Briefing Paper

Addressing Approved Transplant Fellowship Training Programs

Bylaws

OPTN/UNOS Membership and Professional Standards Committee

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Bylaws

Affected Bylaws:


Sponsoring Committee: Membership and Professional Standards
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Executive Summary

Key personnel training pathways in the Bylaws for kidney and liver transplant programs require that the training occurred at a fellowship program approved by the Membership and Professional Standards Committee (MPSC), and that the MPSC will review training programs “every five years or any time the program director changes.” The MPSC does not regularly review or formally approve transplant training programs, nor has it done so historically. This proposal recommends deleting Bylaws that reference the MPSC’s approval and routine review of transplant fellowship programs to address this discrepancy, while retaining language that validates the rigor of the training program cited by a key personnel applicant applying through one of the Bylaws’ training pathways. The proposal also recommends some clerical changes to simplify these Bylaws sections. Making these proposed changes to the Bylaws supports the OPTN strategic plan goal of promoting the efficient management of the OPTN.
What problem will this proposal address?

There is disparity between what is stated in the Bylaws and what the MPSC actually does when considering the transplant training program of key personnel applicants who apply through one of the Bylaws' training pathways. Key personnel training pathways in the Bylaws for kidney and liver transplant programs require that the training occurred at a fellowship program approved by the MPSC, and that the MPSC will review training programs "every five years or any time the program director changes."

Although the MPSC does review where a key personnel applicant gained their fellowship experience when applying through one of the training pathways, the MPSC does not formally approve or regularly review transplant training programs, nor has it done so historically.

Why should you support this proposal?

This proposal addresses longstanding requirements (the OPTN/UNOS Board of Directors adopted the earliest version of these requirements in November 1987) that establish actions that have never been formally undertaken by the MPSC. This proposal eliminates this discrepancy between the Bylaws and how the MPSC functionally operates, while retaining language to define what types of transplant fellowship training programs are acceptable for the purposes of evaluating prospective primary transplant surgeons or primary transplant physicians who apply through one of the Bylaws key personnel training pathways. Adopting this proposal will effectively align the Bylaws with how the MPSC currently operates during the evaluation of key personnel applicants who apply through one of the training pathways in the Bylaws.

How was this proposal developed?

The Bylaws addressed in this proposal evolved directly from language that the OPTN/UNOS Board of Directors originally adopted in November 1987. The Board adopted these Bylaws to define what constituted an accepted training program for evaluating individuals' qualifications to serve as transplant program key personnel. Prior to the Board's decision in November 1987, key personnel requirements were rather basic; for example, primary transplant surgeons needed to be board certified and have one year of "formal training" and one year of experience at a designated transplant program, or three years of experience at a designated transplant program. In processing these early membership applications, the MPSC recognized a need to develop operational guidelines for defining what constituted "formal training."

Subsequent to the development and usage of these operational guidelines, the MPSC recommended their incorporation in the Bylaws. The Board heeded this recommendation, and adopted the MPSC's "formal training" operational guidelines as Bylaws in November 1987.

The Board originally adopted these basic membership requirements to establish a standard that every transplant program is led by experienced individuals. As the field of transplantation began to develop, little distinction was made between training and experience because transplantation was a new field in which new experiences facilitated new knowledge and training. As transplantation became more commonplace and mature as a medical specialty, it was necessary to distinguish appropriate experience gained through training as compared to experience gained during clinical practice for the purpose of recognizing well-qualified key personnel. During the initial development of these Bylaws in the late eighties, extensive, closely-supervised training was provided through programs approved by the American Society of Transplant Surgeons (ASTS). This is reflected in the "formal training" criteria adopted by the OPTN/UNOS Board of Directors in 1987, which includes automatic approval of programs approved for training by ASTS.

Although most primary transplant surgeon applicants obtain their fellowship training at an ASTS approved program, the OPTN is prohibited from endorsing a single entity or business due to anti-competitive legal considerations. To avoid these concerns, the Bylaws also include explicit requirements that detail necessary components of a non-ASTS approved surgical training program. These Bylaws provide a means other than through an ASTS-approved fellowship program to qualify as a transplant program's primary surgeon through an OPTN Bylaws training pathway.
As transplantation has grown and evolved, so have the requirements in the key personnel Bylaws. Key personnel Bylaws now include organ specific considerations and a number of more detailed requirements. Although the key personnel requirements have increased in number and rigor, the Bylaws originally adopted in November 1987 that detail what “formal training” entails are quite similar to current Bylaws, including an expectation that transplant training programs are reviewed every five years, or when the program director changes.

The MPSC has raised questions about the requirement to review transplant training programs, recognizing that the MPSC does not perform such reviews, nor has it done so historically. Furthermore, the MPSC believes that the logistics and resources necessary to regularly monitor fellowship training program requirements would be significant, and likely duplicative of fellowship evaluations and accreditations performed by other organizations. The disparity between what is required in the Bylaws and how the MPSC actually operates prompted the Committee to review the Bylaws pertaining to transplant fellowship program approval by the MPSC.

As the majority of the problematic Bylaws regarding transplant fellowship approval pertain to abdominal primary transplant surgeons, and considering ASTS’ role in developing surgical transplant fellowship curriculum, the MPSC engaged ASTS representatives to provide its feedback and recommendations for modifying these Bylaws. Discussion yielded agreement that the scope of the proposed changes should be focused on the elimination of problematic Bylaws language regarding the MPSC review and approval process, and other changes that would streamline these sections of the Bylaws. The proposed Bylaws changes to those sections that pertain to primary kidney transplant surgeons, primary open living donor kidney surgeons, primary liver transplant surgeons, primary pancreas transplant surgeons, and primary intestine transplant surgeons provided at the end of this proposal are the product of the recommendations provided by ASTS.

Of these proposed edits, the most significant is the elimination of the problematic language regarding MPSC review and approval of fellowship programs. The remaining proposed deletions reflect the elimination of duplicative requirements found elsewhere in the Bylaws or requirements that are arbitrary and thus unenforceable. The few instances of proposed new language reflects an attempt to communicate more clearly the remaining requirements in these Bylaws pertaining to surgical transplant fellowships.

Following the review of those Bylaws focused on surgical transplant fellowships, the MPSC proceeded to engage representatives from the American Society of Transplantation (AST) to address similar problematic language found in OPTN Bylaws Appendix E.4.B (Transplant Physician Fellowship Training Programs), which addresses fellowship experience cited by primary kidney transplant physician applicants. Conversations with AST yielded similar changes: elimination of the problematic language regarding MPSC review and approval of transplant nephrology fellowships; elimination of requirements that are arbitrary to evaluate or duplicative of requirements established elsewhere in the Bylaws; and addition of language intended to make the remaining requirements clearer (included in these additions are formatting changes to align the structure of Appendix E.4.B with what is proposed for the those sections that focus on abdominal surgical transplant fellowships).

A few of the proposed changes to OPTN Bylaws Appendix E.4.B cannot be appropriately labeled with any of these general themes, and are detailed further here. First, the volume of kidney transplants that the training program must perform has been modified to align with what is currently required by the AST Adult Transplant Nephrology Fellowship Training Accreditation Program (a similar change is also proposed in OPTN Bylaws Appendix E.3.A.). Additionally, it is proposed that the biopsy requirement in Appendix E.4.B.5 be eliminated. This section focuses on fellowship program requirements, not individual fellow requirements, and the MPSC believes fellow-specific requirements should be removed from this section. This proposal does not include this requirement elsewhere in the Bylaws, as the inclusion of a biopsy requirement was specifically considered, and ultimately not proposed, with the MPSC’s proposal to

1 http://www.txnephaccreditation.org/list-eligibility-criteria
update the primary kidney transplant physician Bylaws that it distributed for public comment during fall 2016, and that the OPTN/UNOS Board of Directors adopted in December 2016.²

Review of these Bylaws by AST also prompted questions about language that requires transplant medicine fellowship curriculum to be approved by the respective Residency Review Committee (RRC) of the Accreditation Council for Graduate Medical Education (ACGME). Nephrologists representing AST indicated that the RRC/ACGME do not have a role in setting transplant fellowship curriculum, to the extent outlined in these Bylaws, for either nephrology or pancreas physicians. Feedback requested from pediatric transplant nephrologists echoed this sentiment as it pertains to pediatric transplant nephrology fellowships. Considering this guidance, the proposal recommends deleting these references to RRC/ACGME curriculum approval in OPTN Bylaws Appendixes E.3.A, E.3.D, E.3.E, E.5.C, and G.3.A. It is important to note that this proposal does not include changes to RRC/ACGME program accreditation requirements found in OPTN Bylaws Appendix E.3.C and F.3.C (one reference is deleted in E.3.C, but only because it is duplicative of similar language found earlier in that section that will remain). These sections of the Bylaws establish a training pathway for individuals who completed a three-year pediatric nephrology fellowship and a three-year pediatric gastroenterology fellowship, respectively. As the RRC/ACGME does establish fellowship program requirements for these specialties, the MPSC believes that it is appropriate to retain these references in these sections of the Bylaws.³,⁴

Finally, although Appendix J (Membership Requirements for Vascularized Composite Allograft (VCA) Transplant Programs) does not include language regarding periodic MPSC review of approved fellowship programs, it does reference fellowship programs that are “approved by the MPSC.” For consistency throughout the Bylaws, edits are proposed to OPTN Bylaws Appendices J.3.A.2.A and J.3.B.2.A to remove references to “MPSC approved” fellowship programs. With these edits, these sections now just focus on what is required of VCA key personnel applicants without additional qualifiers reiterating that fellowship programs meeting these requirements will be accepted/approved by the MPSC.

How well does this proposal address the problem statement?

This proposal completely addresses the disparity between how the MPSC functionally operates and the process currently established in the Bylaws regarding the MPSC’s ongoing review and approval of transplant fellowship programs. Further, the proposed changes preserve the Bylaws’ recognition of ASTS and AST transplant fellowships while still providing a list of transplant fellowship program minimal requirements to accommodate the possibility of other non-ASTS/non-AST transplant fellowships, and with respect to federal anti-competitive statues.

This proposal could be criticized for proposing the deletion of Bylaws that differ from normal MPSC operations rather than changing the MPSC’s operations such that it adheres to the process established in the Bylaws. The MPSC opted to modify the Bylaws as it did not believe it would be worthwhile for the OPTN to expend the significant resources that would be needed to review transplant fellowship programs regularly. To do so would unnecessarily duplicate the considerable effort and resources that other organizations already invest in this process.

Was this proposal changed in response to public comment?

No. The MPSC voted to send the Bylaws language changes proposed during public comment for the OPTN/UNOS Board of Directors’ final consideration at its December 2017 meeting (34 support, 0 oppose, 0 abstentions).

Prior to reaching this decision, the MPSC reviewed all of the public comments provided in response to this proposal. MPSC discussion yielded the following responses to the feedback provided:

³ http://www.acgme.org/Portals/0/PFAssets/ProgramRequirements/328_nephrology_peds_2016.pdf
⁴ http://www.acgme.org/Portals/0/PFAssets/ProgramRequirements/332_gastroenterology_peds_2016.pdf
• Support for the proposal.
  o This was the predominant response, including support from all eleven regions, AST, ASTS, and NATCO. The MPSC indicated its appreciation for these commenters’ review and support of the proposal.

• An individual commenter stated that requiring that the fellowship program is at an institution that has an ACGME approved training program in general surgery or nephrology is unnecessary as long as the program has been approved for training by the American Society of Transplant Surgeons (AST), American Society of Transplantation (AST) Adult Transplant Nephrology Fellowship Training Program, or the Royal College of Physicians and Surgeons of Canada (RCPSC).
  o The MPSC appreciates the commenter’s review of this proposal. It is important to note that the requirement that a fellowship training program be at an institution that has ACGME approval in general surgery or nephrology specifically applies to those fellowship programs that are not approved by ASTS, AST Adult Transplant Nephrology Fellowship Training Program, or RCPSC. Because the OPTN is prohibited from endorsing specific entities or businesses, these additional fellowship training program requirements are necessary so that a transplant program key personnel applicant has the option of qualifying through one of the fellowship pathways in the Bylaws without necessarily having completed their training at an program approved by ASTS, AST Adult Transplant Nephrology Fellowship Training Program, or RCPSC. Key personnel applicants applying through one of the Bylaws’ fellowship training pathways who did not perform their fellowship training at an ASTS, AST Adult Transplant Nephrology Fellowship Training Program, or RCPSC approved fellowship program must have obtained their fellowship training at an institution with ACGME approval, in addition to the other requirements specified in the proposed Bylaws.

Which populations are impacted by this proposal?

There will be no direct impact to any populations of the transplant community. This proposal addresses Bylaws that establish an MPSC operational action that has historically not been performed. Adopting this proposal will effectively align the Bylaws with how the MPSC currently operates with respects to evaluating key personnel applicants applying through one of the Bylaws’ training pathways.

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: There is no impact to this goal.
3. Improve waitlisted patient, living donor, and transplant recipient outcomes: There is no impact to this goal.
4. Promote living donor and transplant recipient safety: There is no impact to this goal.
5. Promote the efficient management of the OPTN: The efficient management of the OPTN is supported through these proposed changes by aligning the Bylaws with how the MPSC functionally operates with regards to the focus of this proposal and by increasing the consistency of key personnel requirements across all transplant program types.

How will the OPTN implement this proposal?

The MPSC will present these changes for the OPTN/UNOS Board of Directors’ consideration at its December 2017 meeting. Assuming the Board adopts these changes, they would become effective on March 1, 2018.
Implementing the changes detailed in this proposal will align the Bylaws with how the MPSC currently operates when evaluating key personnel applicants who have applied through a “fellowship pathway.” As such, the OPTN’s implementation effort will primarily consist of updating the Bylaws found on the OPTN website on the effective date of these changes.

**How will members implement this proposal?**

No action will be required of members upon the implementation of these proposed Bylaws changes.

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

No, this proposal does not require additional data collection.

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

This proposal primarily eliminates Bylaws that pertain to MPSC approval of fellowship training programs. Compliance with remaining Bylaws will be expected, but there are no member compliance considerations that directly result from these changes.

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

Considering the primary problem driving these proposed changes is operational in nature, deleting Bylaws as recommended in this proposal will successfully address this problem. Nevertheless, the MPSC will monitor if these changes yield consequences that it did not anticipate. Should any unanticipated negative consequences be realized, the MPSC would work towards another solution that corrects those.
Policy or Bylaws Language

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


E.2 Primary Kidney Transplant Surgeon Requirements

A. Formal 2-year Transplant Fellowship Pathway

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

1. The surgeon performed at least 30 kidney transplants as the primary surgeon or first assistant during the 2-year fellowship period. These transplants must be documented in the surgeon’s fellowship operative log. The date of transplant, the role of the surgeon in the procedure, the medical record number or other unique identifier that can be verified by the OPTN Contractor, and the fellowship director’s signature must be provided with this log.

2. The surgeon performed at least 15 kidney procurements as primary surgeon or first assistant. At least 10 of these procurements must be from deceased donors. These procurements must have been performed anytime during the surgeon’s fellowship and the two years immediately following fellowship completion. These procedures must be documented in the surgeon’s fellowship operative log. The date of procurement and Donor ID must be provided with this log.

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

4. This training was completed at a hospital with a kidney transplant training program approved by the Fellowship Training Committee of the American Society of Transplant Surgeons, the Royal College of Physicians and Surgeons of Canada, or another recognized surgical fellowship training program accepted by the OPTN Contractor as described in the Section E.4.
Approved Kidney Transplant Surgeon and Physician Fellowship Training Programs that follows.

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

E.3 Primary Kidney Transplant Physician Requirements

A. Transplant Nephrology Fellowship Pathway

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

1. The physician completed at least 12 consecutive months of specialized training in transplantation under the direct supervision of a qualified kidney transplant physician and along with a kidney transplant surgeon at a kidney transplant program that performs 30 to 50 or more transplants each year. The training must have included at least 6 months of clinical inpatient transplant service. The remaining time must have consisted of transplant-related experience, such as experience in a tissue typing laboratory, on another solid organ transplant service, or conducting basic or clinical transplant research.

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

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

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

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

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

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

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

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

C. Three-year Pediatric Nephrology Fellowship Pathway

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

1. During the 3-year training period the physician was directly involved in the primary care of 10 or more newly transplanted kidney recipients for at least 6 months from the time of transplant and followed 30 transplanted kidney recipients for at least 6 months, under the direct supervision of a qualified kidney transplant physician and in conjunction with a qualified kidney transplant surgeon. The pediatric nephrology program director may elect to have a
portion of the transplant experience completed at another kidney transplant program in order to meet these requirements. This care must be documented in a log that includes the date of transplant, and the recipient medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log must be signed by the training program’s director or the primary physician of the transplant program.

2. The experience caring for pediatric patients occurred with a qualified kidney transplant physician and surgeon at a kidney transplant program that performs an average of at least 10 pediatric kidney transplants a year.

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

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

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

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

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

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

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

2. During the fellowship, the physician was directly involved in the primary care of 10 or more newly transplanted kidney recipients for at least 6 months from the time of transplant and followed 30 transplanted kidney recipients for at least 6 months, under the direct supervision of a qualified kidney transplant physician and in conjunction with a qualified kidney transplant surgeon. The pediatric nephrology program director may elect to have a portion of the transplant experience completed at another kidney transplant program in order to meet these requirements. This care must be documented in a recipient log that includes the date of transplant, and the recipient medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the training program director or the primary physician of the transplant program.

3. The experience in caring for pediatric patients occurred at a kidney transplant program with a qualified kidney transplant physician and surgeon that performs an average of at least 10 pediatric kidney transplants a year.

4. During the four years that include the physician’s three-year pediatric nephrology fellowship and twelve-month pediatric transplant nephrology fellowship, the physician was directly involved in the evaluation of 25 potential kidney recipients, including participation in selection committee meetings. These potential kidney recipient evaluations must be documented in a log that includes each evaluation date and is signed by the director of the training program or the transplant program’s primary transplant physician.

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

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

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

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

E. Combined Pediatric Nephrology Training and Experience Pathway

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

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

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

3. During the 2 or more years of accumulated experience, the physician was directly involved in the primary care of 10 or more newly transplanted kidney recipients for at least 6 months from the time of transplant and followed 30 transplanted kidney recipients for at least 6 months, under the direct supervision of a qualified kidney transplant physician, along with a qualified kidney transplant surgeon. This care must be documented in a recipient log that includes the date of transplant, and the recipient medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the training program director or the primary physician of the transplant program.

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

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

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

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

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

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

A. Transplant Surgeon Fellowship Training Programs

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

1. The program is at a transplant hospital that transplants one or more organs, including kidneys.
2. The program is at an institution that has ACGME approved training in general surgery-a proven commitment to graduate medical education.
3. The program director is a board certified surgeon who meets the OPTN Contractor requirements for primary kidney transplant surgeon.
4. The program is at a hospital that is affiliated with a histocompatibility laboratory that meets the OPTN Contractor requirements for histocompatibility laboratories.
5. The program is at a hospital that is affiliated with an organ procurement organization (OPO) that meets the OPTN Contractor requirements for OPOs.

6. The program performs at least 60 kidney transplants during each year of the fellowship training from deceased or living donors.

7. The program has the resources, including adequate clinical facilities, laboratory research facilities, and appropriately trained faculty and staff, to provide research experience.

Training programs are reviewed by the MPSC every 5 years or any time the program director changes. If a program has no fellows during the 5 years between reviews, it must re-apply as a new program.

B. Transplant Physician Fellowship Training Programs

A formal training program for primary kidney transplant physicians requires that training must be completed at a program approved by the MPSC. Any training program approved by the AST Adult Renal-Transplant Training Accreditation Program is automatically accepted by the MPSC, as well as any program that meets the following criteria:

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

1. The program is at a transplant hospital that transplants one or more organs, including kidneys, must be OPTN approved as a kidney transplant program and be affiliated with an ACGME approved nephrology program. Transplant programs that are not OPTN approved or affiliated with an ACGME approved nephrology program will be evaluated on a case-by-case basis.

2. The program is at a hospital that has an ACGME approved nephrology program.

23. The program performs at least 50 kidney transplants per year if the program is training one transplant nephrology fellow, and performs at least 30 additional kidney transplants per year for each additional fellow it trains. The program must perform at least 10 kidney transplants per year for each first year, general nephrology fellow in training and an additional 30 transplants per year for each kidney transplant fellow to be trained.

34. The program’s must have a full-time faculty member or members capable of teaching a curriculum with a broad base of knowledge in transplant medicine. The curriculum must include training and experience in end-stage renal disease, training in the selection of appropriate transplant recipients and donors, experience in the immediate and long term care of the transplant recipient, and training in the performance of kidney transplant biopsies. Additionally there must be an emphasis on the management of immunosuppressive agents and the evaluation of kidney transplant dysfunction. Combined surgical and medical rounds should be conducted on a regular basis.

45. The program must provide patient co-management responsibility with transplant surgeons from the peri-operative through the outpatient period. The kidney trainee must primarily manage the transplant recipient’s medical care including hypertension, diabetes, and dialytic problems. Trainees must also serve as a primary member of the transplant team and participate in making decisions about immunosuppression. The transplant renal fellow must be primarily responsible for 30 in-patient renal transplant recipients and 30 outpatient recipients over a period of 12 months. Outpatient follow-up must be continuous for a...
minimum of at least 3 months. Training must be completed within 12 continuous months; a minimum of 6 months of training must be performed in inpatient clinical service.

5. The transplant nephrology fellow must perform a minimum of 10 transplant biopsies during the training period.

6. The transplant nephrology fellow must observe at least 3 kidney transplants and at least 3 procurement procedures.

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

C. Conditional Approval for a Pediatric Component

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

1. The program has a qualified primary pediatric kidney physician who meets all of the requirements described in Section E.5.B: Primary Pediatric Kidney Transplant Physician Requirements and a surgeon who meets all of the following requirements:

   a. The surgeon meets all of the requirements described in Section E.2: Primary Kidney Transplant Surgeon Requirements, including completion of at least one of the following training or experience pathways:

      ▪ The formal 2-year transplant fellowship pathway as described in Section E.2.A: Formal 2-year Transplant Fellowship Pathway

      ▪ The kidney transplant program clinical experience pathway, as described in Section E.2.B: Clinical Experience Pathway

   b. The surgeon has performed at least 5 kidney transplants, as the primary surgeon or first assistant, in recipients less than 18 years old at the time of transplant. At least 1 of these kidney transplants must have been in recipients less than 6 years old or weighing less than 25 kilograms at the time of transplant. These transplants must have been performed during or after fellowship, or across both periods. These transplants must be documented in a log that includes the date of transplant, the recipient’s date of birth, the recipient’s weight at transplant if less than 25 kilograms, the role of the surgeon in the procedure, and the medical record number or other unique identifier that can be verified by the OPTN Contractor.

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

2. The program has a qualified primary pediatric kidney surgeon who meets all of the requirements described in Section E.5.A: Primary Pediatric Kidney Transplant Surgeon Requirements and a physician who meets all of the following requirements:

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

c. During the 2 or more years of accumulated experience, the physician was directly involved in the primary care of 5 or more newly transplanted kidney recipients and followed 15 newly transplanted kidney recipients for at least 6 months from the time of transplant, under the direct supervision of a qualified kidney transplant physician, along with a qualified kidney transplant surgeon. This care must be documented in a recipient log that includes the date of transplant and the recipient medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the training program director or the primary physician of the transplant program.

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

e. The physician should have observed at least 3 organ procurements and 3 pediatric kidney transplants. The physician should also have observed the evaluation, the donation process, and management of at least 3 multiple organ donors who donated a kidney. If the physician has completed these observations, they must be documented in a log that includes the date of procurement and Donor ID.

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

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

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

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

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

E.6 Kidney Transplant Programs that Perform Living Donor Recovery

D. Primary Open Living Donor Kidney Surgeon

A kidney donor surgeon who performs open living donor nephrectomies must be on site and must meet one of the following criteria:
Completion of an accredited American Society of Transplant Surgeons (ASTS) 2-year surgical transplant fellowship with kidney certification at a fellowship program approved by the American Society of Transplant Surgeons, the Royal College of Physicians and Surgeons of Canada, or other recognized fellowship training program accepted by the OPTN Contractor as described in Section E.4.A: Transplant Surgeon Fellowship Training Programs.

Completion of at least 10 open nephrectomies, including deceased donor nephrectomies or the removal of diseased kidneys, as primary surgeon, co-surgeon, or first assistant. At least 5 of these open nephrectomies must have been performed as the primary surgeon or co-surgeon. The open nephrectomies must be documented in a log that includes the date of recovery, the role of the surgeon in the procedure, the type of procedure (open or laparoscopic), and the medical record number or Donor ID.

F.3 Primary Liver Transplant Surgeon Requirements

A. Formal 2-year Transplant Fellowship Pathway

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

1. The surgeon performed at least 45 liver transplants as primary surgeon or first assistant during the 2-year fellowship period. These transplants must be documented in the surgeon’s fellowship operative log. The date of transplant, the role of the surgeon in the procedure, the medical record number or other unique identifier that can be verified by the OPTN Contractor, and the fellowship director’s signature must be provided with this log.

2. The surgeon performed at least 20 liver procurements as primary surgeon or first assistant. These procurements must have been performed anytime during the surgeon’s fellowship and the two years immediately following fellowship completion. These procedures must be documented in the surgeon’s fellowship operative log. The date of procurement and Donor ID must be provided with this log.

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

4. The training was completed at a hospital with a liver transplant training program approved by the Fellowship Training Committee of the American Society of Transplant Surgeons, the Royal College of Physicians and Surgeons of Canada, or another recognized fellowship training program accepted by the OPTN Contractor as described in Section F.6: Approved Liver Surgeon Transplant Fellowship Programs that follows.

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

c. A letter from the surgeon that details his or her training and experience in liver transplantation.

F.6 Approved Liver Surgeon Transplant Fellowship Programs

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

1. The program is at a transplant hospital that transplants one or more organs, including livers.
2. The program is at an institution that has ACGME approved training in general surgery a proven commitment to graduate medical education.
3. The program director is a board-certified surgeon who meets the OPTN Contractor requirements for primary liver transplant surgeon.
4. The program is at a hospital that is affiliated with a histocompatibility laboratory that meets the OPTN Contractor requirements for histocompatibility laboratories.
5. The program is at a hospital that is affiliated with an organ procurement organization (OPO) that meets the OPTN Contractor requirements for OPOs.
6. The program performs at least 50 liver transplants during each year of the fellowship training from deceased or living donors.
7. The program has the resources, including adequate clinical facilities, laboratory research facilities, and appropriately trained faculty and staff, to provide research experience.

Training programs are reviewed by the MPSC every 5 years or any time the program director changes. If a program has no fellows during the 5 years between reviews, it must re-apply as a new program.

F.11 Primary Intestine Transplant Surgeon Requirements

A. Full Intestine Surgeon Approval Pathway

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

1. The surgeon performed 7 or more intestine transplants at a designated intestine transplant program, to include the isolated bowel and composite grafts, as primary surgeon or first assistant within the last 10 years. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair from the program where the experience or training was gained.
2. The surgeon performed 3 or more intestine procurements as primary surgeon or first assistant. These procurements must include 1 or more organ recovery that includes a liver.
These procedures must be documented in a log that includes the date of procurement and Donor ID. This log must be signed by the program director, division chief, or department chair from the program where the experience or training was gained.

3. The surgeon has maintained a current working knowledge of intestine transplantation, defined as direct involvement in intestine transplant patient care within the last 5 years. This includes the management of patients with short bowel syndrome or intestinal failure, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, performing the transplant operation, immediate postoperative and continuing inpatient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of intestine allograft dysfunction, histologic interpretation of allograft biopsies, interpretation of ancillary tests for intestine dysfunction, and long term outpatient care.

4. The training was completed at a hospital with an intestinal transplant training program approved by the American Society of Transplant Surgeons (ASTS) or the Royal College of Physicians and Surgeons of Canada, or another recognized fellowship training program accepted by the OPTN Contractor as described in Section F.14: Approved Intestine Transplant Surgeon Fellowship Training Programs that follows.

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

F.14 Approved Intestine Surgeon Transplant Fellowship Programs

Surgeons qualifying as primary transplant surgeon through based on completion of a formal transplant fellowship must complete their training at a fellowship program approved by the American Society of Transplant Surgeons, the Royal College of Physicians and Surgeons of Canada, or another recognized fellowship training program accepted by the OPTN Contractor MPSC. Any program approved by the Fellowship Training Committee of the American Society of Transplant Surgeons is automatically accepted by the MPSC, as well as any program that meets all of the following criteria:

1. The program is at a transplant hospital that transplants one two or more organs, including liver and intestines.
2. The program is at an institution that has ACGME approved training in general surgery a proven commitment to graduate medical education.
3. The program director is a board-certified surgeon who meets the OPTN Contractor requirements for primary intestine transplant surgeon.
4. The program is at a hospital that is affiliated with a histocompatibility laboratory that meets the OPTN Contractor requirements for histocompatibility laboratories.
5. The program is at a hospital that is affiliated with an organ procurement organization (OPO) that
meets the OPTN Contractor requirements for OPOs.

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631 63. The program performs at least 10 intestine transplants during each year of the fellowship training.
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7. The program has the resources, including adequate clinical facilities, laboratory research facilities, and appropriately trained faculty and staff, to provide research experience.

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G.2 Primary Pancreas Transplant Surgeon Requirements

A. Formal 2-year Transplant Fellowship Pathway

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

1. The surgeon performed at least 15 pancreas transplants as primary surgeon or first assistant. These transplants must be documented in the surgeon’s fellowship operative log. The date of transplant, the role of the surgeon in the procedure, the medical record number or other unique identifier that can be verified by the OPTN Contractor, and the fellowship director’s signature must be provided with this log.

2. The surgeon performed at least 10 pancreas procurements as primary surgeon or first assistant. These procurements must have been performed anytime during the surgeon’s fellowship and the two years immediately following fellowship completion. These cases must be documented in the surgeon’s fellowship operative log. The date of procurement, Donor ID, and the fellowship director’s signature must be provided with this log.

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

4. The training was completed at a hospital with a pancreas transplant training program approved by the Fellowship Training Committee of the American Society of Transplant Surgeons, the Royal College of Physicians and Surgeons of Canada, or another recognized fellowship training program accepted by the OPTN Contractor as described in Section G.7: Approved Pancreas Transplant Surgeon Fellowship Training Programs that follows.

5. The following letters are submitted directly to the OPTN Contractor:
   a. A letter from the director of the training program and chairman of the department or hospital credentialing committee verifying that the fellow has met the above requirements and is qualified to direct a pancreas transplant program.
   b. A letter of recommendation from the fellowship training program’s primary surgeon and transplant program director outlining the surgeon’s overall qualifications to act as primary transplant surgeon as well as the surgeon’s personal integrity, honesty, familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request similar letters of recommendation from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
   c. A letter from the surgeon that details the training and experience the surgeon has gained in pancreas transplantation.
G.3 Primary Pancreas Transplant Physician Requirements

A. Twelve-month Transplant Medicine Fellowship Pathway

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

1. The physician completed 12 consecutive months of specialized training in pancreas transplantation at a pancreas transplant program under the direct supervision of a qualified pancreas transplant physician along with a pancreas transplant surgeon. The training must have included at least 6 months on the clinical transplant service. The remaining time must have consisted of transplant-related experience, such as experience in a tissue typing laboratory, on another solid organ transplant service, or conducting basic or clinical transplant research.

2. During the fellowship period, the physician was directly involved in the primary care of 8 or more newly transplanted pancreas recipients and followed these recipients for a minimum of 3 months from the time of transplant. The care must be documented in a log that includes the date of transplant and medical record number or other unique identifier that can be identified by the OPTN Contractor. This recipient log must be signed by the director of the training program or the transplant program’s primary transplant physician.

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

4. The physician must have observed at least 3 pancreas procurements. The physician must have also observed the evaluation, donation process, and management of these donors. These observations must be documented in a log that includes the date of procurement and Donor ID.

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

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

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

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

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

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

1. The program must be located at a transplant hospital that transplants one or more organs, including pancreas.
2. The program must be reviewed every 5 years by the OPTN Contractor.
3. The program must be at an institution that has ACGME approved training in general surgery with a proven commitment to graduate medical education.
4. The program director must be a board certified surgeon who meets the requirements of a primary transplant surgeon.
5. The program must be at an institution affiliated with a histocompatibility laboratory member.
6. The program must be at an institution affiliated with an organ procurement organization member.
7. The program must perform at least 20 pancreas transplants during each year of fellowship training to qualify for pancreas transplantation training.
8. The training program must have adequate clinical and laboratory research facilities.
9. The training program should have adequate faculty with appropriate training to provide proper research experience.

Training programs are reviewed by the MPSC every 5 years or any time the program director changes. If a program has no fellows during the 5 years between reviews, it must re-apply as a new training program.

**J.3 Primary VCA Transplant Surgeon Requirements**

**A. Additional Primary Surgeon Requirements for Upper Limb Transplant Programs**

In addition to the requirements as described in section J.3 above, the surgeon for an upper limb transplant program must meet both of the following:

1. Must meet at least one of the following:
   
   a. Have current certification by the American Board of Plastic Surgery, the American Board of Orthopedic Surgery, the American Board of Surgery, or the foreign equivalent. In the case of a surgeon who has just completed training and whose board certification is pending, the Membership and Professional Standards Committee (MPSC) may grant conditional approval for 24 months to allow time for the surgeon to complete board certification, with the possibility of renewal for an additional 12-month period.
   
   b. If the surgeon does not have board certification, the surgeon may qualify by gaining all of the following relevant clinical experience:
      
      i. Observation of at least 2 multi-organ procurements and acted as the first-assistant or
primary surgeon on at least 1 VCA procurement.

ii. Pre-operative evaluation of at least 3 potential upper limb transplant candidates.

iii. Acted as primary surgeon of a least 1 upper limb transplant.

iv. Post-operative follow-up of at least 1 upper limb recipient for 1 year post-transplant.

The multi-organ procurement experience must be documented in a log that includes the Donor ID or other unique identifier that can be verified by the OPTN Contractor. The experience for upper limb transplant procedures must be documented in a log that includes the dates of procedures and evaluations, the role of the surgeon, 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 where the experience was gained.

If a primary surgeon qualified under 1.b leaves the transplant program, the replacement for this surgeon must meet the requirements of 1.a. As of September 1, 2018, pathway 1.b will no longer be available and all primary surgeons must meet the requirements of 1.a.

2. Completion of at least one of the following:

a. A fellowship program in hand surgery that is approved by the MPSC. Any Accreditation Council of Graduate Medical Education (ACGME) approved fellowship program in hand surgery is automatically accepted by the MPSC.

b. A fellowship program in hand surgery that meets all of the following criteria will also be accepted:

i. The program is at a hospital that has inpatient facilities, operative suites and diagnostic treatment facilities, outpatient facilities, and educational resources.

ii. The program is at an institution that has a proven commitment to graduate medical education.

iii. The program director must have current certification in the sub-specialty by the American Board of Orthopedic Surgery, the American Board of Plastic Surgery, or American Board of Surgery.

iv. The program should have at least 2 physician faculty members with hand surgery experience and current medical licensure who are actively involved in the instruction and supervision of fellows during the time of accredited education.

v. The program is at a hospital that has affiliated rehabilitation medicine services.

vi. The program has the resources, including adequate clinical facilities, laboratory research facilities, and appropriately trained faculty and staff, to provide research experience.

c. At least 2 years of consecutive and independent practice of hand surgery and must have completed a minimum number of upper limb procedures as the primary surgeon shown in Table J-1 below. This includes completion of pre-operative assessments and post-operative care for a minimum of 90 days after surgery. These procedures must be documented in a log that includes the date of the procedure and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair where the experience was gained. Surgery of the hand includes only those procedures performed on the upper limb below the elbow.
Table J-1: Minimum Procedures for Upper Limb Primary Transplant Surgeons

<table>
<thead>
<tr>
<th>Type of Procedure</th>
<th>Minimum Number of Procedures</th>
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<td>Replantation or Transplant</td>
<td>5</td>
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</tbody>
</table>

B. Additional Primary Surgeon Requirements for Head and Neck Transplant Programs

In addition to the requirements as described in section J.3 above, the transplant surgeon for a head and neck transplant program must meet both of the following:

1. Must meet at least one of the following:
   a. Have current certification by the American Board of Plastic Surgery, the American Board of Otolaryngology, American Board of Oral and Maxillofacial Surgery, the American Board of Surgery, or the foreign equivalent. In the case of a surgeon who has just completed training and whose board certification is pending, the Membership and Professional Standards Committee (MPSC) may grant conditional approval for 24 months to allow time for the surgeon to complete board certification, with the possibility of renewal for an additional 12-month period.
   b. If the surgeon does not have board certification, the surgeon may qualify by gaining all of the following relevant clinical experience:
      i. Observation of at least 2 multi-organ procurements and acted as the first-assistant or primary surgeon on at least 1 VCA procurement.
      ii. Pre-operative evaluation of at least 3 potential head and neck transplant candidates.
      iii. Acted as primary surgeon of at least 1 head and neck transplant.
      iv. Post-operative follow up of at least 1 head and neck recipient for 1 year post-transplant.

The multi-organ procurement experience must be documented in a log that includes the Donor ID or other unique identifier that can be verified by the OPTN Contractor. The experience for head and neck procedures must be documented in a log that includes the dates of procedures and evaluations, the role of the surgeon, 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 where the experience was gained.

If a primary surgeon qualified under 1.b leaves the transplant program, the replacement for this surgeon must meet the requirements of 1.a. As of September 1, 2018, pathway 1.b will no longer be available and all primary surgeons must meet the requirements of 1.a.

2. Completion of at least one of the following:
   a. A fellowship program in otolaryngology, plastic, oral and maxillofacial, or craniofacial surgery that is approved by the MPSC. Any ACGME–approved fellowship program in
A fellowship program in otolaryngology, plastic, oral and maxillofacial, or craniofacial surgery that meets all of the following criteria:

i. The program is at a hospital that has inpatient facilities, operative suites and diagnostic treatment facilities, outpatient facilities, and educational resources.

ii. The program is at an institution that has a proven commitment to graduate medical education.

iii. The program director must have current certification in the sub-specialty by the American Board of Plastic Surgery, the American Board of Otolaryngology, American Board of Oral and Maxillofacial Surgery.

iv. The program should have at least two physician faculty members with head and neck surgery experience and current medical licensure who are actively involved in the instruction and supervision of fellows during the time of accredited education.

v. The program is at a hospital that has affiliated rehabilitation medicine services.

vi. The program has the resources, including adequate clinical facilities, laboratory research facilities, and appropriately trained faculty and staff, to provide research experience.

c. At least 2 years of consecutive and independent practice of head and neck surgery. The surgeon must have completed at least 1 face transplant as primary surgeon or first assistant, or a minimum number of head and neck procedures as the primary surgeon as shown in Table J-2 below. This includes completion of pre-operative assessments and post-operative care for a minimum of 90 days after surgery. These procedures must be documented in a log that includes the dates of procedures and evaluations, the role of the surgeon and the medical record number, Donor ID, 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 where the experience was gained.

<table>
<thead>
<tr>
<th>Type of Procedure</th>
<th>Minimum Number of Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facial trauma with bone fixation</td>
<td>10</td>
</tr>
<tr>
<td>Head or neck free tissue</td>
<td>10</td>
</tr>
<tr>
<td>reconstruction</td>
<td></td>
</tr>
</tbody>
</table>