

Updating Primary Kidney Transplant Physician Requirements

OPTN/UNOS Membership and Professional Standards Committee

*Prepared by: Chad Waller
UNOS Member Quality Department*

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Updating Primary Kidney Transplant Physician Requirements

Affected Bylaws: E.3 (Primary Kidney Transplant Physician Requirements)
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.

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

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>

- *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 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 requirements 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.

Was this proposal changed in response to public comment?

Yes. In response to public comment feedback, the MPSC made one post-public comment modification to the originally proposed Bylaws changes, and voted (35- support, 1- oppose, 0- abstentions) to send the modified proposal for the OPTN/UNOS Board of Directors consideration during its December 2016 meeting. The post-public comment change is:

1. *Remove the evaluation of 10 potential living donors requirement from the primary kidney transplant physician "pediatric pathways"- OPTN Bylaws 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 agreed to make this change in response to public comment feedback that indicated living donor evaluations are outside the scope of pediatric nephrology training and should not be expected for pediatric programs. The Committee discussed the importance of individuals leading kidney programs – including programs that predominantly transplant pediatric patients – being familiar with the living donor process. Although the originally proposed changes to these pediatric pathways are intended to reflect a familiarity and understanding of the process, and not necessarily independently conducted living donor evaluation and determinations, the MPSC appreciates the commenters concerns. The Committee did not want to create a possible unintended consequence where numerous pediatric nephrologists believed they did not qualify as a primary kidney transplant physician due to the potential living donor evaluation requirement, and thereby possibly creating staffing difficulties for kidney programs that predominantly transplant pediatric patients. The MPSC suggested modifying the living donor evaluation requirement in the pediatric pathways to state that individuals applying through these pathways "should" have this potential living donor evaluation experience, but eventually agreed this was not an ideal approach with respect to the unenforceability of "should" and keeping the key personnel Bylaws focused on absolute requirements. As such, the Committee ultimately agreed to remove the evaluation of 10 potential living donors requirement from the primary kidney transplant physician "pediatric pathways" as a post-public comment modification.

This proposal also received additional feedback that did not prompt post-public comment modifications. The MPSC's review of these comments yielded the following responses:

- *Support for the proposal.*
 - The MPSC appreciates the commenters' review and support of this proposal.
- Concerns that it may be logistically difficult to obtain the necessary signatures for case volume logs due to the applicant serving in the same roles as the expected signatory.
 - This requirement is intended to achieve a validation of the experiences documented in these logs through the signature of a leadership member of the transplant program where the individual gained this experience. The MPSC's discussion noted that similar language is currently used throughout the Bylaws, and the MPSC was not confident that this language needed to be modified as the Committee is unaware of it causing members' problems when completing OPTN membership applications.
- Concerns that "direct involvement" and the evaluation date in the proposed potential recipient and living donor evaluations is somewhat vague.
 - "Directly involved" is currently used throughout the key personnel Bylaws for primary physicians and across all organs, and is meant to reflect having knowledge and familiarity with the process. The MPSC sees "directly involved" as some participation in these processes, and is different than independently conducting potential recipient or living donor evaluations. Participation at selection committee and donor presentation meetings are common examples of what is expected regarding "directly involved." Along these lines, the required "evaluation date" should indicate the date that the applicant took part in the evaluation process for the particular potential recipient or living donor cited on the log.
- Noting explicit separation between potential recipient and potential living donor evaluations that occurs at some programs to keep these two processes independent of one another, questions were raised regarding how nephrologists in these situations would be expected to meet these proposed requirements which expect involvement with potential living donors and potential transplant recipients.
 - The MPSC believes that familiarity with the living donor evaluation process and potential recipient evaluation process is important knowledge and experience for individuals that are intending to lead a kidney transplant program as the primary transplant physician. The MPSC certainly does not encourage dissolving appropriate boundaries that have been established for living donor and recipient safety so that these new requirements can be fulfilled, but it does believe that this experience can be obtained without jeopardizing or undermining systematic precautions. "Directly involved" is meant to reflect that the applicant has some knowledge and familiarity with these processes, and is different than independently conducting potential recipient or living donor evaluations. Participation at selection committee and donor presentation meetings are common examples of what is expected regarding "directly involved." The MPSC believes this participation can occur without infringing upon the necessary independence between potential living donor evaluation and care and potential transplant recipients evaluation and care.
- Concerns about including these new requirements in the clinical experience pathway, due to the potential complications in documenting this experience if it occurred numerous years in the past.
 - The MPSC appreciates the review and consideration of this proposal, but believes that familiarity with the living donor evaluation process and potential recipient evaluation process is important knowledge and experience for individuals that are intending to lead a kidney transplant program as the primary transplant physician. The Committee did not support including these new requirements in the primary kidney transplant physician

training pathway and not expecting this same standard for those applying through the clinical experience pathway.

- A request for automatic approval of individuals who have previously been approved as key personnel.
 - The MPSC has historically been opposed to this approach for transplant hospital key personnel for multiple reasons. First, some current key personnel may not currently meet all requirements upon submission of another application. For example, someone who currently serves as transplant program key personnel and has let their board certification lapse. Additionally, information provided within a hospital's application is ultimately the property of that applying hospital, and therefore it is not appropriate for the OPTN/MPSC to simply reference past hospital submissions to evaluate a separate hospital's application.
- A request to decrease the number of required evaluations of potential kidney recipients performed by an individual to be considered for the primary transplant physician of a pediatric kidney transplant program. The Pediatric Committee suggested 15 or 20, and the Children's Hospital of Pittsburgh suggested 20.
 - With both commenters suggesting a modification down to 20 potential kidney recipient evaluation, the Committee focused on this possibility for the primary kidney transplant physician "pediatric pathways." Ultimately, the MPSC did not believe reducing the proposed potential kidney recipient evaluation requirement by five was significant. As such, and with respect to consistency across all of the primary kidney physician pathways, key personnel requirements historically stemming from established fellowship requirements, recognizing that applicants can draw from experience over a five year period for the clinical experience pathway, and because this requirement focuses on *potential* transplant recipients, the Committee did not support reducing this requirement in the primary kidney transplant physician "pediatric pathways."
- A request to remove the requirement that the "location of the donor" must be included in the logs that document primary transplant physician donor evaluations and primary transplant surgeon donor procurements.
 - This proposal did not originally address the requirement that key personnel donor logs must include the "location of the donor" but a comment from AST brought this to the Committee's attention. Discussion of this feedback prompted committee members to echo that this information can be difficult to obtain, particularly when citing cases years in the past, and question what the real value of requiring this information is. Unable to justify why this information is absolutely needed, and considering the difficulty to obtain this information, the Committee expressed a strong desire to remove this requirement. Although this proposal originally focused on primary kidney transplant physician Bylaws, the Committee recognized this as an issue that impacts primary surgeon and primary physician applicants across all organs. The Committee supported removing "location of the donor" as it pertains to key personnel donor logs from the entirety of the Bylaws. Because such a change is out of scope for this proposal, the MPSC will work with the OPTN/UNOS Board of Directors to clarify the documentation requirements separately.

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?

1. *Increase the number of transplants:* There is no impact to this goal.
2. *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 expands 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.
3. *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.
4. *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.
5. *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?

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 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~~).

RESOLVED, that changes to Bylaws Appendix E.3 (Primary Kidney Transplant Physician Requirements), are hereby approved, effective pending implementation and notice to members.

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

43 given any grace period and will be referred to the MPSC for appropriate action according to *Appendix*
44 *L* of these Bylaws.

- 45
46 5. The physician must have completed at least one of the pathways listed below:
47
48 a. The ~~12-month~~ transplant nephrology fellowship pathway, as described in *Section E.3.A. ~~Twelve-~~*
49 *month Transplant Nephrology Fellowship Pathway* below.
50 b. The clinical experience pathway, as described in *Section E.3.B. Clinical Experience Pathway*
51 below.
52 c. The 3-year pediatric nephrology fellowship pathway, as described in *Section E.3.C. Three-year*
53 *Pediatric Nephrology Fellowship Pathway* below.
54 d. The 12-month pediatric transplant nephrology fellowship pathway, as described in *Section E.3.D.*
55 *Twelve-month Pediatric Transplant Nephrology Fellowship Pathway* below.
56 e. The combined pediatric nephrology training and experience pathway, as described in *Section*
57 *E.3.E. Combined Pediatric Nephrology Training and Experience Pathway* below.
58 f. The conditional approval pathway, as described in *Section E.3.F. Conditional Approval for*
59 *Primary Transplant Physician* below, if the primary kidney transplant physician changes at an
60 approved kidney transplant program.
61

62 **A. ~~Twelve-month~~ Transplant Nephrology Fellowship Pathway**

63 Physicians can meet the training requirements for a primary kidney transplant physician during a
64 separate ~~12-month~~ transplant nephrology fellowship if the following conditions are met:
65

- 66 1. The physician completed at least 12 consecutive months of specialized training in
67 transplantation under the direct supervision of a qualified kidney transplant physician and
68 along with a kidney transplant surgeon at a kidney transplant program that performs 30 or
69 more transplants each year. The training must have included at least 6 months of clinical
70 inpatient transplant service. The remaining time must have consisted of transplant-related
71 experience, such as experience in a tissue typing laboratory, on another solid organ
72 transplant service, or conducting basic or clinical transplant research.
73 2. During the fellowship period, the physician was directly involved in the primary care of 30 or
74 more newly transplanted kidney recipients and continued ~~to~~ the outpatient follow-up of these
75 recipients for a minimum of 3 months from the time of transplant. If the physician's fellowship
76 was longer than 12 months, the physician also must have been directly involved in the
77 outpatient follow-up of at least 30 kidney recipients for an additional period of 3 consecutive
78 months. The care must be documented in a log that includes the date of transplant and the
79 recipient medical record number or other unique identifier that can be verified by the OPTN
80 Contractor. This recipient log must be signed by the director of the training program or the
81 transplant program's primary transplant physician.
82 3. During the fellowship period, the physician was directly involved in the evaluation of 25
83 potential kidney recipients, including participation in selection committee meetings. These
84 potential kidney recipient evaluations must be documented in a log that includes each
85 evaluation date and is signed by the director of the training program or the transplant
86 program's primary transplant physician.
87 4. During the fellowship period, the physician was directly involved in the evaluation of 10
88 potential living kidney donors, including participation in selection committee meetings. These
89 potential living kidney donor evaluations must be documented in a log that includes each
90 evaluation date and the potential living kidney donor's medical record number or other unique
91 identifier than can be verified by the OPTN Contractor. This potential living kidney donor

92 evaluation log must be signed by the director of the training program or the transplant
93 program's primary transplant physician.

94 3-5. The physician has maintained a current working knowledge of kidney transplantation, defined
95 as direct involvement in kidney transplant care in the last 2 years. This includes the
96 management of patients with end stage renal disease, the selection of appropriate recipients
97 for transplantation, donor selection, histocompatibility and tissue typing, immediate
98 postoperative patient care, the use of immunosuppressive therapy including side effects of
99 the drugs and complications of immunosuppression, differential diagnosis of renal
100 dysfunction in the allograft recipient, histological interpretation of allograft biopsies,
101 interpretation of ancillary tests for renal dysfunction, and long term outpatient care. The
102 curriculum for obtaining this knowledge should be approved by the Residency Review
103 Committee for Internal Medicine (RRC-IM) of the Accreditation Council for Graduate Medical
104 Education (ACGME).

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

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

113 68. The following letters are submitted directly to the OPTN Contractor:

- 114 a. A letter from the director of the training program and the supervising qualified kidney
115 transplant physician verifying that the physician has met the above requirements and is
116 qualified to direct a kidney transplant program.
- 117 b. A letter of recommendation from the fellowship training program's primary physician and
118 transplant program director outlining the physician's overall qualifications to act as a
119 primary transplant physician, as well as the physician's personal integrity, honesty, and
120 familiarity with and experience in adhering to OPTN obligations and compliance
121 protocols, and any other matters judged appropriate. The MPSC may request additional
122 recommendation letters from the primary physician, primary surgeon, director, or others
123 affiliated with any transplant program previously served by the physician, at its discretion.
- 124 c. A letter from the physician that details the training and experience the physician has
125 gained in kidney transplantation.

126
127 The training requirements outlined above are in addition to other clinical requirements for general
128 nephrology training.
129

130 **B. Clinical Experience Pathway**

131 A physician can meet the requirements for a primary kidney transplant physician through
132 acquired clinical experience if the following conditions are met:
133

- 134 1. The physician has been directly involved in the primary care of 45 or more newly transplanted
135 kidney recipients and continued to ~~to~~ the outpatient follow-up of these recipients for a minimum
136 of 3 months from the time of transplant. This patient care must have been provided over a 2
137 to 5-year period on an active kidney transplant service as the primary kidney transplant
138 physician or under the direct supervision of a qualified transplant physician and in conjunction
139 with a kidney transplant surgeon at a designated kidney transplant program. The care must
140 be documented in a log that includes the date of transplant and recipient medical record

- 141 number or other unique identifier that can be verified by the OPTN Contractor. The recipient
142 log should be signed by the program director, division Chief, or department Chair from the
143 program where the physician gained this experience.
- 144 2. The physician was directly involved in the evaluation of 25 potential kidney recipients,
145 including participation in selection committee meetings. These potential kidney recipient
146 evaluations must be documented in a log that includes each evaluation date and is signed by
147 the program director, division Chief, or department Chair from the program where the
148 physician gained this experience.
- 149 3. The physician was directly involved in the evaluation of 10 potential living kidney donors,
150 including participation in selection committee meetings. These potential living kidney donor
151 evaluations must be documented in a log that includes each evaluation date and the potential
152 living kidney donor's medical record number or other unique identifier than can be verified by
153 the OPTN Contractor. This potential living kidney donor evaluation log must be signed by the
154 program director, division Chief, or department Chair from the program where the physician
155 gained this experience.
- 156 24. The physician has maintained a current working knowledge of kidney transplantation, defined
157 as direct involvement in kidney transplant patient care over the last 2 years. This includes the
158 management of patients with end stage renal disease, the selection of appropriate recipients
159 for transplantation, donor selection, histocompatibility and tissue typing, immediate
160 postoperative patient care, the use of immunosuppressive therapy including side effects of
161 the drugs and complications of immunosuppression, differential diagnosis of renal
162 dysfunction in the allograft recipient, histological interpretation of allograft biopsies,
163 interpretation of ancillary tests for renal dysfunction, and long term outpatient care.
- 164 35. The physician must have observed at least 3 kidney procurements, including at least 1
165 deceased donor and 1 living donor. The physician must have observed the evaluation,
166 donation process, and management of these donors. These observations must be
167 documented in a log that includes the date of procurement, location of the donor, and Donor
168 ID.
- 169 46. The physician must have observed at least 3 kidney transplants. The observation of these
170 transplants must be documented in a log that includes the transplant date, donor type, and
171 medical record number or other unique identifier that can be verified by the OPTN Contractor.
- 172 57. The following letters are submitted directly to the OPTN Contractor:
- 173 a. A letter from the qualified transplant physician or the kidney transplant surgeon who has
174 been directly involved with the proposed physician documenting the physician's
175 experience and competence.
- 176 b. A letter of recommendation from the primary physician and transplant program director at
177 the transplant program last served by the physician outlining the physician's overall
178 qualifications to act as a primary transplant physician, as well as the physician's personal
179 integrity, honesty, and familiarity with and experience in adhering to OPTN obligations
180 and compliance protocols, and any other matters judged appropriate. The MPSC may
181 request additional recommendation letters from the primary physician, primary surgeon,
182 director, or others affiliated with any transplant program previously served by the
183 physician, at its discretion.
- 184 c. A letter from the physician that details the training and experience the physician has
185 gained in kidney transplantation.

C. Three-year Pediatric Nephrology Fellowship Pathway

186
187
188 A physician can meet the requirements for primary kidney transplant physician by completion of 3

189 years of pediatric nephrology fellowship training as required by the American Board of Pediatrics
190 in a program accredited by the Residency Review Committee for Pediatrics (RRC-Ped) of the
191 ACGME. The training must contain at least 6 months of clinical care for transplant patients, and
192 the following conditions must be met:

- 193
- 194 1. During the 3-year training period the physician was directly involved in the primary care of 10
195 or more newly transplanted kidney recipients for at least 6 months from the time of transplant
196 and followed 30 ~~newly~~ transplanted kidney recipients for at least 6 months ~~from the time of~~
197 ~~transplant~~, under the direct supervision of a qualified kidney transplant physician and in
198 conjunction with a qualified kidney transplant surgeon. The pediatric nephrology program
199 director may elect to have a portion of the transplant experience completed at another kidney
200 transplant program in order to meet these requirements. This care must be documented in a
201 log that includes the date of transplant, and the recipient medical record number or other
202 unique identifier that can be verified by the OPTN Contractor. This recipient log must be
203 signed by the training program's director or the primary physician of the transplant program.
- 204 2. The experience caring for pediatric patients occurred with a qualified kidney transplant
205 physician and surgeon at a kidney transplant program that performs an average of at least 10
206 pediatric kidney transplants a year.
- 207 3. During the fellowship period, the physician was directly involved in the evaluation of 25
208 potential kidney recipients, including participation in selection committee meetings. These
209 potential kidney recipient evaluations must be documented in a log that includes each
210 evaluation date and is signed by the director of the training program or the transplant
211 program's primary transplant physician.
- 212 34. The physician has maintained a current working knowledge of kidney transplantation, defined
213 as direct involvement in kidney transplant patient care over the last 2 years. This includes the
214 management of pediatric patients with end-stage renal disease, the selection of appropriate
215 pediatric recipients for transplantation, donor selection, histocompatibility and tissue typing,
216 immediate post-operative care including those issues of management unique to the pediatric
217 recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the
218 pediatric recipient including side-effects of drugs and complications of immunosuppression,
219 the effects of transplantation and immunosuppressive agents on growth and development,
220 differential diagnosis of renal dysfunction in the allograft recipient, manifestation of rejection
221 in the pediatric patient, histological interpretation of allograft biopsies, interpretation of
222 ancillary tests for renal dysfunction, and long-term outpatient care of pediatric allograft
223 recipients including management of hypertension, nutritional support, and drug dosage,
224 including antibiotics, in the pediatric patient. The curriculum for obtaining this knowledge must
225 be approved by the Residency Review Committee (RRC) -Ped of the ACGME.
- 226 45. The physician must have observed at least 3 kidney procurements, including at least 1
227 deceased donor and 1 living donor. The physician must have observed the evaluation,
228 donation process and management of these donors. These observations must be
229 documented in a log that includes the date of procurement, location of the donor, and Donor
230 ID.
- 231 56. The physician must have observed at least 3 kidney transplants involving a pediatric
232 recipient. The observation of these transplants must be documented in a log that includes the
233 transplant date, donor type, and medical record number or other unique identifier that can be
234 verified by the OPTN Contractor.
- 235 67. The following letters are submitted directly to the OPTN Contractor:

- 236 a. A letter from the director and the supervising qualified transplant physician and surgeon
237 of the fellowship training program verifying that the physician has met the above
238 requirements and is qualified to direct a kidney transplant program.
239 b. A letter of recommendation from the fellowship training program's primary physician and
240 transplant program director outlining the physician's overall qualifications to act as a
241 primary transplant physician, as well as the physician's personal integrity, honesty, and
242 familiarity with and experience in adhering to OPTN obligations, and any other matters
243 judged appropriate. The MPSC may request additional recommendation letters from the
244 primary physician, primary surgeon, director, or others affiliated with any transplant
245 program previously served by the physician, at its discretion.
246 c. A letter from the physician that details the training and experience the physician has
247 gained in kidney transplantation.
248

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

250 The requirements for the primary kidney transplant physician can be met during a separate
251 pediatric transplant nephrology fellowship if the following conditions are met:
252

- 253 1. The physician has current board certification in pediatric nephrology by the American Board
254 of Pediatrics, the Royal College of Physicians and Surgeons of Canada, or is approved by
255 the American Board of Pediatrics to take the certifying exam.
256 2. During the fellowship, the physician was directly involved in the primary care of 10 or more
257 newly transplanted kidney recipients for at least 6 months from the time of transplant and
258 followed 30 newly transplanted kidney recipients for at least 6 months from the time of
259 transplant, under the direct supervision of a qualified kidney transplant physician and in
260 conjunction with a qualified kidney transplant surgeon. The pediatric nephrology program
261 director may elect to have a portion of the transplant experience completed at another kidney
262 transplant program in order to meet these requirements. This care must be documented in a
263 recipient log that includes the date of transplant, and the recipient medical record number or
264 other unique identifier that can be verified by the OPTN Contractor. This log must be signed
265 by the training program director or the primary physician of the transplant program.
266 3. The experience in caring for pediatric patients occurred at a kidney transplant program with a
267 qualified kidney transplant physician and surgeon that performs an average of at least 10
268 pediatric kidney transplants a year.
269 4. During the four years that include the physician's three-year pediatric nephrology fellowship
270 and twelve-month pediatric transplant nephrology fellowship, the physician was directly
271 involved in the evaluation of 25 potential kidney recipients, including participation in selection
272 committee meetings. These potential kidney recipient evaluations must be documented in a
273 log that includes each evaluation date and is signed by the director of the training program or
274 the transplant program's primary transplant physician.
275 45. The physician has maintained a current working knowledge of kidney transplantation, defined
276 as direct involvement in kidney transplant patient care in the past 2 years. This includes the
277 management of pediatric patients with end-stage renal disease, the selection of appropriate
278 pediatric recipients for transplantation, donor selection, histocompatibility and tissue typing,
279 immediate post-operative care including those issues of management unique to the pediatric
280 recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the
281 pediatric recipient including side-effects of drugs and complications of immunosuppression,
282 the effects of transplantation and immunosuppressive agents on growth and development,
283 differential diagnosis of renal dysfunction in the allograft recipient, manifestation of rejection

- 284 in the pediatric patient, histological interpretation of allograft biopsies, interpretation of
285 ancillary tests for renal dysfunction, and long-term outpatient care of pediatric allograft
286 recipients including management of hypertension, nutritional support, and drug dosage,
287 including antibiotics, in the pediatric patient. The curriculum for obtaining this knowledge must
288 be approved by the Residency Review Committee (RRC) -Ped of the ACGME.
- 289 56. The physician must have observed at least 3 kidney procurements, including at least 1
290 deceased donor and 1 living donor. The physician must have observed the evaluation,
291 donation process, and management of these donors. These observations must be
292 documented in a log that includes the date of procurement, location of the donor, and Donor
293 ID.
- 294 67. The physician must have observed at least 3 kidney transplants involving a pediatric
295 recipient. The observation of these transplants must be documented in a log that includes the
296 transplant date, donor type, and medical record number or other unique identifier that can be
297 verified by the OPTN Contractor.
- 298 78. The following letters are submitted directly to the OPTN Contractor:
- 299 a. A letter from the director and the supervising qualified transplant physician and surgeon
300 of the fellowship training program verifying that the physician has met the above
301 requirements and is qualified to become the primary transplant physician of a designated
302 kidney transplant program.
- 303 b. A letter of recommendation from the fellowship training program's primary physician and
304 transplant program director outlining the physician's overall qualifications to act as a
305 primary transplant physician, as well as the physician's personal integrity, honesty, and
306 familiarity with and experience in adhering to OPTN obligations, and any other matters
307 judged appropriate. The MPSC may request additional recommendation letters from the
308 primary physician, primary surgeon, director, or others affiliated with any transplant
309 program previously served by the physician, at its discretion.
- 310 c. A letter from the physician that details the training and experience the physician has
311 gained in kidney transplantation.

313 E. Combined Pediatric Nephrology Training and Experience Pathway

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

- 316
- 317 1. The physician has current board certification in pediatric nephrology by the American Board
318 of Pediatrics, the Royal College of Physicians and Surgeons of Canada, or is approved by
319 the American Board of Pediatrics to take the certifying exam.
 - 320 2. The physician gained a minimum of 2 years of experience during or after fellowship, or
321 accumulated during both periods, at a kidney transplant program.
 - 322 3. During the 2 or more years of accumulated experience, the physician was directly involved in
323 the primary care of 10 or more newly transplanted kidney recipients for at least 6 months
324 from the time of transplant and followed 30 ~~newly~~ transplanted kidney recipients for at least 6
325 months ~~from the time of transplant~~, under the direct supervision of a qualified kidney
326 transplant physician, along with a qualified kidney transplant surgeon. This care must be
327 documented in a recipient log that includes the date of transplant, and the recipient medical
328 record number or other unique identifier that can be verified by the OPTN Contractor. This log
329 must be signed by the training program director or the primary physician of the transplant
330 program.

- 331 4. The physician was directly involved in the evaluation of 25 potential kidney recipients,
332 including participation in selection committee meetings. These potential kidney recipient
333 evaluations must be documented in a log that includes each evaluation date and be signed by
334 the program director, division Chief, or department Chair from the program where the
335 physician gained this experience.
- 336 45. The physician has maintained a current working knowledge of kidney transplantation, defined
337 as direct involvement in kidney transplant patient care during the past 2 years. This includes
338 the management of pediatric patients with end-stage renal disease, the selection of
339 appropriate pediatric recipients for transplantation, donor selection, histocompatibility and
340 tissue typing, immediate post-operative care including those issues of management unique to
341 the pediatric recipient, fluid and electrolyte management, the use of immunosuppressive
342 therapy in the pediatric recipient including side-effects of drugs and complications of
343 immunosuppression, the effects of transplantation and immunosuppressive agents on growth
344 and development, differential diagnosis of renal dysfunction in the allograft recipient,
345 manifestation of rejection in the pediatric patient, histological interpretation of allograft
346 biopsies, interpretation of ancillary tests for renal dysfunction, and long-term outpatient care
347 of pediatric allograft recipients including management of hypertension, nutritional support,
348 and drug dosage, including antibiotics, in the pediatric patient. The curriculum for obtaining
349 this knowledge must be approved by the Residency Review Committee (RRC) -Ped of the
350 ACGME or a Residency Review Committee.
- 351 56. The physician must have observed at least 3 kidney procurements, including at least 1
352 deceased donor and 1 living donor. The physician must have observed the evaluation,
353 donation process, and management of these donors. These observations must be
354 documented in a log that includes the date of procurement, location of the donor, and Donor
355 ID.
- 356 67. The physician must have observed at least 3 kidney transplants involving a pediatric
357 recipient. The observation of these transplants must be documented in a log that includes the
358 transplant date, donor type, and medical record number or other unique identifier that can be
359 verified by the OPTN Contractor.
- 360 78. The following letters are submitted directly to the OPTN Contractor:
- 361 a. A letter from the supervising qualified transplant physician and surgeon who were directly
362 involved with the physician documenting the physician's experience and competence.
- 363 b. A letter of recommendation from the fellowship training program's primary physician and
364 transplant program director outlining the physician's overall qualifications to act as a
365 primary transplant physician, as well as the physician's personal integrity, honesty, and
366 familiarity with and experience in adhering to OPTN obligations, and any other matters
367 judged appropriate. The MPSC may request additional recommendation letters from the
368 primary physician, primary surgeon, Director, or others affiliated with any transplant
369 program previously served by the physician, at its discretion.
- 370 c. A letter from the physician that details the training and experience the physician has
371 gained in kidney transplantation.

372 373 **F. Conditional Approval for Primary Transplant Physician**

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

- 377
- 378 1. The physician has been involved in the primary care of 23 or more newly transplanted kidney
379 recipients, and has ~~followed~~ continued the outpatient follow-up of these patients for at least 3

- 380 months from the time of their transplant. This care must be documented in a recipient log that
381 includes the date of transplant and the medical record number or other unique identifier that
382 can be verified by the OPTN Contractor. This log must be signed by the program director,
383 division chief, or department chair from the transplant program where the experience was
384 gained.
- 385 2. The physician was directly involved in the evaluation of 25 potential kidney recipients,
386 including participation in selection committee meetings. These potential kidney recipient
387 evaluations must be documented in a log that includes each evaluation date and is signed by
388 the program director, division Chief, or department Chair from the program where the
389 physician gained this experience.
- 390 3. The physician was directly involved in the evaluation of 10 potential living kidney donors,
391 including participation in selection committee meetings. These potential living kidney donor
392 evaluations must be documented in a log that includes each evaluation date and the potential
393 living kidney donor's medical record number or other unique identifier than can be verified by
394 the OPTN Contractor. This potential living kidney donor log must and be signed by program
395 director, division Chief, or department Chair from the program where the physician gained
396 this experience.
- 397 24. The physician has maintained a current working knowledge of kidney transplantation, defined
398 as direct involvement in kidney transplant patient care during the last 2 years. This includes
399 the management of patients with end stage renal disease, the selection of appropriate
400 recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate
401 postoperative patient care, the use of immunosuppressive therapy including side effects of
402 the drugs and complications of immunosuppression, differential diagnosis of renal
403 dysfunction in the allograft recipient, histological interpretation of allograft biopsies,
404 interpretation of ancillary tests for renal dysfunction, and long-term outpatient care.
- 405 35. The physician has 12 months experience on an active kidney inpatient transplant service as
406 the primary kidney transplant physician or under the direct supervision of a qualified kidney
407 transplant physician and in conjunction with a kidney transplant surgeon at a designated
408 kidney transplant program. These 12 months of experience must be acquired within a 2-year
409 period.
- 410 46. The physician must have observed at least 3 kidney procurements, including at least 1
411 deceased donor and 1 living donor. The physician must have observed the evaluation,
412 donation process, and management of these donors. These observations must be
413 documented in a log that includes the date of procurement, location of the donor, and Donor
414 ID.
- 415 57. The physician must have observed at least 3 kidney transplants. The observation of these
416 transplants must be documented in a log that includes the transplant date, donor type, and
417 medical record number or other unique identifier that can be verified by the OPTN Contractor.
- 418 68. The program has established and documented a consulting relationship with counterparts at
419 another kidney transplant program.
- 420 79. The transplant program submits activity reports to the OPTN Contractor every 2 months
421 describing the transplant activity, transplant outcomes, physician recruitment efforts, and
422 other operating conditions as required by the MPSC to demonstrate the ongoing quality and
423 efficient patient care at the program. The activity reports must also demonstrate that the
424 physician is making sufficient progress to meet the required involvement in the primary care
425 of 45 or more kidney transplant recipients, or that the program is making sufficient progress in
426 recruiting a physician who meets all requirements for primary kidney transplant physician and
427 who will be on site and approved by the MPSC to assume the role of primary physician by the
428 end of the 12 month conditional approval period.

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

441
442 The 12-month conditional approval period begins on the initial approval date granted to the
443 personnel change application, whether it is interim approval granted by the MPSC subcommittee,
444 or approval granted by the full MPSC. The conditional approval period ends 12 months after the
445 first approval date of the personnel change application.
446

447 The MPSC may consider on a case-by-case basis and grant a 6-month extension to a transplant
448 program that provides substantial evidence of progress toward fulfilling the requirements but is
449 unable to complete the requirements within one year.
450

451 If the program is unable to demonstrate that it has an individual on site who can meet the
452 requirements as described in *Sections E.3.A through E.3.F* above at the end of the 12-month
453 conditional approval period, it must inactivate. The requirements for program inactivation are
454 described in *Appendix K: Transplant Program Inactivity, Withdrawal, and Termination* of these
455 Bylaws.

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