and who meet all other requirements, should be eligible to qualify as a kidney program's primary transplant physician through the fellowship pathway in the OPTN Bylaws. The group considered creating another fellowship pathway in the Bylaws that was directly related to the alternative pathway for transplant nephrology fellowships. Ultimately, the JSWG decided that this was unnecessary. Instead, the JSWG thought the current primary kidney transplant physician fellowship pathway should be modified to accommodate individuals who have completed their transplant nephrology fellowship through the "alternative pathway." Besides being more general about the time to complete one's fellowship, the volume requirements pertaining to caring for kidney recipients needs to reflect the higher number of cases expected of physicians going through the "alternative pathway" (i.e., care of at least 30 transplant patients for an additional period of three consecutive months).

- *Transplant Patient Case Volumes*- Bylaws currently require that 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." In addition to the primary care of 30 or more newly transplanted kidney recipients, the Transplant Nephrology Fellowship Training Accreditation Program's list of eligibility criteria also requires, "experience evaluating 25 potential kidney transplant recipients, and 10 potential living donors." The Bylaws do not currently include similar requirements.

  The JSWG thought that the experience reflected by both of these requirements is valuable, important, and reasonable to expect of a kidney program's primary transplant physician. To make this a consistent standard across all kidney transplant programs, the JSWG recommended adding similar requirements to the Bylaws.

- *Renal Transplant Biopsies*- Transplant nephrology fellows are required to, "perform a minimum of 10 renal transplant biopsies during the training period;" however, OPTN Bylaws do not include a similar requirement. JSWG members pointed out that the necessity of this requirement in a transplant nephrology fellowship is questioned by some members of the community, but that it remains a fellowship requirement. Other member suggested that transplant nephrologists do not exclusively perform renal biopsies across the community, noting this is done by surgeons at some programs and by transplant staff teams at other programs. The JSWG felt this was an important consideration because an additional biopsy requirement may limit the ability of some programs to propose a primary transplant kidney physician who meets all requirements in the OPTN Bylaws. Considering this, and other questions in the community about requiring transplant nephrology fellows to perform renal biopsies, the JSWG did not think it would be appropriate to add a similar requirement to the OPTN Bylaws.

To summarize its final recommendations, the JSWG recommended modifying Bylaws Appendix E.3 to require that primary transplant kidney physicians must have: evaluated 25 potential kidney recipients and

10 living kidney donors, and to accommodate physicians that opt to complete their transplant nephrology fellowship through the Transplant Nephrology Fellowship Training Accreditation Program's "alternative pathway."

Upon the MPSC's endorsement of these recommendations, it worked to draft Bylaws modifications to incorporate these recommendations. In doing so, questions were raised about the applicability of these recommendations to Appendices E.3.C (Three-year Pediatric Nephrology Fellowship Pathway), E.3.D (Twelve-month Pediatric Transplant Nephrology Fellowship Pathway), and E.3.E (Combined Pediatric Nephrology Training and Experience Pathway).

The MPSC conferred with a number of pediatric transplant nephrologists (including past and present MPSC and OPTN/UNOS Pediatric Transplantation Committee members), who agreed that these changes should also be made to those primary kidney transplant physician pathways that focus on pediatric transplant nephrologists. Focusing on E.3.D, the MPSC discussed if this pathway was still necessary due to the increasing rarity of these types of fellowships. The MPSC considered individuals who may have previously qualified through this pathway and would continue to rely on it to qualify as a primary kidney transplant physician. This consideration and the potential unintended consequences of deleting this pathway relative to the small value that may be gained by doing this, led the MPSC to decide that this pathway should remain in the Bylaws. With that decision, it was suggested that E.3.D should allow experience gained during one's three-year pediatric nephrology fellowship and the 12-month pediatric transplant nephrology fellowship (which would immediately follow one's three-year pediatric nephrology fellowship) to count towards the additional requirements proposed to be added. The group of pediatric transplant nephrologists consulted and the MPSC both agreed that this was necessary because it would likely be challenging for an individual to meet these proposed requirements during a 12-month pediatric transplant nephrology fellowship due to the relatively low number of pediatric transplants that occur.

The relatively low number of pediatric transplants also prompted other proposed modifications within Appendices E.3.C, E.3.D, and E.3.E. A number of concerns have been raised about the second usage of the word "newly" in the experience requirements captured by the language provided below:

"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."

Considering the relatively low volume of pediatric transplants that are performed, there are concerns that it would be extremely challenging for most to have followed 30 "newly" transplanted kidney recipients during a three-year pediatric nephrology fellowship or a twelve-month pediatric transplant nephrology fellowship. To address these concerns, the MPSC proposes deleting the second "newly," thereby allowing the follow-up of any pediatric transplant recipient- regardless of how long ago they were transplanted – to count towards this requirement. In addition to the volume concerns, this is thought to be particularly appropriate for pediatric recipients as their follow-up care is often more challenging as younger recipients progress through adolescence into early adulthood.

The MPSC also considered the applicability of these new requirements to Appendix E.3.G (Conditional Approval for Primary Transplant Physician). Conditional pathways for primary transplant physicians include the same requirements as the other primary transplant physician pathways for each respective organ, except conditional pathways only require half of the case volume experience that is required in each respective primary transplant physician clinical experience pathway. The MPSC considered whether E.3.G should only require half of the proposed potential recipient and living donor evaluations, or if it should include the full requirement of 25 evaluations of potential kidney recipients and 10 evaluations of potential living donors as proposed for the other pathways. The MPSC did not believe that the evaluation of potential kidney recipients and living donors would frequently be a limiting factor for individuals to qualify as a primary kidney transplant physician, and proposed that E.3.G require the same number of potential kidney recipient and living donor evaluations as what is being added to the other primary kidney transplant physician pathways.

## How well does this proposal address the problem statement?

These proposed Bylaws changes will align primary kidney transplant physician requirements with transplant nephrology fellowship requirements allowing the Bylaws to better reflect the current training and experience standards of transplant nephrology. With the exception of requiring a certain number of kidney biopsies and observing a living donor kidney transplant, the proposed changes incorporate all other relevant requirements that must be continually met by transplant programs accredited by the Transplant Nephrology Fellowship Training Accreditation Program that are not already in the Bylaws. 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.

A potential weakness of this proposal is that the additional requirements regarding the evaluation of potential living donors and kidney recipients does increase the expectations to qualify as a primary kidney transplant physician. This higher standard may be problematic for some, and in the most drastic of situations, may cause the closure of some kidney programs who cannot find appropriate staff that fulfill these requirements. The MPSC believes that these new requirements should not be burdensome for appropriately qualified individuals and any reduced access due to kidney program closure would be highly unlikely. Ultimately, the MPSC believes such a risk is worthwhile relative to the value of these additional requirements.

# Which populations are impacted by this proposal?

As primary kidney transplant physicians are required at every kidney transplant program, this proposal has the potential to improve the quality of care for all kidney transplant patients; however, the effect realized by any individual patient or patient population is likely to be negligible as these changes are primarily operational in nature.

# 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:* Adding primary kidney transplant physician requirements to the Bylaws has the potential to impact equity in access to transplants. Additional requirements may not be attainable for certain programs, which could eventually result in the approval of fewer transplant programs. Conversely, proposed Bylaws to accommodate kidney physicians who completed their transplant nephrology fellowship through the Transplant Nephrology Fellowship Training Accreditation Program's alternative pathway expand who can qualify as a primary kidney transplant physician, which theoretically could increase kidney transplant access. Independently, each of these changes are likely to have a negligible impact on transplant access, and this is especially the case if considering the combined impact of these changes.

*Improve waitlisted patient, living donor, and transplant recipient outcomes:* The primary purpose of key personnel Bylaws is to establish a standard that each transplant program is led by individuals who have sufficient training and experience in organ transplantation. Raising the standard to qualify as a primary kidney transplant physician could potentially improve waitlisted patient, living donor, and transplant recipient outcomes.

*Promote living donor and transplant recipient safety:* The primary purpose of key personnel Bylaws is to establish a standard that each transplant program is led by individuals who have sufficient training and experience in organ transplantation. Raising the standard to qualify as a primary kidney transplant physician could potentially improve living donor and transplant recipient safety.

*Promote the efficient management of the OPTN:* These changes will have some impact towards promoting the efficient management of the OPTN. These efficiencies will primarily be gained as member

questions and MPSC discussions about whether someone who completed a transplant nephrology fellowship in more than 12 months can qualify as a primary kidney transplant physician through Appendix E.3.A. This will be accomplished by modifying the Bylaws to accommodate fellowship completion through the Transplant Nephrology Fellowship Training Accreditation Program's alternative pathway.

# How will the OPTN implement this proposal?

If public comment on this proposal is favorable, the MPSC would likely present these changes for the OPTN/UNOS Board of Directors' consideration at its December 2016 meeting. Assuming the Board adopts these changes, members will be alerted through a policy notice. Necessary updates to the membership application prompted by these changes would require approval by the Office of Management and Budget (OMB) prior to the implementation of these Bylaws. After application changes have been approved by OMB, the OPTN will notify the membership of the implementation date for these Bylaws. All applications received on or after this implementation date, would be evaluated by the MPSC considering these new Bylaws.

# How will members implement this proposal?

No immediate action will be required of members upon the implementation of these proposed changes. Membership and key personnel change applications for kidney programs submitted on or after the implementation of these proposed changes will be evaluated relative to these requirements.

## Transplant Hospitals

Upon the adoption and implementation of these changes, primary kidney transplant physician applicants will be required to meet all the requirements of whichever OPTN Bylaws pathway they are applying through.

## Will this proposal require members to submit additional data?

This proposal does not require additional data collection.

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

All membership and key personnel applications proposing a primary kidney transplant physician that are received on or after these proposed Bylaws are implemented will be evaluated against these requirements. Primary kidney transplant physicians who opted to complete their fellowship in more than 12 months, and who are applying through the Appendix E.3.A will also need to document that the applicant was directly involved in outpatient follow-up of at least 30 kidney recipients for an additional period of 3 consecutive months. This will be in addition to the primary care of 30 or more newly transplanted kidney recipients followed for a minimum of 3 months from the time of transplant that is currently required. These cases will need to be documented in a log that includes the date of transplant, the recipient medical record number (or other unique identifier that can be verified by the OPTN Contractor), and the director of the training program's or the transplant program's primary transplant physician's signature.

All primary kidney transplant physician applicants will also be expected to document the evaluation of 25 potential kidney recipients and 10 potential living kidney donors. The potential kidney recipient evaluations must be documented in a log that lists each evaluation date and is signed by program director, division Chief, or department Chair from the program where the applicant gained the experience. Likewise, the 10 potential living donor evaluations must be documented in a log that includes each evaluation date, the potential living donor's medical record number (or other unique identifier than can be

verified by the OPTN Contractor), and a signature from the program director, division Chief, or department Chair from the program where the applicant gained this experience.

# How will the sponsoring Committee evaluate whether this proposal was successful post implementation?

The impact of these changes will be evaluated as the MPSC receives primary kidney transplant physician key personnel applications. The MPSC will assess deficiencies in primary kidney transplant physician applications, as well as the type and frequency of questions raised about these new requirements.

# Policy or Bylaws Language

Proposed new language is underlined (example) and language that is proposed for removal 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 than can be verified by the OPTN Contractor. This potential living kidney donor evaluation log must be signed by the director of the training program or the transplant program's primary transplant physician.
~~3.~~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).

~~4~~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.

~~5~~7. The physician must have observed at least 3 kidney transplants. The observation of these transplants must be documented in a log that includes the transplant date, donor type, and medical record number or other unique identifier that can be verified by the OPTN Contractor.

~~6~~8. The following letters are submitted directly to the OPTN Contractor:

a. A letter from the director of the training program and the supervising qualified kidney transplant physician verifying that the physician has met the above requirements and is qualified to direct a kidney transplant program.

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

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

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

## B. Clinical Experience Pathway

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

1. The physician has been directly involved in the primary care of 45 or more newly transplanted kidney recipients and continued ~~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.

~~2~~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.

~~3~~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.

~~4~~6. The physician must have observed at least 3 kidney transplants. The observation of these transplants must be documented in a log that includes the transplant date, donor type, and medical record number or other unique identifier that can be verified by the OPTN Contractor.

~~5~~7. The following letters are submitted directly to the OPTN Contractor:

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

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

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

## C. Three-year Pediatric Nephrology Fellowship Pathway

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

1. During the 3-year training period the physician was directly involved in the primary care of 10 or more newly transplanted kidney recipients for at least 6 months from the time of transplant

and followed 30 ~~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. During the fellowship period, the physician was directly involved in the evaluation of 10 potential living kidney donors, including participation in selection committee meetings. These potential living kidney donor evaluations must be documented in a log that includes each evaluation date and the potential living kidney donor's medical record number or other unique identifier than can be verified by the OPTN Contractor. This potential living kidney donor evaluation log must be signed by the director of the training program or the transplant program's primary transplant physician.

~~3~~5. 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~~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.

~~5~~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.

~~6~~8. The following letters are submitted directly to the OPTN Contractor:

a. A letter from the director and the supervising qualified transplant physician and surgeon of the fellowship training program verifying that the physician has met the above requirements and is qualified to 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. 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 10 potential living kidney donors, including participation in selection committee meetings. These potential living kidney donor evaluations must be documented in a log that includes each evaluation date and the potential living kidney donor's medical record number or other unique identifier than can be verified by the OPTN Contractor. This potential living kidney donor evaluation log must be signed by the director of the training program or the transplant program's primary transplant physician.
~~4~~6. 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~~7. 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~~8. 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~~9. 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 <u>for at least 6 months from the time of transplant</u> 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 is documented in a log that includes each evaluation date and be signed by the program director, division Chief, or department Chair from the program where the physician gained this experience.

5. The physician 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~~6. 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~~7. 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~~8. 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~~9. 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 ~~K~~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
4. ~~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.
5. ~~3~~. 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.
6. ~~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~~7. The physician must have observed at least 3 kidney transplants. The observation of these transplants must be documented in a log that includes the transplant date, donor type, and medical record number or other unique identifier that can be verified by the OPTN Contractor.

~~6~~8. The program has established and documented a consulting relationship with counterparts at another kidney transplant program.

~~7~~9. The transplant program submits activity reports to the OPTN Contractor every 2 months describing the transplant activity, transplant outcomes, physician recruitment efforts, and other operating conditions as required by the MPSC to demonstrate the ongoing quality and efficient patient care at the program. The activity reports must also demonstrate that the physician is making sufficient progress to meet the required involvement in the primary care of 45 or more kidney transplant recipients, or that the program is making sufficient progress in recruiting a physician who meets all requirements for primary kidney transplant physician and who will be on site and approved by the MPSC to assume the role of primary physician by the end of the 12 month conditional approval period.

~~8~~10. The following letters are submitted directly to the OPTN Contractor:

a. A letter from the supervising qualified transplant physician and surgeon who were directly involved with the physician documenting the physician's experience and competence.

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

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

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

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

If the program is unable to demonstrate that it has an individual on site who can meet the requirements as described in *Sections E.3.A through E.3.F* above at the end of the 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.

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