

*Request for Feedback*

# Update Transplant Program Key Personnel Training and Experience Requirements

*OPTN Membership and Professional Standards Committee*

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# Update Transplant Program Key Personnel Training and Experience Requirements

*Sponsoring Committee: Membership and Professional Standards Committee*  
*Public Comment Period: January 21, 2021 – March 23, 2021*

## Executive Summary

The National Organ Transplant Act (NOTA) and the Final Rule require that the Organ Procurement and Transplantation Network (OPTN) establish membership requirements. The current OPTN contract with the Health Resources and Services Administration (HRSA) requires the creation of a new process for periodically reassessing members' compliance with these OPTN membership requirements, including changes to the OPTN bylaws necessary for the effectiveness of the reassessment process. As there had not been a comprehensive review of all OPTN membership requirement bylaws since the mid-2000s, the OPTN Membership and Professional Standards Committee (MPSC) began a phased project to review all membership requirements. The project goals included ensuring the requirements support a process for periodic evaluation of member compliance with OPTN bylaws, evaluating the requirements' consistency with NOTA, federal regulations and current practice and qualifications, and reducing complexity of the requirements to simplify the application process and the review of applications by the OPTN.

The MPSC has reviewed and is considering changes to the format used to develop transplant program key personnel training and experience requirements. The majority of the organ-specific training and experience requirements for key personnel, primary transplant surgeons and primary transplant physicians, contain the same requirements which have been modified to include organ-specific details. The MPSC is requesting feedback on suggested changes to this format prior to collaborating with OPTN organ-specific committees to apply these changes to the organ-specific training and experience bylaws.

## Purpose

The current OPTN contract with HRSA requires the creation of a process for periodically reassessing members' status in the OPTN, including changes to the bylaws necessary for the effectiveness of the reassessment process. As there had not been a comprehensive review of all OPTN membership requirement bylaws since the mid-2000s, the Membership and Professional Standards Committee (MPSC) began a phased project to review all membership requirements to ensure the requirements will support a process for periodic evaluation of member compliance with OPTN bylaws; to evaluate the requirements for consistency with NOTA, federal regulations and current practice and qualifications; and to reduce complexity of the requirements to simplify the application process and the review of applications by the OPTN.

The MPSC has examined the transplant program primary surgeon and primary physician training and experience requirements based on issues that have arisen in reviews of applications, feedback received from members completing applications for new programs and key personnel changes, and the ability to apply a periodic reassessment of compliance. Based on this review, the MPSC is considering a revised format that can be used for the development of updated training and experience requirements for primary surgeons and physicians. The MPSC is requesting feedback on the format first and will then collaborate with the OPTN organ-specific committees to apply the format to the applicable primary surgeon and primary physician training and experience requirements in OPTN Bylaws, Appendices E through K.

## Background

The OPTN Final Rule requires that the OPTN develop policies regarding the training and experience of transplant surgeons and transplant physicians in designated transplant programs,<sup>1</sup> and requires that designated transplant programs have on site a transplant surgeon and transplant physician who is qualified under the policies developed.<sup>2</sup> Pursuant to the Final Rule requirements, the OPTN has developed training and experience bylaw requirements for primary surgeons and primary physicians for each designated organ transplant program.<sup>3</sup> The OPTN bylaws also contain a requirement for a program coverage plan and defines the qualifications for additional transplant surgeons and additional transplant physicians that can provide coverage, in addition to the primary surgeons and physicians.<sup>4</sup>

The primary transplant surgeon and primary transplant physician are the surgical and medical leaders of a designated transplant program and are generally responsible for ensuring the operation and compliance of the program with OPTN obligations.<sup>5</sup> To promote public health and patient safety in the transplant community, the OPTN bylaws provide the minimum requirements for a transplant surgeon to serve as the primary transplant surgeon and for a transplant physician to serve as the primary transplant physician.<sup>3</sup> Providing specific, detailed, and easily understood requirements for primary transplant surgeons and physicians helps ensure consistency and transparency, and assists members by providing information necessary for a program to assess whether an individual that will potentially be hired to fill the primary role meets the necessary requirements.

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<sup>1</sup> 42 C.F.R. §121.4(a)(4)

<sup>2</sup> *Id.* at §121.9(a)(2)(ii)-(iii)

<sup>3</sup> OPTN Bylaws, Appendices E – J.

<sup>4</sup> OPTN Bylaws, Appendix D, D.7.B.

<sup>5</sup> OPTN Bylaws, Appendix D, D.7.A.

As the MPSC embarked on a review of the primary surgeon and primary physician training and experience requirements, the Committee endorsed a number of principles to guide the review. The principles support the implementation of a process for periodic reassessment of compliance as required by the OPTN contract, simplification of the training and experience requirements, and flexibility for qualified individuals with varying training and experience background. These overarching principles include:

- Incorporating an element of currency, or recency, into the experience requirements
- Consolidating the multiple training and experience pathways into one pathway that can be met through fellowship experience and clinical experience or a combination of both
- Ensuring consistency between all organ-specific training and experience requirements, where possible
- Considering stratification of requirements that would expect only individuals who had not previously served in the position of primary surgeon or physician to meet certain requirements
- Incorporating an option for individuals who trained or gained experience outside of the United States to qualify as a primary surgeon or physician that would be consistent with and equivalent to the requirements for those who trained or gained experience within the United States.

During its evaluation of the primary surgeon and primary physician bylaw requirements, the MPSC evaluated feedback received from members who have submitted key personnel applications, and issues the MPSC has identified during the review of applications. The MPSC consulted state licensing requirements, requirements for various board certifications, fellowship requirements and past briefing papers supporting existing bylaws.

### ***Currency***

The current transplant program key personnel bylaws contain limited requirements regarding a proposed individual's current transplantation experience. The sole requirement is for a proposed primary to demonstrate direct involvement in transplantation in the last two years, meaning a surgeon performed at least one transplant and a physician cared for at least one transplant recipient in the last two years. Otherwise, a surgeon or physician can rely on clinical experience gained during any two to five year period or during a fellowship completed many years ago. For example, under the current bylaws, a proposed individual can be approved for a primary position provided they have performed just one transplant or cared for just one transplant recipient in the last two years, even if the proposed primary otherwise has not been involved in transplantation for 20 years.

To address this issue, the MPSC proposes requiring any experience used to meet the primary surgeon and primary physician requirements be within a certain recent time frame. For example, the bylaws may require the surgeon to have performed X number of transplants within the last 5 years. Requiring documentation of recent experience ensures that the primary surgeon or physician has remained involved in transplantation and maintained knowledge of current practice and OPTN obligations and the necessary skill set in the rapidly changing field of transplantation.

In addition, this proposed change supports the establishment of a periodic assessment of compliance with membership requirements as required by the OPTN contract. Under the current bylaws, a transplant program need only submit documentation for a qualified primary surgeon or physician when there is a change in the individual holding that position. The MPSC has encountered situations, through other monitoring activities, where the individual serving in a primary role is no longer actively involved in transplant or clearly would not meet the current training and experience bylaws for primary surgeons

or physicians. The addition of a reassessment of compliance with membership requirement bylaws will ensure that primary surgeons and physicians have remained involved in transplantation and maintained knowledge of current practice.

### ***Consolidation of Training and Experience Pathways***

The MPSC supports simplifying the requirements through consolidation of multiple pathways into one comprehensive pathway, where possible. Many of the current organ-specific key personnel bylaws contain multiple complex pathways. A single pathway would allow the use of fellowship and clinical experience to meet the specific experience requirements. This concept was successfully applied in the recently implemented intestine transplant key personnel requirements. Without acceptance of combined fellowship and clinical experience through a consolidated single pathway, the MPSC's implementation of the currency requirement, discussed in the previous paragraph, could result in increased rejection of key personnel applications when a proposed individual's most recent experience includes both time during fellowship and post-fellowship experience.

### ***Consistency***

The MPSC has developed the proposed revised format to promote consistency in language between all organ-specific primary surgeon and physician training and experience bylaws. Although all of the organ-specific key personnel requirements follow the same general format, revisions have been made to individual organ-specific requirements over the years. These changes have resulted in inconsistencies in language that are unrelated to a unique organ-specific training or experience characteristic and add complexity and confusion to the application completion and review process. Establishing a consistent format with consistent language for all organ-specific key personnel requirements will reduce the burden on member applicants and on the MPSC members reviewing the application.

### ***Stratification of Select Key Personnel Requirements***

The MPSC examined common barriers experienced by transplant programs completing key personnel applications. One of the most common issues is the inability of senior clinicians with significant experience to produce documentation for some aspects of their experience that they may have gained early in their career or during their fellowship but no longer routinely perform as a senior clinician, such as procurements for surgeons or observations of transplants and procurements for physicians. Currently, all individuals proposed for primary surgeon and physician positions are required to meet all of the training and experience requirements regardless of previous experience in the role of primary surgeon or physician.

The MPSC proposes stratifying requirements so proposed primary surgeons and physicians who have not previously served in a primary role within a certain time period would be required to provide documentation of all experience requirements. Conversely, individuals who have served as a primary physician or surgeon would not need to provide documentation of certain experience. This stratification will ensure that all primary surgeons and physicians have completed the requirement at least once in their career, but will not require seasoned clinicians to maintain recency in that area or repeatedly submit documentation about their experience. The MPSC proposes that the stratification exempt individuals from certain requirements if the individual has served as a primary physician or surgeon within the last 10 years. The MPSC is interested in feedback about this time frame, specifically whether the time frame is too restrictive or too lenient.

### ***Options for Individuals Who Trained or Gained Experience outside the U.S.***

The MPSC is committed to providing options and opportunities for qualified individuals who trained or gained transplant experience outside the United States. However, the MPSC has struggled to clearly define what training or experience would demonstrate equivalency in a way that satisfactorily provides transparency to members and supports consistency in decision-making by the MPSC. Issues of foreign equivalency arise most often in the context of board certification requirements and documentation of experience. The MPSC has identified foreign equivalency as an area about which the committee would appreciate significant input from the community. Additional specific information on the MPSC discussions, the alternatives considered, and specific questions are addressed in a separate section on foreign equivalency.

## **Potential Transplant Program Key Personnel Format**

The proposed new transplant program key personnel bylaw format can be found in Attachment A to this Request for Feedback. For comparison purposes, please review the current OPTN Bylaws on the OPTN website at <https://optn.transplant.hrsa.gov/governance/bylaws/>. Again, the MPSC plans to utilize the format, once it is complete, with the organ-specific OPTN committees to finalize proposed changes to the organ-specific key personnel requirements. The MPSC will then submit the changes for public comment.

In this section, each of the proposed elements of the new transplant program key personnel bylaw format will be addressed, including a summary of the discussion and the basis for the MPSC recommendation. The section is divided into four subsections:

- Subsection 1: Requirements that appear in both the primary surgeon and primary physician requirements
- Subsection 2: Primary surgeon requirements
- Subsection 3: Primary physician requirements
- Subsection 4: Foreign equivalency

## **Requirements that appear in both primary transplant surgeon and primary transplant physician requirements**

Certain requirements are common to both primary surgeons and primary physicians. The MPSC proposes keeping many of these requirements but has made some adjustments to simplify and clarify the requirements. The MPSC's recommendations are based on feedback from the community, MPSC reviewers, and UNOS staff who process key personnel applications. The MPSC proposes the following requirements apply to both surgeons and physicians:

1. The [surgeon][physician] must
  - a. Have an M.D., D.O., or equivalent degree from another country
  - b. Have a current license to practice medicine in the hospital's state or jurisdiction
  - c. Be accepted and a current member in good standing on the hospital's medical staff documented in a certification from the hospital credentialing committee
  - d. Be on site at this hospital.
2. The [surgeon][physician] must have current certification by [list of boards].
3. An OPTN form that certifies that the [surgeon][physician] meets the requirements for a [ORGAN] primary [surgeon][physician], is qualified to lead a [ORGAN] transplant program, is

a person of honesty and integrity and has experience in adhering to OPTN obligations completed by the primary [surgeon][physician], fellowship director, division chief, or department chair from the program where the [surgeon][physician]'s experience or training was gained must be submitted.

4. The [surgeon] [physician] must provide a letter that details the training and experience the [surgeon][physician] has gained in [ORGAN] transplantation.
5. If the proposed [surgeon][physician] has not served as a primary transplant [surgeon][physician] at an OPTN designated transplant program within the last 10 years, the [surgeon][physician] must have completed the OPTN orientation curriculum for primary transplant [surgeons][physicians].

In addition to the above list, the MPSC is also proposing extending the existing primary physician conditional program pathways to surgeons. Each of these proposed requirements is addressed in detail in the discussion below.

The first element requires that the surgeon or physician have an appropriate medical degree including a M.D., D.O. or equivalent degree from another country, have a current medical license in the hospital's state or jurisdiction, be a member in good standing on the hospital's medical staff and be on site. These requirements are all included in the current bylaws. The MPSC considers these to be essential basic qualifications and proposes their retention.

### ***On-site***

The MPSC had substantial discussions on the requirement for the primary surgeon and primary physician to be "on site." The OPTN Final Rule §121.9 requires that "an organ transplant program . . . has on site a transplant surgeon qualified in accordance with policies developed under §121.4 [and] has on site a transplant physician qualified in accordance with policies developed under §121.4." The Final Rule §121.4 requires the development of "[p]olicies regarding the training and experience of transplant surgeons and transplant physicians in designated transplant programs as required by §121.9." Current bylaws require that the transplant program must have key personnel, meaning a primary surgeon and primary physician, "on site" at the hospital. The Final Rule requirement for a transplant surgeon and transplant physician to be on site has been met by the separate OPTN bylaw requirement for a program coverage plan. The program coverage plan requires that a transplant surgeon and transplant physician, either the primary surgeon or physician or an additional surgeon or physician as defined in OPTN bylaws, provide continuous medical and surgical coverage. Programs that do not have any additional surgeons or physicians, and therefore only have coverage by the single primary surgeon or physician, are required to notify patients of the potential unavailability of these individuals which could affect patient care including the ability to accept organ offers, procurement and transplantation. See the requirements for the program coverage plan in Appendix D: *Transplant Hospital Members and Designated Transplant Programs*.

The separate requirement for primary surgeons and primary physicians to be on site at the hospital as noted in item 1.d above is admittedly difficult to operationalize. The OPTN has not expected or required a primary surgeon or physician be at the hospital continuously or even be continuously available to the hospital. Instead, the requirement has been applied to require that the primary surgeon and physician be physically available to provide leadership to the program, actively participate in the provision of transplant services, and ensure the operation of the program is in compliance with OPTN obligations. The MPSC has rejected an application that proposed that an individual serve as the primary for one program while also simultaneously serving a program several states away. Conversely, the MPSC has

approved applications when the proposed primary will serve as primary for two separate programs, if the programs are located in the same geographical area. In these cases, the MPSC has evaluated the ability of the individual to fulfill the primary duties in light of the distance between programs, the programs' transplant volumes, the availability of additional surgeons or physicians, and other relevant factors. The MPSC has struggled to determine language that reflects the availability and commitment of a program's primary surgeon and physician that would provide the necessary level of guidance to members and flexibility to the MPSC in evaluating the unique circumstances of a program, while not inadvertently creating an additional requirement, above the requirements of the Final Rule, that the *primary* physician and surgeon must always be on site in addition to any other physicians and surgeons who are also qualified in accordance with policies developed by the OPTN under §121.4 of the Final Rule. At this time, however, the MPSC supports the continued use of the term "on site" in the primary surgeon and physician requirements and will continue to evaluate compliance with this requirement based on historical precedent as described above. The MPSC requests feedback from the community on this requirement in order to further evaluate the appropriate responsibilities and expectations for primary surgeons and physicians in a separate future project focused solely on this requirement. Keeping in mind that the primary surgeon and physician are the surgical and medical leaders of a transplant program and are responsible for ensuring the program remains in compliance with OPTN obligations, the MPSC is requesting feedback on the following questions:

- What should be the responsibilities of the primary surgeon and primary physician?
- What level of commitment to a transplant program must a surgeon and physician demonstrate to fulfill the role of primary surgeon and primary physician?

### ***Board Certification***

The second element requires appropriate American or Canadian board certification and is a current requirement in the bylaws. The MPSC has reviewed applications proposing individuals who trained outside the United States or Canada, and are therefore, ineligible for American or Canadian board certification, but otherwise appear imminently qualified. In response to a strongly held position that there must be a reasonable pathway for surgeons and physicians trained outside the United States to serve as primaries, the MPSC considered the option of eliminating the requirement for board certification. During the MPSC discussions on this topic, some committee members noted that board certification is unrelated to transplant and suggested requiring transplant fellowships instead of board certifications. The MPSC noted that transplant fellowships are not mandatory, and felt that relying on fellowships would actually exclude qualified individuals from serving in a primary role. The majority of MPSC members noted that the OPTN has a responsibility to patients to ensure that surgeons and physicians are qualified and felt that board certification for American and Canadian trained individuals is a minimum qualification requirement that serves as a base threshold for competence. Maintaining board certification requires the individual to participate in continuing medical education and maintain knowledge of current practice. Accordingly, the MPSC proposes to retain the requirement for certification and maintenance of board certification from an appropriate American or Canadian surgical or physician certifying organization. A list of the current accepted board certifications for each organ can be found in Attachment B. The MPSC recognizes that individuals who train outside of the United States or Canada will be unable to meet this requirement and have addressed this issue in the Foreign Equivalency section below.

### ***Letters of reference and recommendation***

The third element replaces the current bylaw requirements for two separate letters – a letter of reference and a letter of recommendation – with a single OPTN form certifying that the proposed individual meets the requirements for a primary, is qualified to lead a transplant program, is a person of

honesty and integrity, and has experience in adhering to OPTN obligations. An individual in a supervisory position from the program where the individual's experience or training was gained would complete the form. While debating the value of the existing letter requirements, the MPSC noted that the committee was unlikely to reject an application based solely on the contents of these two letters, which often simply copy the necessary language directly from the bylaws rather than providing any assessment of the proposed individual's qualifications. Programs have had issues previously obtaining these letters, particularly if a fellowship was completed many years ago and the fellowship director is retired or deceased. Nevertheless, the MPSC concluded that the certification of an individual with knowledge of the proposed primary's previous experience was valuable to the application review process. Therefore, the MPSC suggested replacing the existing letters with an OPTN produced certification form. The MPSC certification would provide additional evidence and support for the accuracy of the experience logs submitted with the application. In addition, the MPSC concluded that the proposed revisions requiring recent experience to meet the surgeon and physician requirements and the production of an OPTN form that could be submitted electronically would significantly reduce, if not eliminate, the difficulties programs have encountered in obtaining letters.

#### ***Letter of qualification***

The fourth element retains the existing requirement for the proposed individual to provide a letter of qualification detailing his or her training and experience in transplantation. The MPSC concluded that the letter of qualification is helpful in gauging the proposed individual's own assessment of their skills and training that have prepared them for the position, and the level of commitment to transplant and the program. In addition, the submission of the letter of qualification does not constitute a significant burden on the program and applicant.

#### ***OPTN orientation curriculum***

The MPSC has proposed a new requirement for completion of an OPTN orientation curriculum for individuals who have not previously served as a primary surgeon or primary physician for any organ type. The MPSC has suggested that the yet to be developed OPTN orientation curriculum could include education on the role of the OPTN, OPTN bylaws and policies, the transplant system, and the role and responsibilities of the program primaries. The MPSC initially proposed the idea of an OPTN orientation curriculum when considering options for proposed individuals who appeared qualified but who had gained all of their transplant experience outside of the United States transplant system. Upon further discussion, MPSC members also concluded that this curriculum would be invaluable to individuals moving into the role of a primary surgeon or physician for the first time assuming the responsibility for their program's compliance with OPTN obligations. The curriculum would provide an important foundation for success in the primary surgeon or physician role.

#### ***Conditional approval for primary surgeons and physicians***

A conditional pathway allows a physician or surgeon to serve as the primary for a limited time while gaining additional experience necessary to qualify as the primary, or while the program is recruiting an alternative physician or surgeon for the primary position. The conditional pathways require that the surgeon or physician meet all requirements for being a qualified surgeon or physician under the policies developed by the OPTN under §121.4, other than the experience requirements for a certain number of transplants or procurements for surgeons or a certain number of patients for which care was provided for physicians that would be required for a primary. In addition, the conditional pathways require that the surgeon or physician have spent a minimum amount of time on an active transplant service; and that the program establish a mentorship or consulting agreement with a primary from another transplant program and submit periodic reports to the OPTN detailing the program's transplant activity

and outcomes and the surgeon or physician’s progress in meeting requirements or the program’s progress recruiting an alternative. If a primary physician or surgeon is approved under the conditional pathway, the transplant program’s approval status is also conditional. In those instances where the surgeon or physician may be conditionally approved, only one, either the surgeon or physician, can be approved under a conditional pathway. The current bylaws contain conditional approval experience pathways as shown in the table below.

|  | Primary Surgeon | Primary Physician |
|--|-----------------|-------------------|
| Heart  |                 | X                 |
| Kidney   |                 | X                 |
| Liver  |                 | X                 |
| Intestine  | X               | X                 |
| Lung   |                 | X                 |
| Pancreas   |                 | X                 |
| Pediatric components of Heart, Kidney and Liver programs | X               | X                 |

The MPSC supports expanding the conditional pathways to surgeons in all programs where a conditional pathway exists for physicians. However, the MPSC is proposing that the use of the conditional pathways be limited to key personnel changes where the change is occurring due to a sudden vacancy in the position. Examples of acceptable situations would be the sudden death or departure of an existing primary with little to no notice. Through the use of a conditional pathway in these circumstances, the program can continue to provide access to transplant to patients on its waiting list while being monitored for quality control and progress meeting the requirements through periodic reporting to the MPSC. The MPSC does not support the use of a conditional pathway that would accept experience levels lower than the minimum established requirements for a primary surgeon or physician for approval of a new program or in instances where the program had sufficient notice of a departure. In other cases of key personnel changes, transplant programs should engage in succession planning in anticipation of possible primary surgeon and physician departures. The bylaws include this suggestion in the key personnel change provisions contained in *Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs*. The MPSC is interested in feedback on the proposed changes to conditional approval and any possible unintended consequences.

## Primary Transplant Surgeon Requirements

The MPSC proposes that the two current pathways, the fellowship pathway and the clinical experience pathway, be consolidated into one pathway that would require recent transplant experience, but would accept experience gained through any combination of fellowship or clinical experience. Under the proposed single pathway, surgeons who use experience gained during a surgical transplant fellowship must have completed the training at a hospital with a transplant training program accepted by the OPTN as currently defined in the bylaws. Individuals who have not served as a primary surgeon within the last 10 years would be required to provide a log of procurements performed. In addition, the MPSC proposes the addition of an OPTN orientation curriculum for those individuals that have not served as a primary surgeon within the last 10 years. The surgeon specific requirements would include:

1. The surgeon performed [#] or more [ORGAN] transplants at a designated [ORGAN] transplant program as primary surgeon, co-surgeon or first assistant within the last [#] years and participated in pre-operative assessment of [organ] transplant candidates and post-operative care of these recipients. 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 primary surgeon, fellowship director, division chief, or department chair from the program where the experience or training was gained.
2. If the surgeon has not previously served as a primary [ORGAN] transplant surgeon at an OPTN designated transplant program within the last 10 years, the surgeon must have performed [#] or more [ORGAN] procurements as primary surgeon or first assistant. These procedures must be documented in a log that includes the date of procurement and Donor ID. This log must be signed by the primary surgeon, fellowship director, division chief, or department chair from the program where the experience or training was gained.

The MPSC proposes to retain the requirement that a surgeon must have performed a certain number of transplants, including participation in pre-operative assessment and post-operative care, as one of the best indicators of a transplant surgeon's expertise. The language requiring pre-operative assessment and post-operative care would be consistently applied across all organ primary surgeon requirements. Providing clinical care, thereby developing clinical instincts and experience with a variety of clinical presentations and complications, is recognized as an effective tool to develop competency to serve as the surgical leader of a transplant program. Fellowship and residency requirements provide additional evidence of the value of a requirement for a certain volume of procedures.<sup>6 7</sup>

The MPSC proposes removal of the current bylaw requirement that the surgeon demonstrate direct involvement in transplant patient care including an extensive list of various aspects of care, for example the following current requirement for kidney transplant surgeons "[t]he surgeon has maintained a current working knowledge of kidney transplantation, defined as direct involvement in kidney transplant patient care. . . [including] 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." The lists of aspects of care for all organ primary surgeons can be found in Attachment C. The MPSC concluded that these aspects of care are difficult to document and monitor and are subsumed in the requirement that the surgeon participate in "pre-operative assessment of transplant candidates and post-operative care of these recipients." The MPSC is requesting feedback on whether a requirement for participation in pre-operative assessment and post-operative care adequately addresses the range of care for primary surgeons.

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<sup>6</sup> American Society of Transplant Surgeons, Transplant Accreditation & Certification Council's Abdominal Transplant Surgery Fellowship Requirements 2020. Retrieved [https://asts.org/docs/default-source/fellowship-training/asts-fellow-requirements.pdf?sfvrsn=cdb42189\\_35](https://asts.org/docs/default-source/fellowship-training/asts-fellow-requirements.pdf?sfvrsn=cdb42189_35).

<sup>7</sup> American Board of Thoracic Surgery, Operative Requirements. Retrieved 11/21/2020 [https://www.abts.org/ABTS/CertificationWebPages/Operative\\_Requirements\\_Home\\_Page.aspx](https://www.abts.org/ABTS/CertificationWebPages/Operative_Requirements_Home_Page.aspx).

Finally, the MPSC proposes that surgeons would be required to submit a log of procurements if the surgeon has not served as a primary surgeon within the last 10 years. The MPSC recognizes that procurements are an essential part of the transplantation process with which all transplant surgeons, particularly primary surgeons, should have some experience. However, the MPSC considered that many senior surgeons do not regularly perform procurements. As addressed in the stratification discussion above, the MPSC retained the requirement for a procurement log but limited it to only those surgeons who had not previously served as a primary surgeon, thereby ensuring that all primary surgeons have performed procurements but not requiring a seasoned clinician to repeatedly document an area of experience where recency may not be as important. The MPSC is requesting feedback on whether the 10 year time frame is an appropriate limitation for exemption from documentation of procurements for surgeons who have previously served as a primary transplant surgeon.

The number of required transplants and the number of years in which the transplants were performed and the number of procurements will be organ-specific and will be determined in collaboration with the OPTN organ-specific committees in phase two of the project.

## Primary Transplant Physician Requirements

The MPSC proposes that the multiple current pathways for primary transplant physicians in the bylaws be consolidated into one pathway that would allow documentation of recent experience providing care to transplant recipients and participating in the evaluation of potential candidates gained through a fellowship or clinical experience or a combination of both. Physicians who use experience gained during a fellowship must have completed the training at a hospital with a training program accepted by the OPTN. The requirements for kidney and liver primary physicians would have a second pathway for pediatricians that would combine the current three pediatric bylaw pathways. Only individuals who had not served as a primary physician within the last 10 years would be required to provide a log of at least one observation of a transplant and one observation of a procurement. In addition, the MPSC proposes the addition of an OPTN orientation curriculum for those individuals that have not served as a primary physician within the last 10 years. The physician-specific requirements would include:

1. The physician has been directly involved within the last [#] years in the primary care of [#] or more newly transplanted [ORGAN] recipients and continued to follow these recipients for a minimum of 3 months from the time of transplant and participated in pre-operative care of the patient. This clinical experience must be gained as the primary [ORGAN] transplant physician or under the direct supervision of a [ORGAN] transplant physician and in conjunction with an [ORGAN] transplant surgeon at a designated [ORGAN] transplant program. This care must be documented in a log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the primary physician, fellowship director, division chief, or department chair from the program where the experience or training was gained.
2. The physician has been directly involved in the evaluation of [#] potential [ORGAN] recipients, including participation in selection committee meetings. These potential [ORGAN] recipient evaluations must be documented in a log that includes the evaluation date of each potential recipient and is signed by the primary physician, fellowship director, division chief, or department chair from the program where the physician gained this experience.

3. If the proposed physician has not previously served as a primary [ORGAN] transplant physician at an OPTN designated transplant program within the last 10 years, the physician must have observed at least 1 [ORGAN] transplant and at least 1 [ORGAN] procurement. The observations must be documented in a log that includes the date of transplant or procurement. This log must be signed by the primary physician, fellowship director, division chief, or department chair from the program where the experience or training was gained.

The MPSC retained the requirement that a physician must have provided care for a certain number of newly transplanted recipients, followed these patients for at least 3 months post-transplant and participated in pre-operative care of the patient as one of the best indicators of a transplant physician's expertise. In addition, the MPSC proposes to include a requirement for involvement in the evaluation of patients, including participation in selection committee meetings, for all primary physicians. This is currently a requirement for kidney primary physicians and is an integral aspect of the transplant physician role. Providing clinical care, thereby developing clinical instincts and experience with a variety of clinical presentations and complications, is recognized as an effective tool to develop competency to serve as the medical leader of a transplant program. Fellowship and residency requirements provide additional evidence of the value of a requirement for a certain volume of patient care.<sup>8 9</sup>

The MPSC proposes removal of the current bylaw requirement that the physician demonstrate direct involvement in an extensive list of various aspects of care, for example the following current requirement for kidney transplant physicians "[t]he physician has maintained a current working knowledge of kidney transplantation, defined as direct involvement in kidney transplant patient care. . . [including] 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 lists of aspects of care for all organ primary physicians can be found in Attachment C. The MPSC concluded that these aspects of care are difficult to document and monitor and are subsumed in the requirement that the physician participate in evaluations, pre-operative care and post-transplant care. The MPSC is requesting feedback on whether a requirement for participation in evaluations, pre-operative care and post-transplant care adequately addresses the range of care for primary physicians.

The MPSC retained the requirement for a physician to observe a transplant and a procurement but limited this requirement to one observation of each and to physicians who had not previously served as a primary physician in the last 10 years. Observing transplant and procurement procedures provides a physician who will serve as one of the program leaders with an understanding and appreciation for the entire process of transplantation. However, the MPSC does not believe that it is necessary for a physician to repeatedly document this experience. The MPSC is requesting feedback on whether the 10 year time frame is an appropriate limitation for exemption from documentation of observations for physicians who have previously served as a primary transplant physician.

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<sup>8</sup> American Society of Transplantation, Transplant Nephrology Fellowship Training Accreditation Program, LLC, Fellowship Program Details 2015. Retrieved <https://www.txnephaccreditation.org/fellowship-program-details>.

<sup>9</sup> American Board of Internal Medicine, Internal Medicine and Subspecialty Policies 2020. Retrieved <https://www.abim.org/certification/policies/internal-medicine-subspecialty-policies/internal-medicine.aspx>.

The number of transplant recipients cared for and the number of evaluations required, as well as the time period in which those should be done, will be organ-specific and will be determined in collaboration with the OPTN organ-specific committees.

## Foreign Equivalency

### *Background on Board Certification Equivalency*

With the retention of a requirement for appropriate American or Canadian board certification, the MPSC recognizes a need for an appropriate pathway for individuals trained outside the United States and Canada. Historically, the evaluation of an equivalent to board certification for individuals trained outside the United States and Canada has been difficult to develop.

For many years, the OPTN bylaws simply stated the requirement for board certification and tacked on the phrase “or the foreign equivalent.” The MPSC had difficulty determining what training or certification was equivalent, which led to inconsistency often based on the background and experience of the MPSC membership at any one time. Importantly, the vagueness of the language made it difficult for members to assess whether a foreign trained individual would be eligible to serve in a primary role.

In September 2017, a new alternative to board certification was implemented. Under the new pathway, an individual who is not board certified can qualify if the individual is ineligible for American board certification and the program provides:

- A plan for continuing education comparable to American board maintenance of certification
- Two letters of recommendation from directors of designated transplant programs not employed by the applying hospital.

### *Background on Transplant Experience Equivalency*

Prior to September 2017, the bylaws allowed for the submission of documentation of transplant experience “at a designated [organ] transplant program or its foreign equivalent.” The proposal implemented in September 2017 removed the reference to foreign equivalent requiring that all case experience occur at an OPTN designated transplant program. In the 2015 briefing paper proposing this change, the Joint Society Work Group noted that standards vary widely in transplant programs outside the United States and it is difficult to assure the vigor and quality of experience gained at those programs is equivalent to United States’ programs. The briefing paper noted that under the foreign equivalent language, members are not able to determine if a proposed individual is qualified to serve as a primary surgeon or physician until the MPSC’s final decision on the application. In its recent discussions on this topic, the MPSC also indicated it is important for individuals serving as primary surgeon and physician to have experience with the United States transplant system and expressed concerns about an individual whose experience is exclusively outside the United States stepping into the role of primary physician or surgeon.

### *Alternatives Considered and Request for Feedback*

A number of issues have arisen with the current bylaws that have resulted in unintended consequences including the use of the alternative to board certification in situations for which it was not intended, and the rejection of an application for a proposed individual who appeared well qualified but whose transplant experience was gained outside of the United States. Applications have been submitted proposing individuals who lack American board certification not because they trained outside the United

States but because they are ineligible for the relevant American board certification. For example, an individual who completed a fellowship that is not accepted as qualifying was ineligible to take the necessary board exam. In another instance, an individual who trained as a surgeon was proposed for a primary physician position and was not eligible to take the medicine board exam. The MPSC also was required under the current bylaws to reject an application for an individual who could not meet the experience requirements using experience at an OPTN designated transplant program but had extensive experience at a recognized high performing transplant hospital outside the United States. The MPSC has observed that an individual can qualify as a primary surgeon using experience gained during a Canadian fellowship under the current primary surgeon fellowship pathway but the Canadian fellowship director would not be able to qualify using experience at a Canadian hospital under the clinical experience pathway.

The MPSC has considered a number of alternatives that would provide individuals who trained or obtained clinical experience outside the United States a viable pathway to qualify for a primary role. The MPSC wants to ensure that the requirements within such a pathway are equivalent to the rigorosity demanded of individuals who have trained and gained experience in the United States. The MPSC wants the requirements to be as objective and clearly defined as possible in order to provide the necessary guidance and predictability to members who are determining the eligibility of an individual to serve as the primary. At the same time, the MPSC wants the requirements to provide necessary flexibility to accommodate an almost infinite combination of foreign training and experience. Unfortunately, the MPSC has not been able to identify a comprehensive, authoritative source that evaluates equivalency of medical training or experience across the world. In order to provide as much opportunity for qualified individuals with foreign training or experience, some level of predictability will need to be sacrificed. The MPSC discussed the following alternatives:

- Retain the current alternative to board certification, but fix the language regarding ineligibility for American board certification to reflect the original proposal's intent, potentially add a requirement that the individual has met the experience requirements at an OPTN designated transplant program, and retain the current requirements for a plan for CME that is equivalent to requirements for board certified individuals and two letters of recommendation.
- Require completion of a transplant fellowship as an alternative to board certification.
- Require the submission of documentation that demonstrates the completion of an equivalent board or specialty certification, including documentation demonstrating equivalency.
- Require the submission of experience logs from outside United States with demonstration of acceptable 1 year survival and completion of an OPTN orientation curriculum for individuals with experience outside the United States.
- For both board certification and experience, use a similar process to the alternative pathways for predominately pediatric programs that requires submission of documentation of training and experience with an explanation of how the training or experience is equivalent, letters of recommendation from primary surgeons or physicians at OPTN designated transplant programs, completion of an OPTN orientation curriculum if no experience at an OPTN designated transplant program, and participation in an informal discussion with a MPSC subcommittee.

The MPSC is interested in feedback on the above options and any additional suggestions for how to provide a viable option for individuals who trained or gained experience outside the United States while ensuring that the requirements are equivalent to the rigorosity demanded of individuals who have trained and gained experience in the United States. Please consider the following questions:

- How does one evaluate whether an individual has equivalent training to a board certified practitioner?
- Should an individual proposed as primary be required to have some experience with the US transplant system? If yes, for what time period or level of experience?
- Do you support any of the alternatives suggested by the MPSC or a combination of these alternatives? Do you have other suggested options or are there other published standards that could be used to evaluate the qualifications of individuals who trained or gained experience outside the United States?

## Conclusion

The MPSC has evaluated the current transplant program primary surgeon and physician training and experience bylaw requirements and is proposing changes to the general format used for development of the organ-specific primary surgeon and physician requirements. During its evaluation of the bylaw requirements, the MPSC considered feedback from members, the MPSC's experience reviewing key personnel applications, current practice and qualifications as evidenced in transplant fellowship requirements, and revisions needed to implement the OPTN contract task for periodic review for compliance with OPTN membership related bylaws.

The Committee is requesting feedback on both the general proposed revisions to the format for transplant program key personnel experience and training requirements, and specifically on the following questions:

- Do you support the following suggested changes to the training and experience requirements for primary surgeons and primary physicians? Can you identify any unintended consequences if the suggested changes are adopted?
  - Consolidation of the fellowship and clinical experience pathways into one pathway that includes a requirement for recent experience and will accept both fellowship and clinical experience.
  - Using an electronic, OPTN-produced certification form in place of the letters of reference and recommendation.
  - Limiting procurement requirement for surgeons and observation requirements for physicians to individuals who have not served as primary surgeons or physicians in the last 10 years. Is a 10 year time frame an appropriate time limitation for exemption of individuals who have previously served as a primary surgeon or physician?
  - Expanding use of conditional approval pathways to surgeons, in addition to physicians, but limiting the use of the conditional approval pathways to circumstances where there is an unanticipated vacancy with short notice.
  - Eliminating the requirements for surgeons and physicians to document participation in an extensive list of aspects of transplant patient care (*See Attachment C for the current required organ-specific list of aspects of transplant patient care*). Does participation in pre-operative assessment and post-operative care adequately address the range of care for primary surgeons? Does participation in primary care of newly transplanted recipients for a minimum of 3 months, participation in pre-operative care of patients and direct involvement in the evaluation of potential candidates adequately address the range of care for primary physicians?
- Do you support the addition of an OPTN Orientation Curriculum? If yes, what topics should be covered in the OPTN Orientation Curriculum?

- For individuals with foreign training or experience:
  - How does one evaluate whether an individual has equivalent training to a board certified practitioner?
  - Should an individual proposed as primary be required to have some experience with US transplant system? If yes, for what time period or level of experience?
  - Do you support any of the alternatives suggested by the MPSC or a combination of these alternatives? Do you have other suggested options or are there other published standards that could be used to evaluate the qualifications of individuals who trained or gained experience outside the United States?
- For a future project to better define the current requirement that primary surgeons and physicians be “on site”:
  - What should be the responsibilities of the primary surgeon and primary physician?  
What level of commitment to a transplant program must a surgeon and physician demonstrate to fulfill the role of primary surgeon and physician?

## Attachment A: Transplant Program Key Personnel Draft Format Language

### X.1 Membership and Personnel Requirements for [ORGAN] Transplant Programs

This appendix describes the information and documentation transplant hospitals must provide when:

- Submitting a completed membership application to apply for approval as a designated [ORGAN] transplant program.
- Completing a Personnel Change Application for a change in key personnel at a designated [ORGAN] transplant program.

All [ORGAN] transplant programs must also meet general membership requirements, which are described in *Appendix D: Transplant Hospital Membership and Designated Transplant Programs* of these Bylaws.

For more information on the application and review process, see *Appendix A: Membership and Designated Transplant Program Application and Review* of these Bylaws.

### X.2 Primary [ORGAN] Transplant Surgeon, and Primary [ORGAN] Transplant Physician

The program must identify a qualified primary transplant surgeon and a qualified primary transplant physician, as described below. The primary surgeon and primary physician must submit a detailed Program Coverage Plan to the OPTN. For detailed information about the Program Coverage Plan, see *Appendix D, Section XXX: Surgeon and Physician Coverage (Program Coverage Plan)* of these Bylaws.

### X.3 Primary [ORGAN] Transplant Surgeon Requirements

A designated [ORGAN] transplant program must have a primary surgeon who meets *all* of the following requirements through the surgeon's fellowship or through acquired clinical experience (including accumulated training during any surgical transplant fellowships). Surgeons who are using experience gained during an applicable fellowship must have completed training at a hospital with an [ORGAN] transplant training program accepted by the OPTN as described in *Section X.X: Approved [ORGAN] Transplant Surgeon and Physician Fellowship Training Programs*.

1. The surgeon must
  - a. Have an M.D., D.O., or equivalent degree from another country
  - b. Have a current license to practice medicine in the hospital's state or jurisdiction
  - c. Be accepted on and a current member in good standing on the hospital's medical staff documented in a certification from the hospital credentialing committee
  - d. Be on site at this hospital.
2. The surgeon must have current certification by the American Board of [Thoracic] Surgery, the American Board of Osteopathic Surgery, [OTHER ORGAN APPROPRIATE BOARDS] or the Royal College of Physicians and Surgeons of Canada. (*See Attachment B for currently accepted board certification for each organ*).

3. The surgeon performed [#] or more [ORGAN] transplants at a designated [ORGAN] transplant program as primary surgeon, co-surgeon or first assistant within the last [#] years and participated in pre-operative assessment of [organ] transplant candidates and post-operative care of these recipients. 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 primary surgeon, fellowship director, division chief, or department chair from the program where the experience or training was gained.
4. An OPTN form that certifies that the surgeon meets the requirements for a [ORGAN] primary surgeon, is qualified to lead a [ORGAN] transplant program, is a person of honesty and integrity and has experience in adhering to OPTN obligations completed by the primary surgeon, fellowship director, division chief, or department chair from the program where the surgeon's experience or training was gained must be submitted.
5. The surgeon must provide a letter that details the training and experience the surgeon has gained in [ORGAN] transplantation.
6. If the surgeon has not served as a primary [ORGAN] transplant surgeon at an OPTN designated transplant program within the last 10 years, the surgeon must have performed [#] or more [ORGAN] procurements as primary surgeon or first assistant. These procedures must be documented in a log that includes the date of procurement and Donor ID. This log must be signed by the primary surgeon, fellowship director, division chief, or department chair from the program where the experience or training was gained.
7. If the surgeon has not served as a primary transplant surgeon at an OPTN designated transplant program within the last 10 years, the surgeon must have completed the OPTN orientation curriculum for primary transplant surgeons.

#### **X.4 Primary [ORGAN] Transplant Physician Requirements**

A designated [ORGAN] transplant program must have a primary physician who meets the following requirements. Physicians can meet the requirements for a primary [ORGAN] transplant physician during the physician's transplant fellowship or through acquired clinical experience (including accumulated training during any transplant fellowships). Physicians who are using experience gained during a fellowship must have completed training at a hospital with an [ORGAN] transplant training program accepted by the OPTN as described in *Section X.X: Approved [ORGAN] Transplant Surgeon and Physician Fellowship Training Programs*.

1. The physician must
  - a. Have an M.D., D.O., or equivalent degree from another country
  - b. Have a current license to practice medicine in the hospital's state or jurisdiction
  - c. Be accepted on and a current member in good standing on the hospital's medical staff documented in a certification from the hospital credentialing committee
  - d. Be on site at this hospital.
2. The physician must have current board certification in [ORGAN APPROPRIATE BOARDS]. (*See Attachment B for currently accepted board certification for each organ*).
3. The physician must meet the requirements of either General Pathway outlined in X.4.A below or the Pediatric Pathway outlined in X.4.B below

## **A. General Pathway**

1. The physician has been directly involved within the last [#] years in the primary care of [#] or more newly transplanted [ORGAN] recipients and continued to follow these recipients for a minimum of 3 months from the time of transplant and participated in pre-operative care of the patient. This clinical experience must be gained as the primary [ORGAN] transplant physician or under the direct supervision of a [ORGAN] transplant physician and in conjunction with an [ORGAN] transplant surgeon at a designated [ORGAN] transplant program. This care must be documented in a log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the primary physician, fellowship director, division chief, or department chair from the program where the experience or training was gained.
2. The physician has been directly involved in the evaluation of [#] potential [ORGAN] recipients, including participation in selection committee meetings. These potential [ORGAN] recipient evaluations must be documented in a log that includes the evaluation date of each potential recipient and is signed by the primary physician, fellowship director, division chief, or department chair from the program where the physician gained this experience.
3. An OPTN form that certifies that the physician meets the requirements for a [ORGAN] primary physician, is qualified to lead a [ORGAN] transplant program, is a person of honesty and integrity and has experience in adhering to OPTN obligations completed by the primary physician, fellowship director, division chief, or department chair from the program where the physician's experience or training was gained must be submitted.
4. The physician provides a letter that details the training and experience the physician has gained in [ORGAN] transplantation.
5. If the proposed physician has not served as a primary [ORGAN] transplant physician at an OPTN designated transplant program within the last 10 years, the physician must have observed at least 1 [ORGAN] transplant and at least 1 [ORGAN] procurement. The observations must be documented in a log that includes the date of transplant or procurement. This log must be signed by the primary physician, fellowship director, division chief, or department chair from the program where the experience or training was gained.
6. If the proposed physician has not served as a primary transplant physician at an OPTN designated transplant program within the last 10 years, the physician must have completed the OPTN orientation curriculum for primary transplant physicians.

## **B. Pediatric Pathway (Kidney and Liver only)**

*[The MPSC is proposing the consolidation of the three existing pediatric pathways for kidney and liver primary physicians into one following the same format as the general pathway.]*

## **X.6 Conditional Approval for [ORGAN] Program**

As part of a key personnel change at an approved designated [ORGAN] transplant program, a surgeon can serve conditionally as the primary [ORGAN] transplant surgeon or a physician can serve conditionally as the primary [ORGAN] transplant physician for a maximum of 12 months if the conditions below are met. Conditional approval of a primary transplant surgeon or primary transplant physician results in a change in status for the transplant program to conditional approval. The MPSC may consider on a case-by-case basis granting a # month extension to a transplant program that provides substantial evidence of progress toward fulfilling the requirements, but is unable to complete the requirements within the 12-month conditional approval period.

## **A. Conditional Approval for Primary Transplant Surgeon**

A surgeon can serve as the primary [ORGAN] transplant surgeon for a maximum of 12 months if all of the following conditions are met:

1. The program has a qualified primary [ORGAN] transplant physician who meets all of the requirements described in *X.4 Primary [ORGAN] Transplant Physician Requirements*.
2. The change in primary [ORGAN] transplant surgeon was caused by an unanticipated vacancy in the position with short notice.
3. The surgeon must
  - a. Have an M.D., D.O., or equivalent degree from another country
  - b. Have a current license to practice medicine in the hospital's state or jurisdiction
  - c. Be accepted on and a current member in good standing on the hospital's medical staff documented in a certification from the hospital credentialing committee
  - d. Be on site at this hospital.
4. The surgeon must have current certification by the American Board of [Thoracic] Surgery, the American Board of Osteopathic Surgery, [OTHER ORGAN APPROPRIATE BOARDS] or the Royal College of Physicians and Surgeons of Canada. (*See Attachment B for currently accepted board certification for each organ.*)
5. The surgeon has 12 months experience on an active [ORGAN] transplant service as the primary [ORGAN] transplant surgeon or under the direct supervision of a qualified [ORGAN] transplant surgeon along with a [ORGAN] transplant physician at a designated [ORGAN] transplant program. These 12 months of experience must be acquired within the last 2 years.
6. The surgeon develops a formal mentor relationship with a primary [ORGAN] transplant surgeon at another approved [ORGAN] transplant program. The mentor will discuss program requirements, patient and donor selection, recipient management, and be available for consultation as required until full approval conditions are all met.
7. The surgeon performed at least [SOME # LESS THAN THE REQUIRED FOR FULL APPROVAL] [ORGAN] transplants at a designated [ORGAN] transplant program as primary surgeon, co-surgeon or first assistant within the last [#] years and participated in pre-operative assessment of [organ] transplant candidates and post-operative care of these recipients. 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 primary surgeon, fellowship director, division chief, or department chair from the program where the experience or training was gained.
8. An OPTN form that certifies that the physician meets the requirements for a [ORGAN] primary physician, is qualified to lead a [ORGAN] transplant program, is a person of honesty and integrity and has experience in adhering to OPTN obligations completed by the primary physician, fellowship director, division chief, or department chair from the program where the physician's experience or training was gained must be submitted.
9. The surgeon must provide a letter that details the training and experience the surgeon has gained in [ORGAN] transplantation.
10. If the surgeon has not served as a primary [ORGAN] transplant surgeon at an OPTN designated transplant program within the last 10 years, the surgeon must have performed [#] or more [ORGAN] procurements as primary surgeon or first assistant. These procedures must be documented in a log that includes the date of procurement and Donor ID. This log must be signed by the primary surgeon, fellowship director, division chief, or department chair from the program where the experience or training was gained.

11. If the surgeon has not served as a primary transplant surgeon at an OPTN designated transplant program within the last 10 years, the surgeon must have completed the OPTN orientation curriculum for primary transplant surgeons.
12. The transplant program submits activity reports to the OPTN every 2 months describing the transplant activity, transplant outcomes, surgeon recruitment efforts, and other operating conditions as required by the MPSC to demonstrate the ongoing quality and efficient patient care at the program. The activity reports must also demonstrate that the surgeon is making sufficient progress to meet the requirements for full approval, or that the program is making sufficient progress in recruiting a surgeon who meets all requirements for primary [ORGAN] transplant surgeon and who will be on site and approved by the MPSC to assume the role of primary surgeon by the end of the 12 month conditional approval period.

## **B. Conditional Approval for Primary Transplant Physician**

A surgeon can serve as the primary [ORGAN] transplant physician for a maximum of 12 months if all of the following conditions are met:

1. The program has a qualified primary [ORGAN] transplant surgeon who meets all of the requirements described in *X.3 Primary [ORGAN] Transplant Surgeon Requirements*.
2. The change in primary [ORGAN] transplant physician was caused by an unanticipated vacancy in the position with short notice.
3. The physician must
  - a. Have an M.D., D.O., or equivalent degree from another country
  - b. Have a current license to practice medicine in the hospital's state or jurisdiction
  - c. Be accepted on and a current member in good standing on the hospital's medical staff documented in a certification from the hospital credentialing committee
  - d. Be on site at this hospital.
4. The physician must have current board certification in [ORGAN APPROPRIATE BOARDS]. (*See Attachment B for currently accepted board certification for each organ*).
5. The physician has 12 months experience on an active [ORGAN] transplant service as the primary [ORGAN] transplant physician or under the direct supervision of a qualified [ORGAN] transplant physician along with a [ORGAN] transplant surgeon at a designated [ORGAN] transplant program. These 12 months of experience must be acquired within the last 2 years.
6. The physician develops a formal mentor relationship with a primary [ORGAN] transplant physician at another approved designated [ORGAN] transplant program. The mentor will discuss program requirements, patient and donor selection, recipient management, and be available for consultation as required.
7. The physician has been directly involved within the last [#] years in the primary care of at least [SOME # LESS THAN THE REQUIRED FOR FULL APPROVAL] newly transplanted [ORGAN] recipients and continued to follow these recipients for a minimum of 3 months from the time of transplant and participated in pre-operative care of the patient. This clinical experience must be gained as the primary [ORGAN] transplant physician or under the direct supervision of a [ORGAN] transplant physician and in conjunction with an [ORGAN] transplant surgeon at a designated [ORGAN] transplant program. This care must be documented in a log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the primary physician, fellowship director, division chief, or department chair from the program where the experience or training was gained.

8. The physician has been directly involved in the evaluation of at least [SOME # LESS THAN THE REQUIRED FOR FULL APPROVAL] potential [ORGAN] recipients, including participation in selection committee meetings. These potential [ORGAN] recipient evaluations must be documented in a log that includes the evaluation date of each potential recipient and is signed by the primary physician, division chief, or department chair from the program where the physician gained this experience.
9. An OPTN form that certifies that the physician meets the requirements for a [ORGAN] primary physician, is qualified to lead a [ORGAN] transplant program, is a person of honesty and integrity and has experience in adhering to OPTN obligations completed by the primary physician, fellowship director, division chief, or department chair from the program where the physician's experience or training was gained must be submitted.
10. The physician provides a letter that details the training and experience the physician has gained in [ORGAN] transplantation.
11. If the proposed physician has not served as a primary [ORGAN] transplant physician at an OPTN designated transplant program within the last 10 years, the physician must have observed at least 1 [ORGAN] transplant and at least 1 [ORGAN] procurement. The observations must be documented in a log that includes the date of transplant or procurement. This log must be signed by the primary physician, fellowship director, division chief, or department chair from the program where the experience or training was gained.
12. If the proposed physician has not served as a primary transplant physician at an OPTN designated transplant program within the last 10 years, the physician must have completed the OPTN orientation curriculum for primary transplant physicians.
13. The transplant program submits activity reports to the OPTN Contractor every 2 months describing the transplant activity, transplant outcomes, physician recruitment efforts, and other operating conditions as required by the MPSC to demonstrate the ongoing quality and efficient patient care at the program. The activity reports must also demonstrate that the physician is making sufficient progress to meet the requirements for full approval, or that the program is making sufficient progress in recruiting a physician who meets all requirements for primary [ORGAN] transplant physician and who will be on site and approved by the MPSC to assume the role of primary physician by the end of the 12 month conditional approval period.

## **X.7 Approved [ORGAN] 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 surgical transplant fellowship must complete their training at a fellowship program approved by the [ORGAN APPROPRIATE ORGANIZATIONS] or another recognized fellowship training program accepted by the OPTN that meets *all* of the following criteria:

1. The program is at a transplant hospital that transplants two or more organs, including [ORGAN]s.
2. The program is at an institution that has ACGME approved training in general surgery.
3. The program performs at least [#] [ORGAN] transplants during each year of the fellowship training.

**B. Transplant Physician Fellowship Training Programs *[Some current organ specific requirements only include requirements for surgical transplant fellowships]***

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 [ORGAN APPROPRIATE ORGANIZATIONS], or another recognized fellowship training program accepted by the OPTN that meets the following criteria:

1. The program is at a transplant hospital that transplants one or more organs, including [ORGAN]s.
2. The program is at a hospital that has an ACGME approved [SPECIALTY] program.
3. The program performs at least [#] [ORGAN] transplants per year if the program is training one transplant [SPECIALTY] fellow, and performs at least [#] additional [ORGAN] transplants per year for each additional fellow it trains.
4. [KIDNEY EXAMPLE]The program’s 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.
5. [KIDNEY EXAMPLE] 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.

## Attachment B: Board certifications currently accepted for each organ

| <b>Primary Surgeons:</b> |  |
|--------------------------|--|
| <b>Organ</b>             | <b>Boards accepted</b>   |
| Kidney                   | American Board of Surgery<br>American Board of Urology, conditional approval if pending<br>American Board of Osteopathic Surgery<br>Royal College of Physicians and Surgeons of Canada |
| Liver                    | American Board of Surgery<br>American Board of Urology, conditional approval if pending<br>American Board of Osteopathic Surgery<br>Royal College of Physicians and Surgeons of Canada |
| Intestine                | American Board of Surgery<br>American Board of Osteopathic Surgery<br>Royal College of Physicians and Surgeons of Canada   |
| Pancreas                 | American Board of Surgery<br>American Board of Urology, conditional approval if pending<br>American Board of Osteopathic Surgery<br>Royal College of Physicians and Surgeons of Canada |
| Heart                    | American Board of Thoracic Surgery, conditional approval if pending<br>Royal College of Physicians and Surgeons of Canada, Thoracic Surgery  |
| Lung                     | American Board of Thoracic Surgery, conditional approval if pending<br>Royal College of Physicians and Surgeons of Canada, Thoracic Surgery  |

| <b>Primary Physicians:</b> |   |
|----------------------------|---|
| <b>Organ</b>               | <b>Boards accepted</b>  |
| Kidney                     | current certification in nephrology by:<br>American Board of Internal Medicine<br>American Board of Pediatrics<br>Royal College of Physicians and Surgeons of Canada  |
| Liver                      | current board certification in gastroenterology, current board certification in transplant hepatology, or a current pediatric transplant hepatology certification of added qualification by:<br>American Board of Internal Medicine<br>American Board of Pediatrics<br>Royal College of Physicians and Surgeons of Canada |
| Intestine                  | current board certification in gastroenterology by:<br>American Board of Internal Medicine<br>American Board of Pediatrics<br>Royal College of Physicians and Surgeons of Canada  |

| <b>Primary Physicians:</b> |  |
|----------------------------|--|
| Pancreas                   | current board certification in nephrology, endocrinology, or diabetology by:<br>American Board of Internal Medicine<br>American Board of Pediatrics<br>Royal College of Physicians and Surgeons of Canada  |
| Heart                      | current certification in adult or pediatric cardiology or current board certification in advanced heart failure and transplant cardiology by:<br>American Board of Internal Medicine<br>American Board of Pediatrics<br>Royal College of Physicians and Surgeons of Canada |
| Lung                       | current board certification or have achieved eligibility in adult or pediatric pulmonary medicine by:<br>American Board of Internal Medicine<br>American Board of Pediatrics<br>Royal College of Physicians and Surgeons of Canada   |

**Attachment C: Lists of aspects of care a surgeon or physician is currently required to document but are not included in the proposed framework**

| <b>Primary Surgeons:</b> |  |
|--------------------------|--|
| <b>Organ</b>             | <b>Aspects of patient care required</b>  |
| Kidney                   | 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.         |
| Liver                    | Management of patients with end stage liver disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, performing the transplant operation, immediate postoperative and continuing inpatient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of liver dysfunction in the allograft recipient, histologic interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long term outpatient care.           |
| Intestine                | 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. |
| Pancreas                 | 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.       |
| Heart                    | Performing the transplant operation, donor selection, the use of mechanical assist devices, recipient selection, post-operative hemodynamic care, postoperative immunosuppressive therapy, and outpatient follow-up.   |
| Lung                     | Care of acute and chronic lung failure, cardiopulmonary bypass, donor selection, recipient selection, pre- and postoperative ventilator care, postoperative immunosuppressive therapy, histological interpretation and grading of lung biopsies for rejection, and long-term outpatient follow-up.   |

| <b>Primary Physicians:</b> |  |
|----------------------------|--|
| <b>Organ</b>               | <b>Aspects of patient care required</b>  |
| Kidney                     | 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.           |
| Liver                      | management of patients with end stage liver disease, acute liver failure, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of liver allograft dysfunction, histologic interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long term outpatient care.        |
| Intestine                  | Management of patients with intestinal failure, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of intestine allograft dysfunction, histologic interpretation of allograft biopsies, interpretation of ancillary tests for intestine dysfunction, and long term outpatient care.                          |
| Pancreas                   | 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. |
| Heart                      | Care of acute and chronic heart failure, donor selection, use of mechanical circulatory support devices, recipient selection, pre- and post-operative hemodynamic care, post-operative immunosuppressive therapy, histological interpretation and grading of myocardial biopsies for rejection, and long-term outpatient follow-up.  |
| Lung                       | Care of acute and chronic lung failure, cardiopulmonary bypass, donor selection, recipient selection, pre- and postoperative ventilator care, postoperative immunosuppressive therapy, histological interpretation and grading of lung biopsies for rejection, and long-term outpatient follow-up.   |