

**OPTN/UNOS Membership and Professional Standards Committee (MPSC)
Report to the Board of Directors
December 1-2, 2015
Richmond, VA**

**Jonathan M. Chen, MD, Chair
Jeffrey P. Orlowski, MS, CPTC, Vice Chair**

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This report reflects the work of the OPTN/UNOS Membership and Professional Standards Committee (MPSC) between May 2015 and October 2015.

Action Items

1. Key Personnel Procurement Requirements

Public Comment: [August 14 – October 14, 2015](#)

Some transplant program key personnel requirements in OPTN/UNOS Bylaws involving organ procurement experience need to be updated. Specifically, certain Bylaws have been recognized as unnecessary due to the evolution of transplantation, unenforceable as currently written, inconsistent across the different transplant programs, or including periods to obtain necessary procurement experience that have been restrictive and problematic for some members. This Committee developed and distributed a public comment proposal recommending Bylaws changes that address these issues and update transplant program key personnel procurement requirements. Proposed changes stemmed from recommendations provided by a Joint Societies Working Group, and include: deleting multi-organ procurement requirements for all key personnel; requiring that all primary transplant physicians must (as compared to “should”) observe three procurements of the organ that corresponds to the transplant program they are applying to be the primary physician of; removing “selection and management of the donor” requirements from the primary liver transplant surgeon pathways; and extending the time period for performing the requisite number of procurements in each primary transplant surgeon training pathway. Clarifying and updating these Bylaws primarily supports the OPTN strategic plan key goal of promoting the efficient management of the OPTN.

During its October 2015 meeting, the MPSC reviewed and considered all the public comment feedback provided in response to this proposal (**Exhibit A**). After making changes to address the public comment feedback provided, the MPSC voted in support (29 For, 0 Against, 0 Abstentions) of the following resolution to send these proposed changes to the OPTN/UNOS Board of Directors for consideration during its December 2015 meeting.

RESOLVED, that changes to Bylaws Appendices E.2.A (Formal 2-year Transplant Fellowship Pathway), E.2.B (Clinical Experience Pathway), E.3.A (Twelve-month Transplant Nephrology Fellowship Pathway), E.3.B (Clinical Experience Pathway), E.3.C (Three-year Pediatric Nephrology Fellowship Pathway), E.3.D (Twelve-month Pediatric Transplant Nephrology Fellowship Pathway), E.3.E (Combined Pediatric Nephrology Training and Experience Pathway), E.3.G (Conditional Approval for Primary Transplant Physician), F.2.A (Formal 2-year Transplant Fellowship Pathway), F.2.B (Clinical Experience Pathway), F.3.A (12-month Transplant Hepatology Fellowship Pathway), F.3.B (Clinical Experience Pathway), F.3.C (Three-year Pediatric Gastroenterology Fellowship Pathway), F.3.D (Pediatric Transplant Hepatology Fellowship Pathway), F.3.E (Combined Pediatric Gastroenterology/Transplant

Hepatology Training and Experience Pathway), F.3.G (Conditional Approval for Primary Transplant Physician), F.10.A (Full Intestine Surgeon Approval Pathway), F.10.B (Conditional Intestine Surgeon Approval Pathway), G.2.A (Formal 2-year Transplant Fellowship Pathway), G.3.A (Twelve-month Transplant Medicine Fellowship Pathway), G.3.B (Clinical Experience Pathway), G.3.D (Conditional Approval for Primary Transplant Physician), H.2.A (Cardiothoracic Surgery Residency Pathway), H.2.B (Twelve-month Heart Transplant Fellowship Pathway), H.3.A (Twelve-month Transplant Cardiology Fellowship Pathway), H.3.B (Clinical Experience Pathway), H.3.D (Conditional Approval for Primary Transplant Physician), I.2.A (Cardiothoracic Surgery Residency Pathway), I.2.B (Twelve-month Lung Transplant Fellowship Pathway), I.3.A (Twelve-month Transplant Pulmonary Fellowship Pathway), I.3.B (Clinical Experience Pathway), I.3.D (Conditional Approval for Primary Transplant Physician), as set forth below, are hereby approved, effective March 1, 2016.

2. Delete "Foreign Equivalent" from Bylaws

Public Comment: [August 14 – October 14, 2015](#)

OPTN/UNOS Bylaws' transplant program key personnel requirements use the term "foreign equivalent." Specifically, transplant program key personnel are required to have current American board certification or the "foreign equivalent," and cited experience must have been obtained at a designated transplant program or the "foreign equivalent." This term is unclear for members when assessing if certain staff are qualified to serve as transplant program key personnel and for the Committee when evaluating membership applications and determining if a board certification or case experience performed outside the United States should be considered equivalent. To address this problem, and after consideration by a Joint Societies Working Group, the MPSC proposes deleting the term "foreign equivalent" from the Bylaws (except for vascularized composite allograft (VCA) program key personnel); permitting board certification by the Royal College of Physicians and Surgeons of Canada in addition to American board certification; and establishing a new process for those individuals who are not American or Canadian board certified to qualify as transplant program key personnel. These proposed changes are anticipated to advance the OPTN Strategic Plan key goals of promoting living donor and transplant recipient safety and the efficient management of the OPTN. Changing the Bylaws to better reflect the training and experience expected of transplant program key personnel should contribute positively to increased transplant recipient safety. Additionally, removing the ambiguous term "foreign equivalent" and providing a detailed option to qualify as key personnel for those who do not possess American board certification should help promote the efficient management of the OPTN.

During its October 2015 meeting, the MPSC reviewed and considered all the public comment feedback provided in response to this proposal (**Exhibit B**). After making changes to address some of the public comment feedback provided, the MPSC voted in support (29 For, 0 Against, 0 Abstentions) of the following resolution to send these proposed changes to the OPTN/UNOS Board of Directors for consideration during its December 2015 meeting.

RESOLVED, that changes to Bylaws Appendices E.2. (Primary Kidney Transplant Surgeon Requirements), E.2.A (Formal 2-year Transplant Fellowship Pathway), E.2.B (Clinical Experience Pathway), E.3 (Primary Kidney Transplant Physician Requirements), E.3.A (Twelve-month Transplant Nephrology Fellowship Pathway), E.3.B (Clinical Experience Pathway), E.3.C (Three-year Pediatric Nephrology Fellowship Pathway), E.3.D (Twelve-month Pediatric Transplant Nephrology

Fellowship Pathway), E.3.E (Combined Pediatric Nephrology Training and Experience Pathway), E.3.G (Conditional Approval for Primary Transplant Physician), F.2 (Primary Liver Transplant Surgeon Requirements), F.2.A (Formal 2-year Transplant Fellowship Pathway), F.2.B (Clinical Experience Pathway), F.3 (Primary Liver Transplant Physician Requirements), F.3.B (Clinical Experience Pathway), F.3.C (Three-year Pediatric Gastroenterology Fellowship Pathway), F.3.D (Pediatric Transplant Hepatology Fellowship Pathway), F.3.E (Combined Pediatric Gastroenterology/Transplant Hepatology Training and Experience Pathway), F.3.G (Conditional Approval for Primary Transplant Physician), F.4 (Requirements for Director of Liver Transplant Anesthesia), F.10 (Primary Intestine Transplant Surgeon Requirements), F.10.A (Full Intestine Surgeon Approval Pathway), F.10.B (Conditional Intestine Surgeon Approval Pathway), F.11 (Primary Intestine Transplant Physician Requirements), F.11.B (Conditional Intestine Physician Approval Pathway,) G.2 (Primary Pancreas Transplant Surgeon Requirements), G.2.A (Formal 2-year Transplant Fellowship Pathway), G.2.B (Clinical Experience Pathway), G.3 (Primary Pancreas Transplant Physician Requirements), G.3.B (Clinical Experience Pathway), G.3.D (Conditional Approval for Primary Transplant Physician), H.2 (Primary Heart Transplant Surgeon Requirements), H.2.A (Cardiothoracic Surgery Residency Pathway), H.2.B (Twelve-month Heart Transplant Fellowship Pathway), H.2.C (Clinical Experience Pathway), H.3 (Primary Heart Transplant Physician Requirements), H.3 (Primary Heart Transplant Physician Requirements), H.3.A (Twelve-month Transplant Cardiology Fellowship Pathway), H.3.B (Clinical Experience Pathway), H.3.D (Conditional Approval for Primary Transplant Physician), I.2 (Primary Lung Transplant Surgeon Requirements), I.2.A (Cardiothoracic Surgery Residency Pathway), I.2.B (Twelve-month Lung Transplant Fellowship Pathway), I.2.C (Clinical Experience Pathway), I.3 (Primary Lung Transplant Physician Requirements), I.3.A (Twelve-month Transplant Pulmonary Fellowship Pathway), I.3.B (Clinical Experience Pathway), I.3.D (Conditional Approval for Primary Transplant Physician), as set forth in Exhibit A, are hereby approved, effective March 1, 2016.

3. Remove Reference to Time Frames from Bylaws regarding Inactivation after Conditional Approval

Public Comment: N/A

The Committee is proposing a non-substantive change to the Bylaws regarding inactivation of a program after a period of conditional approval because the current bylaws are misleading. There are two main things contributing to this.

- The Bylaws stating that the program must inactivate after a fixed length of time are counter to the Bylaws stating that the approval period may vary depending on whether or not the conditional approval is extended at the discretion of the MPSC. The periods of time vary by program type.
- The paragraph in each section that explains extension of a conditional approval is after the paragraph that requires the transplant program to inactivate if they do not receive full approval at the end of their conditional approval period. It is in neither chronological nor logical order.

Changing the language to make it consistent provides more transparency about what may happen if a conditionally approved transplant program is unable to meet the full requirements for program approval by the end of its conditional approval period. It also provides clear guidance for the actions of the OPTN regarding decisions about conditionally approved transplant programs and living donor components.

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During its October meeting, the Committee reviewed the proposed bylaw language and unanimously approved the language for consideration by the Board of Directors (29 For, 0 Against, 0 Abstentions).

RESOLVED, that Bylaws Appendixes E.3.G (Conditional Approval for Primary Transplant Physician), F.3.G (Conditional Approval for Primary Transplant Physician), F.7.F (Rejection of Conditional Approval), F.12.B. (Rejection of Conditional Approval), G.3.D (Conditional Approval for Primary Transplant Physician), H.3.D (Conditional Approval for Primary Transplant Physician), I.3.D (Conditional Approval for Primary Transplant Physician) as set forth in Exhibit C, are hereby approved effective March 1, 2016.

4. Membership Status Changes and Application Issues

Public Comment: N/A

The Committee is charged with determining whether member clinical transplant programs, organ procurement organizations, histocompatibility laboratories, and non-institutional members meet and remain in compliance with membership criteria. During each meeting, it considers actions regarding the status of current members and new applicants. The Committee reviewed the applications and status changes listed below and recommend that the Board of Directors take the following actions:

New Members

- Fully approve 1 new transplant hospital
- Fully approve 5 individual members
- Fully approve 2 public organizations
- Fully approve 1 medical/scientific organization
- Fully approve 2 business members

Existing Members

- Fully approve 12 transplant programs
- Fully approve 7 transplant program components
- Fully approve reactivation of 8 transplant programs and 1 living donor component
- Fully approve the reclassification of a laboratory from independent to hospital based
- Fully approve 1 conditional program and 2 conditional living donor components

Committee Projects

5. Transplant Hospital Definition

Public Comment: [September – December 2014](#)

Public Comment: August 2016 (Estimated)

Board Consideration: December 2016 (Estimated)

During its July meeting, the Committee continued its discussion of the proposal to clarify the definition of a transplant hospital in the Bylaws. Specifically, the Committee discussed whether a member should be able to perform transplants at more than one site, and if so, what membership requirements would apply to each individual site rather than the member. The Committee also discussed whether there are certain scenarios in which a member should not be permitted to perform transplants in more than one site.

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During its August 2015 meeting, the Committee received an update on recent Transplant Hospital Definition Work Group teleconferences and additional considerations that were prompted by these discussions. The work group had primarily focused on:

- The possibility of establishing transplant “sites” that are affiliated with a transplant hospital.
- Characteristics that define a site and differentiate single-site and multi-site transplant hospitals.
- Preliminary discussions regarding the association between CMS and the OPTN’s definitions of a transplant hospital.

The Work Group suggested that each transplant “site” must have independent key personnel, functional and inactivity reviews, and coverage plans. Additionally, each transplant hospital member must at least have HLA and blood bank services, mental health and social services, clinical and financial coordinators, and a transplant pharmacist available (not necessarily dedicated to) for each of its transplant sites. Subsequent work group discussions started to define a “transplant site” as characterized by a dedicated OR, post-operative care unit, and transplant ICU/floor, but each “site” cannot have more than one program within the same contiguous campus.

UNOS staff and the Committee Vice Chair further reviewed and discussed these potential elements of a transplant hospital definition. That discussion prompted additional options for the Committee to consider:

- Move away from the concept of “sites” as it seemingly creates another layer of complexity without comparable value or benefit for members.
- Establish that a transplant hospital includes all facilities within a contiguous campus, all facilities within the radius of a to-be-determined distance, and other scenarios outside of these criteria as reviewed and approved at the discretion of the MPSC.
- Establishing that a transplant hospital may include multiple ORs, ICUs, post-OP care units, etc. as long as these facilities include the appropriate infrastructure for transplant patient care and are documented with the OPTN.

To conclude the Transplant Hospital Definition Work Group update presentation, the Committee reviewed maps of some cities with transplant hospitals to consider how these potential transplant hospital definition elements may be applied.

Committee members questioned if it was necessary to mandate that individuals could only serve as key personnel at one program, providing the example of a small-volume pediatric program in close proximity to adult programs. Committee members replied that they are aware of individual key personnel leading multiple successful programs, but that it is a challenging endeavor, which would not likely be successful in all situations. The Work Group agreed to continue discussing whether the Bylaws should prevent individuals from serving as key personnel at more than one hospital.

Another Committee member raised questions about multi-organ transplants performed at transplant hospitals with separate facilities for separate organs. Is this something that should also be considered? What assurances are there that systems and resources are in place to safely and effectively perform complicated multi-organ transplants at transplant hospitals organized this way? The Vice Chair replied that the working group had not discussed multi-organ transplants in the context of defining a transplant hospital, and that this is another topic to be considered.

UNOS Staff asked the Committee if it had any particular comment on the distance that could define a transplant hospital if the facilities are not on a contiguous campus. While any

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distance will be arbitrary, the intention of this consideration is to accommodate facilities not located in one connected area (e.g., transplant hospitals in urban environments) and considering the possibility of hospital expansion. The Committee initially responded that the boundary should not be extremely expansive, and only allow situations that the Committee would always consider appropriate. Essential to this approach is also allowing members to explain their scenario and make a case to the MPSC if it falls outside these criteria. Regarding the distance itself, and noting that the ease at which one can traverse a mile is different depending on the city, a Committee member suggested the driving time between locations as another alternative measure. Others replied that driving time is also relative, depending on the time of day, who is driving, and other unpredictable events. Committee members responded that an expected response time is often required by hospitals upon hiring clinicians, and although relative, it would not be that unique of a consideration. Another Committee member proposed a two-mile radius, noting most can walk a mile in about fifteen minutes, which would allow approximately 30 minutes to traverse between sites in just about all scenarios.

The OPTN Vice President asked about the necessity of a distance boundary. It seems as though the distance boundary is to assure that medical expertise is in close proximity to care for urgent patients. What if a member can demonstrate sufficient services exist outside the boundary? In response, the Vice Chair stated that the geographic component to accommodate urban hospital facilities that are not within a contiguous campus and hospitals that may expand beyond their campus is the more challenging aspect of this potential definition. Because of these known scenarios, it seems necessary to establish a reasonable threshold that can help explicitly characterize a transplant hospital for the purpose of executing the OPTN's responsibilities. Recognizing that this definition will not accommodate all transplant hospital arrangements is part of the rationale for recommending that members are also allowed to engage the MPSC to make their case if they fall outside of the established criteria.

During its October meeting, the Committee received an update on the Working Group September's teleconference. First, the MPSC reviewed the transplant hospital definition elements that had been agreed to thus far:

- All transplant hospitals must continue to meet current requirements outlined in Appendix D (Membership Requirements for Transplant Hospitals and Transplant Programs). E.g.:
 - Primary transplant physician and primary transplant surgeon
 - Functional and inactivity reviews
 - Coverage plan
 - HLA and blood bank services available for each site
 - Clinical and financial coordinators, pharmacist, mental and social support services available for each site
- Additionally, all of a member's transplant facilities
 - Must have common executive leadership and shared governance structure demonstrated to satisfaction of the MPSC
 - Must all be within a single DSA
- Transplant hospital includes either:
 - Facilities within a "contiguous campus"
 - Facilities within a specific distance
 - Other scenarios outside of these criteria may be reviewed and approved at the discretion of the MPSC; two locations not approved as a single member would need separate OPTN memberships

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- The transplant hospital may include multiple ORs, ICUs, post-op care units, for transplant patient care
 - The operating room locations must be preemptively documented with the OPTN
 - Transplant hospital must assure that appropriate infrastructure to care for transplant patients is in place at each location

Prompted by feedback provided during the MPSC's August meeting, the Work Group presented other considerations for the full committee's review:

- *Expand on what defines a "continuous campus"*- The Work Group agreed to the following definition to define a "continuous campus:"
"The physical area within a boundary line drawn on a map that exclusively encompasses land and buildings owned by the hospital. The exclusion of separate commercial or residential property adjacent to hospital property dictates the placement of this boundary line."
- *Radial distance from main hospital if transplant facilities on a noncontiguous campus*- After discussing numerous options, and the pros/cons of each, the Work Group agreed to one mile walking distance. Acknowledging the arbitrary nature of any decision to this point, the Work Group agreed that this suggestion would be a reasonable recommendation to present and continue discussing. In considering this definition, it is important to note that a more restrictive radius would likely increase the frequency of cases that fall outside of the standard criteria and that would be presented for the MPSC's review. The amount of new MPSC work created by this proposal will need to be monitored upon implementation of these Bylaws. UNOS staff also noted that it appears the approval of transplant hospital facilities not included on a contiguous campus will heavily depend on the member demonstrating common governance and leadership. As such, the OPTN and MPSC will need clear documentation to validate this, and it will be important to know what resources could be used for this purpose.
- *Key personnel at more than one transplant hospital*- Previously, the work group agreed that key personnel should only be allowed to serve in this role for one transplant hospital. Committee members expressed concern with this approach. The Work Group discussed this further during its September meeting, and agreed that a proposal to update the transplant hospital definition should not include changes to the current key personnel Bylaws. Although there are still concerns about individuals' ability to uphold all key personnel responsibilities at multiple transplant hospitals, in addition to other issues related to coverage plans at multiple transplant hospitals, the Work Group made this suggestion considering the potential that addressing key personnel in this proposal may incite additional controversy and distract discussion from the main focus of the proposal. If the MPSC believes that additional key personnel restrictions are necessary, then this issue can be explored separately from the transplant hospital definition discussions.
- Work Group discussion of key personnel segued into discussions about assuring that each transplant hospital only had one designated transplant program for each organ. The Work Group agreed this should be the case, and that the proposed Bylaws should incorporate considerations that only one transplant hospital can be approved for any particular hospital campus (as defined by one of the three options to be proposed; contiguous campus, within a one mile walking radius, or as approved per the discretion of the MPSC). This perspective prompted questions about how to handle pediatric hospitals that share a campus with another hospital, and that may want to retain (or obtain) a separate OPTN membership. The Work

Group replied that it would seem necessary for proposed Bylaws to accommodate these situations. Accordingly, the Work Group modified its previous recommendation and stated that only one transplant hospital could be approved for any given campus area, unless the second proposed transplant hospital within that same area is a children's hospital.

In response to this recommendation, UNOS staff asked the work group how it envisioned operationalizing this distinction. The MPSC Vice Chair referred to the CMS conditions of participation for pediatric transplants to help the OPTN address this matter. Specifically, an approved pediatric program must perform 50% or more of its transplants in pediatric patients over a 12-month period. The work group thought a similar requirement would be appropriate to distinguish pediatric transplant hospitals for the purpose of allowing two discrete transplant hospitals within the same general campus area. The 50% or greater threshold should capture all hospitals that would traditionally be thought of as children's hospitals, while still allowing sufficient flexibility for the member to care for adult transplant candidates as is deemed necessary (e.g., congenital heart patients who are older than 18 years of age). The "children's transplant hospital" would be regularly monitored to assure that it is above this 50% threshold, and OPTN membership would be in jeopardy if this threshold is not sustained.

- *Multi-organ transplant considerations*- a final consideration raised by the MPSC pertained to multi-organ transplants, and whether the transplant hospital definition needed additional considerations to assure these more challenging procedures are approached safely. The Work Group considered this topic, and opined that the current construct of requiring individual program approval for each organ involved in a potential multi-organ transplant is effective.

The MPSC expressed its gratitude for the Work Group's efforts and indicated that it generally supported the concepts presented. Members noted that questions will likely be raised about the "one-mile walking distance" parameter, and that the MPSC should continue to build its arguments for explaining this decision. Understanding that every transplant hospital may not fit into the contiguous campus or one mile walking distance definitions, the third option of allowing a transplant hospital to present their case before the MPSC seems to be a critical component that will bolster support for this proposal. The MPSC also raised questions about how this definition will accommodate Veteran Affairs (VA) hospitals. The Working Group had not explicitly discussed VA hospitals, but indicated it would do so during its next teleconference. Additionally, the Work Group will also begin creating draft Bylaws that incorporate these concepts. These draft Bylaws will be presented for the full Committee's consideration after the Work Group has sufficiently reviewed and refined the language. The Committee also suggested that it should reach out to interested stakeholders to build consensus around its proposed solution prior to distributing a public comment proposal.

6. Transplant Program Performance Measures Review (Outcome Measures)

The charge of the work group is to evaluate ways to decrease the perceived disincentives to transplant created by the current system for reviewing post-transplant outcomes. The ultimate goal of this evaluation is to discover ways to increase transplants. Since the last Board meeting, the MPSC work group, joined by representatives from ASTS, AST, AOPO and UNOS leadership, met on May 28, June 29, August 4, September 18, and October 20. The work group has focused initially on modifying the methodology for post-transplant outcomes review for kidneys.

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The work group has reviewed data on characteristics of discarded kidneys as well as the outcomes associated with similar kidneys that were transplanted to determine the appropriate criteria for those transplants that would be excluded from post-transplant outcomes reports. The work group has also reviewed literature on the characteristics of discarded organs. In addition, the Scientific Registry of Transplant Recipients (SRTR) has provided data on the effect of decreased discard rates on program evaluations and on a SRTR suggestion to reweight low and high risk transplants, thereby putting less emphasis on the higher risk transplants rather than excluding them from the model altogether. An update on the project was provided to the Committee at its July 2015 meeting. The work group has developed a draft proposal that was presented to the Committee at its October 2015 meeting.

The draft proposal provides that the Committee would only make an inquiry to a kidney transplant program if the program falls outside the threshold for review of kidney graft or patient survival using all kidneys currently included in the analysis, and if they fall outside the threshold for review when kidneys from donors with Kidney Profile Donor Index (KDPI) greater than 85% or age greater than 65 are excluded from the analysis. The work group considered whether the criteria should include recipient characteristics but concluded that there was not enough data available to determine appropriate characteristics. In addition, the work group decided that the criteria should be kept simple; noting that the more complicated the criteria, the less likely it would affect change in behavior. There was significant discussion of the possibility of initially excluding programs that are currently under review for post-transplant outcomes. After discussion, the work group concluded that all kidney programs would be evaluated initially using the proposed operational rule. One outstanding issue was put before the Committee when the proposal was presented in October 2015. Should minimum survival criteria for these high-risk kidney transplants be established? If a program fell below a minimum survival requirement, the program would no longer be eligible to have these high-risk kidneys excluded from the MPSC post-transplant outcomes reports. The Committee did not make a decision on this issue.

Following discussion at the October 2015 meeting, the Committee did not approve the release of the proposal for feedback during the next spring public comment period. Questions were raised during the discussion about whether the workgroup's decision not to include recipient characteristics in the criteria was wise, and several suggested that EPTS scores could be used to identify appropriate candidates for high-risk kidneys. There was also considerable discussion about the proposed evaluation plan for the proposal. The Committee requested that the work group review additional data and conduct additional investigation of other options to fulfill the goal of the work group and report back to the Committee at its March 2016 meeting.

7. Multi-organ Outcomes Work Group Update

There is no update on this project since the June 2015 Board meeting.

8. Projects Referred to the Joint Society Working Group

During its May 2015 teleconference, the MPSC reviewed draft Bylaws language that incorporated the Joint Society Working Group's recommendations. The Committee worked to finalize this language in anticipation of distributing these proposed Bylaws for public comment. Ultimately, the following efforts were not distributed for public comment because the Executive Committee placed these projects on hold during its June 2015 realignment of OPTN/UNOS committee projects with the new strategic plan that was passed by the OPTN/UNOS Board of Directors at its June 2015 meeting.

Aligning Primary Kidney Transplant Physician Bylaws and Transplant Nephrology Fellowship Requirements

The Committee discussed questions regarding OPTN/UNOS Bylaws Appendix E.3.C (Three-year Pediatric Nephrology Fellowship Pathway), E.3.D (Twelve-Month Pediatric Transplant Nephrology Fellowship Pathway), and E.3.E (Pediatric Nephrology Training and Experience Pathway).

The first question focused on current Bylaws language in each of these pathways that states, “the physician was directly involved in the primary care of 10 or more newly transplanted kidney recipients and followed 30 newly transplanted kidney recipients for at least 6 months from the time of transplant.” Considering the relatively low volume of pediatric transplants that are performed, concerns were raised that it would be extremely challenging for most to have followed 30 “newly” transplanted kidney recipients during a three-year pediatric nephrology fellowship or a twelve-month pediatric transplant nephrology fellowship. This requirement could be even more challenging to meet if a kidney program has a year that they perform less kidney transplants than normally expected. As such, the MPSC was asked to consider deletion the second “newly,” thereby allowing the follow-up of any pediatric transplant recipient- regardless of how long ago they were transplanted – to count towards this requirement. In addition to the volume concerns, this is thought to be particularly appropriate for pediatric recipients, as their follow-up care is often more challenging as younger recipients progress through adolescence into early adulthood. The MPSC agreed with these points and indicated its support for deleting the second “newly” in this requirement across all pathways. In addition to deleting the second newly, the MPSC also requested that it be specified that the primary care of 10 newly transplanted recipients must have occurred for at least 6 months from the time of transplant.

The MPSC also considered if E.3.D (Twelve-Month Pediatric Transplant Nephrology Fellowship Pathway) should remain, as these types of fellowships are increasingly rare. The MPSC suggested that others who have completed a 12-month pediatric transplant nephrology fellowship in the past might be reliant on this pathway to qualify as a primary transplant physician. Ultimately, the MPSC agreed that retaining this pathway did not create any issues, nor did deleting this pathway solve any problem, so the MPSC opted not to delete Appendix E.3.D as a pathway for individuals to qualify as a primary kidney transplant physician.

With the decision to retain this pathway, the final question pertained to requirements that are proposed to be added to Appendix E.3.A (Twelve-month Transplant Nephrology Fellowship Pathway) and E.3.B (Clinical Experience Pathway). Specifically, the requirement that the physician was directly involved in the evaluation of 25 potential kidney recipients and 10 living kidney donors. Suggestions had been made to add these requirements to Appendix E.3.C, E.3.D, and E.3.E. for consistency across the primary kidney transplant physician pathways. A problem with this approach is that it would be unlikely that an individual could meet this requirement during a twelve-month pediatric transplant nephrology fellowship due to the inherently low volume of pediatric transplants. To accommodate this scenario, UNOS staff recommended (after communication with multiple pediatric transplant nephrologists) that cases from one’s three-year pediatric nephrology fellowship (which necessarily precedes a 12-month pediatric transplant nephrology fellowship) be allowed to count towards these new requirements. So, those applying through the 12-month pediatric

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transplant nephrology fellowship would be allowed to cite cases from their 12-month pediatric transplant nephrology fellowship and their three-year pediatric nephrology fellowship to meet the new requirements to be proposed by the MPSC. The MPSC did not object to this approach, recognizing the value in maximizing consistency across pathways and acknowledging the relatively low volume of pediatric transplants that occur.

To conclude the discussion about better aligning primary kidney transplant physician Bylaws and transplant nephrology fellowship requirements, the MPSC supported a motion (26 For, 0 Against, 0 Abstentions) to propose the modified Bylaws language reviewed, including those changes discussed on the teleconference, during the next public comment cycle.

Approved Training Programs

Staff presented the most recent draft of these proposed changes. No specific questions about this topic or the draft language had been provided prior to the MPSC's teleconference. The MPSC did not raise any questions or points of concern, and proceeded to support a motion (26 For, 0 Against, 0 Abstentions) to propose the modified Bylaws language reviewed on the call during the next public comment cycle.

Primary Surgeon Qualification - Primary or First Assistant on Transplant Cases

During the MPSC's April teleconference, it requested that the term "co-surgeon" be explicitly included in these requirements and that "co-surgeon" cases be treated the same as primary surgeon cases for the purposes of these Bylaws. UNOS staff obliged this request, and asked the Committee to verify that the appropriate additions had been made to these draft Bylaws. Specifically, the Committee was asked to confirm that "co-surgeon" should not be included in fellowship pathways and that it should be included in the primary heart and primary lung transplant surgeon pathways. The MPSC confirmed that "co-surgeon" should not be added to fellowship pathways. As for inclusion of "co-surgeon" in the thoracic primary transplant surgeon pathways, thoracic surgeons on the Committee indicated that this term generally is not used to differentiate or document a surgeon's role in cardiothoracic surgery. Those instances where it is used would not be reflective of the experience that this requirement intends to highlight, and so the MPSC agreed that "co-surgeon" should not be included in the thoracic primary transplant surgeon pathways.

UNOS staff proceeded to respond to another recommendation about this section of the Bylaws made by the MPSC during its April 2015 meeting. During that call, the MPSC noted that the primary open living donor kidney surgeon does not require any living donor open nephrectomies. Briefly discussing what should be required, the MPSC suggested that ASTS fellowship requirements be reviewed. During this meeting, UNOS staff reported that it did not appear that ASTS currently requires living donor open nephrectomies to complete a transplant fellowship. Conferring with the JSWG chair about this, he indicated that new requirements had just recently been passed and that the OPTN should wait for those to be implemented before addressing this question. The MPSC agreed and indicated its support of this approach.

UNOS staff also directed the MPSC to a technicality in OPTN Bylaws Appendix E.5.E (Primary Laparoscopic Living Donor Kidney Surgeon) that has raised concerns, and seemingly could be addressed within this effort. UNOS staff reported that primary laparoscopic living kidney donor surgeon applications usually cite cases that were performed during the surgeon's clinical practice; however, the Bylaws require that the

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experience should be documented in a letter from the “fellowship program director.” To accommodate the more common scenarios provided on primary laparoscopic living kidney donor surgeon applications, UNOS staff asked if this letter could also come from the “program director, division Chief, or department Chair from the program where the surgeon gained this experience.” The MPSC stated this was a necessary change to correct what was seemingly an oversight.

The MPSC proceeded to support a motion (27 support, 0 oppose, 0 abstentions) to propose the modified Bylaws language reviewed on the call during the next public comment cycle.

Primary Physician Specialty/Subspecialty Board Certifications (Liver)

Staff presented the most recent draft of the proposed changes for primary liver transplant physicians. Specifically, transplant hepatology board certification or pediatric transplant hepatology certificate of added qualification will replace the gastroenterology board certification as a requirement for primary liver transplant physicians. No specific questions about these modified Bylaws had been provided prior to the MPSC’s teleconference. The MPSC reiterated that they thought these changes are reasonable, and agreed that this could be included with the other modified Bylaws to be voted on simultaneously.

The Committee also discussed a similar subspecialty board certification that has been created by the American Board of Internal Medicine (ABIM) - advanced heart failure and transplant cardiology. The JSWG generally thought this certification should eventually be included in the Bylaws, but not at this time since it is still relatively new. MPSC members stated that moving forward, sitting for the advanced heart failure and transplant cardiology certification exam will require the physician to have completed an advanced heart failure and transplant cardiology fellowship. It was also noted that the advanced heart failure and transplant cardiology certification exam is offered every other year, and that the frequency of this exam may pose a challenge for some heart programs if this subspecialty certification was included in this proposal as a requirement for primary heart transplant physicians. The MPSC agreed that it would not propose any changes with this proposal regarding the advanced heart failure and transplant cardiology certification, but that this is something the Committee should keep in mind for the future.

The MPSC proceeded to support a motion (27 For, 0 Against, 0 Abstentions) to propose the modified Bylaws language reviewed on the call during the next public comment cycle.

Committee Projects Pending Implementation

None

Implemented Committee Projects

9. Quality Assessment and Process Improvement Requirements (QAPI)

Public Comment: [September 29– December 5, 2014](#)

Board Approval: [June 2015](#)

Implementation Date: [September 1, 2015](#)

These bylaws created a general requirement that Organ Procurement Organization and Transplant Hospital members develop, implement, and maintain a QAPI program. The Bylaws also require that these members document that their plan has been implemented.

Review of Public Comment Proposals

10. Proposal to Increase Committee Terms to Three Years

The Committee reviewed this proposal during its meeting on August 31, and had no significant concerns.

11. Revise OPTN/UNOS Data Release Policies

The Committee reviewed this proposal during its meeting on August 31, and had no significant concerns.

12. Establish and Clarify Policy Requirements for Therapeutic Organ Donation

The Committee reviewed this proposal during its meeting on August 31. It appreciates the efforts to clarify which policies apply to domino donors, but it would like to see more details regarding what could be programmed for these donors.

The MPSC raised concerns about the therapeutic donors addressed in this proposal who are not domino donors. They did not support extending the policy exceptions to this group, and believed that these non-domino therapeutic donors still need all the protections established by living donor policies. Specifically, they expressed the following concerns:

Consent

Consent from the donor is still necessary, just as for any other living donor. The proposal highlights two examples of a therapeutic donor with a renal cell carcinoma and a ureteral trauma. If kidneys from these donors could be safely transplanted to another individual, why would they not be auto-transplanted? If the donor does not want the kidney to be auto-transplanted, then the donor should be treated as a living kidney donor just like all other living kidney donors. In those cases, it would be appropriate to include additional informed consent regarding that possibility. If kidney removal is just one of many possible treatment options available to a non-domino therapeutic donor, the therapeutic donor should be required to meet with an independent living donor advocate and undergo the same informed consent process that is provided to a living donor regarding the risk associated with donation.

Follow-up

Follow-up is still necessary. Removing the follow-up requirement creates conflicts within the Policies 18.5.A and 18.5.B (Living Donor Data Submission Requirements) that detail follow-up form submission requirements. Additionally, the proposed policy and current programming will not be aligned since follow-up forms for these donors will be created and appear as expected for the transplant hospital.

Programs are also required to report all living donor deaths within two years of donation under Policy 18.5.C (Reporting of Living Donor Adverse Events), and the MPSC is required to review all of these reports. Because this policy proposal does not require members to follow therapeutic donors after donation, the MPSC is concerned that not all therapeutic donor deaths will be reported. It is important to have death of these donors reported to the OPTN to ensure sufficient oversight.

Evaluation

There is still a risk of disease transmission with these donors, but the proposal does not specify who is responsible for these evaluations, even though it is specified for other living donors.

If the Living Donor Committee does go forward with these exemptions for all therapeutic donors, the MPSC has the following additional concerns:

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- This proposal creates a possible loophole by which members could approve an individual as a therapeutic donor that does not meet living donor criteria. For example, active malignancy is an exclusion criterion specified in current OPTN living donor policy. According to the proposal, potential therapeutic donors may have conditions such as renal cell carcinoma. What if a hospital, during its evaluation of a potential living donor, determines that the donor has renal cell carcinoma? What would prevent the program from classifying the individual as a therapeutic donor, rather than a living donor, and allow the patient to donate their kidney without completing all living donor evaluation requirements and without any follow up after donation? There is not a sufficient system in place, nor does the proposal address how, to evaluate whether programs are accurately classifying potential donors as therapeutic or living donors. If the above scenario was referred to the MPSC, the MPSC may need to determine whether the program appropriately classified the donor as therapeutic. Should there at least be a requirement that the hospital document the clinical justification for the organ removal?
- It is unclear which polices would apply if a kidney from a therapeutic donor was part of KPD.

13. Simultaneous Liver Kidney (SLK) Allocation Policy

The Chair of the Kidney Transplantation Committee (the Kidney Committee) presented this proposal to the MPSC during the September meeting. Upon the conclusion of the presentation, the MPSC raised the following questions and comments:

- Referencing the proposed SLK chronic kidney disease eligibility criteria of a GFR threshold of 35 mL/min or less, what are the expectations if a patient's condition improves and GFR increases? The Kidney Committee chair responded that it is critical that this proposal include an eligibility threshold, and the Kidney Committee spent a lot of time discussing the appropriate balance for determining this value. The Kidney Committee agreed to a GFR of 35 mL/min or less, and once someone meets this SLK eligibility threshold they indefinitely remain eligible. This threshold defines *eligibility* to obtain liver and kidney offers simultaneously, but the transplant program is not obligated to accept that offer. Ultimately, if a patient's condition improves such that a kidney transplant may not be necessary at the same time as the liver transplant, then the transplant hospital is not required to accept the kidney offer. Kidney transplant programs will be expected to use discretion and their medical judgment to determine what is necessary and appropriate.
- What are the expectations if the patient is suffering from chronic kidney disease, but the transplant program does not have an extended relationship with this patient and cannot validate that their GFR was 60 mL/min or less for 90 days or more? The Kidney Committee Chair replied that the transplant program could see if their new patient meets any of the other eligibility criteria. If none of those criteria can be met, this scenario is not something that has been addressed in this proposal. The Kidney Committee Chair encouraged the MPSC to include this question in its public comment feedback so that the Kidney Committee could discuss this during its review of public comment feedback.
- In response to requests for feedback about the possibility of national SLK sharing, the MPSC stated it is increasingly seeing more sensitized candidates in need of a liver and kidney transplant. This patient population would seem to benefit from national SLK sharing considerations, and is something worth exploring further.

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- Some concerns were expressed about patients who do not receive an SLK transplant, and rely on the “safety net” provided for in the proposal. Receiving the liver transplant has the potential to increase the patient’s sensitization, which may further complicate, and extend the time for, obtaining an appropriate isolated kidney offer. The MPSC member was concerned that this extended period may negatively affect outcomes. The Kidney Committee chair reminded the Committee that if these patients become highly sensitized, then they would also obtain the regional and national priority that is currently provided in policy for highly sensitized kidney candidates. The MPSC and Kidney Committee Chairs encouraged the committee to keep thinking about this proposal, and to email any additional questions or concerns that they may have.

14. Reduce the Documentation Shipped with Organs

The Chair of Organ Procurement Organization Committee (the OPO Committee) presented this proposal to the MPSC. Upon the conclusion of the presentation, the MPSC asked whether there was a plan in place to get CMS policy changed, since OPOs would still have to include this documentation under CMS regulations. The OPO Committee chair stated that CMS had been engaged, but there was no resolution yet.

15. Revise Facilitated Pancreas Allocation Policy

A representative of the Pancreas Transplantation Committee (Pancreas Committee) presented this proposal to the MPSC. Upon the conclusion of the presentation, the Committee raised the following questions and comments:

- There was uncertainty about how five was chosen as the required number of transplants, and the Committee recommended continued evaluation of this threshold post-implementation. The Pancreas Committee representative responded that the committee did analyze several options before deciding on 5 years.
- Would OPOs be able to make back-up offers using the facilitated allocation system after local allocation? The Pancreas Committee representative responded that this was a good idea, and something that the committee could add.
- How does this idea intersect with multi-organ allocation? Would it be possible to expand this concept to include kidney/pancreas candidates in the facilitated pancreas placement? This was suggested as a possible related project for the Pancreas Committee. The Pancreas Committee representative agreed to take this idea back to the Pancreas Committee.

16. Establish Pediatric Training and Experience Requirements in the Bylaws

During the September meeting, the Chair of the Pediatric Transplantation Committee (Pediatric Committee) presented this proposal for the MPSC. Upon the conclusion of the presentation, the Committee raised the following questions and comments:

- The Committee is supportive of the proposal overall, and the effort that has been made to incorporate earlier feedback. The Committee appreciates the long period allowed for fully ramping up the requirements.
- Most lung programs would not have the transplant volume numbers to qualify today. The MPSC would like to see at least one qualifying program in each region by the time this takes effect. As of today, there would be none in Region 6, and only one in Region 5 (which is a large percentage of the population in the country) that would qualify. This seems to indicate that the volumes may be

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somewhat off what they should be for lung programs. The Pediatric Committee chair expressed an expectation that there would be ramping up in Washington and California to meet those needs.

The MPSC expressed concern it may be difficult to balance the experience requirements for heart transplantation because the expertise difference is based more on the types of diagnoses and not patient size. The Pediatric Committee chair responded that 60% of the heart transplants in patients under 18 in the last 5 years have been patients under 6 years old, and under 25kg.

During its meeting in October the Committee was updated on the status of this proposal and the post-public comment amendments being considered by the Pediatric Committee. As the Committee did not have specific language to review, the Chair asked the Committee if it had any preliminary response to the general concepts that may be included as amendments, including: an exception clause for programs that do not have a designated pediatric component, removal of pediatric transplant lung surgeon and physician requirements, and reducing the transplant patient age that would necessitate a transplant program to have a pediatric component. The Committee briefly discussed these considerations, indicating that changes of this nature would be substantive and suggesting that an amended proposal should be redistributed for public comment.

Other Committee Work

17. Primary Heart Transplant Surgeon- VAD Training and Experience Requirements

During its July meeting, the MPSC received an update on the OPTN/UNOS Thoracic Organ Transplantation Committee's (Thoracic Committee) recent discussion about forming a joint working group to consider pursuing primary heart transplant surgeon bylaws that address experience with ventricular assist devices (VADs). The Thoracic Committee ultimately decided that it did not think it was necessary to pursue such bylaws changes at this time.

Some disagreement with the Thoracic Committee's perspectives prompted further discussion about this topic. In response, MPSC members noted the volume of VADs that are implanted today essentially means that all new cardiothoracic transplant fellows will be exposed to VADs during their training. Additional concerns were raised about creating requirements for pre-transplant care procedures, and that the real problem is non-transplant surgeons who are implanting VADs (something the OPTN can't truly impact). Also considering limited success of advancing VAD primary transplant heart surgeon requirements without the Thoracic Committee's support, the Committee ultimately agreed to continue monitoring this matter but not actively pursue any changes at this time.

18. Living Donor Follow-up Reporting

Policy 18.5.A (Reporting Requirements after Living Kidney Donation) requires that hospitals report accurate complete and timely follow-up donor status and clinical information for at least 60% of living kidney donors and report laboratory data for at least 50% of living kidney donors who donated between February 1, 2013, and December 31, 2013. The thresholds will increase for donors who donated in 2014 and again for donors who donate in 2015.

During the July meeting, the Committee reviewed new reports of members not meeting the thresholds for submission of one-year follow-up forms for 2013 donors. Sixty-five total members were identified. The Committee voted to send letters to newly identified programs providing resources and asking for a corrective action plan. The Committee also decided to send letters to programs that were previously identified but still fell below thresholds, and programs that were no longer identified for review reminding them of the policy

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requirements, and that the Committee may take action on compliance in the future. The Committee did not review any living donor follow up members in December, and plans to review all members once a year in July for all form submission. The Committee will continue to refine its review process as more cohorts of forms become available.

19. Member and Applicant Related Report of Committee Actions

The Committee reviewed and approved the following actions:

- 157 applications for changes in transplant program personnel
- 12 applications for changes in histocompatibility lab personnel

The Committee also received notice of the following membership changes:

- 5 transplant programs inactivated
- 2 transplant programs withdrew from membership
- 3 living donor components withdrew from membership
- 9 OPO key personnel changes

The Committee discussed and made recommendation on several issues related to histocompatibility laboratories, OPOs, and transplant hospitals.

20. Living Donor Adverse Events Reporting

As required in Policy 18.5.C (Submission of Living Donor Death and Organ Failure), transplant programs must report all instances of live donor deaths and failure of the live donor's native organ function within 72 hours after the program becomes aware of the live donor death or failure of the live donors' native organ function. During its July meeting, the Committee reviewed three mandatory reported cases, all living donor deaths. The Committee was also informed of a voluntary report of a living donor death after two years and unrelated to donation. The Committee is not recommending any further action to the Board at this time for any of the issues. The Committee will review additional reports at its December 2015 meeting.

21. OPO Metrics

During the July and October meetings, the Committee continued to review organ procurement organizations (OPOs) for lower than expected organ yields.

At its October meeting, the Committee also received an update from the OPO Metrics Focus Group. The focus group met on October 12, to discuss whether it was an appropriate time for the group to review and evaluate the current yield model produced by the Scientific Registry of Transplant Recipients (SRTR). The SRTR plans to evaluate the model in late 2016. The focus group plans to review what is currently included in the model and the data currently collected in UNet and develop a list additional data that should be considered for inclusion in the model. The group will also consider whether there is additional data that should be collected by the OPTN for inclusion in the model. Following this review, a memo will be sent to the OPO Committee providing its findings and suggesting a joint work group to evaluate the yield model and provide feedback to the SRTR. In addition, if the focus group determines that additional data should be collected, a memo will be sent to the Data Advisory Committee (DAC) requesting that the DAC consider the inclusion of this data in data collection.

22. Due Process Proceedings and Informal Discussions

During the July, August, and October meetings, the Committee conducted interviews, hearings, and informal discussions with member transplant hospitals, and organ

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procurement organizations. The hearing, interviews, and informal discussion were convened as provided for in Appendix L (Reviews, Actions, and Due Process) of the Bylaws.

23. Approval of Committee Actions

During the meetings held on May 19, July 14-16, August 31, and September 9, and October 26-29, 2015, the Committee unanimously agreed that actions regarding Bylaws, Policy, and program-specific decisions made during the OPTN session would be accepted as UNOS actions.

Meeting Summaries

The Committee held meetings on the following dates:

- May 19, 2015
- July 14-16, 2015
- August 31, 2015
- September 9, 2015
- October 26-29, 2015

Meetings summaries for this Committee are available on the OPTN website at:
<http://optn.transplant.hrsa.gov/converge/members/committeesDetail.asp?ID=8>.

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Changes to Transplant Program Key Personnel Procurement Requirements

*Prepared by:
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Changes to Transplant Program Key Personnel Procurement Requirements

Executive Summary

Some transplant program key personnel requirements in OPTN/UNOS Bylaws involving organ procurement experience need to be updated. Specifically, the Bylaws addressed in this proposal are unnecessary due to the evolution of transplantation, unenforceable as currently written, inconsistent across the different transplant programs, or include periods to obtain necessary procurement experience that have been restrictive and problematic for some members. This proposal recommends Bylaws changes that address these issues and update transplant program key personnel procurement requirements. Proposed changes include deleting multi-organ procurement requirements for all key personnel; requiring that all primary transplant physicians must (as compared to “should”) observe three procurements of the organ that corresponds to the transplant program they are applying to be the primary physician of; removing “selection and management of the donor” requirements from the primary liver transplant surgeon pathways; and extending the time period for performing the requisite number of procurements in each primary transplant surgeon training pathway. Clarifying and updating these Bylaws primarily supports the OPTN strategic plan key goal of promoting the efficient management of the OPTN.

Changes to Transplant Program Key Personnel Procurement Requirements

Affected Bylaws: OPTN Bylaws Appendices E.2.A (Formal 2-year Transplant Fellowship Pathway), E.2.B (Clinical Experience Pathway), E.3.A (Twelve-month Transplant Nephrology Fellowship Pathway), E.3.B (Clinical Experience Pathway), E.3.C (Three-year Pediatric Nephrology Fellowship Pathway), E.3.D (Twelve-month Pediatric Transplant Nephrology Fellowship Pathway), E.3.E (Combined Pediatric Nephrology Training and Experience Pathway), E.3.G (Conditional Approval for Primary Transplant Physician), F.2.A (Formal 2-year Transplant Fellowship Pathway), F.2.B (Clinical Experience Pathway), F.3.A (12-month Transplant Hepatology Fellowship Pathway), F.3.B (Clinical Experience Pathway), F.3.C (Three-year Pediatric Gastroenterology Fellowship Pathway), F.3.D (Pediatric Transplant Hepatology Fellowship Pathway), F.3.E (Combined Pediatric Gastroenterology/Transplant Hepatology Training and Experience Pathway), F.3.G (Conditional Approval for Primary Transplant Physician), F.10.A (Full Intestine Surgeon Approval Pathway), F.10.B (Conditional Intestine Surgeon Approval Pathway), G.2.A (Formal 2-year Transplant Fellowship Pathway), G.3.A (Twelve-month Transplant Medicine Fellowship Pathway), G.3.B (Clinical Experience Pathway), G.3.D (Conditional Approval for Primary Transplant Physician), H.2.A (Cardiothoracic Surgery Residency Pathway), H.2.B (Twelve-month Heart Transplant Fellowship Pathway), H.3.A (Twelve-month Transplant Cardiology Fellowship Pathway), H.3.B (Clinical Experience Pathway), H.3.D (Conditional Approval for Primary Transplant Physician), I.2.A (Cardiothoracic Surgery Residency Pathway), I.2.B (Twelve-month Lung Transplant Fellowship Pathway), I.3.A (Twelve-month Transplant Pulmonary Fellowship Pathway), I.3.B (Clinical Experience Pathway), I.3.D (Conditional Approval for Primary Transplant Physician)

Sponsoring Committee: Membership and Professional Standards Committee

Public Comment Period: August 14, 2015 – October 14, 2015

What problem will this proposal solve?

The OPTN/UNOS Membership and Professional Standards Committee (MPSC) receives approximately 350 key personnel change applications annually. This proposal will solve numerous problems with the OPTN Bylaws pertaining to transplant program key personnel procurement requirements. Specifically:

- Inconsistent key personnel procurement requirements in the Bylaws: experience with procurements involving multi-organ donors is only required of primary kidney transplant surgeons; and separately, experience in donor selection and management is only required of primary liver transplant surgeons. These surgical experiences are not exclusive to each respective organ, and it is not clear why the Bylaws specify these requirements for these isolated organs.
- Questionable necessity of specifying primary transplant physicians must observe multi-organ donor procurements: Bylaws pertaining to primary transplant physicians' exposure to organ procurements state that physicians should have observed three multiple organ donor procurements. The majority of deceased donors today are multi-organ donors. Looking at data from 2012-2014, 92.2 percent (23,604 of 25,007 total donors) of donors had more than one organ recovered. This prompted the Committee to question whether the Bylaws need to include this level of specificity, which further complicate the requirements to qualify as a primary transplant physician.
- Primary transplant physician Bylaws that state these individuals "should" have observed three procurements: it is generally accepted that primary transplant physicians need to have some

familiarity with the organ procurement process. This expectation is unenforceable as written due to inclusion of the word “should.”

- Surgeons applying through the fellowship pathway who did not complete the requisite number of procurements during their fellowship, but would otherwise qualify as a program’s primary transplant surgeon: The MPSC receives primary transplant surgeon applications from individuals applying through a training pathway who have completed the requisite number of procurements, but not all of the reported procurements were performed during their training period. The MPSC generally feels these individuals are qualified to serve as the program’s primary transplant surgeon, but is obligated to reject these applications per the current Bylaws requirement.

Why should you support this proposal?

The changes presented in this proposal stem directly from recommendations developed by a Joint Societies Working Group (JSWG), and are representative of a collaborative effort between the American Society of Transplantation (AST), the American Society of Transplant Surgeons (ASTS), the North American Transplant Coordinators Organization (NATCO), and the MPSC.

The proposed Bylaws changes address a number of issues that the MPSC has noted:

- Inconsistent key personnel procurement requirements in the Bylaws: the proposed changes recommend deleting requirements that are only found in the primary kidney transplant surgeon pathways (“At least three of these organ procurements must be multiple organ procurements”) and the primary liver transplant surgeon pathways (“At least 3 of these procurements must include selection and management of the donor”), respectively. The proposed deletion of these requirements would effectively address this inconsistency with key personnel procurement requirements. Consistent Bylaws would somewhat simplify the completion (by members) and review (by the MPSC) of membership applications, and contribute to the OPTN Strategic Plan goal of promoting the efficient management of the OPTN.
- Necessity of specifying primary transplant physicians must observe multi-organ donor procurements: the proposed changes also recommend deleting primary transplant physician Bylaws pertaining to the observation of multi-organ donors. Although familiarity with multi-organ donor procurements is important, this exposure would likely occur without explicitly requiring this in the Bylaws considering the observation of three procurements will be required and multiple organs are procured from the overwhelming majority of deceased donors. This proposed deletion simplifies the Bylaws, and the completion and review of membership applications, thereby contributing to the OPTN Strategic Plan goal of promoting the efficient management of the OPTN.
- Primary transplant physician Bylaws that state these individuals “should” have observed three procurements and three transplants: the proposed changes clarify that primary transplant physicians “must” (instead of “should”) have observed three organ procurements and three transplants that corresponds to the transplant program they are applying to be the primary physician of. Making this change will address numerous questions received by UNOS and the MPSC, thereby contributing to the OPTN Strategic Plan goal of promoting the efficient management of the OPTN. Additionally, considering the value of these observations and the patient safety aspect of key personnel requirements, requiring primary transplant physicians to observe donor procurements could also help advance the OPTN Strategic Plan goal of promoting living donor and transplant recipient safety.
- Primary transplant surgeons applying through the fellowship pathway who did not complete the requisite number of procurements during their fellowship, but would otherwise qualify as a program’s primary transplant surgeon: the proposed changes extend the period for reported procurements when primary transplant surgeons are proposed through fellowship or residency pathways. The proposed Bylaws would allow procurements that occurred during the two years that immediately follow the completion of their training period to be reported. This change provides an extended opportunity for primary transplant surgeon applicants applying through a training pathway to perform the requisite number of procurements. This is intended to address those primary transplant surgeon training

pathway applications received by the MPSC that are generally believed to be appropriate as a transplant program's primary surgeon, but are not approved due to the strict requirements in the Bylaws. Modifying the Bylaws to allow the MPSC to approve key personnel applicants it believes are qualified, and providing a recent position on these particular training pathway requirements that are often questioned by members, should contribute towards the OPTN Strategic Plan goal of promoting the efficient management of the OPTN. Although it wouldn't be expected to have a significant impact, making this requirement more inclusive could lead to the approval of more transplant programs, and thereby contributing to the OPTN Strategic Plan key goal of providing equity in access to transplants.

How was this proposal developed?

In 2013, the MPSC created a working group to address a number of aspects in the Bylaws' key personnel requirements that had repeatedly been noted as ambiguous, unenforceable, or regularly yielding questions from members or the MPSC. Included in the topics assigned to this working group were a number of issues that pertained to key personnel procurement requirements. While the MPSC Working Group began addressing the list of topics it had been assigned, the Joint Societies Policy Steering Committee met in May 2014 and opted for the formation of a JSWG to address the key personnel Bylaws projects being worked on by the MPSC.

The proposed Bylaws changes can be categorized under one of four main topics involving key personnel procurement requirements: inconsistent primary transplant surgeon procurement requirements, the necessity of specifying primary transplant physicians must observe multi-organ donor procurements, expectations for primary transplant physician observation of procurements, and the time frame for primary transplant surgeons applying through a training pathway to perform the requisite number of procurements. The development of the proposed edits to address each of these topics primarily stemmed from JSWG discussions that are summarized below:

- *Inconsistent primary transplant surgeon procurement requirements*- The JSWG was asked to consider two particular requirements that are only required for primary kidney transplant surgeons and primary liver transplant surgeons, respectively. Only primary kidney transplant surgeons are required to document their involvement with at least three procurements from deceased donors who had multiple organs recovered. Separately, only primary liver transplant surgeons are required to document involvement with at least three procurements that "include selection and management of the donor." The JSWG indicated that neither of these surgical experiences is exclusive to that particular organ. The JSWG nor UNOS staff could explain why these particular requirements would only be expected of primary kidney transplant surgeons or primary liver transplant surgeons, respectively. Subsequent analysis indicated that these inconsistencies likely stemmed from developing organ specific requirements in isolation instead of developing cross organ requirements.

Focusing on the multi-organ procurement requirement for primary kidney transplant surgeons, the JSWG recognized the importance of experience working with multiple teams on a single donor. The JSWG first thought to add this requirement to the primary transplant surgeon pathways for all other organs to reflect this experience and because this additional requirement should be easily attainable for all primary transplant surgeon applicants. Noting that this requirement would be easily attainable for all primary surgeons because the overwhelming number of deceased donors have more than one organ recovered prompted the JSWG to reconsider the necessity of this requirement. Looking at data from 2012-2014, 92.2 percent (23,604 of 25,007) of donors had more than one organ recovered. Because it is relatively rare that only a single organ is recovered from any donor, the JSWG agreed that the purpose of a multi-organ donor requirement would be realized on most deceased donor recoveries, regardless of the organ of focus and if the Bylaws include such a requirement. Considering this, that the Bylaws already include a certain number of procurements that all primary transplant surgeons must perform, and the desire for simplicity and consistency (as appropriate) across all the organ-specific key personnel Bylaws, the JSWG recommended deleting the current multiple organ procurement requirement found in the primary kidney transplant surgeon pathways.

Focusing on the donor selection and management component found in each of the primary liver transplant surgeon pathways, the JSWG addressed the topics of donor selection and donor management separately. Regarding donor selection, the JSWG acknowledged the importance of experience with accepting and declining organs, and indicated that more should be done to prepare fellows for this important part of the transplant process. That being said, the JSWG did not think OPTN obligations were the best way to increase this knowledge and experience. The JSWG suggested that modifications to how individuals are trained would better impact the need for this experience, as compared to the impact that may be achieved through the OPTN Bylaws. Additionally, donor selection is often done in groups and there are no standardized forms or expectations for documenting donor selection analysis and decisions, making it difficult to document and validate these cases. Because donor selection is integral to the transplant process and is a regularly occurring event for transplant programs, the JSWG believes that appropriate donor selection experience can be effectively monitored with transplant program metrics that assess organ turndowns, mortality on the waiting list, and outcomes, and without primary surgeon donor selection requirements that are not meaningful. Regarding donor management, the JSWG stated this requirement does not fit well with the current field of transplantation. Specifically, OPO medical directors are almost exclusively responsible for donor management, and therefore transplant surgeons are rarely, if ever, actively involved in managing donors. Considering these points, the JSWG agreed that donor management and selection requirements are not necessary to include in OPTN Bylaws, and this specific requirement should be removed from the primary liver transplant surgeon pathways.

- *Necessity of specifying primary transplant physicians must observe multi-organ donor procurements-* The JSWG's recommendation to remove the multi-organ donor procurement requirement from the primary transplant kidney surgeon requirements prompted it to also consider if this requirement was necessary for all primary transplant physicians. Considering the relatively small number of single-organ deceased donors, and following the same logic as above, the JSWG agreed that requiring physicians to observe multiple-organ donor procurements is an unnecessary level of detail to be included in the Bylaws. As such, the JSWG also recommended deleting the multi-organ procurement observation requirement found in each primary transplant physician pathway.
- *Expectations for primary transplant physician observation of procurements-* current Bylaws state that a primary physician (regardless of the organ or pathway) "should" have observed at least three organ procurements and three transplants. As written, these requirements are not enforceable due to the word "should." The JSWG agreed it is important that transplant physicians have a baseline of familiarity and understanding with the organ procurement process. The JSWG felt that observations of the procurement processes is sufficient for achieving this familiarity, and recommended requiring primary physicians to observe at least three organ procurements. Reviewing the current Bylaws, the JSWG specified that primary physicians must also have observed at least three transplants, and that the observed procurements and transplants must include the organ type that corresponds to the program that they are applying to be the primary physician of (i.e., it wouldn't be reasonable for the primary physician applicant of a heart program to report the observation of a recovery from a liver-only donor). The JSWG also noted that proceeding with "must" in these instances will align these sections of the Bylaws with current transplant nephrology fellowship requirements.

The JSWG also considered if these requirements need to specify deceased donor, or require any experience with living donors. Citing nephrology fellowship requirements and the desire to align OPTN Bylaws with those, participants suggested specifying that at least one living donor kidney procurement should be required of a kidney program's primary physician.¹ The group did not think it

¹ *List of eligibility criteria | AST TNFTAP.* (2014, September 4). Retrieved <http://www.txnephaccreditation.org/node/6>

would be appropriate to extend this living donor consideration to the primary physician requirements for the other organ specific transplant programs.

- *Time frame for primary transplant surgeons applying through a training pathway to perform the requisite number of procurements-* Primary surgeon fellowship pathways require the set number of organ procurements be performed during the time frame of their fellowship/training (e.g., the primary pancreas surgeon formal 2-year transplant fellowship pathway requires that, “The surgeon performed at least 10 pancreas procurements as primary surgeon or first assistant during the 2-year period”). Occasionally the MPSC will receive an application where the primary surgeon is applying through the fellowship pathway and meets all the requirements, except all of the requisite number of procurements were not performed exclusively during their fellowship. Although the MPSC often believes these individuals are suitably qualified, it feels obligated to reject the applications because they do not strictly meet the requirements outlined in the Bylaws.

The JSWG indicated it was hesitant to modify the training pathways to include requirements that are obtained outside the time of one’s fellowship or residency. Making numerous modifications along these lines will undermine the purpose and structure of the key personnel training pathways. That being said, the JSWG believed it would be reasonable to approve key personnel described above, who apply through a fellowship pathway and have performed the requisite number of procurements throughout their career. The JSWG was clear that this open time period to meet the procurement requirement in the fellowship pathway should not be extended to any other fellowship pathway requirement. Further reflection on this caution prompted questions if the expanded time frame to obtain the necessary procurements should be more directly tied to the time when an applicant’s fellowship or residency was completed. After additional discussion by the JSWG, it modified its recommendation to allow surgeons applying through a training pathway to report procurements performed during the two years immediately following the completion of their fellowship or residency training. The JSWG felt that doubling the amount of time to obtain the requisite number of procurements found in the primary surgeon fellowship pathways should be sufficient. If a surgeon cannot meet the primary surgeon fellowship pathway procurement requirements during their training and this additional two year period, the JSWG felt it was necessary for that person to qualify as the primary transplant surgeon through the respective clinical experience pathway.

The JSWG presented these recommendations to the MPSC and the Joint Societies Policy Steering Committee during spring 2015. Both groups endorsed the proposed changes with no concerns raised. Upon the MPSC’s endorsement, it drafted proposed Bylaws modifications to accommodate these recommendations. An additional consideration raised by the MPSC while drafting this proposal were questions about current Bylaws language associated with the primary transplant physician procurement observation requirements. Specifically, direction that the physician must have observed the “evaluation, the donation process, and management” of the donors. OPO representatives on the MPSC thought that these were vague terms and had operational concerns about how these requirements could be documented and validated. The MPSC ultimately thought it would be more meaningful to replace this guidance with an expectation that the primary transplant physician observe “the organ allocation and procurement processes” for these donors.

How well does this proposal address the problem statement?

These proposed changes effectively address the inconsistencies found in the primary surgeon procurement requirements by removing those particular requirements from the Bylaws. The MPSC believes this is an appropriate approach because transplantation has evolved such that the intent of these particular requirements will likely be realized regardless if there are OPTN Bylaws that speak to these experiences. Likewise, the evolution of transplantation has rendered other Bylaws requirements unnecessary; specifically, requirements pertaining to multi-organ procurements from a deceased donor and a transplant surgeon’s involvement in donor management.

These proposed changes also effectively address current Bylaws requirements that are felt to be important, but currently unenforceable, by changing “should” to “must” in the Bylaws pertaining to primary transplant physician observation of procurements and transplants. This change also helps to align the Bylaws with transplant nephrology fellowship requirements. A possible weakness of this change is that more rigorous key personnel requirements could impact the approval of some kidney programs in the future. Ultimately, considering only three procurement and transplant observations are required and that this is already a transplant nephrology fellowship requirement, any impact this change may have on the approval of kidney transplant programs is expected to be negligible.

Finally, doubling the amount of time for primary transplant surgeons applying through training pathways to perform the necessary number of procurements is expected to address a lot of the situations faced by the MPSC when a primary surgeon applicant is seemingly well qualified, but did not perform the requisite number of procurements during their fellowship or residency. In addition to expanding the time frame to meet this requirement, this also serves as a recent position on this particular requirement that is sometimes questioned by members. A weakness for this proposed change is that the additional two years after one’s training is somewhat arbitrary. The JSWG considered this, but recognized there would be no way to find numerical data that would definitively guide this decision. As such, the JSWG felt its experience and expertise would have to suffice as evidence for this proposed modification.

Was this proposal changed in response to public comment?

This proposal was included on the regional meeting non-discussion agenda, and received minimal feedback. At its October 2015 meeting, the MPSC reviewed the public comment feedback provided in response to this proposal. The comments received for this proposal are on the Organ Procurement and Transplantation Network (OPTN) web site at <http://optn.transplant.hrsa.gov/governance/public-comment/>. Below are the general themes of the feedback provided, a summary of the MPSC’s consideration of this feedback, and a description of the post-public comment changes made by the MPSC after its review:

- A concern was raised that the following proposed language is confusing: “These procurements must have been performed during the surgeon’s fellowship and the two years immediately following fellowship completion.” The comment suggested that this sentence should read, “...during the surgeon’s fellowship and/or the two years...”
 - While reviewing this feedback, UNOS staff directed the MSPC to the OPTN Policy and Bylaws style guide, which prohibits the use of the phrase “and/or.” To clarify this proposed sentence, the MPSC considered and agreed to the following: “These procurements must have been performed anytime during the surgeons’ fellowship and the two years immediately following fellowship completion.”
 - *Post-public comment changes-* The word “anytime” has been incorporated throughout the proposed Bylaws as indicated in the above sentence.
- Although not explicitly raised during public comment, the MPSC also considered if these changes should be applied to OPTN Bylaws Appendix F.10 (Primary Intestine Transplant Surgeon Requirements).
 - The OPTN/UNOS Board of Directors adopted OPTN Bylaws Appendix F.10 (Primary Intestine Transplant Surgeon Requirements) at its June 2015 meeting, after the MPSC finalized the modified Bylaws to be included in this proposal. For consistency, and recognizing that the OPTN/UNOS Liver and Intestinal Organ Transplantation Committee modeled the intestine transplant program Bylaws after the liver transplant program Bylaws, the MPSC agreed that the changes from this proposal should also be applied to Appendix F.10 and included with this proposal as a post-public comment consideration.
 - *Post-public comment changes-* References to donor “selection and evaluation” in Appendix F.10 have been deleted and included in this proposal as post-public comment considerations.

- During its review of public comment feedback, the MPSC also raised questions about the following language included in the proposal, “The physician must have observed the organ allocation and procurement processes for these donors.”
 - MPSC members asked what this requirement actually entailed, suggesting that organ allocation observations do not really occur. Other members responded that there should be a greater focus on this requirement, supporting the need for clarification of this requirement. The Committee debated this language, understanding that these proposed modifications were exclusively included for clarification purposes. Since these changes were not an explicit focus of this proposal, and considering the attempts at clarification prompted additional questions about the new language, the MPSC ultimately agreed not to address this language with this proposal, leaving it as found in the current Bylaws: “The physician ~~should also~~ must have observed the evaluation, ~~the~~ donation process, and management of these donors.”

Which populations are impacted by this proposal?

As key personnel are required at every transplant program, and as these proposed changes address key personnel requirements, the proposed changes have the potential to impact all patient populations; however, the effect realized by any individual patient or patient population is likely to be negligible.

This proposal will increase the documentation of required procurement observations included in every future primary transplant physician application. These proposed changes should also simplify every primary kidney transplant surgeon application (no longer need to document involvement with multi-organ donor procurements) and every primary liver transplant surgeon application (no longer need to document involvement in donor management and selection). These changes also have the potential to impact every primary transplant surgeon application applying through a fellowship pathway. It is not exactly clear how many primary transplant surgeon fellowship pathway applications this may impact as the requirements have been made less restrictive such that applications that previously would have been rejected (and accordingly, may not have been submitted) would now be approved by the MPSC. These changes will similarly impact additional transplant hospital staff that may be responsible for compiling these applications, e.g., transplant administrators.

How does this proposal support the OPTN Strategic Plan?

1. *Increase the number of transplants:* There is no impact to this goal.
2. *Improve equity in access to transplants:*
 - Modifying the current multi-organ procurement requirements has the potential to impact equity in access to transplants. Eliminating key personnel requirements minimizes potential barriers that could prevent program approval, potentially resulting in the approval of more transplant programs.

Ultimately, the JSWG's recommendation will likely have negligible impact on this goal considering their primary rationale for removing multi-organ donor requirements is a belief that they introduce an unnecessary level of specificity in the Bylaws. This specificity is unnecessary because potential transplant program key personnel will be exposed to multi-organ donors during their training/experience, regardless of an OPTN requirement, because single-organ donors are increasingly rare.

- Additional requirements to qualify as a transplant program's primary transplant physician has the potential to impact equity in access to transplants. Additional requirements may not be attainable for certain programs, which would eventually result in the approval of fewer transplant programs.

Ultimately, the JSWG's recommendation will likely have negligible impact on equity in access to transplants as the additional requirements are already commonly performed (especially during fellowship) and multi-organ procurement requirement recommended for elimination introduces unnecessarily specific requirement that would likely be attained regardless of the existence of that requirement.

- Expanding the time to meet the procurement requirement for primary transplant surgeons applying through the fellowship pathway reduces barriers that could prevent program approval, potentially resulting in the approval of more transplant programs. This modification will likely have a small impact on this goal.
3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:*
 - Key personnel Bylaws are intended to promote patient safety by assuring that each transplant program is led by individuals who have sufficient training and experience in organ transplantation. Modifying the Bylaws pertaining to procurement observations will assure that every primary transplant physician has been directly exposed to the organ procurement process. Changing the Bylaws to better reflect the training and experience that would be expected of a primary transplant physician should help to improve outcomes of waitlisted patients, living donors, and transplant recipients.
 4. *Promote living donor and transplant recipient safety:*
 - Key personnel Bylaws are intended to promote patient safety by assuring that each transplant program is led by individuals who have sufficient training and experience in organ transplantation. Modifying the Bylaws pertaining to procurement observations will assure that every primary transplant physician has been directly exposed to the organ procurement process. Changing the Bylaws to better reflect the training and experience that would be expected of a primary transplant physician should contribute positively to increased transplant recipient safety.
 5. *Promote the efficient management of the OPTN:*
 - Currently, OPTN Bylaws are inconsistent in requiring surgeons to perform a set number of multi-organ donor procurements. A consistent approach to this requirement will likely result in less confusion among the community, especially if the requirement is eliminated. Similarly, deleting the primary surgeon requirement to observe multi-organ donor procurements eliminates a point of potential confusion in the key personnel application process and would be one less set of data that needs to be provided by members, validated by UNOS staff, and reviewed by the MPSC.
 - MPSC occasionally receives primary transplant surgeon applications that meet all requirements outlined in the respective fellowship pathway, except the individual did not perform the requisite number of procurements during their fellowship. Extending the time period will allow some flexibility for members, and will provide an updated position (that is seen as more reasonable) on these types of scenarios to guide the MPSC in future reviews of key personnel applications.
 - Deleting the primary physician requirement to observe multi-organ donor procurements eliminates a point of potential confusion in the key personnel application process and would be one less set of data that needs to be provided by members, validated by UNOS staff, and reviewed by the MPSC. Conversely, clarifying that primary transplant physicians must observe three procurements and three transplants will add to what needs to be provided and reviewed on applications proposing a primary transplant physician. Although these Bylaws modifications are also adding new requirements, this should not significantly increase the key personnel application process burden as this requirement is already routinely provided by members (and reviewed by UNOS staff and the MPSC). The proposed Bylaws additions are

clarifications to prevent the approval of the occasional primary transplant physician applicant that does not report any organ procurement or transplant observations.

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

The impact of these changes will be evaluated on a case by case basis as the MPSC receives applications proposing individuals as key personnel.

How will the OPTN implement this proposal?

Assuming the Board adopts these changes, they would be effective on March 1, 2016. These changes do not require programming to implement. All applications received on or after March 1, 2016, would be evaluated by the MPSC considering these new Bylaws. Members will be alerted of these changes, and the official implementation date, through a policy notice.

These changes will also necessitate updates to each respective membership application. The application changes will require review and approval by the U.S. Office of Management and Budget (OMB). The OPTN will send these application changes to OMB, and approval is expected, well before the March 1, 2016, implementation date.

Implementation of this proposal will have minimal impact on OPTN resources.

How will members implement this proposal?

No immediate action will be required of members upon the implementation of these proposed changes. Membership and key personnel change applications submitted on or after the implementation of these proposed changes will be evaluated relative to these requirements. Currently approved transplant programs will not be impacted by these changes until other transplant program circumstances make it necessary to submit a key personnel application change.

Will this proposal require members to submit additional data?

This proposal impacts what information will need to be provided on each membership application that proposes transplant program key personnel. Adoption of this proposal will require all primary transplant physician applications to document the required procurement observations. These proposed changes will also simplify what needs to be provided on every primary kidney transplant surgeon application (documentation of involvement with multi-organ donor procurements no longer necessary) and every primary liver transplant surgeon application (documentation of involvement in donor management and selection no longer necessary).

How will members be evaluated for compliance with this proposal?

All membership and key personnel applications proposing key personnel that are received by UNOS on or after the implementation date of these changes would be evaluated by the MPSC against the new requirements proposed below.

Policy or Bylaw Language

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

1
 2 **RESOLVED, that changes to Bylaws Appendices E.2.A (Formal 2-year Transplant Fellowship**
 3 **Pathway), E.2.B (Clinical Experience Pathway), E.3.A (Twelve-month Transplant Nephrology**
 4 **Fellowship Pathway), E.3.B (Clinical Experience Pathway), E.3.C (Three-year Pediatric Nephrology**
 5 **Fellowship Pathway), E.3.D (Twelve-month Pediatric Transplant Nephrology Fellowship Pathway),**
 6 **E.3.E (Combined Pediatric Nephrology Training and Experience Pathway), E.3.G (Conditional**
 7 **Approval for Primary Transplant Physician), F.2.A (Formal 2-year Transplant Fellowship Pathway),**
 8 **F.2.B (Clinical Experience Pathway), F.3.A (12-month Transplant Hepatology Fellowship Pathway),**
 9 **F.3.B (Clinical Experience Pathway), F.3.C (Three-year Pediatric Gastroenterology Fellowship**
 10 **Pathway), F.3.D (Pediatric Transplant Hepatology Fellowship Pathway), F.3.E (Combined Pediatric**
 11 **Gastroenterology/Transplant Hepatology Training and Experience Pathway), F.3.G (Conditional**
 12 **Approval for Primary Transplant Physician), F.10.A (Full Intestine Surgeon Approval Pathway),**
 13 **F.10.B (Conditional Intestine Surgeon Approval Pathway), G.2.A (Formal 2-year Transplant**
 14 **Fellowship Pathway), G.3.A (Twelve-month Transplant Medicine Fellowship Pathway), G.3.B**
 15 **(Clinical Experience Pathway), G.3.D (Conditional Approval for Primary Transplant Physician),**
 16 **H.2.A (Cardiothoracic Surgery Residency Pathway), H.2.B (Twelve-month Heart Transplant**
 17 **Fellowship Pathway), H.3.A (Twelve-month Transplant Cardiology Fellowship Pathway), H.3.B**
 18 **(Clinical Experience Pathway), H.3.D (Conditional Approval for Primary Transplant Physician),**
 19 **I.2.A (Cardiothoracic Surgery Residency Pathway), I.2.B (Twelve-month Lung Transplant**
 20 **Fellowship Pathway), I.3.A (Twelve-month Transplant Pulmonary Fellowship Pathway), I.3.B**
 21 **(Clinical Experience Pathway), I.3.D (Conditional Approval for Primary Transplant Physician), as**
 22 **set forth below, are hereby approved, effective March 1, 2016.**
 23

24 ***Appendix E:***

25 ***Membership and Personnel Requirements for Kidney*** 26 ***Transplant Programs***

27 **E.2 Primary Kidney Transplant Surgeon Requirements**

28 **A. Formal 2-year Transplant Fellowship Pathway**

29 Surgeons can meet the training requirements for primary kidney transplant surgeon by
 30 completing a 2-year transplant fellowship if the following conditions are met:
 31

- 32 1. The surgeon performed at least 30 kidney transplants as the primary surgeon or first
 33 assistant during the 2-year fellowship period. These transplants must be documented in a log
 34 that includes the date of transplant, the role of the surgeon in the procedure, and medical
 35 record number or other unique identifier that can be verified by the OPTN Contractor. This log
 36 must be signed by the director of the training program.
- 37 2. The surgeon performed at least 15 kidney procurements as primary surgeon or first assistant
 38 ~~over the 2-year period. At least 3 of these procurements must be multiple organ~~
 39 ~~procurements and at least 10 of these procurements~~ must be from deceased donors. These
 40 procurements must have been performed anytime during the surgeon's fellowship and the
 41 two years immediately following fellowship completion. These procedures must be

- 42 documented in a log that includes the date of procurement, location of the donor, and Donor
 43 ID.
- 44 3. The surgeon has maintained a current working knowledge of kidney transplantation, defined
 45 as direct involvement in kidney transplant patient care in the last 2 years. This includes the
 46 management of patients with end stage renal disease, the selection of appropriate recipients
 47 for transplantation, donor selection, histocompatibility and tissue typing, performing the
 48 transplant operation, immediate postoperative and continuing inpatient care, the use of
 49 immunosuppressive therapy including side effects of the drugs and complications of
 50 immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient,
 51 histological interpretation of allograft biopsies, interpretation of ancillary tests for renal
 52 dysfunction, and long term outpatient care.
- 53 4. This training was completed at a hospital with a kidney transplant training program approved
 54 by the Fellowship Training Committee of the American Society of Transplant Surgeons or
 55 accepted by the OPTN Contractor as described in the *Section E.4 Approved Kidney*
 56 *Transplant Surgeon and Physician Fellowship Training Programs* that follows. Foreign
 57 training programs must be accepted as equivalent by the Membership and Professional
 58 Standards Committee (MPSC).
- 59 5. The following letters are submitted directly to the OPTN Contractor:
- 60 a. A letter from the director of the training program and chairman of the department or
 61 hospital credentialing committee verifying that the surgeon has met the above
 62 requirements and is qualified to direct a kidney transplant program.
- 63 b. A letter of recommendation from the fellowship training program's primary surgeon and
 64 transplant program director outlining the surgeon's overall qualifications to act as a
 65 primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and
 66 familiarity with and experience in adhering to OPTN obligations, and any other matters
 67 judged appropriate. The MPSC may request additional recommendation letters from the
 68 primary physician, primary surgeon, director, or others affiliated with any transplant
 69 program previously served by the surgeon, at its discretion.
- 70 c. A letter from the surgeon that details the training and experience the surgeon has gained
 71 in kidney transplantation.

72

73 **B. Clinical Experience Pathway**

74 Surgeons can meet the requirements for primary kidney transplant surgeon through clinical
 75 experience gained post-fellowship if the following conditions are met:

- 76
- 77 1. The surgeon has performed 45 or more kidney transplants over a 2 to 5-year period as
 78 primary surgeon or first assistant at a designated kidney transplant program, or its foreign
 79 equivalent. The transplants must be documented in a log that includes the date of transplant,
 80 the role of the surgeon in the procedure, and medical record number or other unique identifier
 81 that can be verified by the OPTN Contractor. The log should be signed by the program
 82 director, division chief, or department chair from the program where the experience was
 83 gained. Each year of the surgeon's experience must be substantive and relevant and include
 84 pre-operative assessment of kidney transplant candidates, performance of transplants as
 85 primary surgeon or first assistant, and post-operative care of kidney recipients.
- 86 2. The surgeon has performed at least 15 kidney procurements as primary surgeon or first
 87 assistant. At least 3 of these procurements must be multiple organ procurements and at least
 88 10 of these procurements must be from deceased donors. These cases must be documented
 89 in a log that includes the date of procurement, location of the donor, and Donor ID.

- 90 3. The surgeon has maintained a current working knowledge of kidney transplantation, defined
- 91 as direct involvement in kidney transplant patient care in the last 2 years. This includes the
- 92 management of patients with end stage renal disease, the selection of appropriate recipients
- 93 for transplantation, donor selection, histocompatibility and tissue typing, performing the
- 94 transplant operation, immediate postoperative and continuing inpatient care, the use of
- 95 immunosuppressive therapy including side effects of the drugs and complications of
- 96 immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient,
- 97 histological interpretation of allograft biopsies, interpretation of ancillary tests for renal
- 98 dysfunction, and long term outpatient care.
- 99 4. The following letters are submitted directly to the OPTN Contractor:
- 100 a. A letter from the director of the transplant program and Chairman of the department or
- 101 hospital credentialing committee verifying that the surgeon has met the above
- 102 qualifications and is qualified to direct a kidney transplant program.
- 103 b. A letter of recommendation from the primary surgeon and transplant program director at
- 104 the transplant program last served by the surgeon outlining the surgeon’s overall
- 105 qualifications to act as a primary transplant surgeon, as well as the surgeon’s personal
- 106 integrity, honesty, and familiarity with and experience in adhering to OPTN obligations
- 107 and compliance protocols, and any other matters judged appropriate. The MPSC may
- 108 request additional recommendation letters from the primary physician, primary surgeon,
- 109 director, or others affiliated with any transplant program previously served by the
- 110 surgeon, at its discretion.
- 111 c. A letter from the surgeon that details the training and experience the surgeon has gained
- 112 in kidney transplantation.
- 113

E.3 Primary Kidney Transplant Physician Requirements

A. Twelve-month Transplant Nephrology Fellowship Pathway

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

- 116 1. The physician has current board certification in nephrology by the American Board of Internal
- 117 Medicine or the foreign equivalent.
- 118 2. The physician completed 12 consecutive months of specialized training in transplantation
- 119 under the direct supervision of a qualified kidney transplant physician and along with a kidney
- 120 transplant surgeon at a kidney transplant program that performs 30 or more transplants each
- 121 year. The training must have included at least 6 months of clinical transplant service. The
- 122 remaining time must have consisted of transplant-related experience, such as experience in a
- 123 tissue typing laboratory, on another solid organ transplant service, or conducting basic or
- 124 clinical transplant research.
- 125 3. During the fellowship period, the physician was directly involved in the primary care of 30 or
- 126 more newly transplanted kidney recipients and continued to follow these recipients for a
- 127 minimum of 3 months from the time of transplant. The care must be documented in a log that
- 128 includes the date of transplant and the recipient medical record number or other unique
- 129 identifier that can be verified by the OPTN Contractor. This recipient log must be signed by
- 130 the director of the training program or the transplant program’s primary transplant physician.
- 131 4. The physician has maintained a current working knowledge of kidney transplantation, defined
- 132 as direct involvement in kidney transplant care in the last 2 years. This includes the
- 133 management of patients with end stage renal disease, the selection of appropriate recipients
- 134 for transplantation, donor selection, histocompatibility and tissue typing, immediate
- 135
- 136

137 postoperative patient care, the use of immunosuppressive therapy including side effects of
 138 the drugs and complications of immunosuppression, differential diagnosis of renal
 139 dysfunction in the allograft recipient, histological interpretation of allograft biopsies,
 140 interpretation of ancillary tests for renal dysfunction, and long term outpatient care. The
 141 curriculum for obtaining this knowledge should be approved by the Residency Review
 142 Committee for Internal Medicine (RRC-IM) of the Accreditation Council for Graduate Medical
 143 Education (ACGME).

- 144 5. The physician ~~should~~ must have observed at least 3 ~~organ kidney procurements, including at~~
 145 ~~least 1 deceased donor and 1 living donor. and 3 kidney transplants.~~ The physician ~~should~~
 146 ~~also~~ must have observed the evaluation, ~~the~~ donation process, and management of these
 147 ~~donors. at least 3 multiple organ donors who donated a kidney. If the physician has~~
 148 ~~completed these observations, they~~ These observations must be documented in a log that
 149 includes the date of procurement, location of the donor, and Donor ID.
- 150 6. The physician must have observed at least 3 kidney transplants. The observation of these
 151 transplants must be documented in a log that includes the transplant date, donor type, and
 152 medical record number or other unique identifier that can be verified by the OPTN Contractor.
- 153 6.7 The following letters are submitted directly to the OPTN Contractor:
 154 a. A letter from the director of the training program and the supervising qualified kidney
 155 transplant physician verifying that the physician has met the above requirements and is
 156 qualified to direct a kidney transplant program.
 157 b. A letter of recommendation from the fellowship training program’s primary physician and
 158 transplant program director outlining the physician’s overall qualifications to act as a
 159 primary transplant physician, as well as the physician’s personal integrity, honesty, and
 160 familiarity with and experience in adhering to OPTN obligations and compliance
 161 protocols, and any other matters judged appropriate. The MPSC may request additional
 162 recommendation letters from the primary physician, primary surgeon, director, or others
 163 affiliated with any transplant program previously served by the physician, at its discretion.
 164 c. A letter from the physician that details the training and experience the physician has
 165 gained in kidney transplantation.

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

169 **B. Clinical Experience Pathway**

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

- 173 1. The physician has been directly involved in the primary care of 45 or more newly transplanted
 174 kidney recipients and continued to follow these recipients for a minimum of 3 months from the
 175 time of transplant. This patient care must have been provided over a 2 to 5-year period on an
 176 active kidney transplant service as the primary kidney transplant physician or under the direct
 177 supervision of a qualified transplant physician and in conjunction with a kidney transplant
 178 surgeon at a Kidney transplant program or the foreign equivalent. The care must be
 179 documented in a log that includes the date of transplant and recipient medical record number
 180 or other unique identifier that can be verified by the OPTN Contractor. The recipient log
 181 should be signed by the program director, division Chief, or department Chair from the
 182 program where the physician gained this experience.
- 183 2. The physician has maintained a current working knowledge of kidney transplantation, defined
 184 as direct involvement in kidney transplant patient care over the last 2 years. This includes the
 185 management of patients with end stage renal disease, the selection of appropriate recipients

186 for transplantation, donor selection, histocompatibility and tissue typing, immediate
 187 postoperative patient care, the use of immunosuppressive therapy including side effects of
 188 the drugs and complications of immunosuppression, differential diagnosis of renal
 189 dysfunction in the allograft recipient, histological interpretation of allograft biopsies,
 190 interpretation of ancillary tests for renal dysfunction, and long term outpatient care.

- 191 3. The physician ~~should~~ must have observed at least 3 ~~organ~~ kidney procurements, including at
 192 least 1 deceased donor and 1 living donor. ~~and 3 kidney transplants.~~ The physician ~~should~~
 193 ~~also~~ must have observed the evaluation, ~~the~~ donation process, and management of these
 194 donors. ~~at least 3 multiple organ donors who donated a kidney. If the physician has~~
 195 ~~completed these observations, they~~ These observations must be documented in a log that
 196 includes the date of procurement, location of the donor, and Donor ID.
- 197 4. The physician must have observed at least 3 kidney transplants. The observation of these
 198 transplants must be documented in a log that includes the transplant date, donor type, and
 199 medical record number or other unique identifier that can be verified by the OPTN Contractor.
- 200 45. The following letters are submitted directly to the OPTN Contractor:
 - 201 a. A letter from the qualified transplant physician or the kidney transplant surgeon who has
 202 been directly involved with the proposed physician documenting the physician's
 203 experience and competence.
 - 204 b. A letter of recommendation from the primary physician and transplant program director at
 205 the transplant program last served by the physician outlining the physician's overall
 206 qualifications to act as a primary transplant physician, as well as the physician's personal
 207 integrity, honesty, and familiarity with and experience in adhering to OPTN obligations
 208 and compliance protocols, and any other matters judged appropriate. The MPSC may
 209 request additional recommendation letters from the primary physician, primary surgeon,
 210 director, or others affiliated with any transplant program previously served by the
 211 physician, at its discretion.
 - 212 c. A letter from the physician that details the training and experience the physician has
 213 gained in kidney transplantation.

214
 215 **C. Three-year Pediatric Nephrology Fellowship Pathway**

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

- 221 1. The physician has current board certification in nephrology by the American Board of
 222 Pediatrics, or the foreign equivalent.
- 223 2. During the 3-year training period the physician was directly involved in the primary care of 10
 224 or more newly transplanted kidney recipients and followed 30 newly transplanted kidney
 225 recipients for at least 6 months from the time of transplant, under the direct supervision of a
 226 qualified kidney transplant physician and in conjunction with a qualified kidney transplant
 227 surgeon. The pediatric nephrology program director may elect to have a portion of the
 228 transplant experience completed at another kidney transplant program in order to meet these
 229 requirements. This care must be documented in a log that includes the date of transplant,
 230 and the recipient medical record number or other unique identifier that can be verified by the
 231 OPTN Contractor. This recipient log must be signed by the training program's director or the
 232 primary physician of the transplant program.
 233

- 234 3. The experience caring for pediatric patients occurred with a qualified kidney transplant
 235 physician and surgeon at a kidney transplant program that performs an average of at least 10
 236 pediatric kidney transplants a year.
- 237 4. The physician has maintained a current working knowledge of kidney transplantation, defined
 238 as direct involvement in kidney transplant patient care over the last 2 years. This includes the
 239 management of pediatric patients with end-stage renal disease, the selection of appropriate
 240 pediatric recipients for transplantation, donor selection, histocompatibility and tissue typing,
 241 immediate post-operative care including those issues of management unique to the pediatric
 242 recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the
 243 pediatric recipient including side-effects of drugs and complications of immunosuppression,
 244 the effects of transplantation and immunosuppressive agents on growth and development,
 245 differential diagnosis of renal dysfunction in the allograft recipient, manifestation of rejection
 246 in the pediatric patient, histological interpretation of allograft biopsies, interpretation of
 247 ancillary tests for renal dysfunction, and long-term outpatient care of pediatric allograft
 248 recipients including management of hypertension, nutritional support, and drug dosage,
 249 including antibiotics, in the pediatric patient. The curriculum for obtaining this knowledge must
 250 be approved by the Residency Review Committee (RRC) -Ped of the ACGME.
- 251 5. The physician ~~should~~ must have observed at least 3 organ kidney procurements, including at
 252 least 1 deceased donor and 1 living donor. and 3 pediatric kidney transplants. The physician
 253 ~~should also~~ must have observed the evaluation, ~~the~~ donation process, and management of
 254 these donors. at least 3 multiple organ donors who donated a kidney. If the physician has
 255 ~~completed these observations, they~~ These observations must be documented in a log that
 256 includes the date of procurement, location of the donor, and Donor ID.
- 257 6. The physician must have observed at least 3 kidney transplants involving a pediatric
 258 recipient. The observation of these transplants must be documented in a log that includes the
 259 transplant date, donor type, and medical record number or other unique identifier that can be
 260 verified by the OPTN Contractor.
- 261 6.7 The following letters are submitted directly to the OPTN Contractor:
- 262 a. A letter from the director and the supervising qualified transplant physician and surgeon
 263 of the fellowship training program verifying that the physician has met the above
 264 requirements and is qualified to direct a kidney transplant program.
- 265 b. A letter of recommendation from the fellowship training program's primary physician and
 266 transplant program director outlining the physician's overall qualifications to act as a
 267 primary transplant physician, as well as the physician's personal integrity, honesty, and
 268 familiarity with and experience in adhering to OPTN obligations, and any other matters
 269 judged appropriate. The MPSC may request additional recommendation letters from the
 270 primary physician, primary surgeon, director, or others affiliated with any transplant
 271 program previously served by the physician, at its discretion.
- 272 c. A letter from the physician that details the training and experience the physician has
 273 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:

- 277 1. The physician has current board certification in pediatric nephrology by the American Board
 278 of Pediatrics or the foreign equivalent, or is approved by the American Board of Pediatrics to
 279 take the certifying exam.
 280
 281

- 282 2. During the fellowship, the physician was directly involved in the primary care of 10 or more
 283 newly transplanted kidney recipients and followed 30 newly transplanted kidney recipients for
 284 at least 6 months from the time of transplant, under the direct supervision of a qualified
 285 kidney transplant physician and in conjunction with a qualified kidney transplant surgeon. The
 286 pediatric nephrology program director may elect to have a portion of the transplant
 287 experience completed at another Kidney transplant program in order to meet these
 288 requirements. This care must be documented in a recipient log that includes the date of
 289 transplant, and the recipient medical record number or other unique identifier that can be
 290 verified by the OPTN Contractor. This log must be signed by the training program director or
 291 the primary physician of the transplant program.
- 292 3. The experience in caring for pediatric patients occurred at a kidney transplant program with a
 293 qualified kidney transplant physician and surgeon that performs an average of at least 10
 294 pediatric kidney transplants a year.
- 295 4. The physician has maintained a current working knowledge of kidney transplantation, defined
 296 as direct involvement in kidney transplant patient care in the past 2 years. This includes the
 297 management of pediatric patients with end-stage renal disease, the selection of appropriate
 298 pediatric recipients for transplantation, donor selection, histocompatibility and tissue typing,
 299 immediate post-operative care including those issues of management unique to the pediatric
 300 recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the
 301 pediatric recipient including side-effects of drugs and complications of immunosuppression,
 302 the effects of transplantation and immunosuppressive agents on growth and development,
 303 differential diagnosis of renal dysfunction in the allograft recipient, manifestation of rejection
 304 in the pediatric patient, histological interpretation of allograft biopsies, interpretation of
 305 ancillary tests for renal dysfunction, and long-term outpatient care of pediatric allograft
 306 recipients including management of hypertension, nutritional support, and drug dosage,
 307 including antibiotics, in the pediatric patient. The curriculum for obtaining this knowledge must
 308 be approved by the Residency Review Committee (RRC) -Ped of the ACGME.
- 309 5. The physician ~~should~~ must have observed at least 3 ~~organ kidney procurements, including at~~
 310 ~~least 1 deceased donor and 1 living donor. and 3 pediatric kidney transplants.~~ The physician
 311 ~~should also~~ must have observed the evaluation, ~~the~~ donation process, and management of
 312 ~~these donors. of at least 3 multiple organ donors who donated a kidney. If the physician has~~
 313 ~~completed these observations, they~~ These observations must be documented in a log that
 314 includes the date of procurement, location of the donor, and Donor ID.
- 315 6. The physician must have observed at least 3 kidney transplants involving a pediatric
 316 recipient. The observation of these transplants must be documented in a log that includes the
 317 transplant date, donor type, and medical record number or other unique identifier that can be
 318 verified by the OPTN Contractor.
- 319 6.7 The following letters are submitted directly to the OPTN Contractor:
- 320 a. A letter from the director and the supervising qualified transplant physician and surgeon
 321 of the fellowship training program verifying that the physician has met the above
 322 requirements and is qualified to become the primary transplant physician of a designated
 323 kidney transplant program.
- 324 b. A letter of recommendation from the fellowship training program's primary physician and
 325 transplant program director outlining the physician's overall qualifications to act as a
 326 primary transplant physician, as well as the physician's personal integrity, honesty, and
 327 familiarity with and experience in adhering to OPTN obligations, and any other matters
 328 judged appropriate. The MPSC may request additional recommendation letters from the
 329 primary physician, primary surgeon, director, or others affiliated with any transplant
 330 program previously served by the physician, at its discretion.

- 331 c. A letter from the physician that details the training and experience the physician has
- 332 gained in kidney transplantation.
- 333

334 **E. Combined Pediatric Nephrology Training and Experience Pathway**

335 A physician can meet the requirements for primary kidney transplant physician if the following

336 conditions are met:

337

- 338 1. The physician has current board certification in pediatric nephrology by the American Board
- 339 of Pediatrics or the foreign equivalent, or is approved by the American Board of Pediatrics to
- 340 take the certifying exam.
- 341 2. The physician gained a minimum of 2 years of experience during or after fellowship, or
- 342 accumulated during both periods, at a kidney transplant program.
- 343 3. During the 2 or more years of accumulated experience, the physician was directly involved in
- 344 the primary care of 10 or more newly transplanted kidney recipients and followed 30 newly
- 345 transplanted kidney recipients for at least 6 months from the time of transplant, under the
- 346 direct supervision of a qualified kidney transplant physician, along with a qualified kidney
- 347 transplant surgeon. This care must be documented in a recipient log that includes the date of
- 348 transplant, and the recipient medical record number or other unique identifier that can be
- 349 verified by the OPTN Contractor. This log must be signed by the training program director or
- 350 the primary physician of the transplant program.
- 351 4. The physician has maintained a current working knowledge of kidney transplantation, defined
- 352 as direct involvement in kidney transplant patient care during the past 2 years. This includes
- 353 the management of pediatric patients with end-stage renal disease, the selection of
- 354 appropriate pediatric recipients for transplantation, donor selection, histocompatibility and
- 355 tissue typing, immediate post-operative care including those issues of management unique to
- 356 the pediatric recipient, fluid and electrolyte management, the use of immunosuppressive
- 357 therapy in the pediatric recipient including side-effects of drugs and complications of
- 358 immunosuppression, the effects of transplantation and immunosuppressive agents on growth
- 359 and development, differential diagnosis of renal dysfunction in the allograft recipient,
- 360 manifestation of rejection in the pediatric patient, histological interpretation of allograft
- 361 biopsies, interpretation of ancillary tests for renal dysfunction, and long-term outpatient care
- 362 of pediatric allograft recipients including management of hypertension, nutritional support,
- 363 and drug dosage, including antibiotics, in the pediatric patient. The curriculum for obtaining
- 364 this knowledge must be approved by the Residency Review Committee (RRC) -Ped of the
- 365 ACGME or a Residency Review Committee.
- 366 5. The physician ~~should~~ must have observed at least 3 organ kidney procurements, including at
- 367 least 1 deceased donor and 1 living donor. and 3 pediatric kidney transplants. The physician
- 368 ~~should also~~ must have observed the evaluation, the donation process, and management of
- 369 ~~these donors. at least 3 multiple organ donors who donated a kidney. If the physician has~~
- 370 ~~completed these observations, they~~ These observations must be documented in a log that
- 371 includes the date of procurement, location of the donor, and Donor ID.
- 372 6. The physician must have observed at least 3 kidney transplants involving a pediatric
- 373 recipient. The observation of these transplants must be documented in a log that includes the
- 374 transplant date, donor type, and medical record number or other unique identifier that can be
- 375 verified by the OPTN Contractor.
- 376 67 The following letters are submitted directly to the OPTN Contractor:
- 377 a. A letter from the supervising qualified transplant physician and surgeon who were directly
- 378 involved with the physician documenting the physician's experience and competence.

- 379 b. A letter of recommendation from the fellowship training program’s primary physician and
- 380 transplant program director outlining the physician’s overall qualifications to act as a
- 381 primary transplant physician, as well as the physician’s personal integrity, honesty, and
- 382 familiarity with and experience in adhering to OPTN obligations, and any other matters
- 383 judged appropriate. The MPSC may request additional recommendation letters from the
- 384 primary physician, primary surgeon, Director, or others affiliated with any transplant
- 385 program previously served by the physician, at its discretion.
- 386 c. A letter from the physician that details the training and experience the physician has
- 387 gained in kidney transplantation.
- 388

389 **G. Conditional Approval for Primary Transplant Physician**

390 If the primary kidney transplant physician changes at an approved Kidney transplant program, a
 391 physician can serve as the primary kidney transplant physician for a maximum of 12 months if the
 392 following conditions are met:

- 393
- 394 1. The physician has current board certification in nephrology by the American Board of Internal
- 395 Medicine, the American Board of Pediatrics, or the foreign equivalent.
- 396 2. The physician has been involved in the primary care of 23 or more newly transplanted kidney
- 397 recipients, and has followed these patients for at least 3 months from the time of their
- 398 transplant. This care must be documented in a recipient log that includes the date of
- 399 transplant and the medical record number or other unique identifier that can be verified by the
- 400 OPTN Contractor. This log must be signed by the program director, division chief, or
- 401 department chair from the transplant program where the experience was gained.
- 402 3. The physician has maintained a current working knowledge of kidney transplantation, defined
- 403 as direct involvement in kidney transplant patient care during the last 2 years. This includes
- 404 the management of patients with end stage renal disease, the selection of appropriate
- 405 recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate
- 406 postoperative patient care, the use of immunosuppressive therapy including side effects of
- 407 the drugs and complications of immunosuppression, differential diagnosis of renal
- 408 dysfunction in the allograft recipient, histological interpretation of allograft biopsies,
- 409 interpretation of ancillary tests for renal dysfunction, and long-term outpatient care.
- 410 4. The physician has 12 months experience on an active kidney transplant service as the
- 411 primary kidney transplant physician or under the direct supervision of a qualified kidney
- 412 transplant physician and in conjunction with a kidney transplant surgeon at a designated
- 413 kidney transplant program or the foreign equivalent. These 12 months of experience must be
- 414 acquired within a 2-year period.
- 415 5. The physician ~~should~~ must have observed at least 3 ~~organ kidney procurements, including at~~
- 416 ~~least 1 deceased donor and 1 living donor. and 3 kidney transplants.~~ The physician ~~should~~
- 417 ~~also~~ must have observed the evaluation, the donation process, and management of these
- 418 ~~donors. at least 3 multiple organ donors who donated a kidney. If the physician has~~
- 419 ~~completed these observations, they~~ These observations must be documented in a log that
- 420 includes the date of procurement, location of the donor, and Donor ID.
- 421 6. The physician must have observed at least 3 kidney transplants. The observation of these
- 422 transplants must be documented in a log that includes the transplant date, donor type, and
- 423 medical record number or other unique identifier that can be verified by the OPTN Contractor.
- 424 67 The program has established and documented a consulting relationship with counterparts at
- 425 another kidney transplant program.

426 78 The transplant program submits activity reports to the OPTN Contractor every 2 months
 427 describing the transplant activity, transplant outcomes, physician recruitment efforts, and
 428 other operating conditions as required by the MPSC to demonstrate the ongoing quality and
 429 efficient patient care at the program. The activity reports must also demonstrate that the
 430 physician is making sufficient progress to meet the required involvement in the primary care
 431 of 45 or more kidney transplant recipients, or that the program is making sufficient progress in
 432 recruiting a physician who meets all requirements for primary kidney transplant physician and
 433 who will be on site and approved by the MPSC to assume the role of primary physician by the
 434 end of the 12 month conditional approval period.

- 435 89 The following letters are submitted directly to the OPTN Contractor:
- 436 a. A letter from the supervising qualified transplant physician and surgeon who were directly
 437 involved with the physician documenting the physician's experience and competence.
 - 438 b. A letter of recommendation from the primary physician and director at the transplant
 439 program last served by the physician outlining the physician's overall qualifications to act
 440 as a primary transplant physician, as well as the physician's personal integrity, honesty,
 441 and familiarity with and experience in adhering to OPTN obligations, and any other
 442 matters judged appropriate. The MPSC may request additional recommendation letters
 443 from the primary physician, primary surgeon, director, or others affiliated with any
 444 transplant program previously served by the physician, at its discretion.
 - 445 c. A letter from the physician that details the training and experience the physician has
 446 gained in kidney transplantation.

447
 448 The 12-month conditional approval period begins on the initial approval date granted to the
 449 personnel change application, whether it is interim approval granted by the MPSC subcommittee,
 450 or approval granted by the full MPSC. The conditional approval period ends 12 months after the
 451 first approval date of the personnel change application.

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

458
 459 The MPSC may consider on a case-by-case basis and grant a 6-month extension to a transplant
 460 program that provides substantial evidence of progress toward fulfilling the requirements but is
 461 unable to complete the requirements within one year.

462
 463 **Appendix F:**
 464 **Membership and Personnel Requirements for Liver**
 465 **Transplant Programs**

466 **F.2 Primary Liver Transplant Surgeon Requirements**

467 **A. Formal 2-year Transplant Fellowship Pathway**

468 Surgeons can meet the training requirements for primary liver transplant surgeon by completing a
 469 2-year transplant fellowship if the following conditions are met:

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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 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 director of the training program.
2. The surgeon performed at least 20 liver procurements as primary surgeon or first assistant ~~during the 2-year period. At least 3 of these procurements must include selection and management of the donor.~~ 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 a log that includes the date of procurement, location of the donor, and Donor ID. This log must be signed by the director of the training program.
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 transplant training program approved by the Fellowship Training Committee of the American Society of Transplant Surgeons or accepted by the OPTN Contractor as described in *Section F.5. Approved Liver Surgeon Transplant Fellowship Programs* that follows. Foreign training programs must be accepted as equivalent by the Membership and Professional Standards Committee (MPSC).
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.

B. Clinical Experience Pathway

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Surgeons can meet the requirements for primary liver transplant surgeon through clinical experience gained post-fellowship, if the following conditions are met:

1. The surgeon has performed 60 or more liver transplants over a 2 to 5-year period as primary surgeon or first assistant at a designated liver transplant program, or its foreign equivalent. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and medical record number or other unique identifier that can be verified by the OPTN Contractor. This log should be signed by the program director,

- 518 division chief, or department chair from the program where the experience was gained. Each
 519 year of the surgeon's experience must be substantive and relevant and include pre-operative
 520 assessment of liver transplant candidates, transplants performed as primary surgeon or first
 521 assistant, and post-operative management of liver recipients.
- 522 2. The surgeon has performed at least 30 liver procurements as primary surgeon or first
 523 assistant. ~~At least 3 of these procurements must include selection and management of the~~
 524 ~~donor.~~ These procedures must be documented in a log that includes the date of procurement,
 525 location of the donor, and Donor ID.
 - 526 3. The surgeon has maintained a current working knowledge of liver transplantation, defined as
 527 direct involvement in liver transplant patient care within the last 2 years. This includes the
 528 management of patients with end stage liver disease, the selection of appropriate recipients
 529 for transplantation, donor selection, histocompatibility and tissue typing, performing the
 530 transplant operation, immediate postoperative and continuing inpatient care, the use of
 531 immunosuppressive therapy including side effects of the drugs and complications of
 532 immunosuppression, differential diagnosis of liver dysfunction in the allograft recipient,
 533 histologic interpretation of allograft biopsies, interpretation of ancillary tests for liver
 534 dysfunction, and long term outpatient care.
 - 535 4. The following letters are sent directly to the OPTN Contractor:
 - 536 a. A letter from the director of the transplant program and chairman of the department or
 537 hospital credentialing committee verifying that the surgeon has met the above
 538 requirements, and is qualified to direct a liver transplant program.
 - 539 b. A letter of recommendation from the primary surgeon and transplant program director at
 540 the transplant program last served by the surgeon outlining the surgeon's overall
 541 qualifications to act as primary transplant surgeon, as well as the surgeon's personal
 542 integrity, honesty, familiarity with and experience in adhering to OPTN obligations, and
 543 other matters judged appropriate. The MPSC may request additional recommendation
 544 letters from the primary physician, primary surgeon, director, or others affiliated with any
 545 transplant program previously served by the surgeon, at its discretion.
 - 546 c. A letter from the surgeon that details the training and experience the surgeon gained in
 547 liver transplantation.

549 **F.3 Primary Liver Transplant Physician Requirements**

550 **A. 12-month Transplant Hepatology Fellowship Pathway**

- 551 Physicians can meet the training requirements for a primary liver transplant physician during a
 552 separate 12-month transplant hepatology fellowship if the following conditions are met:
 553
- 554 1. The physician completed 12 consecutive months of specialized training in transplantation
 555 under the direct supervision of a qualified liver transplant physician and in conjunction with a
 556 liver transplant surgeon at a liver transplant program. The training must have included at least
 557 3 months of clinical transplant service. The remaining time must have consisted of transplant-
 558 related experience, such as experience in a tissue typing laboratory, on another solid organ
 559 transplant service, or conducting basic or clinical transplant research.
 - 560 2. During the fellowship period, the physician was directly involved in the primary care of 30 or
 561 more newly transplanted liver recipients, and continued to follow these recipients for a
 562 minimum of 3 months from the time of transplant. The care must be documented in a log that
 563 includes the date of transplant and the medical record number or other unique identifier that

- 564 can be verified by the OPTN Contractor. This log must be signed by the director of the
 565 training program or the transplant program’s primary transplant physician.
 566 3. The physician has maintained a current working knowledge of liver transplantation, defined
 567 as direct involvement in liver transplant patient care within the last 2 years. This includes the
 568 management of patients with end stage liver disease, acute liver failure, the selection of
 569 appropriate recipients for transplantation, donor selection, histocompatibility and tissue
 570 typing, immediate post-operative patient care, the use of immunosuppressive therapy
 571 including side effects of the drugs and complications of immunosuppression, differential
 572 diagnosis of liver allograft dysfunction, histologic interpretation of allograft biopsies,
 573 interpretation of ancillary tests for liver dysfunction, and long term outpatient care.
 574 4. The physician ~~should~~ must have observed at least 3 ~~organ liver~~ procurements and 3 liver
 575 ~~transplants~~. The physician ~~should also~~ must have observed the evaluation, ~~the~~ donation
 576 process, and management of these donors. ~~at least 3 multiple organ donors who donated a~~
 577 ~~liver. If the physician has completed these observations, they~~ These observations must be
 578 documented in a log that includes the date of procurement, location of the donor, and Donor
 579 ID.
 580 5. The physician must have observed at least 3 liver transplants. The observation of these
 581 transplants must be documented in a log that includes the transplant date, donor type, and
 582 medical record number or other unique identifier that can be verified by the OPTN Contractor.
 583 56. The following letters are submitted directly to the OPTN Contractor:
 584 a. A letter from the director of the training program and the supervising liver transplant
 585 physician verifying that the physician has met the above requirements and is qualified
 586 to direct a liver transplant program.
 587 b. A letter of recommendation from the fellowship training program’s primary physician
 588 and transplant program director outlining the physician’s overall qualifications to act
 589 as a primary transplant physician, as well as the physician’s personal integrity,
 590 honesty, and familiarity with and experience in adhering to OPTN obligations, and
 591 any other matters judged appropriate. The MPSC may request additional
 592 recommendation letters from the primary physician, primary surgeon, director, or
 593 others affiliated with any transplant program previously served by the physician, at its
 594 discretion.
 595 c. A letter from the physician writes that details the training and experience the
 596 physician gained in liver transplantation.

598 The training requirements outlines above are in addition to other clinical requirements for general
 599 gastroenterology training.
 600

601 **B. Clinical Experience Pathway**

602 A physician can meet the requirements for a primary liver transplant physician through acquired
 603 clinical experience if the following conditions are met:
 604

- 605 1. The physician has been directly involved in the primary care of 50 or more newly transplanted
 606 liver recipients and continued to follow these recipients for a minimum of 3 months from the
 607 time of transplant. This patient care must have been provided over a 2 to 5-year period on an
 608 active liver transplant service as the primary liver transplant physician or under the direct
 609 supervision of a qualified liver transplant physician and in conjunction with a liver transplant
 610 surgeon at a liver transplant program or the foreign equivalent. This care must be
 611 documented in a log that includes the date of transplant and the medical record number or

612 other unique identifier that can be verified by the OPTN Contractor. This recipient log should
 613 be signed by the program director, division chief, or department chair from the program
 614 where the physician gained this experience.

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

623 3. The physician ~~should~~ must have observed at least 3 ~~organ liver~~ procurements ~~and 3 liver~~
 624 ~~transplants~~. The physician ~~should also~~ must have observed the evaluation, ~~the~~ donation
 625 process, and management of these donors. ~~at least 3 multiple organ donors who donated a~~
 626 ~~liver. If the physician has completed these observations, they~~ These observations must be
 627 documented in a log that includes the date of procurement, the location of the donor, and
 628 Donor ID.

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

- 633 45. The following letters are submitted directly to the OPTN Contractor:
- 634 a. A letter from the qualified transplant physician or the liver transplant surgeon who has
 635 been directly involved with the proposed physician documenting the physician’s
 636 experience and competence.
 - 637 b. A letter of recommendation from the primary physician and transplant program director at
 638 the transplant program last served by the physician outlining the physician’s overall
 639 qualifications to act as a primary transplant physician, as well as the physician’s personal
 640 integrity, honesty, and familiarity with and experience in adhering to OPTN obligations,
 641 and any other matters judged appropriate. The MPSC may request additional
 642 recommendation letters from the primary physician, primary surgeon, director, or others
 643 affiliated with any transplant program previously served by the physician, at its discretion.
 - 644 c. A letter from the physician that details the training and experience the physician gained in
 645 liver transplantation.

647 **C. Three-year Pediatric Gastroenterology Fellowship Pathway**

648 A physician can meet the requirements for primary liver transplant physician by completion of 3
 649 years of pediatric gastroenterology fellowship training as required by the American Board of
 650 Pediatrics in a program accredited by the Residency Review Committee for Pediatrics (RRC-Ped)
 651 of the Accreditation Council for Graduate Medical Education (ACGME). The training must contain
 652 at least 6 months of clinical care for transplant patients, and meet the following conditions:
 653

- 654 1. The physician has current board certification in gastroenterology by the American Board of
 655 Pediatrics, or the foreign equivalent.
- 656 2. During the 3-year training period the physician was directly involved in the primary care of 10
 657 or more newly transplanted pediatric liver recipients and followed 20 newly transplanted liver
 658 recipients for a minimum of 3 months from the time of transplant, under the direct supervision
 659 of a qualified liver transplant physician along with a qualified liver transplant surgeon. The

- 660 physician was also directly involved in the preoperative, peri-operative and post-operative
 661 care of 10 or more liver transplants in pediatric patients. The pediatric gastroenterology
 662 program director may elect to have a portion of the transplant experience carried out at
 663 another transplant service, to meet these requirements. This care must be documented in a
 664 log that includes the date of transplant, the medical record number or other unique identifier
 665 that can be verified by the OPTN Contractor. This recipient log must be signed by the training
 666 program director or the transplant program's primary transplant physician.
- 667 3. The experience caring for pediatric patients occurred at a liver transplant program with a
 668 qualified liver transplant physician and a qualified liver transplant surgeon that performs an
 669 average of at least 10 liver transplants on pediatric patients per year.
 - 670 4. The physician ~~should~~ must have observed at least 3 ~~organ liver~~ procurements ~~and 3 liver~~
 671 ~~transplants. In addition, the~~ The physician should also must have observed the evaluation,
 672 ~~the~~ donation process, and management of ~~these donors. -at least 3 multiple organ donors~~
 673 ~~who donated a liver. If the physician has completed these observations, they~~ These
 674 observations must be documented in a log that includes the date of procurement, location of
 675 the donor and Donor ID.
 - 676 5. The physician must have observed at least 3 liver transplants. The observation of these
 677 transplants must be documented in a log that includes the transplant date, donor type, and
 678 medical record number or other unique identifier that can be verified by the OPTN Contractor.
 - 679 56. The physician has maintained a current working knowledge of liver transplantation, defined
 680 as direct involvement in liver transplant patient care within the last 2 years. This includes the
 681 management of pediatric patients with end-stage liver disease acute liver failure, the
 682 selection of appropriate pediatric recipients for transplantation, donor selection,
 683 histocompatibility and tissue typing, immediate postoperative care including those issues of
 684 management unique to the pediatric recipient, fluid and electrolyte management, the use of
 685 immunosuppressive therapy in the pediatric recipient including side-effects of drugs and
 686 complications of immunosuppression, the effects of transplantation and immunosuppressive
 687 agents on growth and development, differential diagnosis of liver dysfunction in the allograft
 688 recipient, manifestation of rejection in the pediatric patient, histological interpretation of
 689 allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long-term
 690 outpatient care of pediatric allograft recipients including management of hypertension,
 691 nutritional support, and drug dosage, including antibiotics, in the pediatric patient.
 - 692 67. The following letters are submitted directly to the OPTN Contractor:
 - 693 a. A letter from the director of the pediatric gastroenterology training program, and the
 694 qualified liver transplant physician and surgeon of the fellowship training program
 695 verifying that the physician has met the above requirements, and is qualified to act as a
 696 liver transplant physician and direct a liver transplant program.
 - 697 b. A letter of recommendation from the fellowship training program's primary physician and
 698 transplant program director outlining the physician's overall qualifications to act as a
 699 primary transplant physician, as well as the physician's personal integrity, honesty, and
 700 familiarity with and experience in adhering to OPTN obligations, and any other matters
 701 judged appropriate. The MPSC may request additional recommendation letters from the
 702 primary physician, primary surgeon, director, or others affiliated with any transplant
 703 program previously served by the physician, at its discretion.
 - 704 c. A letter from the physician that details the training and experience the physician gained in
 705 liver transplantation.

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D. Pediatric Transplant Hepatology Fellowship Pathway

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

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1. The physician has current board certification in pediatric gastroenterology by the American Board of Pediatrics or the foreign equivalent, or is approved by the American Board of Pediatrics to take the certifying exam.

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2. During the fellowship, the physician was directly involved in the primary care of 10 or more newly transplanted pediatric liver recipients and followed 20 newly transplanted liver recipients for at least 3 months from the time of transplant, under the direct supervision of a qualified liver transplant physician and in conjunction with a qualified liver transplant surgeon. The physician must have been directly involved in the pre-operative, peri-operative and post-operative care of 10 or more liver transplants in pediatric patients. The pediatric gastroenterology program director may elect to have a portion of the transplant experience completed at another liver transplant program in order to meet these requirements. 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 recipient log must be signed by the training program director or the transplant program primary transplant physician.

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

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5. The physician ~~should~~ must have observed at least 3 ~~organ liver procurements and 3 liver transplants. In addition, the~~ The physician should also must have observed the evaluation, the donation process, and management of ~~these donors. at least 3 multiple organ donors who donated a liver. If the physician has completed these observations, they~~ These observations must be documented in a log that includes the date of procurement, location of the donor and Donor ID.

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6. The physician must have observed at least 3 liver 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.

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

- a. A letter from the director of the pediatric transplant hepatology training program, and the qualified liver transplant physician and surgeon of the fellowship training program

- 754 verifying that the physician has met the above requirements, and is qualified to act as a
 755 liver transplant physician and direct a liver transplant program.
- 756 b. A letter of recommendation from the fellowship training program's primary physician and
 757 transplant program director outlining the physician's overall qualifications to act as a
 758 primary transplant physician, as well as the physician's personal integrity, honesty, and
 759 familiarity with and experience in adhering to OPTN obligations, and any other matters
 760 judged appropriate. The MPSC may request additional recommendation letters from the
 761 primary physician, primary surgeon, director, or others affiliated with any transplant
 762 program previously served by the physician, at its discretion.
- 763 c. A letter from the physician that details the training and experience the physician gained in
 764 liver transplantation.

765 **E. Combined Pediatric Gastroenterology/Transplant Hepatology**

766 **Training and Experience Pathway**

767
 768 A physician can meet the requirements for primary liver transplant physician if the following
 769 conditions are met:

- 770
- 771 1. The physician has current board certification in pediatric gastroenterology by the American
 772 Board of Pediatrics or the foreign equivalent, or is approved by the American Board of
 773 Pediatrics to take the certifying exam.
 - 774 2. The physician gained a minimum of 2 years of experience during or after fellowship, or
 775 accumulated during both periods, at a liver transplant program.
 - 776 3. During the 2 or more years of accumulated experience, the physician was directly involved in
 777 the primary care of 10 or more newly transplanted pediatric liver recipients and followed 20
 778 newly transplanted liver recipients for a minimum of 6 months from the time of transplant,
 779 under the direct supervision of a qualified liver transplant physician and along with a qualified
 780 liver transplant surgeon. The physician must have been directly involved in the pre-operative,
 781 peri-operative and post-operative care of 10 or more pediatric liver transplants recipients.
 782 This care must be documented in a log that includes at the date of transplant and the medical
 783 record number or other unique identifier that can be verified by the OPTN Contractor. This
 784 recipient log must be signed by the training program director or the transplant program
 785 primary transplant physician.
 - 786 4. The individual has maintained a current working knowledge of liver transplantation, defined
 787 as direct involvement in liver transplant patient care within the last 2 years. This includes the
 788 management of pediatric patients with end-stage liver disease, the selection of appropriate
 789 pediatric recipients for transplantation, donor selection, histocompatibility and tissue typing,
 790 immediate post-operative care including those issues of management unique to the pediatric
 791 recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the
 792 pediatric recipient including side-effects of drugs and complications of immunosuppression,
 793 the effects of transplantation and immunosuppressive agents on growth and development,
 794 differential diagnosis of liver dysfunction in the allograft recipient, manifestation of rejection in
 795 the pediatric patient, histological interpretation of allograft biopsies, interpretation of ancillary
 796 tests for liver dysfunction, and long-term outpatient care of pediatric allograft recipients
 797 including management of hypertension, nutritional support, and drug dosage, including
 798 antibiotics, in the pediatric patient.
 - 799 5. The physician ~~should~~ must have observed at least 3 organ liver procurements and 3 liver
 800 ~~transplants. In addition, the~~ The physician should also must have observed the evaluation,
 801 ~~the donation process, and management of these donors. at least 3 multiple organ donors~~

802 ~~who donated a liver. If the physician has completed these observations, they~~ These
 803 observations must be documented in a log that includes the date of procurement, location of
 804 the donor, and Donor ID.

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

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

- 809 a. A letter from the qualified liver transplant physician and surgeon who have been directly
 810 involved with the physician documenting the physician’s experience and competence.
- 811 b. A letter of recommendation from the primary physician and transplant program director at
 812 the fellowship training program or transplant program last served by the physician
 813 outlining the physician’s overall qualifications to act as a primary transplant physician, as
 814 well as the physician’s personal integrity, honesty, and familiarity with and experience in
 815 adhering to OPTN obligations, and any other matters judged appropriate. The MPSC
 816 may request additional recommendation letters from the primary physician, primary
 817 surgeon, director, or others affiliated with any transplant program previously served by
 818 the physician, at its discretion.
- 819 c. A letter from the physician that details the training and experience the physician gained in
 820 liver transplantation.

821

822 **G. Conditional Approval for Primary Transplant Physician**

823 If the primary liver transplant physician changes at an approved liver transplant program, a
 824 physician can serve as the primary liver transplant physician for a maximum of 12 months if the
 825 following conditions are met:

- 826 1. The physician has current board certification in gastroenterology by the American Board of
 827 Internal Medicine, the American Board of Pediatrics, or the foreign equivalent.
- 828 2. The physician has been involved in the primary care of 25 or more newly transplanted liver
 829 recipients, and has followed these patients for at least 3 months from the time of their
 830 transplant. This care must be documented in a recipient log that includes the date of
 831 transplant and the medical record number or other unique identifier that can be verified by the
 832 OPTN Contractor. This log must be signed by the program director, division chief, or
 833 department chair from the transplant program where the experience was gained.
- 834 3. The physician has maintained a current working knowledge of liver transplantation, defined
 835 as direct involvement in liver transplant patient care during the last 2 years. This includes the
 836 management of patients with end stage liver disease, acute liver failure, the selection of
 837 appropriate recipients for transplantation, donor selection, histocompatibility and tissue
 838 typing, immediate post-operative patient care, the use of immunosuppressive therapy
 839 including side effects of the drugs and complications of immunosuppression, differential
 840 diagnosis of liver allograft dysfunction, histologic interpretation of allograft biopsies,
 841 interpretation of ancillary tests for liver dysfunction, and long term outpatient care.
- 842 4. The physician has 12 months experience on an active liver transplant service as the primary
 843 liver transplant physician or under the direct supervision of a qualified liver transplant
 844 physician along with a liver transplant surgeon at a designated liver transplant program, or
 845 the foreign equivalent. These 12 months of experience must be acquired within a 2-year
 846 period.
- 847 5. The physician ~~should~~ must have observed at least 3 ~~organ~~ liver procurements ~~and 3 liver~~
 848 ~~transplants~~. The physician ~~should also~~ must have observed the evaluation, ~~the~~ donation
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850 process, and management ~~of these donors, of at least 3 multiple organ donors who are~~
 851 ~~donating a liver. If the physician has completed these observations, they~~ These observations
 852 must be documented in a log that includes the date of procurement, location of the donor,
 853 and Donor ID.

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

857 ~~67.~~ The transplant program submits activity reports to the OPTN Contractor every 2 months
 858 describing the transplant activity, transplant outcomes, physician recruitment efforts, and
 859 other operating conditions as required by the MPSC to demonstrate the ongoing quality and
 860 efficient patient care at the program. The activity reports must also demonstrate that the
 861 physician is making sufficient progress to meet the required involvement in the primary care
 862 of 50 or more liver transplant recipients, or that the program is making sufficient progress in
 863 recruiting a physician who meets all requirements for primary liver transplant physician and
 864 who will be on site and approved by the MPSC to assume the role of primary physician by the
 865 end of the 12 month conditional approval period.

866 ~~78.~~ The program has established and documented a consulting relationship with counterparts at
 867 another liver transplant program.

868 ~~89.~~ The following letters are submitted directly to the OPTN Contractor:

- 869 a. A letter from the qualified liver transplant physician and surgeon who were directly
 870 involved with the physician verifying that the physician has satisfactorily met the above
 871 requirements to become the primary transplant physician of a liver transplant program.
- 872 b. A letter of recommendation from the primary physician and transplant program director at
 873 the transplant program last served by the physician outlining the physician's overall
 874 qualifications to act as a primary transplant physician, as well as the physician's personal
 875 integrity, honesty, and familiarity with and experience in adhering to OPTN obligations,
 876 and any other matters judged appropriate. The MPSC may request additional
 877 recommendation letters from the primary physician, primary surgeon, director, or others
 878 affiliated with any transplant program previously served by the physician, at its discretion.
- 879 c. A letter from the physician sends that details the training and experience the physician
 880 gained in liver transplantation.

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

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

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

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 897 **F.10 Primary Intestine Transplant Surgeon Requirements**
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A. Full Intestine Surgeon Approval Pathway

Surgeons can be fully approved as a primary intestine transplant surgeon by completing a formal 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 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 selection and evaluation of the donor.~~ 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, location of the donor, 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 a transplant training program approved by the American Society of Transplant Surgeons (ASTS) or accepted by the OPTN Contractor as described in *Section F.13 Approved Intestine Transplant Surgeon Fellowship Training Programs* that follows. Foreign training programs must be accepted as equivalent by the Membership and Professional Standards Committee (MPSC).
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.

B. Conditional Intestine Surgeon Approval Pathway

Surgeons can meet the requirements for conditional approval as primary intestine transplant surgeon through experience gained during or post-fellowship, if *all* of the following conditions are met:

1. The surgeon has performed at least 4 intestine transplants that include the isolated bowel and composite grafts and must perform 3 or more intestine transplants over the next 3

- 954 consecutive years as primary surgeon or first assistant at a designated intestine transplant
 955 program, or its foreign equivalent. These transplants must be documented in a log that
 956 includes the date of transplant, the role of the surgeon in the procedure, and medical record
 957 number or other unique identifier that can be verified by the OPTN Contractor. This log must
 958 be signed by the program director, division chief, or department chair from the program
 959 where the experience or training was gained. Each year of the surgeon's experience must be
 960 substantive and relevant and include pre-operative assessment of intestine transplant
 961 candidates, transplants performed as primary surgeon or first assistant and post-operative
 962 management of intestine recipients.
- 963 2. The surgeon has performed at least 3 intestine procurements as primary surgeon or first
 964 assistant. These procurements must include at least 1 procurement of a graft that includes a
 965 liver, ~~and selection and evaluation of the donor~~. This procedure must be documented in a log
 966 that includes the date of procurement, location of the donor, and Donor ID.
 - 967 3. The surgeon has maintained a current working knowledge of intestine transplantation,
 968 defined as direct involvement in intestine transplant patient care within the last 5 years. This
 969 includes the management of patients with short bowel syndrome or intestinal failure, the
 970 selection of appropriate recipients for transplantation, donor selection, histocompatibility and
 971 tissue typing, performing the transplant operation, immediate postoperative and continuing
 972 inpatient care, the use of immunosuppressive therapy including side effects of the drugs and
 973 complications of immunosuppression, differential diagnosis of intestine dysfunction in the
 974 allograft recipient, histologic interpretation of allograft biopsies, interpretation of ancillary tests
 975 for intestine dysfunction, and long term outpatient care.
 - 976 4. The surgeon develops a formal mentor relationship with a primary intestine transplant
 977 surgeon at another approved intestine transplant program. The mentor will discuss program
 978 requirements, patient and donor selection, recipient management, and be available for
 979 consultation as required until full approval conditions are all met.
 - 980 5. The following letters are sent to the OPTN Contractor:
 - 981 a. A letter from the director of the transplant program and chair of the department or hospital
 982 credentialing committee verifying that the surgeon has met the above requirements and
 983 is qualified to direct an intestine transplant program.
 - 984 b. A letter of recommendation from the primary surgeon and transplant program director at
 985 the transplant program last served by the surgeon, outlining the surgeon's overall
 986 qualifications to act as primary transplant surgeon, as well as the surgeon's personal
 987 integrity, honesty, familiarity with and experience in adhering to OPTN obligations, and
 988 other matters judged appropriate. The MPSC may request additional recommendation
 989 letters from the primary surgeon, primary physician, director, or others affiliated with any
 990 transplant program previously served by the surgeon, at its discretion.
 - 991 c. A letter from the surgeon that details the training and experience the surgeon gained in
 992 intestine transplantation as well as detailing the plan for obtaining full approval within the
 993 3-year conditional approval period.
 - 994 d. A letter of commitment from the surgeon's mentor supporting the detailed plan developed
 995 by the surgeon to obtain full approval.

997 **Appendix G:**
 998 **Membership and Personnel Requirements for**
 999 **Pancreas and Pancreatic Islet Transplant Programs**

1000 **G.2 Primary Pancreas Transplant Surgeon Requirements**

1001 **A. Formal 2-year Transplant Fellowship Pathway**

1002 Surgeons can meet the training requirements for primary pancreas transplant surgeon by
 1003 completing a 2-year transplant fellowship if the following conditions are met:

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1. The surgeon performed at least 15 pancreas transplants as primary surgeon or first assistant during the 2-year fellowship period. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the director of the training program.
 2. The surgeon performed at least 10 pancreas procurements as primary surgeon or first assistant during the 2-year period. 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 a log that includes the date of procurement, location of the donor, and Donor ID. This log must be signed by the director of the training program.
 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 or accepted by the OPTN Contractor as described in *Section G.7. Approved Pancreas Transplant Surgeon Fellowship Training Programs* that follows. Foreign training programs will be reviewed by the MPSC and only those programs that are accepted as equivalent will be granted approval.
 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.

1045 **G.3 Primary Pancreas Transplant Physician Requirements**

1046 **A. Twelve-month Transplant Medicine Fellowship Pathway**

1047 Physicians can meet the training requirements for a primary pancreas transplant physician during
 1048 a separate 12-month transplant medicine fellowship if the following conditions are met:
 1049

- 1050 1. The physician completed 12 consecutive months of specialized training in pancreas
 1051 transplantation at a pancreas transplant program under the direct supervision of a qualified
 1052 pancreas transplant physician along with a pancreas transplant surgeon. The training must
 1053 have included at least 6 months on the clinical transplant service. The remaining time must
 1054 have consisted of transplant-related experience, such as experience in a tissue typing
 1055 laboratory, on another solid organ transplant service, or conducting basic or clinical transplant
 1056 research.
- 1057 2. During the fellowship period, the physician was directly involved in the primary care of 8 or
 1058 more newly transplanted pancreas recipients and followed these recipients for a minimum of
 1059 3 months from the time of transplant. The care must be documented in a log that includes the
 1060 date of transplant and medical record number or other unique identifier that can be identified
 1061 by the OPTN Contractor. This recipient log must be signed by the director of the training
 1062 program or the transplant program's primary transplant physician.
- 1063 3. The physician has maintained a current working knowledge of pancreas transplantation,
 1064 defined as direct involvement in pancreas transplant patient care within the last 2 years. This
 1065 includes the management of patients with end stage pancreas disease, the selection of
 1066 appropriate recipients for transplantation, donor selection, histocompatibility and tissue
 1067 typing, immediate post-operative patient care, the use of immunosuppressive therapy
 1068 including side effects of the drugs and complications of immunosuppression, differential
 1069 diagnosis of pancreas dysfunction in the allograft recipient, histological interpretation of
 1070 allograft biopsies, interpretation of ancillary tests for pancreas dysfunction, and long term
 1071 outpatient care.
- 1072 4. The physician ~~should~~ must have observed at least 3 ~~organ pancreas~~ procurements ~~and 3~~
 1073 ~~pancreas transplants~~. The physician ~~should~~ must have observed the evaluation, ~~the~~ donation
 1074 process, and management of ~~these donors~~, ~~at least 3 multiple organ donors who donated a~~
 1075 ~~pancreas~~. ~~If the physician completed these observations, they~~ These observations must be
 1076 documented in a log that includes the date of procurement, location of the donor, and Donor
 1077 ID.
- 1078 5. The physician must have observed at least 3 pancreas transplants. The observation of these
 1079 transplants must be documented in a log that includes the transplant date and medical record
 1080 number or other unique identifier that can be verified by the OPTN Contractor.
- 1081 ~~56.~~ The curriculum of this transplant medicine fellowship should be approved by the Residency
 1082 Review Committee for Internal Medicine (RRC-IM) of the Accreditation Council for Graduate
 1083 Medical Education (ACGME).
- 1084 ~~67.~~ The following letters are submitted directly to the OPTN Contractor:
- 1085 a. A letter from director of the training program and supervising qualified pancreas
 1086 transplant physician send a letter directly to the OPTN Contractor verifying that the fellow
 1087 has met the above requirements and is qualified to direct a pancreas transplant program.
- 1088 b. A letter of recommendation from the fellowship training program's primary physician and
 1089 transplant program director outlining the physician's overall qualifications to act as
 1090 primary transplant physician as well as the physician's personal integrity, honesty,
 1091 familiarity with and experience in adhering to OPTN obligations, and any other matters
 1092 judged appropriate. The MPSC may request similar letters of recommendation from the
 1093 primary physician, primary surgeon, director, or others affiliated with any transplant
 1094 program that the physician previously served, at its discretion.
- 1095 c. A letter from the physician that details the training and experience the physician has
 1096 gained in pancreas transplantation.
 1097

1098 The above training is in addition to other clinical requirements for general nephrology,
 1099 endocrinology, or diabetology training.

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B. Clinical Experience Pathway

1102 A physician can meet the requirements for a primary transplant physician through acquired
 1103 clinical experience if the following conditions are met:

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1. The physician has been directly involved in the primary care of 15 or more newly transplanted pancreas recipients and continued to follow these recipients for a minimum of 3 months from the time of transplant. This patient care must have been provided over a 2 to 5-year period on an active pancreas transplant service as the primary pancreas transplant physician or under the direct supervision of a qualified pancreas transplant physician along with a pancreas transplant surgeon at a pancreas transplant program, or its foreign equivalent. The 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 recipient log should be signed by the program director, division chief, or department chair from the program where the physician gained this experience.
2. The physician 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.
3. The physician ~~should~~ must have observed at least 3 ~~organ pancreas~~ procurements ~~and 3 pancreas transplants~~. The physician ~~should~~ must have ~~also~~ observed the evaluation, ~~the~~ donation process, and management of ~~these donors~~. ~~at least 3 multiple organ donors who donated a pancreas. If the physician has completed these observations, they~~ These observations must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
4. 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.
45. The following letters are submitted directly to the OPTN Contractor:
 - a. A letter from the qualified pancreas transplant physician or surgeon who has been directly involved with the physician documenting the physician's experience and competence.
 - b. A letter of recommendation from the primary physician and director at the transplant program last served by the physician outlining the physician's overall qualifications to act as 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 the physician previously served, at its discretion.
 - c. A letter from the physician that details the training and experience the physician has gained in pancreas transplantation.

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D. Conditional Approval for Primary Transplant Physician

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

1. The physician has been involved in the primary care of 8 or more newly transplanted pancreas recipients, and has followed these patients for at least 3 months from the time of their transplant. This care must be documented in a recipient log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log should be signed by the program director, division chief, or department chair from the transplant program where the experience was gained.
2. 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.
3. The physician has 12 months experience on an active pancreas transplant service as the primary pancreas transplant physician or under the direct supervision of a qualified pancreas transplant physician along with a pancreas transplant surgeon at a designated pancreas transplant program, or its foreign equivalent. This 12-month period of experience on the transplant service must have been acquired over a maximum of 2 years.
4. The physician ~~should~~ must have observed at least 3 ~~organ pancreas~~ procurements ~~and 3 pancreas transplants~~. The physician ~~should also~~ must have observed the evaluation, the donation process, and management of ~~these donors~~ at least 3 multiple organ donors who are donating a pancreas. ~~If the physician has completed these observations, they~~ These observations must be documented in a log that includes the date of procurement, location of the donor, 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.
- ~~56.~~ The program has established and documented a consulting relationship with counterparts at another pancreas transplant program.
- ~~67.~~ 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 in meeting the required involvement in the primary care of 15 or more pancreas transplant recipients, or that the program is making sufficient progress in recruiting a physician 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.
- ~~78.~~ The following letters are submitted directly to the OPTN Contractor:
 - a. A letter from the qualified pancreas transplant physician and surgeon who were directly involved with the physician documenting the physician's experience and competence.

- 1194 b. A letter of recommendation from the primary physician and director at the transplant
 1195 program last served by the physician outlining the physician's overall qualifications to act
 1196 as a primary transplant physician, as well as the physician's personal integrity, honesty,
 1197 and familiarity with and experience in adhering to OPTN obligations, and any other
 1198 matters judged appropriate. The MPSC may request additional recommendation letters
 1199 from the primary physician, primary surgeon, director, or others affiliated with any
 1200 transplant program previously served by the physician, at its discretion.
 1201 c. A letter from the physician that details the training and experience the physician has
 1202 gained in pancreas transplantation.
 1203

1204 The 12-month conditional approval period begins on the initial approval date granted to the
 1205 personnel change application, whether it is interim approval granted by the MPSC subcommittee,
 1206 or approval granted by the full MPSC. The conditional approval period ends 12 months after the
 1207 first approval date of the personnel change application.
 1208

1209 If the transplant program is unable to demonstrate that it has an individual on site who can meet
 1210 the requirements as described in *Sections G.3.A through G.3.C* above at the end of the 12-month
 1211 conditional approval period, it must inactivate. The requirements for program inactivation are
 1212 described in *Appendix K: Transplant Program Inactivity, Withdrawal and Termination* of these
 1213 Bylaws.
 1214

1215 The MPSC may consider on a case-by-case basis and grant a 6-month extension to a transplant
 1216 program that provides substantial evidence of progress toward fulfilling the requirements but is
 1217 unable to complete the requirements within one year.
 1218

1219 **Appendix H:**

1220 **Membership and Personnel Requirements for Heart**

1221 **Transplant Programs**

1222 **H.2 Primary Heart Transplant Surgeon Requirements**

1223 **A. Cardiothoracic Surgery Residency Pathway**

1224 Surgeons can meet the training requirements for primary heart transplant surgeon by completing
 1225 a cardiothoracic surgery residency if *all* the following conditions are met:
 1226

- 1227 1. The surgeon performed at least 20 heart or heart/lung transplants as primary surgeon or first
 1228 assistant during the cardiothoracic surgery residency. These transplants must be
 1229 documented in a log that includes the date of transplant, role of the surgeon in the procedure,
 1230 and medical record number or other unique identifier that can be verified by the OPTN
 1231 Contractor. This log must be signed by the director of the training program.
- 1232 2. The surgeon performed at least 10 heart or heart/lung procurements as primary surgeon or
 1233 first assistant under the supervision of a qualified heart transplant surgeon ~~during the~~
 1234 ~~cardiothoracic surgery residency~~. These procurements must have been performed anytime
 1235 during the surgeon's cardiothoracic surgery residency and the two years immediately
 1236 following cardiothoracic surgery residency completion. These procedures must be
 1237 documented in a log that includes the date of procurement, location of the donor, and Donor
 1238 ID. This log must be signed by the director of the training program.

- 1239 3. The surgeon has maintained a current working knowledge of all aspects of heart
- 1240 transplantation, defined as a direct involvement in heart transplant patient care within the last
- 1241 2 years. This includes performing the transplant operation, donor selection, use of
- 1242 mechanical assist devices, recipient selection, post-operative hemodynamic care,
- 1243 postoperative immunosuppressive therapy, and outpatient follow-up.
- 1244 4. This training was completed at a hospital with a cardiothoracic surgery training program
- 1245 approved by the American Board of Thoracic Surgery, or its foreign equivalent, as accepted
- 1246 by the MPSC with a recommendation from the Thoracic Organ Transplantation Committee.
- 1247 5. The following letters are submitted directly to the OPTN Contractor:
- 1248 a. A letter from the director of the training program verifying that the surgeon has met the
- 1249 above requirements and is qualified to direct a heart transplant program.
- 1250 b. A letter of recommendation from the training program’s primary surgeon and transplant
- 1251 program director outlining the individual’s overall qualifications to act as primary
- 1252 transplant surgeon, as well as the surgeon’s personal integrity, honesty, and familiarity
- 1253 with and experience in adhering to OPTN obligations, and any other matters judged
- 1254 appropriate. The MPSC may request additional recommendation letters from the primary
- 1255 physician, primary surgeon, director, or others affiliated with any transplant program
- 1256 previously served by the surgeon, at its discretion.
- 1257 c. A letter from the surgeon that details the training and experience the surgeon has gained
- 1258 in heart transplantation.
- 1259

B. Twelve-month Heart Transplant Fellowship Pathway

1261 Surgeons can meet the training requirements for primary heart transplant surgeon by completing
 1262 a 12-month heart transplant fellowship if the following conditions are met:

- 1263
- 1264 1. The surgeon performed at least 20 heart or heart/lung transplants as primary surgeon or first
- 1265 assistant during the 12-month heart transplant fellowship. These transplants must be
- 1266 documented in a log that includes the date of transplant, the role of the surgeon in the
- 1267 procedure, and the medical record number or other unique identifier that can be verified by
- 1268 the OPTN Contractor. This log must be signed by the director of the training program.
- 1269 2. The surgeon performed at least 10 heart or heart/lung procurements as primary surgeon or
- 1270 first assistant under the supervision of a qualified heart transplant surgeon ~~during the 12-~~
- 1271 ~~month heart transplant fellowship.~~ These procurements must have been performed anytime
- 1272 during the surgeon’s fellowship and the two years immediately following fellowship
- 1273 completion. These procedures must be documented in a log that includes the date of
- 1274 procurement, location of the donor, and Donor ID. This log must be signed by the director of
- 1275 the training program.
- 1276 3. The surgeon has maintained a current working knowledge of all aspects of heart
- 1277 transplantation, defined as a direct involvement in heart transplant patient care within the last
- 1278 2 years. This includes performing the transplant operation, donor selection, the use of
- 1279 mechanical circulatory assist devices, recipient selection, post-operative hemodynamic care,
- 1280 postoperative immunosuppressive therapy, and outpatient follow-up.
- 1281 4. This training was completed at a hospital with a cardiothoracic surgery training program
- 1282 approved by the American Board of Thoracic Surgery, or its foreign equivalent, as accepted
- 1283 by the MPSC with a recommendation from the Thoracic Organ Transplantation Committee.
- 1284 5. The following letters are submitted directly to the OPTN Contractor:
- 1285 a. A letter from the director of the training program verifying that the surgeon has met the
- 1286 above requirements and is qualified to direct a heart transplant program.

- 1287 b. A letter of recommendation from the training program's primary surgeon and transplant
 1288 program director outlining the individual's overall qualifications to act as primary
 1289 transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity
 1290 with and experience in adhering to OPTN obligations, and any other matters judged
 1291 appropriate. The MPSC may request additional recommendation letters from the primary
 1292 physician, primary surgeon, director, or others affiliated with any transplant program
 1293 previously served by the surgeon, at its discretion.
 1294 c. A letter from the surgeon that details the training and experience the surgeon has gained
 1295 in heart transplantation.
 1296

1297 H.3 Primary Heart Transplant Physician Requirements

1298 A. Twelve-month Transplant Cardiology Fellowship Pathway

1299 Physicians can meet the training requirements for primary heart transplant physician during a 12-
 1300 month transplant cardiology fellowship if the following conditions are met:

- 1301
- 1302 1. During the fellowship period, the physician was directly involved in the primary care of at least
 1303 20 newly transplanted heart or heart/lung recipients. This training will have been under the
 1304 direct supervision of a qualified heart transplant physician and in conjunction with a heart
 1305 transplant surgeon. This care must be documented in a log that includes the date of
 1306 transplant and the medical record number or other unique identifier that can be verified by the
 1307 OPTN Contractor. This recipient log must be signed by the director of the training program or
 1308 the primary transplant physician at the transplant program.
 - 1309 2. The physician has maintained a current working knowledge of heart transplantation, defined
 1310 as direct involvement in heart transplant patient care within the last 2 years. This includes the
 1311 care of acute and chronic heart failure, donor selection, the use of mechanical circulatory
 1312 support devices, recipient selection, pre- and post-operative hemodynamic care, post-
 1313 operative immunosuppressive therapy, histological interpretation and grading of myocardial
 1314 biopsies for rejection, and long-term outpatient follow-up.
 - 1315 3. The physician ~~should~~ must have observed at least 3 ~~organ heart procurements and 3 heart~~
 1316 ~~transplants~~. The physician ~~should also~~ must have observed the evaluation, ~~the donation~~
 1317 ~~process, and management of these donors. 3 multiple organ donors who are donating a heart~~
 1318 ~~or heart/lungs. If the physician has completed these observations, they~~ These observations
 1319 must be documented in a log that includes the date of procurement, location of the donor,
 1320 and Donor ID.
 - 1321 4. The physician must have observed at least 3 heart transplants. The observation of these
 1322 transplants must be documented in a log that includes the transplant date and medical record
 1323 number or other unique identifier that can be verified by the OPTN Contractor.
 - 1324 45. This training was completed at a hospital with an American Board of Internal Medicine
 1325 certified fellowship training program in adult cardiology or American Board of Pediatrics
 1326 certified fellowship training program in pediatric cardiology or its foreign equivalent, as
 1327 accepted by the MPSC.
 - 1328 56. The following letters are submitted directly to the OPTN Contractor:
 1329 a. A letter from the director of the training program and the supervising qualified heart
 1330 transplant physician verifying that the physician has met the above requirements and is
 1331 qualified to direct a heart transplant program.
 1332 b. A letter of recommendation from the training program's primary physician and transplant
 1333 program director outlining the physician's overall qualifications to act as primary

1334 transplant physician, as well as the physician’s personal integrity, honesty, and familiarity
 1335 with and experience in adhering to OPTN obligations, and any other matters judged
 1336 appropriate. The MPSC may request additional recommendation letters from the Primary
 1337 Physician, primary surgeon, director, or others affiliated with any transplant program
 1338 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 heart transplantation.

B. Clinical Experience Pathway

A physician can meet the requirements for primary heart transplant physician through acquired clinical experience if the following conditions are met.

1. The physician has been directly involved in the primary care of 20 or more newly transplanted heart or heart/lung recipients and continued to follow these recipients for a minimum of 3 months from transplant. This patient care must have been provided over a 2 to 5-year period on an active heart transplant service as the primary heart transplant physician or under the direct supervision of a qualified heart transplant physician and in conjunction with a heart transplant surgeon at a heart transplant program or its foreign equivalent. This care must be documented in a log that includes the date of transplant and medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log should be signed by the director or the primary transplant physician at the transplant program where the physician gained this experience.
2. The physician has maintained a current working knowledge of heart transplantation, defined as direct involvement in heart transplant patient care within the last 2 years. This includes the 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.
3. The physician ~~should~~ must have observed at least 3 ~~organ heart~~ procurements and ~~3 heart transplants~~. The physician ~~should also~~ must have observed the evaluation, ~~the~~ donation process, and management of ~~these donors. 3 multiple organ donors who are donating a heart or heart/lungs. If the physician has completed these observations, they~~ These observations must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
4. The physician must have observed at least 3 heart 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.
45. The following letters are submitted directly to the OPTN Contractor:
 - a. A letter from the heart transplant physician or the heart transplant surgeon who has been directly involved with the physician at the transplant program verifying the physician’s competence.
 - b. A letter of recommendation from the primary physician and transplant program director at the transplant program last served by the physician outlining the physician’s overall qualifications to act as 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.

- 1382 c. A letter from the physician that details the training and experience the physician has
 1383 gained in heart transplantation.
 1384

1385 **D. Conditional Approval for Primary Transplant Physician**

1386 If the primary heart transplant physician changes at an approved heart transplant program, a
 1387 physician can serve as the primary heart transplant physician for a maximum of 12 months if the
 1388 following conditions are met:
 1389

- 1390 1. The physician has current board certification in cardiology by the American Board of Internal
 1391 Medicine, the American Board of Pediatrics, or the foreign equivalent.
 1392 2. The physician has 12 months experience on an active heart transplant service as the primary
 1393 heart transplant physician or under the direct supervision of a qualified heart transplant
 1394 physician and in conjunction with a heart transplant surgeon at a designated heart transplant
 1395 program. These 12 months of experience must be acquired within a 2-year period.
 1396 3. The physician has maintained a current working knowledge of heart transplantation, defined
 1397 as direct involvement in heart transplant patient care within the last 2 years. This includes
 1398 knowledge of acute and chronic heart failure, donor selection, the use of mechanical
 1399 circulatory support devices, recipient selection, pre- and post-operative hemodynamic care,
 1400 post-operative immunosuppressive therapy, histological interpretation in grading of
 1401 myocardial biopsies for rejection, and long-term outpatient follow-up.
 1402 4. The physician has been involved in the primary care of 10 or more newly transplanted heart
 1403 or heart/lung transplant recipients as the heart transplant physician or under the direct
 1404 supervision of a qualified heart transplant physician or in conjunction with a heart transplant
 1405 surgeon. The physician will have followed these patients for a minimum of 3 months from the
 1406 time of transplant. This care must be documented in a log that includes the date of transplant
 1407 and medical record or other unique identifier that can be verified by the OPTN Contractor.
 1408 This recipient log should be signed by the program director or the primary transplant
 1409 physician at the transplant program where the physician gained experience.
 1410 5. The physician ~~should~~ must have observed at least 3 ~~organ heart~~ procurements and 3 heart
 1411 ~~transplants~~. The physician ~~should also~~ must have observed the evaluation, the donation
 1412 process, and management of these donors. ~~at least 3 multiple organ donors who donated a~~
 1413 ~~heart or heart/lungs. If the physician has completed these observations, they~~ These
 1414 observations must be documented in a log that includes the date of procurement, location of
 1415 the donor, and Donor ID.
 1416 6. The physician must have observed at least 3 heart transplants. The observation of these
 1417 transplants must be documented in a log that includes the transplant date and medical record
 1418 number or other unique identifier that can be verified by the OPTN Contractor.
 1419 ~~67.~~ The program has established and documented a consulting relationship with counterparts at
 1420 another heart transplant program.
 1421 ~~78.~~ The transplant program submits activity reports to the OPTN Contractor every 2 months
 1422 describing the transplant activity, transplant outcomes, physician recruitment efforts, and
 1423 other operating conditions as required by the MPSC to demonstrate the ongoing quality and
 1424 efficient patient care at the program. The activity reports must also demonstrate that the
 1425 physician is making sufficient progress to meet the required involvement in the primary care
 1426 of 20 or more heart transplant recipients, or that the program is making sufficient progress in
 1427 recruiting a physician who meets all requirements for primary heart transplant physician by
 1428 the end of the 12 month conditional approval period.
 1429 ~~89.~~ The following letters are submitted directly to the OPTN Contractor:

- 1430 a. A letter from the heart transplant physician or the heart transplant surgeon who has been
 1431 directly involved with the physician at the transplant program verifying the physician's
 1432 competence.
- 1433 b. A letter of recommendation from the primary physician and director at the transplant
 1434 program last served by the physician outlining the physician's overall qualifications to act
 1435 as primary transplant physician, as well as the physician's personal integrity, honesty,
 1436 and familiarity with and experience in adhering to OPTN obligations, and any other
 1437 matters judged appropriate. The MPSC may request additional recommendation letters
 1438 from the primary physician, primary surgeon, director, or others affiliated with any
 1439 transplant program previously served by the physician, at its discretion.
- 1440 c. A letter from the physician that details the training and experience the physician has
 1441 gained in heart transplantation.

1442

1443 The 12-month conditional approval period begins on the first approval date granted to the
 1444 personnel change application, whether it is an interim approval granted by the MPSC
 1445 subcommittee, or an approval granted by the full MPSC. The conditional approval period ends
 1446 exactly 12 months after this first approval date of the personnel change application.

1447

1448 If the program is unable to demonstrate that it has an individual on site who can meet the
 1449 requirements as described in *Sections H.3.A through H.3.C* above at the end of the 12-month
 1450 conditional approval period, it must inactivate. The requirements for program inactivation are
 1451 described in *Appendix K: Transplant Program Inactivity, Withdrawal, and Termination* of these
 1452 Bylaws.

1453

1454 The MPSC may consider on a case-by-case basis and grant a 6-month extension to a transplant
 1455 program that provides substantial evidence of progress toward fulfilling the requirements but is
 1456 unable to complete the requirements within one year.

1457

1458 ***Appendix I:***

1459 ***Membership and Personnel Requirements for Lung***

1460 ***Transplant Programs***

1461 **I.2 Primary Lung Transplant Surgeon Requirements**

1462 **A. Cardiothoracic Surgery Residency Pathway**

1463 Surgeons can meet the training requirements for primary lung transplant surgeon by completing a
 1464 cardiothoracic surgery residency if the following conditions are met:

1465

- 1466 1. During the cardiothoracic surgery residency, the surgeon has performed at least 15 lung or
 1467 heart/lung transplants as primary surgeon or first assistant under the direct supervision of a
 1468 qualified lung transplant surgeon and in conjunction with a lung transplant physician at a lung
 1469 transplant program. At least half of these transplants must be lung procedures. These
 1470 transplants must be documented in a log that includes the date of transplant, role of the
 1471 surgeon in the procedure, and medical record number or other unique identifier that can be
 1472 verified by the OPTN Contractor. This log must be signed by the director of the training
 1473 program.

- 1474 2. The surgeon performed at least 10 lung procurements as primary surgeon or first assistant
 1475 under the supervision of a qualified lung transplant surgeon. These procurements must have
 1476 been performed anytime during the surgeon's cardiothoracic surgery residency and the two
 1477 years immediately following cardiothoracic surgery residency completion. These procedures
 1478 must be documented in a log that includes the date of procurement, location of the donor,
 1479 and Donor ID.
- 1480 3. The surgeon has maintained a current working knowledge of all aspects of lung
 1481 transplantation, defined as a direct involvement in lung transplant patient care within the last
 1482 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass,
 1483 donor selection, recipient selection, pre- and postoperative ventilator care, postoperative
 1484 immunosuppressive therapy, histological interpretation and grading of lung biopsies for
 1485 rejection, and long-term outpatient follow-up. This training must also include the other clinical
 1486 requirements for thoracic surgery
- 1487 4. This training was completed at a hospital with a cardiothoracic training program approved by
 1488 the American Board of Thoracic Surgery, or its foreign equivalent. Foreign programs must
 1489 have a recommendation from the Thoracic Organ Transplantation Committee and be
 1490 accepted as equivalent by the MPSC.
- 1491 5. The following letters are submitted directly to the OPTN Contractor:
- 1492 a. A letter from the director of the training program verifying that the surgeon has met the
 1493 above requirements and is qualified to direct a lung transplant program.
- 1494 b. A letter of recommendation from the program's primary surgeon and transplant program
 1495 director outlining the individual's overall qualifications to act as primary transplant
 1496 surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and
 1497 experience in adhering to OPTN obligations and compliance protocols, and any other
 1498 matters judged appropriate. The MPSC may request additional recommendation letters
 1499 from the primary physician, primary surgeon, director, or others affiliated with any
 1500 transplant program previously served by the surgeon, at its discretion.
- 1501 c. A letter from the surgeon that details the training and experience the surgeon has gained
 1502 in lung transplantation.

1504 B. Twelve-month Lung Transplant Fellowship Pathway

1505 Surgeons can meet the training requirements for primary lung transplant surgeon by completing a
 1506 12-month lung transplant fellowship if the following conditions are met:

- 1507
- 1508 1. The surgeon has performed at least 15 lung or heart/lung transplants under the direct
 1509 supervision of a qualified lung transplant surgeon and in conjunction with a qualified lung
 1510 transplant physician as primary surgeon or first assistant during the 12-month lung transplant
 1511 fellowship. At least half of these transplants must be lung procedures. These transplants
 1512 must be documented in a log that includes the date of transplant, the role of the surgeon in
 1513 the procedure, and the medical record number or other unique identifier that can be verified
 1514 by the OPTN Contractor. This log must be signed by the director of the program.
- 1515 2. The surgeon has performed at least 10 lung procurements as primary surgeon or first
 1516 assistant under the supervision of a qualified lung transplant surgeon ~~during the 12-month~~
 1517 ~~lung transplant fellowship.~~ These procurements must have been performed anytime during
 1518 the surgeon's fellowship and the two years immediately following fellowship completion.
 1519 These procedures must be documented in a log that includes the date of procurement,
 1520 location of the donor, and Donor ID.

- 1521 3. The surgeon has maintained a current working knowledge of all aspects of lung
 1522 transplantation, defined as a direct involvement in lung transplant patient care within the last
 1523 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass,
 1524 donor selection, recipient selection, pre- and postoperative ventilator care, postoperative
 1525 immunosuppressive therapy, histological interpretation and grading of lung biopsies for
 1526 rejection, and long-term outpatient follow-up.
- 1527 4. This training was completed at a hospital with a cardiothoracic training program approved by
 1528 the American Board of Thoracic Surgery, or its foreign equivalent. Foreign programs must
 1529 have a recommendation from the Thoracic Organ Transplantation Committee and be
 1530 accepted as equivalent by the MPSC.
- 1531 5. The following letters are submitted directly to the OPTN Contractor:
- 1532 a. A letter from the director of the training program verifying that the surgeon has met the
 1533 above requirements and is qualified to direct a lung transplant program.
- 1534 b. A letter of recommendation from the training program's primary surgeon and transplant
 1535 program director outlining the individual's overall qualifications to act as primary
 1536 transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity
 1537 with and experience in adhering to OPTN obligations, and any other matters judged
 1538 appropriate. The MPSC may request additional recommendation letters from the primary
 1539 physician, primary surgeon, director, or others affiliated with any transplant program
 1540 previously served by the surgeon, at its discretion.
- 1541 c. A letter from the surgeon that details the training and experience the surgeon has gained
 1542 in lung transplantation.
 1543

1544 I.3 Primary Lung Transplant Physician Requirements

1545 A. Twelve-month Transplant Pulmonary Fellowship Pathway

1546 Physicians can meet the training requirements for primary lung transplant physician during a 12-
 1547 month transplant pulmonary fellowship if the following conditions are met:
 1548

- 1549 1. The physician was directly involved in the primary and follow-up care of at least 15 newly
 1550 transplanted lung or heart/lung recipients. This training will have been under the direct
 1551 supervision of a qualified lung transplant physician and in conjunction with a lung transplant
 1552 surgeon. At least half of these patients must be single or double-lung transplant recipients.
 1553 This care must be documented in a log that includes the date of transplant and the medical
 1554 record number or other unique identifier that can be verified by the OPTN Contractor. This
 1555 recipient log must be signed by the director of the training program or the primary transplant
 1556 physician at the transplant program.
- 1557 2. The physician has maintained a current working knowledge of all aspects of lung
 1558 transplantation, defined as a direct involvement in lung transplant patient care within the last
 1559 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass,
 1560 donor selection, recipient selection, pre- and postoperative ventilator care, postoperative
 1561 immunosuppressive therapy, histological interpretation and grading of lung biopsies for
 1562 rejection, and long-term outpatient follow-up.
- 1563 3. The physician ~~should~~ must have observed at least 3 lung or heart/lung procurements ~~and 3~~
 1564 ~~lung transplants~~. The physician ~~should also~~ must have observed the evaluation, the donation
 1565 process, and management of these donors. ~~3 multiple organ donors who are donating a lung~~
 1566 ~~or heart/lungs. If the physician has completed these observations, they~~ These observations

- 1567 must be documented in a log that includes the date of procurement, location of the donor,
 1568 and Donor ID.
- 1569 4. The physician must have observed at least 3 lung transplants. The observation of these
 1570 transplants must be documented in a log that includes the transplant date and medical record
 1571 number or other unique identifier that can be verified by the OPTN Contractor.
- 1572 45. This training was completed at a hospital with an American Board of Internal Medicine
 1573 certified fellowship training program in adult pulmonary medicine, an American Board of
 1574 Pediatrics-certified fellowship training program in pediatric medicine, or its foreign equivalent.
 1575 Foreign programs must have a recommendation from the Thoracic Organ Transplantation
 1576 Committee and be accepted as equivalent by the MPSC.
- 1577
- 1578 56. The following letters are submitted directly to the OPTN Contractor:
- 1579 a. A letter from the director of the training program verifying that the physician has met the
 1580 above requirements and is qualified to direct a lung transplant program.
- 1581 b. A letter of recommendation from the training program’s primary physician and transplant
 1582 program director outlining the physician’s overall qualifications to act as primary
 1583 transplant physician, as well as the physician’s personal integrity, honesty, and familiarity
 1584 with and experience in adhering to OPTN obligations, and any other matters judged
 1585 appropriate. The MPSC may request additional recommendation letters from the primary
 1586 physician, primary surgeon, director, or others affiliated with any transplant program
 1587 previously served by the physician, at its discretion.
- 1588 c. A letter from the physician that details the training and experience the physician has
 1589 gained in lung transplantation.
- 1590

1591 **B. Clinical Experience Pathway**

1592 A physician can meet the requirements for primary lung transplant physician through acquired
 1593 clinical experience if the following conditions are met.

1594

- 1595 1. The physician has been directly involved in the primary care of 15 or more newly transplanted
 1596 lung or heart/lung recipients and continued to follow these recipients for a minimum of 3
 1597 months from the time of transplant. At least half of these transplant must be lung transplants.
 1598 This patient care must have been provided over a 2 to 5-year period on an active lung
 1599 transplant program or its foreign equivalent. This care must have been provided as the lung
 1600 transplant physician or directly supervised by a qualified lung transplant physician along with
 1601 a lung transplant surgeon. This care must be documented in a log that includes the date of
 1602 transplant and medical record number or other unique identifier that can be verified by the
 1603 OPTN Contractor. This recipient log should be signed by the director or the primary
 1604 transplant physician at the transplant program where the physician gained this experience.
- 1605 2. The physician has maintained a current working knowledge of all aspects of lung
 1606 transplantation, defined as a direct involvement in lung transplant patient care within the last
 1607 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass,
 1608 donor selection, recipient selection, pre- and postoperative ventilator care, postoperative
 1609 immunosuppressive therapy, histological interpretation and grading of lung biopsies for
 1610 rejection, and long-term outpatient follow-up.
- 1611 3. The physician ~~should~~ must observe at least 3 lung or heart/lung procurements ~~and 3 lung~~
 1612 ~~transplants.~~ The physician ~~should also~~ must have observed the evaluation, ~~the donation~~
 1613 ~~process, and management of these donors.~~ ~~3 multiple organ donors who are donating a lung~~
 1614 ~~or heart/lungs. If the physician has completed these observations, they~~ These observations

- 1615 must be documented in a log that includes the date of procurement, location of the donor,
 1616 and Donor ID.
- 1617 4. The physician must have observed at least 3 lung transplants. The observation of these
 1618 transplants must be documented in a log that includes the transplant date and medical record
 1619 number or other unique identifier that can be verified by the OPTN Contractor.
- 1620 45. The following letters are submitted directly to the OPTN Contractor:
- 1621 a. A letter from the lung transplant physician or surgeon of the training program who has
 1622 been directly involved with the physician documenting the physician's competence.
- 1623 b. A letter of recommendation from the primary physician and transplant program director at
 1624 the transplant program last served by the physician outlining the physician's overall
 1625 qualifications to act as primary transplant physician, as well as the physician's personal
 1626 integrity, honesty, and familiarity with and experience in adhering to OPTN obligations,
 1627 and any other matters judged appropriate. The MPSC may request additional
 1628 recommendation letters from the primary physician, primary surgeon, director, or others
 1629 affiliated with any transplant program previously served by the physician, at its discretion.
- 1630 c. A letter from the physician that details the training and experience the physician has
 1631 gained in lung transplantation.
 1632

1633 **D. Conditional Approval for Primary Transplant Physician**

1634 If the primary lung transplant physician changes at an approved lung transplant program, a
 1635 physician can serve as the primary lung transplant physician for a maximum of 12 months if the
 1636 following conditions are met:
 1637

- 1638 1. The physician is a pulmonologist with current board certification in pulmonary medicine by the
 1639 American Board of Internal Medicine, the American Board of Pediatrics, or the foreign
 1640 equivalent.
- 1641 2. The physician has 12 months of experience on an active lung transplant service as the
 1642 primary lung transplant physician or under the direct supervision of a qualified lung transplant
 1643 physician and in conjunction with a lung transplant surgeon at a designated lung transplant
 1644 program. These 12 months of experience must be acquired within a 2-year period.
- 1645 3. The physician has been involved in the primary care of 8 or more newly transplanted lung or
 1646 heart/lung transplant recipients as the lung transplant physician or under the direct
 1647 supervision of a qualified lung transplant physician and in conjunction with a lung transplant
 1648 surgeon. At least half of these patients must be lung transplant recipients. This care must be
 1649 documented in a recipient log that includes the date of transplant and medical record or other
 1650 unique identifier that can be verified by the OPTN Contractor. This log should be signed by
 1651 the program director or the primary transplant physician at the transplant program where the
 1652 physician gained experience.
- 1653 4. The physician has maintained a current working knowledge of all aspects of lung
 1654 transplantation, defined as a direct involvement in lung transplant patient care within the last
 1655 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass,
 1656 donor selection, recipient selection, pre- and postoperative ventilator care, postoperative
 1657 immunosuppressive therapy, histological interpretation and grading of lung biopsies for
 1658 rejection, and long-term outpatient follow-up.
- 1659 5. The physician ~~should~~ must have observed at least 3 lung or heart/lung procurements ~~and 3~~
 1660 ~~lung transplants.~~ The physician ~~should also~~ must have observed the evaluation, the donation
 1661 process, and management of these donors. ~~3 multiple organ donors who are donating a lung~~
 1662 ~~or heart/lungs. If the physician has completed these observations, they~~ These observations

- 1663 must be documented in a log that includes the date of procurement, location of the donor,
 1664 and Donor ID.
- 1665 6. The physician must have observed at least 3 lung transplants. The observation of these
 1666 transplants must be documented in a log that includes the transplant date and medical record
 1667 number or other unique identifier that can be verified by the OPTN Contractor.
- 1668 ~~67.~~ The program has established and documented a consulting relationship with counterparts at
 1669 another lung transplant program.
- 1670 ~~78.~~ The transplant program submits activity reports to the OPTN Contractor every 2 months
 1671 describing the transplant activity, transplant outcomes, physician recruitment efforts, and
 1672 other operating conditions as required by the MPSC to demonstrate the ongoing quality and
 1673 efficient patient care at the program. The activity reports must also demonstrate that the
 1674 physician is making sufficient progress to meet the required involvement in the primary care
 1675 of 20 or more lung transplant recipients, or that the program is making sufficient progress in
 1676 recruiting a physician who meets all requirements for primary lung transplant physician by the
 1677 end of the 12 month conditional approval period.
- 1678 ~~89.~~ The following letters are submitted directly to the OPTN Contractor:
- 1679 a. A letter from the supervising lung transplant physician or surgeon of the training program
 1680 documenting the physician’s competence.
- 1681 b. A letter of recommendation from the training program’s primary physician and director
 1682 outlining the physician’s overall qualifications to act as primary transplant physician of the
 1683 transplant program last served by the physician, as well as the physician’s personal
 1684 integrity, honesty, and familiarity with and experience in adhering to OPTN obligations,
 1685 and any other matters judged appropriate. The MPSC may request additional
 1686 recommendation letters from the primary physician, primary surgeon, director, or others
 1687 affiliated with any transplant program previously served by the physician, at its discretion.
- 1688 c. A letter from the physician that details the training and experience the physician has
 1689 gained in lung transplantation.

1690

1691 The 12-month conditional approval period begins on the first approval date granted to the
 1692 personnel change application, whether it is an interim approval granted by the MPSC
 1693 subcommittee, or approval granted by the full MPSC. The conditional approval period ends
 1694 exactly 12 months after this first approval date of the personnel change application.

1695

1696 If the program is unable to demonstrate that it has an individual practicing on site who can meet
 1697 the requirements as described in *Sections 1.3.A through 1.3.C* above at the end of the 12-month
 1698 conditional approval period, it must inactivate. The requirements for transplant program
 1699 inactivation are described in *Appendix K: Transplant Program Inactivity, Withdrawal, and*
 1700 *Termination* of these Bylaws.

1701

1702 The MPSC may consider on a case-by-case basis and grant a 6-month extension to a transplant
 1703 program that provides substantial evidence of progress toward fulfilling the requirements but is
 1704 unable to complete the requirements within one year.

1705

1706 #

OPTN/UNOS Membership and Professional Standards Committee

Addressing the Term “Foreign Equivalent” in OPTN/UNOS Bylaws

*Prepared by:
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UNOS Member Quality Department*

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Addressing the Term “Foreign Equivalent” in OPTN/UNOS Bylaws

Executive Summary

OPTN/UNOS Bylaws' transplant program key personnel requirements use the term “foreign equivalent.” Specifically, transplant program key personnel are required to have current American board certification or the “foreign equivalent,” and cited experience must have been obtained at a designated transplant program or the “foreign equivalent.” This term is unclear for members when assessing if certain staff are qualified to serve as transplant program key personnel and for the OPTN/UNOS Membership and Professional Standards Committee (MPSC) when evaluating membership applications and determining if a board certification or case experience performed outside the United States should be considered equivalent. To address this problem, and after consideration by a Joint Societies Working Group (JSWG), the MPSC proposes deleting the term “foreign equivalent” from the Bylaws (except for vascularized composite allograft (VCA) program key personnel); permitting board certification by the Royal College of Physicians and Surgeons of Canada in addition to American board certification; and establishing a new process for those individuals who are not American or Canadian board certified to qualify as transplant program key personnel. These proposed changes are anticipated to advance the OPTN Strategic Plan key goals of promoting living donor and transplant recipient safety and the efficient management of the OPTN. Changing the Bylaws to better reflect the training and experience expected of transplant program key personnel should contribute positively to increased transplant recipient safety. Additionally, removing the ambiguous term “foreign equivalent” and providing a detailed option to qualify as key personnel for those who do not possess American board certification should help promote the efficient management of the OPTN.

Addressing the Term “Foreign Equivalent” in OPTN/UNOS Bylaws

Affected Bylaws: OPTN Bylaws Appendices E.2. (Primary Kidney Transplant Surgeon Requirements), E.2.A (Formal 2-year Transplant Fellowship Pathway), E.2.B (Clinical Experience Pathway), E.3 (Primary Kidney Transplant Physician Requirements), E.3.A (Twelve-month Transplant Nephrology Fellowship Pathway), E.3.B (Clinical Experience Pathway), E.3.C (Three-year Pediatric Nephrology Fellowship Pathway), E.3.D (Twelve-month Pediatric Transplant Nephrology Fellowship Pathway), E.3.E (Combined Pediatric Nephrology Training and Experience Pathway), E.3.G (Conditional Approval for Primary Transplant Physician), F.2 (Primary Liver Transplant Surgeon Requirements), F.2.A (Formal 2-year Transplant Fellowship Pathway), F.2.B (Clinical Experience Pathway), F.3 (Primary Liver Transplant Physician Requirements), F.3.B (Clinical Experience Pathway), F.3.C (Three-year Pediatric Gastroenterology Fellowship Pathway), F.3.D (Pediatric Transplant Hepatology Fellowship Pathway), F.3.E (Combined Pediatric Gastroenterology/Transplant Hepatology Training and Experience Pathway), F.3.G (Conditional Approval for Primary Transplant Physician), F.4 (Requirements for Director of Liver Transplant Anesthesia), F.10 (Primary Intestine Transplant Surgeon Requirements), F.10.A (Full Intestine Surgeon Approval Pathway), F.10.B (Conditional Intestine Surgeon Approval Pathway), F.11 (Primary Intestine Transplant Physician Requirements), F.11.B (Conditional Intestine Physician Approval Pathway), G.2 (Primary Pancreas Transplant Surgeon Requirements), G.2.A (Formal 2-year Transplant Fellowship Pathway), G.2.B (Clinical Experience Pathway), G.3 (Primary Pancreas Transplant Physician Requirements), G.3.B (Clinical Experience Pathway), G.3.D (Conditional Approval for Primary Transplant Physician), H.2 (Primary Heart Transplant Surgeon Requirements), H.2.A (Cardiothoracic Surgery Residency Pathway), H.2.B (Twelve-month Heart Transplant Fellowship Pathway), H.2.C (Clinical Experience Pathway), H.3 (Primary Heart Transplant Physician Requirements), H.3.A (Twelve-month Transplant Cardiology Fellowship Pathway), H.3.B (Clinical Experience Pathway), H.3.D (Conditional Approval for Primary Transplant Physician), I.2 (Primary Lung Transplant Surgeon Requirements), I.2.A (Cardiothoracic Surgery Residency Pathway), I.2.B (Twelve-month Lung Transplant Fellowship Pathway), I.2.C (Clinical Experience Pathway), I.3 (Primary Lung Transplant Physician Requirements), I.3.A (Twelve-month Transplant Pulmonary Fellowship Pathway), I.3.B (Clinical Experience Pathway), I.3.D (Conditional Approval for Primary Transplant Physician)

Sponsoring Committee: Membership and Professional Standards Committee

Public Comment Period: August 14, 2015 – October 14, 2015

What problem will this proposal solve?

OPTN/UNOS Bylaws transplant program key personnel requirements include the term “foreign equivalent.” Lacking further definition, this term is unclear for members in determining if certain staff (or staff being recruited) are qualified to serve as transplant program key personnel. This term is also problematic for the OPTN/UNOS MPSC when evaluating membership applications and determining if a certain board certification or case experience performed outside the United States should be considered a “foreign equivalent.”

When the MPSC reviews applications that cite a non-American board certification, there is often discussion whether it is equivalent to the respective American board certification required in the Bylaws, and if the applicant truly meets the intent of the board certification requirement. These discussions have highlighted many MPSC members’ opinions that there are no equivalents to American board certification. Similar questions are raised when a key personnel application cites experience that was not performed at

an OPTN-designated transplant hospital. The experience gained at a designated transplant hospital “foreign equivalent” is practically impossible to validate, including whether the experience was obtained at a hospital that would be considered by most as equivalent to the standards and expectations required of designated transplant programs.

The MPSC’s need to evaluate “foreign equivalence” on a case-by-case basis, and recurring questions and concerns among MPSC members during those case-by-case evaluations, highlights the burden placed on members resulting from the usage of this term. If a member completes and submits an application proposing key personnel that includes a “foreign equivalent” consideration, they cannot be sure that the proposed individual will qualify as key personnel until after the MPSC’s deliberations. This is particularly concerning for situations in which an individual is being recruited to serve as key personnel for a transplant program.

Finally, the primary purpose of transplant program key personnel requirements is to promote transplant patient safety by establishing minimal training and experience requirements for the leaders of each transplant program. If there is no reasonable ability to verify the standards and quality of transplant training and experience gained outside of an OPTN-designated transplant program, it must be considered whether the requirement as written is actually promoting its intended goal.

Why should you support this proposal?

The changes presented in this proposal stem directly from recommendations developed by a JSWG, and are representative of a collaborative effort between the American Society of Transplantation (AST), the American Society of Transplant Surgeons (ASTS), the North American Transplant Coordinators Organization (NATCO), and the MPSC.

The proposed changes to the Bylaws support the OPTN strategic plan goal of promoting the efficient management of the OPTN, and may also help promote living donor and transplant recipient safety and improved outcomes. The proposed changes clarify Bylaws language that has proven to be problematic for members and the MPSC, while providing a mechanism to qualify as key personnel of a transplant program for individuals who do not meet explicit board certification requirements but can otherwise demonstrate that they are well-suited to serve in that capacity. These changes will provide clearer guidance on key personnel requirements for members and for the MPSC.

The proposed changes clarify the current Bylaws and address the problem by deleting the ambiguous term “foreign equivalent,” and all its derivatives, from the Bylaws. The one exception is the usage of this term in the vascularized composite allograft (VCA) transplant program requirements. This change was not applied to VCA transplant program key personnel requirements per ASTS feedback, and considering the relative infancy of VCA and the OPTN/UNOS membership requirements for VCA transplant programs. Many VCA surgeons and physicians acquire transplant expertise outside of the United States, and the United States does not yet have VCA transplant fellowship programs or certifications. Applicability of the term “foreign equivalent” in the VCA transplant program membership requirements is a matter that will continue to be monitored by the MPSC and OPTN/UNOS VCA Committee.

Deleting the term “foreign equivalent” in isolation would not be sufficient because the Bylaws would then prohibit individuals from qualifying as transplant program key personnel who are inarguably qualified to do so. To accommodate such individuals, two significant additions are proposed. The first proposed addition would permit current board certification by the Royal College of Physicians and Surgeons of Canada, in addition to American board certification. The rationale behind this addition stems from the fact that individuals who complete Canadian transplant fellowships are able to sit for American board

examinations.^{1, 2, 3, 4, 5, 6, 7, 8} Considering this perspective by the respective American boards, discussion around this topic suggested that the OPTN should also accept Royal College of Physicians and Surgeons of Canada board certification.

The second addition establishes a process for individuals who do not possess current American or Canadian board certification to qualify as key personnel. Although it cannot be predicted how many future applications may use this proposed process, historical information indicates that the overwhelming majority of designated transplant program key personnel do possess American board certification. Analyzing active programs as of July 25, 2014, approximately 5% of key personnel positions (117 of 2172) are filled by an individual who is not American board certified. It is important to note that these numbers reflect the number of key personnel *positions* filled by an individual who is not American board certified, not necessarily the number of individuals. Individuals are counted multiple times towards this tally if they serve as key personnel for multiple organs, e.g., an individual with a “foreign equivalent” board certification who serves as the primary surgeon for a transplant hospital’s kidney and liver programs.

Central to the discussions of the term “foreign equivalent” was acknowledgement that there are individuals outside the United States who are very well trained in transplantation and would be exceedingly qualified as a transplant program’s primary transplant physician or surgeon. A mechanism containing the following components is proposed to accommodate these individuals:

- *The individual must qualify through the respective clinical experience pathway.* Discussion of this potential process suggested that it would not be appropriate for someone to lead a program if they have never practiced in the United States. The JSWG believed experience on-service at a designated transplant program was necessary to reflect an exposure to the American medical system and the knowledge and skills that are required to lead a successful transplant program, in addition to medical expertise and technical proficiency.
- *There must be a plan for continuing medical education which at least requires that the key personnel applicant obtains 40 hours of Category I continuing medical education (CME) credits with self-assessment every two years.* Outside of member and MPSC confusion around the term “foreign equivalent,” another major deficiency with the usage of this term is the foreign equivalent board certification’s possible lack of maintenance certification requirements, or a lack of adherence to what is required. Discussion suggested that if an individual does not possess American or Canadian board certification, they must participate in some continuing medical education efforts to qualify as a key personnel at a transplant program. As continued medical education is inherent to American board certification, the purpose of this requirement is to establish a standard of continued learning for all transplant program key personnel. Multiple discussions ultimately concluded that individuals who qualify as key personnel through this process must obtain 40 CME credits with self-assessment every two years. It is important to note that the OPTN will not be actively monitoring adherence to the provided continuing medical education plan; it is the transplant program’s responsibility to monitor

¹ *Internal Medicine and Nephrology Policies | Become ABIM Certified Physician.* (2007, November 4). Retrieved <http://www.abim.org/certification/policies/imss/neph.aspx>

² *Become Certified in the Subspecialty of Gastroenterology | ABIM Certification.* (2007, November 4). Retrieved <http://www.abim.org/certification/policies/imss/gastro.aspx>

³ *Internal Medicine and Cardiovascular Disease | Become ABIM Certified.* (2007, November 4). Retrieved <http://www.abim.org/certification/policies/imss/card.aspx>

⁴ *Become Certified in the Subspecialty of Pulmonary Disease | ABIM Certification.* (2007, November 4). Retrieved <http://www.abim.org/certification/policies/imss/pulm.aspx>

⁵ *About ABS Certification – For the Public | American Board of Surgery.* (2011, November 13). Retrieved <http://www.absurgery.org/default.jsp?publiccertprocess>

⁶ *Residency Requirements.* (2012, June 6). Retrieved <https://www.abu.org/residencyRequirements.aspx>

⁷ *Protocol for Certification | American Osteopathic Board of Surgery.* (2005, February 10). Retrieved <http://www.aobs.org/protocol-for-certification#mn-main>

⁸ *American Board of Thoracic Surgery.* (2013, March 20). Retrieved <https://www.abts.org/root/home/certification/general-requirements.aspx>

and document adherence to the provided plan. Evidence of adherence to the provided plan may be requested by the OPTN as deemed necessary.

- *Two letters of attestation from program directors not affiliated with the applying hospital must be provided.* JSWG discussions reiterated the belief that American board certification is the ultimate standard for OPTN transplant physicians and surgeons. Although there are individuals who trained outside the United States that lack American board certification but would be exceedingly qualified as transplant program key personnel, these are unique individuals and this is an uncommon scenario. Accordingly, the JSWG reasoned that these individuals should be well known among the community such that two letters of attestation that speak to the individual's qualifications should be required.

Other minor changes are proposed that align requirements pertaining to board certification that is pending by the American Board of Urology. Specifically, Bylaws currently permit a 12-month conditional approval period for primary kidney, liver, and pancreas transplant surgeons whose certification by the American Board of Urology is pending.⁹ The American Board of Urology has a standard 16-month period before individuals are allowed to sit for their final board certification examination. To address this discrepancy and any undue burden it may yield, this proposal recommends changing the Bylaws to permit a 16-month conditional approval for this scenario.

In addition to operational efficiencies that are anticipated from these proposed changes, living donor and transplant safety may also improve as a result. Bylaws currently require that experience reported on a key personnel application must have been obtained at a designated transplant program or the “foreign equivalent.” Applying the recommendation to remove the term “foreign equivalent” from the Bylaws would also apply in these instances, thereby requiring that all key personnel case experience included on an application have occurred at an OPTN designated transplant program. This approach eliminates concerns about the rigor and quality of the experience obtained at a designated transplant program “foreign equivalent,” as these aspects are the most concerning relative to the transplant experience gained and what these requirements are intended to reflect. Additionally, the rigor and quality of the experience gained is extremely challenging to confirm during membership application reviews. Considering the value and purpose of transplant program key personnel requirements relative to living donor and transplant patient safety, requiring key personnel applicants to have obtained the required experience at an OPTN-designated hospital establishes a consistent standard that will be expected of all key personnel. Establishing this expectation for key personnel at every transplant program, and eliminating the possibility that less-meaningful experience gained outside the United States could count towards key personnel requirements in the Bylaws, further advances patient safety which is one of the main purposes for key personnel requirements.

How was this proposal developed?

In 2013, the MPSC created a working group to address a number of aspects in the Bylaws' key personnel requirements that had repeatedly been noted as ambiguous, unenforceable, or regularly yielding questions from members or the MPSC. Included in this list of efforts was clarification of the term “foreign equivalent.” This project was approved by the OPTN/UNOS Executive Committee in November 2013. The MPSC's working group preliminarily discussed this topic, reiterating the importance of American board certification and questioning whether a transplant surgeon or transplant physician that does not possess American board certification should be allowed to qualify as key personnel of a designated transplant program.

As the MPSC Working Group began making progress on possible solutions to clarify the term “foreign equivalent,” the Joint Societies Policy Steering Committee met in May 2014 and opted for the formation of a Joint Societies Working Group (JSWG) to address this topic, along with other key personnel Bylaws

⁹ *The American Board of Urology, Inc. 2016 Information for Applicants and Candidates*. 63rd ed. 22. Retrieved <https://www.abu.org/downloads/pt2/2016CertHandbook.pdf>.

clarifications that were being addressed by the MPSC's working group. This decision resulted in the dissolution of the MPSC's Working Group while the MPSC awaited final recommendations on these topics from the JSWG.

The JSWG first focused on the term "foreign equivalent" as it used in the Bylaws relative to American board certification. JSWG discussion reiterated the necessity of requiring that transplant program key personnel have American board certification, and that the Bylaws usage of the term "foreign equivalent" with respect to American board certification is problematic because it did not believe certification from any other country could legitimately be viewed as equivalent.

To better understand the magnitude of this issue, the JSWG reviewed a list of non-American board certifications possessed by current key personnel approved by the MPSC. Citing a report that analyzed active programs as of July 25, 2014, 97 primary transplant surgeon positions and 20 primary transplant physician positions were filled by an individual who is not American board certified. (Again, it is important to note that these numbers represent positions, not the total number of individuals.) The JSWG commented that there were more of these situations than they had originally anticipated, but that these data show that the majority of key personnel are American board certified (there are approximately 1100 programs in total and each requires one primary transplant surgeon and one primary transplant physician). The group considered creating a list of other board certifications that the MPSC could view as equivalent, based on the certifications of those already approved, but the JSWG's firm belief that there are no American board certification foreign equivalents prevented further consideration of this approach. Reviewing the compiled list of foreign board certifications that had previously been accepted by the MPSC did prompt additional discussion about board certification by the Royal College of Physicians and Surgeons of Canada. Considering that individuals who have completed a Canadian transplant fellowship are eligible to sit for American board certification examinations, the JSWG suggested that the Bylaws stipulate that board certification by the Royal College of Physicians and Surgeons of Canada would be accepted by the MPSC/OPTN, in addition to American board certification. The JSWG was explicitly asked if board certification from any other country should be included in the Bylaws, and the JSWG definitively responded no. As such, the JSWG agreed that the Bylaws should continue to require American board certification as the primary standard, that board certification from the Royal College of Physicians and Surgeons of Canada should also be accepted, and that another means to qualify as transplant program key personnel should be developed for highly-skilled, well-qualified transplant clinicians who do not possess American or Canadian board certification.

The JSWG proceeded to discuss the primary concerns that it felt were necessary to address in the development of a pathway for well-qualified individuals without American or Canadian board certification to serve as transplant program key personnel. Specifically, familiarity with the American medical system and the ethics, principles of care, teamwork, etc., that are expected, and the lack of a maintenance of certification process, which the JSWG indicated is one of main problems with accepting foreign board certification. American board requirements to maintain credentialing are becoming more rigorous, and JSWG members indicated they observe minimal ongoing certification maintenance for individuals certified by a foreign board. This is problematic because without ongoing maintenance of certification, there are no formal assurances that these individuals remain active and competent while continuing to stay current with the field.

Primary Transplant Surgeons

The JSWG first focused on the American Board of Surgery (ABS) maintenance of certification requirements, which has four main parts- professional standing, lifelong learning and self-assessment, cognitive expertise, and evaluation of performance in practice.¹⁰ The JSWG ultimately decided that its

¹⁰ *ABS MOC Requirements | American Board of Surgery*. (2011, November 13). Retrieved <http://www.absurgery.org/default.jsp?exam-mocreqs>

recommendations should include the professional standing and lifelong learning and self-assessment components. The cognitive expertise component was excluded primarily because of logistical and resource concerns. Although periodic examination may be the most insightful of these four components with regard to ongoing learning and an increased knowledge base, the JSWG did not think it would be reasonable for the OPTN to expend the resources necessary to create, proctor, evaluate, and monitor these examinations. The JSWG also opted to exclude the evaluation of performance in practice because it felt the ongoing performance review of each transplant program by the OPTN sufficed for purposes of this requirement.

Next, the JSWG considered what the Bylaws need to require as a surrogate for demonstrating lifelong learning and self-assessment. The JSWG discussed the limitations of continuing medical education (CME) credits (obtaining CMEs is sometimes perfunctory, and not really reflective of ongoing learning; rising costs to obtain necessary CMEs; and legal questions about maintenance of certification that have recently been pursued), but ultimately it agreed that CMEs are expected to maintain American board certification, and the best tool available to the OPTN for clinicians without American or Canadian board certification to demonstrate ongoing, lifelong learning. The JSWG concluded that any process to qualify as a primary transplant surgeon for surgeons without American or Canadian board certification must require a plan for continuing education that, at a minimum, includes obtaining a certain amount of CME credits with self-assessment.

The JSWG also discussed how this requirement would be monitored, realizing the extensive amount of time, effort, and attention that would be necessary to assure adherence to the provided continuing medical education plans, including the required CME credits. Considering this, and the JSWG's perceived necessity of a continuing medical education requirement, the JSWG made clear (and later reiterated by the MPSC) that the OPTN would not actively monitor adherence to the plan provided for continuing medical education. Instead, the OPTN will rely on transplant hospitals to document and assure adherence to the proposed Bylaws requirements. Adhering to the continuing medical education plan would be a Bylaws requirement, and as such, documentation of adherence to this plan may be requested by the OPTN as deemed necessary. These considerations also prompted the JSWG to discuss the course of action if the continuing medical education plan has not been followed. In an instance when the OPTN becomes aware of continuing medical education plan deficiencies, the transplant program will have a six-month grace period to address these deficiencies. If the primary transplant surgeon or physician has not fulfilled the requirements after the six-month grace period, and a key personnel change application has not been submitted, then the transplant program will be referred to the MPSC for appropriate action. If the OPTN becomes aware that primary transplant surgeon or physician has not been compliant for 12 months or more and deficiencies still exist, then the transplant program will not be given any grace period and will be referred to the MPSC for appropriate action.

In addition to ongoing and lifelong medical education, the JSWG also thought it was important to include requirements to demonstrate that the non-American, non-Canadian board certified surgeon had some familiarity with the American system. The JSWG thought this assurance is critical, stating that good patient care includes more than just medical expertise and technical proficiencies. Its preliminary discussions suggested that the individual should have first been involved with an OPTN-designated transplant program for a couple of years, that the individual has been involved with a set number of transplants at a designated transplant program, and that other individuals who are familiar with this person's work would vouch for their abilities to serve as transplant program key personnel.

These discussions yielded the following general list of elements that the JSWG thought would be necessary for individuals without American or Canadian board certification to demonstrate to qualify as key personnel at a transplant program:

- Attending at a designated transplant program for a minimum of 2-3 years
- Endorsement from the hospital's leadership and credentialing committee that the individual is continuing to practice in good standing
- Some transplant volume requirement
- Structured plan for continuing medical education that is comparable to American board maintenance of certification, including a set number of CME credits to be obtained yearly.
- Periodic attestation from colleagues in the field that individuals are in good standing

During its review of this list for further refinement, the JSWG realized that the clinical experience pathway for each respective organ and key personnel position already incorporates the first three bullets above. As such, the JSWG agreed that anyone without American or Canadian board certification must qualify through the respective clinical experience pathway, and fulfill the additional requirements included in this proposal.

As for the requisite number of CME credits with self-assessment, the JSWG referenced the ABS maintenance of certification requirements. Mirroring the current requirements for ABS maintenance of certification, the JSWG initially recommended that the surgeon must obtain 30 hours per year of Category I CMEs with self-assessment. Preliminary feedback from the ASTS on this recommendation suggested that 20 hours per year of Category I CMEs with self-assessment was more appropriate, and closely aligned with what is expected of surgeons with ABS certification (60 Category I CMEs with self-assessment over three years).¹¹ As such, the ASTS opined that OPTN Bylaws should require the least amount of CMEs that is currently expected of any practicing transplant surgeon. The JSWG obliged this request, modifying its recommendation to 20 hours per year of Category I CMEs with self-assessment.

Regarding colleague attestation, the JSWG noted individuals who trained outside the United States and lack American or Canadian board certification, but who would be exceedingly qualified transplant program key personnel, are unique individuals and this is an uncommon scenario. Accordingly, the JSWG reasoned that these individuals should be well known among the community such that two letters of attestation that speak to the individual's qualifications should be required. To reinforce the special consideration of the individual's qualifications, and to assure no other interests are the compelling motivation for these letters of attestation, the JSWG specified that these letters must be written by program directors who are not employed by the applying hospital.

Primary Transplant Physicians

As the JSWG had primarily focused its initial discussions on primary transplant surgeons, it proceeded to consider if these refined requirements should also apply to primary transplant physicians who are not American or Canadian board certified. Citing the relatively small number of primary transplant physician roles that are filled by individuals who are not American or Canadian board certified, and a belief that American (and Canadian) board certification is unparalleled, initial discussion questioned if a process to qualify as key personnel should even be established for such individuals. In response, and alluding to leaders in the field of transplantation who do not currently practice in the United States, JSWG members did not think it would be reasonable if the Bylaws essentially prohibited these well-qualified transplant clinicians from serving as a transplant program's primary physician. Considering this, and the pursuit of more consistent Bylaws (to the extent possible) between primary transplant surgeon and primary transplant physician pathways, the JSWG ultimately decided that these same requirements should also be expected of a primary transplant physician applicant who does not possess American or Canadian board certification.

Designated Transplant Program or the Foreign Equivalent

¹¹ *American Board of Surgery MOC Program*. (2014, June). Retrieved http://www.absurgery.org/xfer/abs_moc_slides.pdf

In addition to focusing on the Bylaws usage of “foreign equivalent” as it pertains to American board certification, JSWG discussion also noted that it would be necessary to address usage of this term with respect to requirements that case experience must be obtained at a, “designated transplant program or the foreign equivalent.” Required case experience ranges across organs, pathway, and key personnel position. For example, primary kidney transplant surgeons applying through the fellowship pathway are expected to have performed at least 30 kidney transplants during their two year fellowship; primary kidney transplant surgeons applying through the clinical experience pathway are expected to have performed 45 kidney transplants over a two- to five-year period; and primary liver transplant physicians applying through the clinical experience pathway are to have been directly involved in the primary care of at least 50 newly transplanted liver recipients for a minimum of three months. Details for each pathway and key personnel position can be found in OPTN Bylaws Appendix E (Membership and Personnel Requirements for Kidney Transplant Programs) through Appendix J (Membership Requirements for Vascularized Composite Allograft (VCA) Transplant Programs), respectively.

The JSWG recommended that “foreign equivalent” be removed in all these instances, effectively requiring all case experience reported on a key personnel application to have occurred at an OPTN-designated transplant program. The JSWG discussed the difficulty of assuring the rigor and quality of the experience gained at transplant programs outside the U.S. This recommendation does not ignore fact that quality experience can be gained outside of the U.S., rather, it focuses on the notion that standards vary widely across the globe. Considering the goal of these Bylaws is patient safety, the JSWG believed that the potential for the Bylaws to allow experience that is sub-standard to what would be expected should be avoided. The JSWG considered establishing a process by which the applicant could make a case before the MPSC as to why their case experience outside of the United States should count towards the Bylaws requirements (similar to what is established in the “Alternative Pathway for Predominantly Pediatric Programs” for each organ). This idea was not pursued because it only proliferated the problem of members needing the MPSC’s final decision to determine if an applicant was qualified to serve as a program’s primary transplant surgeon or physician. The JSWG concluded that the best way to address the usage of “foreign equivalent” in this respect was to delete this term, thereby requiring that all reported key personnel experience must have occurred at an OPTN-designated transplant program.

Although the JSWG agreed this is the best approach, it acknowledged that an unintended consequence of this change could be increased logistical challenges and costs for an individual to obtain the requisite experience outside of a transplant fellowship to qualify as transplant program key personnel. JSWG members stated that individuals who do not have enough experience to qualify as transplant program key personnel should be able to establish relationships with other institutions around the country to obtain the requisite experience. Other members cautioned that establishing these relationships can be challenging and relatively expensive, and that this change has the potential to further exasperate those issues. The JSWG ultimately agreed that it should require all key personnel case experience to have occurred at an OPTN-designated transplant program, but that increased complexity and costs to make arrangements for an individual to obtain the requisite experience outside of a transplant fellowship could be an unintended consequence that would prove to be a weakness of this proposed solution.

Final Recommendations

The JSWG’s final recommendations on this topic, which were separately endorsed by the Joint Societies Policy Steering Committee and the MPSC, are as follows:

- Delete all references to “foreign equivalent,” including those references in the case volume requirements
 - Proceeding with this recommendation will require all reported case experience to be obtained at an OPTN-approved transplant hospital
 - Considering the relative infancy of the vascularized composite allograft (VCA) field, and the recently developed OPTN Bylaws focused on membership requirements for VCA transplant programs, it may not be appropriate to apply these recommendations to the VCA program

Bylaws. The appropriate applicability will be further considered by the OPTN VCA Committee, in conjunction with the MPSC.

- Include certification by the Royal College of Physicians and Surgeons of Canada in the list of acceptable certifications
- Create additional, organ-specific pathways for proposed primary transplant surgeons and primary transplant physicians who are not American or Canadian board certified, that require the individual to:
 - Meet all other key personnel requirements included in the clinical experience pathway
 - Provide two letters of attestation from program directors not affiliated with the applying hospital
 - Obtain continuing medical education credits with self-assessment, comparable to what is expected of American board maintenance of certification for that respective field
 - E.g., primary surgeons without American board certification would be expected to obtain 20 hours per year of continuing education credits, similar to what is expected of individuals certified by the American Board of Surgery
 - Individuals who qualify through this pathway, and the associated transplant hospital, will be responsible for maintaining documentation of adherence to this continuing education requirement. This documentation will be subject to review by the MPSC and the OPTN, upon request.

Upon the MPSC's endorsement, the JSWG worked to draft proposed Bylaws modifications to incorporate these recommendations. Focusing on the CME recommendation, the MPSC thought it would be more effective to set the required number of CMEs and extend the requirement over a two-year period. The MPSC agreed to propose 40 hours of Category I CMEs with self-assessment every two years. This would provide added consistency and clarity, and will allow some flexibility in case of a particularly busy year or other life events that prevent one from obtaining the necessary CMEs in a calendar year.

Drafting proposed Bylaws changes also highlighted a few other issues within these Bylaws that had not explicitly been addressed by the JSWG. The first issue considered by the MPSC is whether the proposed process for primary transplant physicians who are not American or Canadian board certified should be allowed for individuals applying through the primary transplant physician conditional pathway. The MPSC concluded that if this process is being treated as a surrogate for American or Canadian board certification for the purpose of these Bylaws, then it stands to reason that this option should be applied to all pathways, including the primary transplant physician conditional pathways. As such, additional language is proposed in each organ's section of primary transplant physician requirements to stipulate that this proposed process also applies to physicians applying through the conditional pathway. In such a circumstance, the individual will initially need to qualify through the conditional pathway instead of the clinical experience pathway.

The MPSC also realized the term "foreign equivalent" is also used in OPTN Bylaws Appendix F.4 (Requirements for Director of Liver Transplant Anesthesia), "The director of liver transplant anesthesia must be a Diplomate of the American Board of Anesthesiology, or the foreign equivalent." Considering that the American Society of Anesthesiologists (ASA) was integral in the development of these Bylaws, the MPSC wanted its feedback before proposing any changes to OPTN Bylaws Appendix F.4. Through the MPSC's ASA representative, the ASA provided proposed changes to OPTN Bylaws Appendix F.4 that do not include the term "foreign equivalent." The exact changes provided by ASA have been incorporated into the proposed Bylaws language below.

Finally, minor changes are proposed that align requirements pertaining to board certification that is pending by the American Board of Urology. Specifically, Bylaws currently permit a 12-month conditional approval period for primary kidney, liver, and pancreas transplant surgeons whose certification by the American Board of Urology is pending. The American Board of Urology has a standard 16-month period before individuals are allowed to sit for their final board certification examination.¹² To address this

¹² The Certification Process. (2012, September 27). Retrieved June 22, 2015, from <https://www.abu.org/certification.aspx>

discrepancy and any undue burden it may yield, the MPSC agreed that these Bylaws should be changed to permit a 16-month conditional approval for those who have qualified as a primary transplant surgeon with pending certification by the American Board of Urology.

How well does this proposal address the problem statement?

This proposal effectively addresses the ambiguous term “foreign equivalent” by proposing that it be deleted from the Bylaws. In addition to addressing this term, the proposed Bylaws also accommodate individuals who are not American or Canadian board certified that may have relied on the Bylaws inclusion of this term by establishing a detailed mechanism for them to qualify as transplant program key personnel.

The requirements included in the proposed Bylaws changes are primarily rooted in the medical expertise and judgement of the JSWG members that provided recommendations on this topic. To help guide the JSWG’s decisions it reviewed maintenance of certification requirements for different American boards, primarily focusing on what is required by the American Board of Surgery. In addition to the JSWG’s support for these recommendations, both the MPSC and Joint Societies Policy Steering Committee indicated their support for these changes.

There was one potential unintended consequence of these proposed changes that was noted as a possible weakness. The JSWG specifically noted that requiring all transplant case experience to have been obtained at a designated transplant program could increase logistical challenges and costs for an individual to obtain the requisite experience outside of a transplant fellowship to qualify as transplant program key personnel. JSWG members stated that individuals who do not have enough experience to qualify as transplant program key personnel would need to establish relationships with other institutions around the country to obtain the requisite experience. Other members cautioned that establishing these relationships can be challenging and relatively expensive, and that this change has the potential to further exasperate those issues. Ultimately, the JSWG agreed that knowing key personnel obtained their requisite experience at a designated transplant program was more critical, but that increased complexity and costs to make arrangements for an individual to obtain the requisite experience outside of a transplant fellowship may prove to be a weakness of this proposed solution.

Another weakness of this proposal is that the term “foreign equivalent” is still included in the VCA program key personnel requirements. This was felt to be necessary because of the infancy of VCA transplantation, but the problems that prompted this proposal will continue to impact VCA program applications.

Was this proposal changed in response to public comment?

This proposal received limited feedback, primarily during OPTN/UNOS regional meeting. The comments received for this proposal are on the Organ Procurement and Transplantation Network (OPTN) web site at <http://optn.transplant.hrsa.gov/governance/public-comment/>. During a few presentations of this proposal, questions were raised about how these proposed requirements would apply to transplant programs and key personnel that have already been approved. This consideration is addressed in the original proposal distributed for public comment, and responses to these questions included clarifying and confirming that current key personnel and designated transplant programs will not be impacted by the Bylaws modifications in this proposal. These Bylaws will only be used for evaluating transplant program applications that are submitted on or after the date these proposed Bylaws are implemented.

At its October 2015 meeting, the MPSC reviewed all the public comment feedback provided in response to this proposal. Below are the general themes of the feedback provided, a summary of the MPSC’s consideration of this feedback, and a description of the post-public comment changes made by the MPSC after its review:

- In addition to the OPTN Bylaws clinical experience pathways, individuals without American or Canadian board certification should be allowed to qualify through the respective training/fellowship pathways found in the OPTN Bylaws. Three regions, AST, and ASTS suggested this change.
 - The original rationale for requiring key personnel applicants without American or Canadian board certification to apply through the clinical experience pathway was to assure that the applicant had spent some time practicing transplant in America. During its discussions, the JSWG noted that qualifying through the current clinical experience pathways would essentially address these intentions as it requires the citation of cases from a “2 to 5-year period.” In response to the public comment feedback provided, the MPSC indicated that the completion of a certified transplant fellowship program, and the ability to qualify as key personnel through the respective OPTN Bylaws fellowship pathway, would also effectively achieve the original intent of these considerations. The MPSC proceeded to consider if certain pathways should be excluded as options for key personnel applicants who are not American or Canadian board certified. After brief discussion, the MPSC agreed that this proposal will not specify which key personnel pathway that the applicant must qualify through.
 - *Post-public comment changes-* Proposed language specifying that key personnel applicants without American or Canadian board certification must qualify through the clinical experience pathway has been deleted throughout the proposal. As such, and assuming the other requirements established by this proposal are met, key personnel applicants without American or Canadian board certification may qualify through any key personnel pathway outlined in OPTN Bylaws.
- Recommendations that the proposed CME requirement be increased to reflect the current ABS requirement (90 CMEs/ 3 years versus 40 CMEs/ 2 years, as currently written in the proposal). Two regions raised this concern.
 - The December 2014 progress report provided to the MPSC and the societies participating in the JSWG originally recommended a requirement that would mandate the completion of approximately 30 CME credits every year. In response to this progress report, the ASTS council suggested that the lowest number of required CMEs that currently applies is what should be expected by the OPTN. To support this recommendation it was noted that the previous ABS maintenance of certification requirement equated approximately 20 CME credits per year, and that many surgeons were previously approved under and allowed to continue the 20 CME credit per year requirement when the ABS increased the maintenance of certification CME requirement. The JSWG accommodated this request and recommended that the CME requirement reflect the lowest number of credits currently allowed for each respective certification. When the MPSC reviewed this final recommendation, it agreed to establish the same number of required Category 1 CME credits for both primary surgeons and physicians (20 Category 1 CMEs per year) and that this requirement should be extended to a two-year period (40 Category 1 CMEs every two years) in case a particularly busy year or other unexpected life events makes it burdensome to meet this requirement in any given year. Upon reviewing the public comment feedback received, the MPSC did not have a strong opinion on this matter but it did want to oblige the request made by ASTS in response to the December 2014 JSWG progress report. The MPSC ultimately agreed to keep the baseline expectation of approximately 20 Category 1 CME’s per year, but that it would extend this requirement over a three year period, to mirror the same time frame as the ABS maintenance of certification cycle.
 - *Post-public comment changes-* The proposed Bylaws have been modified to require that each key personnel applicant without American or Canadian board certification must provide a plan for continuing education that at least includes 60 hours of Category 1 continuing medical education credits with self-assessment every three years (as compared to 40 hours of Category 1 continuing medical education credits with self-assessment every two years, as written in the original proposal).
- The proposed Bylaws need to be clarified to state that the pathway for accommodating those who are not American board certified should only be an option for those who trained and are boarded outside of the United States. The option provided in this proposal should not be applicable for American

surgeons and physicians who did not sit for or pass the respective American boards exam. One region raised this concern.

- The MPSC agreed that the proposed Bylaws needs clarification to this point. The Committee considered language that these new Bylaws would only apply to individuals who possessed board certification from another country. Committee members suggested that wording the requirement this way may exclude appropriate individuals; e.g., individuals who come from countries that do not have a formal medical board certification process. The Committee agreed it would be more appropriate to limit these new Bylaws to those who are “ineligible for American board certification.”
 - *Post-public comment changes-* The Bylaws established by this proposal now specify that a key personnel applicant who is not American or Canadian Board certified must be “ineligible for American board certification.”
- Key personnel applicants who are board certified by the Royal College of Physicians and Surgeons of Canada should be permitted to qualify with case experience obtained at transplant programs in Canada. One region raised this concern.
 - In addition to addressing the term “foreign equivalent” as it pertains to board certification, this proposal also addresses this term in the context of case experience reported on applications that must have occurred at a designated transplant program or the “foreign equivalent.” Although substantial transplant experience can be gained outside of an OPTN-designated program, this quality and rigor of this experience is often challenging to validate. Considering the patient safety considerations of these Bylaws, the JSWG and MPSC believed that the potential for the Bylaws to allow experience that is sub-standard to what would be expected should be avoided. Additionally, the JSWG and the MPSC also thought transplant program key personnel should have some experience practicing transplant in the United States before leading a transplant program. In response to the public comment feedback received, the MPSC considered if the Bylaws should allow transplant experience obtained from Canadian transplant programs. Discussion indicated continued support for its original recommendation and the corresponding rationale, and the MPSC did not believe the proposal should be modified to also allow the inclusion of transplant case experience gained at a Canadian transplant hospital.
 - *Post-public comment changes-* No changes.
- The proposed Bylaws language should specify that the letters of recommendations must come from a U.S. or Canadian transplant program director. The current language would allow the letter to come from the transplant program director of a hospital anywhere in the world. One region raised this concern.
 - The MPSC agreed that the Bylaws should be specified to clarify that these letters should come from program directors of OPTN transplant hospitals. Canadian program directors were not included because Canadian trained individuals should not need these letters with the acceptance of certification by the Royal College of Physicians and Surgeons of Canada. Additionally, the purpose of this requirement is to demonstrate that the key personnel applicant is known and respected in the field, and seen as suitable to serve as key personnel at a designated transplant program. To comment appropriately on an applicant’s abilities to serve as key personnel of a designated transplant program, it seems that some perspective from within the OPTN would be necessary.
 - *Post-public comment changes-* The proposed Bylaws now specify that the applicant must provide two letters of recommendation from directors of “designated” transplant programs not employed by the applying hospital.
- Ensure that wording of this proposal that conflicts with the wording contained in the other proposal also sponsored by the MPSC’s “Changes to Transplant Program Key Personnel Procurement Requirements” is addressed if both proposals are passed by the Board. For example, the elimination of the requirement to observe multi-organ procurements remains in this proposal. Similarly, if the pediatric program proposal is passed the changes of both the proposals sponsored by the MPSC will need to be incorporated into the language of the “Proposal to Establish Pediatric Training and Experience Requirements in the Bylaws.”

- If the OPTN/UNOS Board of Directors adopts the changes included in this proposal, these changes will be applied to all other applicable proposals adopted by the Board during this same meeting. Additionally, the MPSC also considered if these changes should be applied to OPTN Bylaws Appendix F.10 (Primary Intestine Transplant Surgeon Requirements), which the Board recently adopted at its June 2015 meeting, and after the MPSC finalized the modified Bylaws included in this proposal. For consistency, and recognizing that the OPTN/UNOS Liver and Intestinal Organ Transplantation Committee modeled the intestine transplant program Bylaws after the liver transplant program Bylaws, the MPSC agreed that the changes from this proposal should also be applied to Appendix F.10 and included with this proposal as a post-public comment consideration.
 - *Post-public comment changes-* The changes included in this proposal have been applied to the intestine transplant program Bylaws adopted by the Board at its June 2015 meeting. The Bylaws changes that stem from this proposal will also be applied to other proposals that include language similar to what is addressed with this proposal and that will be considered by the Board during the same meeting.
- Clinical pathway should require that a surgeon be the primary surgeon for transplant experience, not the first assistant. The group understood that this language is currently in place and not part of this proposal. There was some support for making this a requirement for all primary surgeons, but at a minimum, it should be included in this proposal.
 - The MPSC agrees that the primary transplant surgeon Bylaws regarding primary surgeon/first assistant transplant experience are problematic. Addressing the primary surgeon/first assistant Bylaws language was one of the MPSC's projects assigned to the JSWG. The MPSC was working on a public comment proposal that incorporated the JSWG's recommendations on this topic, but those efforts were indefinitely tabled upon this project being placed on hold by the Executive Committee in June 2015. The MPSC did not believe it could incorporate all of its recommendations from that draft proposal into this proposal as post-public considerations without the benefit of another public comment cycle.
 - *Post-public comment changes-* No changes.
- A concern was raised that this proposal would make it difficult to recruit non-U.S. surgeons and physicians since they would not be able to come in as the primary from day one.
 - A fundamental consideration of this proposal is that transplant program key personnel should have spent some time practicing transplant in the United States. The raised concern is not a goal of this proposal, but could be an unintended consequence if serving as key personnel is a critical consideration of individuals outside the United States who may be recruited to practice at a designated transplant program. The MPSC expressed continued support for the underlying principles of this proposal, and did not make any changes to this proposal in response to this concern.
 - *Post-public comment changes-* No changes.
- Several members of Region 10 also requested that the goal statement be revised to remove the statement that this proposal is aimed at making transplant safer for patients. They feel that there are many foreign trained individuals successfully practicing within the region and are not supportive of the characterization that requiring US training or experience ensures that patients receive better care.
 - The MPSC clarified that it did not intend for this proposal to insinuate that US training or experience ensures that patients receive better care. Patient safety was included as a goal of this proposal because key personnel Bylaws are intended to promote patient safety by assuring that each transplant program is led by individuals who have sufficient training and experience in organ transplantation. As such, changing the Bylaws to better reflect the training and experience that would be expected of a primary transplant physician or primary transplant surgeon (e.g., continuing medical education requirements) should – *generally speaking-* contribute positively to increased transplant recipient safety and improved outcomes. This is not to say that individuals who have trained and gained transplant experience outside of the United States cannot routinely perform safe and effective transplants; rather, this proposal goal focuses on potential gains if

these Bylaws intended to support patient safety are more consistent and more representative of what would be expected of all transplant program key personnel.

- *Post-public comment changes*- No changes. Comments pertained to the proposal document, not the proposed Bylaws.

Finally, a formatting change has also been included in the proposed Bylaws as a post-public comment change. Currently, each section of the Bylaws that list primary surgeon or primary physician requirements (e.g., OPTN Bylaws Appendix E.2 (Primary Kidney Transplant Surgeon Requirements), and Appendix E.3 (Primary Kidney Transplant Physician Requirements)) includes a list of four general requirements. These sections then proceed to state that an additional requirement is that the applicant must have completed one of the training or experience pathways included in the Bylaws. To clarify these Bylaws, completion of one of the pathways outlined in the Bylaws has been included as the final item in the listed requirements, and each available pathway has been listed.

Which populations are impacted by this proposal?

These proposed changes should promote more consistent standards for all transplant program key personnel, which could improve transplant patient safety and outcomes. As key personnel are required at every transplant program, and as these proposed changes address key personnel requirements, this proposal has the potential to impact all patient populations; however, the effect realized by any individual patient or patient population is likely to be negligible as these changes are primarily operational in nature.

How does this proposal support the OPTN Strategic Plan?

1. *Increase the number of transplants*: There is no impact to this goal.
2. *Improve equity in access to transplants*: Modifying Bylaws pertaining to "foreign equivalent" board certification and transplant hospitals has the potential to impact equity in access to transplants. Additional requirements may not be attainable for certain programs, which would eventually result in the approval of fewer transplant programs. The proposed changes are not anticipated to have a significant impact on access as the overwhelming majority of key personnel applicants are American board certified, and report transplant cases from OPTN-approved transplant programs. Key personnel applicants who may have opted to gain necessary experience outside the United States will likely be most impacted by this proposal.
3. *Improve waitlisted patient, living donor, and transplant recipient outcomes*: Key personnel Bylaws are intended to promote patient safety by assuring that each transplant program is led by individuals who have sufficient training and experience in organ transplantation. Due to the perspective that there are no equivalents to American board certification, and that it is hard to document and validate the possible equivalent nature of non-US transplant programs/hospitals, modifying the Bylaws pertaining to "foreign equivalent" board certification and transplant hospitals will assure that key personnel at every transplant program have approximately the same baseline of training, experience, and ongoing education. Changing the Bylaws to better reflect the training and experience that would be expected of a primary transplant physician or primary transplant surgeon could positively impact outcomes of waitlisted patients, living donors, and transplant recipients.
4. *Promote living donor and transplant recipient safety*: Key personnel Bylaws are intended to promote patient safety by assuring that each transplant program is led by individuals who have sufficient training and experience in organ transplantation. Due to the perspective that there are no equivalents to American board certification, and that it is hard to document and validate the possible equivalent nature of non-US transplant programs/hospitals, modifying the Bylaws pertaining to "foreign equivalent" board certification and transplant hospitals will assure that key personnel at every transplant program have approximately the same baseline of training, experience, and ongoing education. Changing the Bylaws to better reflect the training and

experience that would be expected of a primary transplant physician or primary transplant surgeon should contribute positively to increased transplant recipient safety.

5. *Promote the efficient management of the OPTN:* The definition of "foreign equivalent" as currently included in the OPTN Bylaws is often questioned by members submitting applications and by the MPSC when reviewing applications in which "foreign equivalent" training/experience is cited. Additionally, these applications require additional research and processing by UNOS staff to assist the MPSC in deciding whether or not the reported information is a "foreign equivalent." Creating specific requirements for those who have non-US board certification should alleviate further confusion, and thereby promote the efficient management of the OPTN, regarding what is necessary for these individuals to qualify as key personnel of a transplant program.

The proposed pathway requires ongoing continuing education that must be documented by individuals applying through this pathway, and the associated transplant hospital. These records are subject to review by the OPTN. Although it is expected that the individual and hospital will keep up with this requirement, and that the OPTN would rarely need to review these records, the rare occasions necessitating follow-up on this requirement would be a new effort, and could be seen as detrimentally impacting the efficient management of the OPTN.

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

The impact of these changes will be evaluated as the MPSC receives applications proposing individuals as key personnel who are not American or Canadian board certified. The MPSC will assess the frequency and types of questions that are raised.

How will the OPTN implement this proposal?

Assuming the Board adopts these changes, they will be effective on March 1, 2016. These changes do not require programming to implement. All applications received on or after March 1, 2016, will be evaluated by the MPSC considering these new Bylaws. Members will be alerted of these changes, and the official implementation date, through a policy notice.

These changes will also necessitate updates to each respective membership application. The application changes will require review and approval by the U.S. Office of Management and Budget (OMB). The OPTN will send these application changes to OMB, and approval is expected, well before the March 1, 2016, implementation date.

Implementation of this proposal will have minimal impact on OPTN resources.

How will members implement this proposal?

No immediate action will be required of members upon the implementation of these proposed changes. Membership and key personnel change applications submitted on or after the implementation of these proposed changes will be evaluated relative to these requirements. Currently approved transplant programs will not be impacted by these changes until other transplant program circumstances make it necessary to submit a key personnel application change.

Transplant program key personnel who are not American or Canadian board certified and who are approved by the MPSC after the implementation of these Bylaws changes will be responsible for adhering to the continuing medical education plan provided with their application. The OPTN will not regularly monitor adherence to this plan, but may request documentation of this adherence as deemed necessary.

Will this proposal require members to submit additional data?

This proposal does not require additional data collection, but does impact what information will need to be provided on each membership application that proposes transplant program key personnel who do not possess current American or Canadian board certification.

How will members be evaluated for compliance with this proposal?

All membership and key personnel applications received after these Bylaws are implemented that propose an individual who is not American board certified will be evaluated against the requirements included in these proposed Bylaws. Proposed key personnel who are not American board certified, but meet these new Bylaws requirements, will be approved by the MPSC. These individuals will be expected to adhere to the continuing medical education plan provided with their application.

UNOS will not regularly monitor adherence of the provided continuing medical education plan, but may request that the transplant program provide documentation of plan adherence as it deems necessary. If the MPSC does not believe that the plan has been satisfactorily adhered to, the transplant program will have a six-month grace period to address these deficiencies. If the requirements have still not been fulfilled after the six-month grace period, and a key personnel change application has not been submitted, then the transplant program will be referred to the MPSC for appropriate action according to Appendix L of the Bylaws. If UNOS/MPSC becomes aware that key personnel has not been compliant for 12 months or more and deficiencies still exist, then the transplant program will not be given any grace period and will be referred to the MPSC for appropriate action according to *Appendix L* of the Bylaws.

Policy or Bylaw Language

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

1 **RESOLVED**, that changes to Bylaws Appendices E.2. (Primary Kidney Transplant Surgeon
 2 Requirements), E.2.A (Formal 2-year Transplant Fellowship Pathway), E.2.B (Clinical Experience
 3 Pathway), E.3 (Primary Kidney Transplant Physician Requirements), E.3.A (Twelve-month
 4 Transplant Nephrology Fellowship Pathway), E.3.B (Clinical Experience Pathway), E.3.C (Three-
 5 year Pediatric Nephrology Fellowship Pathway), E.3.D (Twelve-month Pediatric Transplant
 6 Nephrology Fellowship Pathway), E.3.E (Combined Pediatric Nephrology Training and Experience
 7 Pathway), E.3.G (Conditional Approval for Primary Transplant Physician), F.2 (Primary Liver
 8 Transplant Surgeon Requirements), F.2.A (Formal 2-year Transplant Fellowship Pathway), F.2.B
 9 (Clinical Experience Pathway), F.3 (Primary Liver Transplant Physician Requirements), F.3.B
 10 (Clinical Experience Pathway), F.3.C (Three-year Pediatric Gastroenterology Fellowship Pathway),
 11 F.3.D (Pediatric Transplant Hepatology Fellowship Pathway), F.3.E (Combined Pediatric
 12 Gastroenterology/Transplant Hepatology Training and Experience Pathway), F.3.G (Conditional
 13 Approval for Primary Transplant Physician), F.4 (Requirements for Director of Liver Transplant
 14 Anesthesia), F.10 (Primary Intestine Transplant Surgeon Requirements), F.10.A (Full Intestine
 15 Surgeon Approval Pathway), F.10.B (Conditional Intestine Surgeon Approval Pathway), F.11
 16 (Primary Intestine Transplant Physician Requirements), F.11.B (Conditional Intestine Physician
 17 Approval Pathway,) G.2 (Primary Pancreas Transplant Surgeon Requirements), G.2.A (Formal 2-
 18 year Transplant Fellowship Pathway), G.2.B (Clinical Experience Pathway), G.3 (Primary Pancreas
 19 Transplant Physician Requirements), G.3.B (Clinical Experience Pathway), G.3.D (Conditional
 20 Approval for Primary Transplant Physician), H.2 (Primary Heart Transplant Surgeon
 21 Requirements), H.2.A (Cardiothoracic Surgery Residency Pathway), H.2.B (Twelve-month Heart
 22 Transplant Fellowship Pathway), H.2.C (Clinical Experience Pathway), H.3 (Primary Heart
 23 Transplant Physician Requirements), H.3 (Primary Heart Transplant Physician Requirements),
 24 H.3.A (Twelve-month Transplant Cardiology Fellowship Pathway), H.3.B (Clinical Experience
 25 Pathway), H.3.D (Conditional Approval for Primary Transplant Physician), I.2 (Primary Lung
 26 Transplant Surgeon Requirements), I.2.A (Cardiothoracic Surgery Residency Pathway), I.2.B
 27 (Twelve-month Lung Transplant Fellowship Pathway), I.2.C (Clinical Experience Pathway), I.3
 28 (Primary Lung Transplant Physician Requirements), I.3.A (Twelve-month Transplant Pulmonary
 29 Fellowship Pathway), I.3.B (Clinical Experience Pathway), I.3.D (Conditional Approval for Primary
 30 Transplant Physician), as set forth in Exhibit A, are hereby approved, effective March 1, 2016.

31

32 ***Appendix E:*** 33 ***Membership and Personnel Requirements for Kidney*** 34 ***Transplant Programs***

35 **E.2 Primary Kidney Transplant Surgeon Requirements**

36 A designated kidney transplant program must have a primary surgeon who meets *all* the following
 37 requirements:

38

- 39 1. The surgeon must have an M.D., D.O., or equivalent degree from another country, with a current
 40 license to practice medicine in the hospital's state or jurisdiction.
- 41 2. The surgeon must be accepted onto the hospital's medical staff, and be on site at this hospital.

- 42 3. The surgeon must have documentation from the hospital credentialing committee that it has verified
 43 the surgeon's state license, board certification, training, and transplant continuing medical education,
 44 and that the surgeon is currently a member in good standing of the hospital's medical staff.
 45 4. The surgeon must have current certification by the American Board of Surgery, the American Board
 46 of Urology, the American Board of Osteopathic Surgery, or the Royal College of Physicians and
 47 Surgeons of Canada ~~the foreign equivalent~~. In the case of a surgeon who has just completed training
 48 and whose ~~board American Board of Urology~~ certification in urology is pending, the Membership and
 49 Professional Standards Committee (MPSC) may grant conditional approval for ~~42~~16 months to allow
 50 time for the surgeon to complete board certification, with the possibility of ~~renewal for~~ one additional
 51 ~~42~~16-month period extension.

52
 53 In place of current certification by the American Board of Surgery, the American Board of Urology, the
 54 American Board of Osteopathic Surgery, the Royal College of Physicians and Surgeons of Canada,
 55 or pending certification by the American Board of Urology, the surgeon must:

- 56 a. Be ineligible for American board certification.
 57 b. Provide a plan for continuing education that is comparable to American board maintenance of
 58 certification. This plan must at least require that the surgeon obtains 60 hours of Category I
 59 continuing medical education (CME) credits with self-assessment that are relevant to the
 60 individual's practice every three years. Self-assessment is defined as a written or electronic
 61 question-and-answer exercise that assesses understanding of the material in the CME program.
 62 A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve
 63 an acceptable self-assessment score are allowed. The transplant hospital must document
 64 completion of this continuing education.
 65 c. Provide to the OPTN Contractor two letters of recommendation from directors of designated
 66 transplant programs not employed by the applying hospital. These letters must address:
 67 i. Why an exception is reasonable.
 68 ii. The surgeon's overall qualifications to act as a primary kidney transplant surgeon.
 69 iii. The surgeon's personal integrity, honesty, and familiarity with and experience in adhering to
 70 OPTN obligations and compliance protocols.
 71 iv. Any other matters judged appropriate.

72
 73 If the surgeon has not adhered to the plan for maintaining continuing education or has not obtained
 74 the necessary CME credits with self-assessment, the transplant program will have a six-month grace
 75 period to address these deficiencies. If the surgeon has not fulfilled the requirements after the six-
 76 month grace period, and a key personnel change application has not been submitted, then the
 77 transplant program will be referred to the MPSC for appropriate action according to Appendix L of
 78 these Bylaws. If the OPTN Contractor becomes aware that a primary surgeon has not been compliant
 79 for 12 months or more and deficiencies still exist, then the transplant program will not be given any
 80 grace period and will be referred to the MPSC for appropriate action according to Appendix L of these
 81 Bylaws.

- 82 5. ~~In addition, t~~ The primary transplant surgeon must have completed at least one of the training or
 83 experience pathways listed below:
 84 ■ a. The formal 2-year transplant fellowship pathway, as described in Section E.2.A. Formal 2-year
 85 Transplant Fellowship Pathway below.
 86 ■ b. The kidney transplant program clinical experience pathway, as described in Section E.2.B.
 87 Clinical Experience Pathway below.
 88 ■ c. The alternative pathway for predominantly pediatric programs, as described in Section E.2.C.
 89 Alternative Pathway for Predominantly Pediatric Programs below.

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A. Formal 2-year Transplant Fellowship Pathway

Surgeons can meet the training requirements for primary kidney transplant surgeon by completing a 2-year 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 a log that includes the date of transplant, the role of the surgeon in the procedure, and medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the director of the training program.
2. The surgeon performed at least 15 kidney procurements as primary surgeon or first assistant over the 2-year period. At least 3 of these procurements must be multiple organ procurements and at least 10 must be from deceased donors. These procedures must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
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 accepted by the OPTN Contractor as described in the *Section E.4 Approved Kidney Transplant Surgeon and Physician Fellowship Training Programs* that follows. ~~Foreign training programs must be accepted as equivalent by the Membership and Professional Standards Committee (MPSC).~~
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.

B. Clinical Experience Pathway

Surgeons can meet the requirements for primary kidney transplant surgeon through clinical experience gained post-fellowship if the following conditions are met:

- 138 1. The surgeon has performed 45 or more kidney transplants over a 2 to 5-year period as
 139 primary surgeon or first assistant at a designated kidney transplant program, ~~or its foreign~~
 140 ~~equivalent~~. The transplants must be documented in a log that includes the date of transplant,
 141 the role of the surgeon in the procedure, and medical record number or other unique identifier
 142 that can be verified by the OPTN Contractor. The log should be signed by the program
 143 director, division chief, or department chair from the program where the experience was
 144 gained. Each year of the surgeon's experience must be substantive and relevant and include
 145 pre-operative assessment of kidney transplant candidates, performance of transplants as
 146 primary surgeon or first assistant, and post-operative care of kidney recipients.
- 147 2. The surgeon has performed at least 15 kidney procurements as primary surgeon or first
 148 assistant. At least 3 of these procurements must be multiple organ procurements and at least
 149 10 must be from deceased donors. These cases must be documented in a log that includes
 150 the date of procurement, location of the donor, and Donor ID.
- 151 3. The surgeon has maintained a current working knowledge of kidney transplantation, defined
 152 as direct involvement in kidney transplant patient care in the last 2 years. This includes the
 153 management of patients with end stage renal disease, the selection of appropriate recipients
 154 for transplantation, donor selection, histocompatibility and tissue typing, performing the
 155 transplant operation, immediate postoperative and continuing inpatient care, the use of
 156 immunosuppressive therapy including side effects of the drugs and complications of
 157 immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient,
 158 histological interpretation of allograft biopsies, interpretation of ancillary tests for renal
 159 dysfunction, and long term outpatient care.
- 160 4. The following letters are submitted directly to the OPTN Contractor:
- 161 a. A letter from the director of the transplant program and Chairman of the department or
 162 hospital credentialing committee verifying that the surgeon has met the above
 163 qualifications and is qualified to direct a kidney transplant program.
- 164 b. A letter of recommendation from the primary surgeon and transplant program director at
 165 the transplant program last served by the surgeon outlining the surgeon's overall
 166 qualifications to act as a primary transplant surgeon, as well as the surgeon's personal
 167 integrity, honesty, and familiarity with and experience in adhering to OPTN obligations
 168 and compliance protocols, and any other matters judged appropriate. The MPSC may
 169 request additional recommendation letters from the primary physician, primary surgeon,
 170 director, or others affiliated with any transplant program previously served by the
 171 surgeon, at its discretion.
- 172 c. A letter from the surgeon that details the training and experience the surgeon has gained
 173 in kidney transplantation.
- 174

175 **E.3 Primary Kidney Transplant Physician Requirements**

176 A designated kidney transplant program must have a primary physician who meets *all* the following
 177 requirements:

- 178
- 179 1. The physician must have an M.D., D.O., or equivalent degree from another country, with a current
 180 license to practice medicine in the hospital's state or jurisdiction.
- 181 2. The physician must be accepted onto the hospital's medical staff, and be on site at this hospital.
- 182 3. The physician must have documentation from the hospital credentialing committee that it has verified
 183 the physician's state license, board certification, training, and transplant continuing medical education
 184 and that the physician is currently a member in good standing of the hospital's medical staff.

185 4. The physician must have current certification in nephrology by the American Board of Internal
 186 Medicine, the American Board of Pediatrics, or the Royal College of Physicians and Surgeons of
 187 Canada ~~the foreign equivalent~~.

188

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

- 192 a. Be ineligible for American board certification.
- 193 b. Provide a plan for continuing education that is comparable to American board maintenance of
 194 certification. This plan must at least require that the physician obtains 60 hours of Category I
 195 continuing medical education (CME) credits with self-assessment that are relevant to the
 196 individual's practice every three years. Self-assessment is defined as a written or electronic
 197 question-and-answer exercise that assesses understanding of the material in the CME program.
 198 A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve
 199 an acceptable self-assessment score are allowed. The transplant hospital must document
 200 completion of this continuing education.
- 201 c. Provide to the OPTN Contractor two letters of recommendation from directors of designated
 202 transplant programs not employed by the applying hospital. These letters must address:
 - 203 i. Why an exception is reasonable.
 - 204 ii. The physician's overall qualifications to act as a primary kidney transplant physician.
 - 205 iii. The physician's personal integrity, honesty, and familiarity with and experience in adhering to
 206 OPTN obligations and compliance protocols.
 - 207 iv. Any other matters judged appropriate.

208

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

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219 ~~5. In addition, t~~ 5. The primary transplant physician must have completed at least one of the training or
 220 experience pathways listed below:

221

- 222 ■ a. The 12-month transplant nephrology fellowship pathway, as described in Section
 223 E.3.A. Twelve-month Transplant Nephrology Fellowship Pathway below.
- 224 ■ b. The clinical experience pathway, as described in Section E.3.B. Clinical Experience Pathway
 225 below.
- 226 ■ c. The 3-year pediatric nephrology fellowship pathway, as described in Section E.3.C. Three-year
 227 Pediatric Nephrology Fellowship Pathway below.
- 228 ■ d. The 12-month pediatric transplant nephrology fellowship pathway, as described in Section
 229 E.3.D. Twelve-month Pediatric Transplant Nephrology Fellowship Pathway below.
- 230 ■ e. The combined pediatric nephrology training and experience pathway, as described in Section
 231 E.3.E. Combined Pediatric Nephrology Training and Experience Pathway below.

232 ■ f. The alternative pathway for predominantly pediatric programs, as described in Section E.3.F.
 233 Alternative Pathway for Predominantly Pediatric Programs below.

234 ■ g. The conditional approval pathway, as described in Section E.3.G. Conditional Approval for
 235 Primary Transplant Physician below, if the primary kidney transplant physician changes at an
 236 approved kidney transplant program.

237

238 **A. Twelve-month Transplant Nephrology Fellowship Pathway**

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

241

242 1. ~~The physician has current board certification in nephrology by the American Board of Internal~~
 243 ~~Medicine or the foreign equivalent.~~

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

251 32. During the fellowship period, the physician was directly involved in the primary care of 30 or
 252 more newly transplanted kidney recipients and continued to follow these recipients for a
 253 minimum of 3 months from the time of transplant. The care must be documented in a log that
 254 includes the date of transplant and the recipient medical record number or other unique
 255 identifier that can be verified by the OPTN Contractor. This recipient log must be signed by
 256 the director of the training program or the transplant program's primary transplant physician.

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

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

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

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

277 b. A letter of recommendation from the fellowship training program's primary physician and
 278 transplant program director outlining the physician's overall qualifications to act as a

- 279 primary transplant physician, as well as the physician’s personal integrity, honesty, and
 280 familiarity with and experience in adhering to OPTN obligations and compliance
 281 protocols, and any other matters judged appropriate. The MPSC may request additional
 282 recommendation letters from the primary physician, primary surgeon, director, or others
 283 affiliated with any transplant program previously served by the physician, at its discretion.
 284 c. A letter from the physician that details the training and experience the physician has
 285 gained in kidney transplantation.
 286

287 The training requirements outlined above are in addition to other clinical requirements for general
 288 nephrology training.
 289

290 **B. Clinical Experience Pathway**

291 A physician can meet the requirements for a primary kidney transplant physician through
 292 acquired clinical experience if the following conditions are met:
 293

- 294 1. The physician has been directly involved in the primary care of 45 or more newly transplanted
 295 kidney recipients and continued to follow these recipients for a minimum of 3 months from the
 296 time of transplant. This patient care must have been provided over a 2 to 5-year period on an
 297 active kidney transplant service as the primary kidney transplant physician or under the direct
 298 supervision of a qualified transplant physician and in conjunction with a kidney transplant
 299 surgeon at a designated kidney ~~Kidney~~ transplant program ~~or the foreign equivalent~~. The
 300 care must be documented in a log that includes the date of transplant and recipient medical
 301 record number or other unique identifier that can be verified by the OPTN Contractor. The
 302 recipient log should be signed by the program director, division Chief, or department Chair
 303 from the program where the physician gained this experience.
- 304 2. The physician has maintained a current working knowledge of kidney transplantation, defined
 305 as direct involvement in kidney transplant patient care over the last 2 years. This includes the
 306 management of patients with end stage renal disease, the selection of appropriate recipients
 307 for transplantation, donor selection, histocompatibility and tissue typing, immediate
 308 postoperative patient care, the use of immunosuppressive therapy including side effects of
 309 the drugs and complications of immunosuppression, differential diagnosis of renal
 310 dysfunction in the allograft recipient, histological interpretation of allograft biopsies,
 311 interpretation of ancillary tests for renal dysfunction, and long term outpatient care.
- 312 3. The physician should have observed at least 3 organ procurements and 3 kidney transplants.
 313 The physician should also have observed the evaluation, the donation process, and
 314 management of at least 3 multiple organ donors who donated a kidney. If the physician has
 315 completed these observations, they must be documented in a log that includes the date of
 316 procurement, location of the donor, and Donor ID.
- 317 4. The following letters are submitted directly to the OPTN Contractor:
 - 318 a. A letter from the qualified transplant physician or the kidney transplant surgeon who has
 319 been directly involved with the proposed physician documenting the physician’s
 320 experience and competence.
 - 321 b. A letter of recommendation from the primary physician and transplant program director at
 322 the transplant program last served by the physician outlining the physician’s overall
 323 qualifications to act as a primary transplant physician, as well as the physician’s personal
 324 integrity, honesty, and familiarity with and experience in adhering to OPTN obligations
 325 and compliance protocols, and any other matters judged appropriate. The MPSC may
 326 request additional recommendation letters from the primary physician, primary surgeon,

- 327 director, or others affiliated with any transplant program previously served by the
 328 physician, at its discretion.
- 329 c. A letter from the physician that details the training and experience the physician has
 330 gained in kidney transplantation.

331

332 **C. Three-year Pediatric Nephrology Fellowship Pathway**

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

338

339 ~~1. The physician has current board certification in nephrology by the American Board of~~
 340 ~~Pediatrics, or the foreign equivalent.~~

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

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

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

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

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

- 374 a. A letter from the director and the supervising qualified transplant physician and surgeon
 375 of the fellowship training program verifying that the physician has met the above
 376 requirements and is qualified to direct a kidney transplant program.
 377 b. A letter of recommendation from the fellowship training program's primary physician and
 378 transplant program director outlining the physician's overall qualifications to act as a
 379 primary transplant physician, as well as the physician's personal integrity, honesty, and
 380 familiarity with and experience in adhering to OPTN obligations, and any other matters
 381 judged appropriate. The MPSC may request additional recommendation letters from the
 382 primary physician, primary surgeon, director, or others affiliated with any transplant
 383 program previously served by the physician, at its discretion.
 384 c. A letter from the physician that details the training and experience the physician has
 385 gained in kidney transplantation.
 386

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

388 The requirements for the primary kidney transplant physician can be met during a separate
 389 pediatric transplant nephrology fellowship if the following conditions are met:
 390

- 391 1. The physician has current board certification in pediatric nephrology by the American Board
 392 of Pediatrics, ~~the Royal College of Physicians and Surgeons of Canada, or the foreign~~
 393 ~~equivalent~~, or is approved by the American Board of Pediatrics to take the certifying exam.
 394 2. During the fellowship, the physician was directly involved in the primary care of 10 or more
 395 newly transplanted kidney recipients and followed 30 newly transplanted kidney recipients for
 396 at least 6 months from the time of transplant, under the direct supervision of a qualified
 397 kidney transplant physician and in conjunction with a qualified kidney transplant surgeon. The
 398 pediatric nephrology program director may elect to have a portion of the transplant
 399 experience completed at another Kidney transplant program in order to meet these
 400 requirements. This care must be documented in a recipient log that includes the date of
 401 transplant, and the recipient medical record number or other unique identifier that can be
 402 verified by the OPTN Contractor. This log must be signed by the training program director or
 403 the primary physician of the transplant program.
 404 3. The experience in caring for pediatric patients occurred at a kidney transplant program with a
 405 qualified kidney transplant physician and surgeon that performs an average of at least 10
 406 pediatric kidney transplants a year.
 407 4. The physician has maintained a current working knowledge of kidney transplantation, defined
 408 as direct involvement in kidney transplant patient care in the past 2 years. This includes the
 409 management of pediatric patients with end-stage renal disease, the selection of appropriate
 410 pediatric recipients for transplantation, donor selection, histocompatibility and tissue typing,
 411 immediate post-operative care including those issues of management unique to the pediatric
 412 recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the
 413 pediatric recipient including side-effects of drugs and complications of immunosuppression,
 414 the effects of transplantation and immunosuppressive agents on growth and development,
 415 differential diagnosis of renal dysfunction in the allograft recipient, manifestation of rejection
 416 in the pediatric patient, histological interpretation of allograft biopsies, interpretation of
 417 ancillary tests for renal dysfunction, and long-term outpatient care of pediatric allograft
 418 recipients including management of hypertension, nutritional support, and drug dosage,
 419 including antibiotics, in the pediatric patient. The curriculum for obtaining this knowledge must
 420 be approved by the Residency Review Committee (RRC) -Ped of the ACGME.

- 421 5. The physician should have observed at least 3 organ procurements and 3 pediatric kidney
 422 transplants. The physician should also have observed the evaluation, the donation process,
 423 and management of at least 3 multiple organ donors who donated a kidney. If the physician
 424 has completed these observations, they must be documented in a log that includes the date
 425 of procurement, location of the donor, and Donor ID.
- 426 6. The following letters are submitted directly to the OPTN Contractor:
- 427 a. A letter from the director and the supervising qualified transplant physician and surgeon
 428 of the fellowship training program verifying that the physician has met the above
 429 requirements and is qualified to become the primary transplant physician of a designated
 430 kidney transplant program.
- 431 b. A letter of recommendation from the fellowship training program's primary physician and
 432 transplant program director outlining the physician's overall qualifications to act as a
 433 primary transplant physician, as well as the physician's personal integrity, honesty, and
 434 familiarity with and experience in adhering to OPTN obligations, and any other matters
 435 judged appropriate. The MPSC may request additional recommendation letters from the
 436 primary physician, primary surgeon, director, or others affiliated with any transplant
 437 program previously served by the physician, at its discretion.
- 438 c. A letter from the physician that details the training and experience the physician has
 439 gained in kidney transplantation.
 440

441 **E. Combined Pediatric Nephrology Training and Experience Pathway**

442 A physician can meet the requirements for primary kidney transplant physician if the following
 443 conditions are met:
 444

- 445 1. The physician has current board certification in pediatric nephrology by the American Board
 446 of Pediatrics, the Royal College of Physicians and Surgeons of Canada, or the foreign
 447 equivalent, or is approved by the American Board of Pediatrics to take the certifying exam.
- 448 ~~2-~~ The physician gained a minimum of 2 years of experience during or after fellowship, or
 449 accumulated during both periods, at a kidney transplant program.
- 450 ~~3-~~ During the 2 or more years of accumulated experience, the physician was directly involved in
 451 the primary care of 10 or more newly transplanted kidney recipients and followed 30 newly
 452 transplanted kidney recipients for at least 6 months from the time of transplant, under the
 453 direct supervision of a qualified kidney transplant physician, along with a qualified kidney
 454 transplant surgeon. This care must be documented in a recipient log that includes the date of
 455 transplant, and the recipient medical record number or other unique identifier that can be
 456 verified by the OPTN Contractor. This log must be signed by the training program director or
 457 the primary physician of the transplant program.
- 458 4- The physician has maintained a current working knowledge of kidney transplantation, defined
 459 as direct involvement in kidney transplant patient care during the past 2 years. This includes
 460 the management of pediatric patients with end-stage renal disease, the selection of
 461 appropriate pediatric recipients for transplantation, donor selection, histocompatibility and
 462 tissue typing, immediate post-operative care including those issues of management unique to
 463 the pediatric recipient, fluid and electrolyte management, the use of immunosuppressive
 464 therapy in the pediatric recipient including side-effects of drugs and complications of
 465 immunosuppression, the effects of transplantation and immunosuppressive agents on growth
 466 and development, differential diagnosis of renal dysfunction in the allograft recipient,
 467 manifestation of rejection in the pediatric patient, histological interpretation of allograft
 468 biopsies, interpretation of ancillary tests for renal dysfunction, and long-term outpatient care

469 of pediatric allograft recipients including management of hypertension, nutritional support,
 470 and drug dosage, including antibiotics, in the pediatric patient. The curriculum for obtaining
 471 this knowledge must be approved by the Residency Review Committee (RRC) -Ped of the
 472 ACGME or a Residency Review Committee.

- 473 5. The physician should have observed at least 3 organ procurements and 3 pediatric kidney
 474 transplants. The physician should also have observed the evaluation, the donation process,
 475 and management of at least 3 multiple organ donors who donated a kidney. If the physician
 476 has completed these observations, they must be documented in a log that includes the date
 477 of procurement, location of the donor, and Donor ID.
- 478 6. The following letters are submitted directly to the OPTN Contractor:
 - 479 a. A letter from the supervising qualified transplant physician and surgeon who were directly
 480 involved with the physician documenting the physician's experience and competence.
 - 481 b. A letter of recommendation from the fellowship training program's primary physician and
 482 transplant program director outlining the physician's overall qualifications to act as a
 483 primary transplant physician, as well as the physician's personal integrity, honesty, and
 484 familiarity with and experience in adhering to OPTN obligations, and any other matters
 485 judged appropriate. The MPSC may request additional recommendation letters from the
 486 primary physician, primary surgeon, Director, or others affiliated with any transplant
 487 program previously served by the physician, at its discretion.
 - 488 c. A letter from the physician that details the training and experience the physician has
 489 gained in kidney transplantation.

491 **G. Conditional Approval for Primary Transplant Physician**

492 If the primary kidney transplant physician changes at an approved Kidney transplant program, a
 493 physician can serve as the primary kidney transplant physician for a maximum of 12 months if the
 494 following conditions are met:

- 495 ~~1. The physician has current board certification in nephrology by the American Board of Internal
 496 Medicine, the American Board of Pediatrics, or the foreign equivalent.~~
- 497 21. The physician has been involved in the primary care of 23 or more newly transplanted kidney
 498 recipients, and has followed these patients for at least 3 months from the time of their
 499 transplant. This care must be documented in a recipient log that includes the date of
 500 transplant and the medical record number or other unique identifier that can be verified by the
 501 OPTN Contractor. This log must be signed by the program director, division chief, or
 502 department chair from the transplant program where the experience was gained.
- 503 ~~32.~~ 32. The physician has maintained a current working knowledge of kidney transplantation, defined
 504 as direct involvement in kidney transplant patient care during the last 2 years. This includes
 505 the management of patients with end stage renal disease, the selection of appropriate
 506 recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate
 507 postoperative patient care, the use of immunosuppressive therapy including side effects of
 508 the drugs and complications of immunosuppression, differential diagnosis of renal
 509 dysfunction in the allograft recipient, histological interpretation of allograft biopsies,
 510 interpretation of ancillary tests for renal dysfunction, and long-term outpatient care.
- 511 ~~43.~~ 43. The physician has 12 months experience on an active kidney transplant service as the
 512 primary kidney transplant physician or under the direct supervision of a qualified kidney
 513 transplant physician and in conjunction with a kidney transplant surgeon at a designated
 514 kidney transplant program ~~or the foreign equivalent~~. These 12 months of experience must be
 515 acquired within a 2-year period.

- 516 ~~54.~~ The physician should have observed at least 3 organ procurements and 3 kidney transplants.
- 517 The physician should also have observed the evaluation, the donation process, and
- 518 management of at least 3 multiple organ donors who donated a kidney. If the physician has
- 519 completed these observations, they must be documented in a log that includes the date of
- 520 procurement, location of the donor, and Donor ID.
- 521 ~~65.~~ The program has established and documented a consulting relationship with counterparts at
- 522 another kidney transplant program.
- 523 ~~76.~~ The transplant program submits activity reports to the OPTN Contractor every 2 months
- 524 describing the transplant activity, transplant outcomes, physician recruitment efforts, and
- 525 other operating conditions as required by the MPSC to demonstrate the ongoing quality and
- 526 efficient patient care at the program. The activity reports must also demonstrate that the
- 527 physician is making sufficient progress to meet the required involvement in the primary care
- 528 of 45 or more kidney transplant recipients, or that the program is making sufficient progress in
- 529 recruiting a physician who meets all requirements for primary kidney transplant physician and
- 530 who will be on site and approved by the MPSC to assume the role of primary physician by the
- 531 end of the 12 month conditional approval period.
- 532 ~~87.~~ The following letters are submitted directly to the OPTN Contractor:
- 533 a. A letter from the supervising qualified transplant physician and surgeon who were directly
- 534 involved with the physician documenting the physician’s experience and competence.
- 535 b. A letter of recommendation from the primary physician and director at the transplant
- 536 program last served by the physician outlining the physician’s overall qualifications to act
- 537 as a primary transplant physician, as well as the physician’s personal integrity, honesty,
- 538 and familiarity with and experience in adhering to OPTN obligations, and any other
- 539 matters judged appropriate. The MPSC may request additional recommendation letters
- 540 from the primary physician, primary surgeon, director, or others affiliated with any
- 541 transplant program previously served by the physician, at its discretion.
- 542 c. A letter from the physician that details the training and experience the physician has
- 543 gained in kidney transplantation.

544
 545 The 12-month conditional approval period begins on the initial approval date granted to the
 546 personnel change application, whether it is interim approval granted by the MPSC subcommittee,
 547 or approval granted by the full MPSC. The conditional approval period ends 12 months after the
 548 first approval date of the personnel change application.

549
 550 If the program is unable to demonstrate that it has an individual on site who can meet the
 551 requirements as described in *Sections E.3.A through E.3.F* above at the end of the 12-month
 552 conditional approval period, it must inactivate. The requirements for program inactivation are
 553 described in *Appendix K: Transplant Program Inactivity, Withdrawal, and Termination* of these
 554 Bylaws.

555
 556 The MPSC may consider on a case-by-case basis and grant a 6-month extension to a transplant
 557 program that provides substantial evidence of progress toward fulfilling the requirements but is
 558 unable to complete the requirements within one year.

560 **Appendix F:**
 561 **Membership and Personnel Requirements for Liver**
 562 **Transplant Programs**

563

564 **F.2 Primary Liver Transplant Surgeon Requirements**

565 A designated liver transplant program must have a primary surgeon who meets *all* of the following
 566 requirements:

567

- 568 1. The surgeon must have an M.D., D.O., or equivalent degree from another country, with a current
 569 license to practice medicine in the hospital's state or jurisdiction.
- 570 2. The surgeon must be accepted onto the hospital's medical staff, and be on site at this hospital.
- 571 3. The surgeon must have documentation from the hospital credentialing committee that it has verified
 572 the surgeon's state license, board certification, training, and transplant continuing medical education,
 573 and that the surgeon is currently a member in good standing of the hospital's medical staff.
- 574 4. The surgeon must have current certification by the American Board of Surgery, the American Board
 575 of Urology, the American Board of Osteopathic Surgery, or the Royal College of Physicians and
 576 Surgeons of Canada ~~foreign equivalent~~. In the case of a surgeon who has just completed training and
 577 whose ~~board~~ American Board of Urology certification in urology is pending, the Membership and
 578 Professional Standards Committee (MPSC) may grant conditional approval for ~~12~~16 months to allow
 579 time for the surgeon to complete board certification, with the possibility of ~~renewal~~ for one additional
 580 ~~12~~16-month ~~period~~ extension.

581

582 In place of current certification by the American Board of Surgery, the American Board of Urology, the
 583 American Board of Osteopathic Surgery, the Royal College of Physicians and Surgeons of Canada,
 584 or pending certification by the American Board of Urology, the surgeon must:

585

- 586 a. Be ineligible for American board certification.
- 587 b. Provide a plan for continuing education that is comparable to American board maintenance of
 588 certification. This plan must at least require that the surgeon obtains 60 hours of Category I
 589 continuing medical education (CME) credits with self-assessment that are relevant to the
 590 individual's practice every three years. Self-assessment is defined as a written or electronic
 591 question-and-answer exercise that assesses understanding of the material in the CME program.
 592 A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve
 593 an acceptable self-assessment score are allowed. The transplant hospital must document
 594 completion of this continuing education.
- 595 c. Provide to the OPTN Contractor two letters of recommendation from directors of designated
 596 transplant programs not employed by the applying hospital. These letters must address:
- 597 i. Why an exception is reasonable.
- 598 ii. The surgeon's overall qualifications to act as a primary liver transplant surgeon.
- 599 iii. The surgeon's personal integrity, honesty, and familiarity with and experience in adhering to
 600 OPTN obligations and compliance protocols.
- 601 iv. Any other matters judged appropriate.

601

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

609 grace period and will be referred to the MPSC for appropriate action according to Appendix L of these
 610 Bylaws.

611 5. ~~In addition, t~~ The primary transplant surgeon must have completed at least one of the training or
 612 ~~experience~~ pathways listed below:

- 613
- 614 ■ a. The formal 2-year transplant fellowship pathway, as described in *Section F.2.A. Formal 2-year*
 615 *Transplant Fellowship Pathway* below.
- 616 ■ b. The liver transplant program clinical experience pathway, as described in *Section F.2.B.*
 617 *Clinical Experience Pathway* below.
- 618 ■ c. The alternative pathway for predominantly pediatric programs, as described in Section F.2.C.
 619 Alternative Pathway for Predominantly Pediatric Programs below.
- 620

621 **A. Formal 2-year Transplant Fellowship Pathway**

622 Surgeons can meet the training requirements for primary liver transplant surgeon by completing a
 623 2-year transplant fellowship if the following conditions are met:

- 624
- 625 1. The surgeon performed at least 45 liver transplants as primary surgeon or first assistant
 626 during the 2-year fellowship period. These transplants must be documented in a log that
 627 includes the date of transplant, the role of the surgeon in the procedure, and the medical
 628 record number or other unique identifier that can be verified by the OPTN Contractor. This log
 629 must be signed by the director of the training program.
- 630 2. The surgeon performed at least 20 liver procurements as primary surgeon or first assistant
 631 during the 2-year period. At least 3 of these procurements must include selection and
 632 management of the donor. These procedures must be documented in a log that includes the
 633 date of procurement, location of the donor, and Donor ID. This log must be signed by the
 634 director of the training program.
- 635 3. The surgeon has maintained a current working knowledge of liver transplantation, defined as
 636 direct involvement in liver transplant patient care within the last 2 years. This includes the
 637 management of patients with end stage liver disease, the selection of appropriate recipients
 638 for transplantation, donor selection, histocompatibility and tissue typing, performing the
 639 transplant operation, immediate postoperative and continuing inpatient care, the use of
 640 immunosuppressive therapy including side effects of the drugs and complications of
 641 immunosuppression, differential diagnosis of liver allograft dysfunction, histologic
 642 interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and
 643 long term outpatient care.
- 644 4. The training was completed at a hospital with a transplant training program approved by the
 645 Fellowship Training Committee of the American Society of Transplant Surgeons, the Royal
 646 College of Physicians and Surgeons of Canada, or accepted by the OPTN Contractor as
 647 described in *Section F.5. Approved Liver Surgeon Transplant Fellowship Programs* that
 648 follows. ~~Foreign training programs must be accepted as equivalent by the Membership and~~
 649 ~~Professional Standards Committee (MPSC).~~
- 650 5. The following letters are submitted directly to the OPTN Contractor:
 651 a. A letter from the director of the training program verifying that the surgeon has met the
 652 above requirements, and is qualified to direct a liver transplant program.
 653 b. A letter of recommendation from the fellowship training program's primary surgeon and
 654 transplant program director outlining the surgeon's overall qualifications to act as primary
 655 transplant surgeon, as well as the surgeon's personal integrity, honesty, familiarity with
 656 and experience in adhering to OPTN obligations, and other matters judged appropriate.

- 657 The MPSC may request additional recommendation letters from the primary physician,
 658 primary surgeon, director, or others affiliated with any transplant program previously
 659 served by the surgeon, at its discretion.
 660 c. A letter from the surgeon that details his or her training and experience in liver
 661 transplantation.
 662

663 **B. Clinical Experience Pathway**

664 Surgeons can meet the requirements for primary liver transplant surgeon through clinical
 665 experience gained post-fellowship, if the following conditions are met:
 666

- 667 1. The surgeon has performed 60 or more liver transplants over a 2 to 5-year period as primary
 668 surgeon or first assistant at a designated liver transplant program ~~or the foreign equivalent~~.
 669 These transplants must be documented in a log that includes the date of transplant, the role
 670 of the surgeon in the procedure, and medical record number or other unique identifier that
 671 can be verified by the OPTN Contractor. This log should be signed by the program director,
 672 division chief, or department chair from the program where the experience was gained. Each
 673 year of the surgeon’s experience must be substantive and relevant and include pre-operative
 674 assessment of liver transplant candidates, transplants performed as primary surgeon or first
 675 assistant, and post-operative management of liver recipients.
 676 2. The surgeon has performed at least 30 liver procurements as primary surgeon or first
 677 assistant. At least 3 of these procurements must include selection and management of the
 678 donor. These procedures must be documented in a log that includes the date of procurement,
 679 location of the donor, and Donor ID.
 680 3. The surgeon has maintained a current working knowledge of liver transplantation, defined as
 681 direct involvement in liver transplant patient care within the last 2 years. This includes the
 682 management of patients with end stage liver disease, the selection of appropriate recipients
 683 for transplantation, donor selection, histocompatibility and tissue typing, performing the
 684 transplant operation, immediate postoperative and continuing inpatient care, the use of
 685 immunosuppressive therapy including side effects of the drugs and complications of
 686 immunosuppression, differential diagnosis of liver dysfunction in the allograft recipient,
 687 histologic interpretation of allograft biopsies, interpretation of ancillary tests for liver
 688 dysfunction, and long term outpatient care.
 689 4. The following letters are sent directly to the OPTN Contractor:
 690 a. A letter from the director of the transplant program and chairman of the department or
 691 hospital credentialing committee verifying that the surgeon has met the above
 692 requirements, and is qualified to direct a liver transplant program.
 693 b. A letter of recommendation from the primary surgeon and transplant program director at
 694 the transplant program last served by the surgeon outlining the surgeon’s overall
 695 qualifications to act as primary transplant surgeon, as well as the surgeon’s personal
 696 integrity, honesty, familiarity with and experience in adhering to OPTN obligations, and
 697 other matters judged appropriate. The MPSC may request additional recommendation
 698 letters from the primary physician, primary surgeon, director, or others affiliated with any
 699 transplant program previously served by the surgeon, at its discretion.
 700 c. A letter from the surgeon that details the training and experience the surgeon gained in
 701 liver transplantation.
 702

703 F.3 Primary Liver Transplant Physician Requirements

704 A designated liver transplant program must have a primary physician who meets *all* the following
705 requirements:

- 706
- 707 1. The physician must have an M.D., D.O., or equivalent degree from another country, with a current
708 license to practice medicine in the hospital's state or jurisdiction.
 - 709 2. The physician must be accepted onto the hospital's medical staff, and be on site at this hospital.
 - 710 3. The physician must have documentation from the hospital credentialing committee that it has verified
711 the physician's state license, board certification, training, and transplant continuing medical education
712 and that the physician is currently a member in good standing of the hospital's medical staff.
 - 713 4. The physician must have current board certification in gastroenterology by the American Board of
714 Internal Medicine, the American Board of Pediatrics, or the Royal College of Physicians and
715 Surgeons of Canada foreign equivalent.

716

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

- 720 a. Be ineligible for American board certification.
- 721 b. Provide a plan for continuing education that is comparable to American board maintenance of
722 certification. This plan must at least require that the physician obtains 60 hours of Category I
723 continuing medical education (CME) credits with self-assessment that are relevant to the
724 individual's practice every three years. Self-assessment is defined as a written or electronic
725 question-and-answer exercise that assesses understanding of the material in the CME program.
726 A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve
727 an acceptable self-assessment score are allowed. The transplant hospital must document
728 completion of this continuing education.
- 729 c. Provide to the OPTN Contractor two letters of recommendation from directors of designated
730 transplant programs not employed by the applying hospital. These letters must address:
 - 731 i. Why an exception is reasonable.
 - 732 ii. The physician's overall qualifications to act as a primary liver transplant physician.
 - 733 iii. The physician's personal integrity, honesty, and familiarity with and experience in adhering to
734 OPTN obligations and compliance protocols.
 - 735 iv. Any other matters judged appropriate.

736

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

- 746 5. ~~In addition, t~~ The primary transplant physician must have completed at least one of the training or
747 experience pathways listed below:
- 748 ■ a. The 12-month transplant hepatology fellowship pathway, as described in Section F.3.A. 12-
749 month Transplant Hepatology Fellowship Pathway below.

- 750 ■ b. The clinical experience pathway, as described in *Section F.3.B. Clinical Experience Pathway*
751 below.
- 752 ■ c. The 3-year pediatric gastroenterology fellowship pathway, as described in *Section F.3.C.*
753 *Three-year Pediatric Gastroenterology Fellowship Pathway* below.
- 754 ■ d. The 12-month pediatric transplant hepatology fellowship pathway, as described in *Section*
755 *F.3.D. Pediatric Transplant Hepatology Fellowship Pathway* below.
- 756 ■ e. The combined pediatric gastroenterology or transplant hepatology training and experience
757 pathway, as described in *Section F.3.E. Combined Pediatric Gastroenterology/Transplant*
758 *Hepatology Training and Experience Pathway* below.
- 759 ■ f. The alternative pathway for predominantly pediatric programs, as described in *Section F.3.F.*
760 *Alternative Pathway for Predominantly Pediatric Programs* below.
- 761 ■ g. The conditional approval pathway, as described in *Section F.3.G. Conditional Approval for*
762 *Primary Transplant Physician* below, if the primary liver transplant physician changes at an
763 approved liver transplant program.
764

765 Pediatric liver transplant programs should have a board certified pediatrician (~~or the foreign equivalent~~)
766 who meets the criteria for primary liver transplant physician. If a qualified pediatric physician is not on staff
767 at the program, a physician meeting the criteria as a primary liver transplant physician for adults can
768 function as the primary liver transplant physician for the pediatric program, if a pediatric gastroenterologist
769 is involved in the care of the pediatric liver transplant recipients.
770

771 **B. Clinical Experience Pathway**

772 A physician can meet the requirements for a primary liver transplant physician through acquired
773 clinical experience if the following conditions are met:
774

- 775 1. The physician has been directly involved in the primary care of 50 or more newly transplanted
776 liver recipients and continued to follow these recipients for a minimum of 3 months from the
777 time of transplant. This patient care must have been provided over a 2 to 5-year period on an
778 active liver transplant service as the primary liver transplant physician or under the direct
779 supervision of a qualified liver transplant physician and in conjunction with a liver transplant
780 surgeon at a designated liver transplant program ~~or the foreign equivalent~~. This care must be
781 documented in a log that includes the date of transplant and the medical record number or
782 other unique identifier that can be verified by the OPTN Contractor. This recipient log should
783 be signed by the program director, division chief, or department chair from the program
784 where the physician gained this experience.
- 785 2. The physician has maintained a current working knowledge of liver transplantation, defined
786 as direct involvement in liver transplant patient care within the last 2 years. This includes the
787 management of patients with end stage liver disease, acute liver failure, the selection of
788 appropriate recipients for transplantation, donor selection, histocompatibility and tissue
789 typing, immediate post-operative patient care, the use of immunosuppressive therapy
790 including side effects of the drugs and complications of immunosuppression, differential
791 diagnosis of liver allograft dysfunction, histologic interpretation of allograft biopsies,
792 interpretation of ancillary tests for liver dysfunction, and long term outpatient care.
- 793 3. The physician should have observed at least 3 organ procurements and 3 liver transplants.
794 The physician should also have observed the evaluation, the donation process, and
795 management of at least 3 multiple organ donors who donated a liver. If the physician has

- 796 completed these observations, they must be documented in a log that includes the date of
 797 procurement, the location of the donor, and Donor ID.
- 798 4. The following letters are submitted directly to the OPTN Contractor:
- 799 a. A letter from the qualified transplant physician or the liver transplant surgeon who has
 800 been directly involved with the proposed physician documenting the physician's
 801 experience and competence.
- 802 b. A letter of recommendation from the primary physician and transplant program director at
 803 the transplant program last served by the physician outlining the physician's overall
 804 qualifications to act as a primary transplant physician, as well as the physician's personal
 805 integrity, honesty, and familiarity with and experience in adhering to OPTN obligations,
 806 and any other matters judged appropriate. The MPSC may request additional
 807 recommendation letters from the primary physician, primary surgeon, director, or others
 808 affiliated with any transplant program previously served by the physician, at its discretion.
- 809 c. A letter from the physician that details the training and experience the physician gained in
 810 liver transplantation.

811 **C. Three-year Pediatric Gastroenterology Fellowship Pathway**

813 A physician can meet the requirements for primary liver transplant physician by completion of 3
 814 years of pediatric gastroenterology fellowship training as required by the American Board of
 815 Pediatrics in a program accredited by the Residency Review Committee for Pediatrics (RRC-Ped)
 816 of the Accreditation Council for Graduate Medical Education (ACGME). The training must contain
 817 at least 6 months of clinical care for transplant patients, and meet the following conditions:

- 818
- 819 1. The physician has current board certification in pediatric gastroenterology by the American
 820 Board of Pediatrics; or the ~~foreign equivalent~~ the Royal College of Physicians and Surgeons
 821 of Canada.
- 822 2. During the 3-year training period the physician was directly involved in the primary care of 10
 823 or more newly transplanted pediatric liver recipients and followed 20 newly transplanted liver
 824 recipients for a minimum of 3 months from the time of transplant, under the direct supervision
 825 of a qualified liver transplant physician along with a qualified liver transplant surgeon. The
 826 physician was also directly involved in the preoperative, peri-operative and post-operative
 827 care of 10 or more liver transplants in pediatric patients. The pediatric gastroenterology
 828 program director may elect to have a portion of the transplant experience carried out at
 829 another transplant service, to meet these requirements. This care must be documented in a
 830 log that includes the date of transplant, the medical record number or other unique identifier
 831 that can be verified by the OPTN Contractor. This recipient log must be signed by the training
 832 program director or the transplant program's primary transplant physician.
- 833 3. The experience caring for pediatric patients occurred at a liver transplant program with a
 834 qualified liver transplant physician and a qualified liver transplant surgeon that performs an
 835 average of at least 10 liver transplants on pediatric patients per year.
- 836 4. The physician should have observed at least 3 organ procurements and 3 liver transplants. In
 837 addition, the physician should have observed the evaluation, the donation process, and the
 838 care of at least 3 multiple organ donors who donated a liver. If the physician has completed
 839 these observations, they must be documented in a log that includes the date of procurement,
 840 location of the donor and Donor ID.
- 841 5. The physician has maintained a current working knowledge of liver transplantation, defined
 842 as direct involvement in liver transplant patient care within the last 2 years. This includes the
 843 management of pediatric patients with end-stage liver disease acute liver failure, the

- 844 selection of appropriate pediatric recipients for transplantation, donor selection,
 845 histocompatibility and tissue typing, immediate postoperative care including those issues of
 846 management unique to the pediatric recipient, fluid and electrolyte management, the use of
 847 immunosuppressive therapy in the pediatric recipient including side-effects of drugs and
 848 complications of immunosuppression, the effects of transplantation and immunosuppressive
 849 agents on growth and development, differential diagnosis of liver dysfunction in the allograft
 850 recipient, manifestation of rejection in the pediatric patient, histological interpretation of
 851 allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long-term
 852 outpatient care of pediatric allograft recipients including management of hypertension,
 853 nutritional support, and drug dosage, including antibiotics, in the pediatric patient.
- 854 6. The following letters are submitted directly to the OPTN Contractor:
- 855 a. A letter from the director of the pediatric gastroenterology training program, and the
 856 qualified liver transplant physician and surgeon of the fellowship training program
 857 verifying that the physician has met the above requirements, and is qualified to act as a
 858 liver transplant physician and direct a liver transplant program.
- 859 b. A letter of recommendation from the fellowship training program's primary physician and
 860 transplant program director outlining the physician's overall qualifications to act as a
 861 primary transplant physician, as well as the physician's personal integrity, honesty, and
 862 familiarity with and experience in adhering to OPTN obligations, and any other matters
 863 judged appropriate. The MPSC may request additional recommendation letters from the
 864 primary physician, primary surgeon, director, or others affiliated with any transplant
 865 program previously served by the physician, at its discretion.
- 866 c. A letter from the physician that details the training and experience the physician gained in
 867 liver transplantation.
- 868

869 **D. Pediatric Transplant Hepatology Fellowship Pathway**

870 The requirements for primary liver transplant physician can be met during a separate pediatric
 871 transplant hepatology fellowship if the following conditions are met:

872

- 873 1. The physician has current board certification in pediatric gastroenterology by the American
 874 Board of Pediatrics, the Royal College of Physicians and Surgeons of Canada, or the foreign
 875 equivalent, or is approved by the American Board of Pediatrics to take the certifying exam.
- 876 2. During the fellowship, the physician was directly involved in the primary care of 10 or more
 877 newly transplanted pediatric liver recipients and followed 20 newly transplanted liver
 878 recipients for at least 3 months from the time of transplant, under the direct supervision of a
 879 qualified liver transplant physician and in conjunction with a qualified liver transplant surgeon.
 880 The physician must have been directly involved in the pre-operative, peri-operative and post-
 881 operative care of 10 or more liver transplants in pediatric patients. The pediatric
 882 gastroenterology program director may elect to have a portion of the transplant experience
 883 completed at another liver transplant program in order to meet these requirements. This care
 884 must be documented in a log that includes the date of transplant and the medical record
 885 number or other unique identifier that can be verified by the OPTN Contractor. This recipient
 886 log must be signed by the training program director or the transplant program primary
 887 transplant physician.
- 888 3. The experience in caring for pediatric liver patients occurred at a liver transplant program with
 889 a qualified liver transplant physician and surgeon that performs an average of at least 10
 890 pediatric liver transplants a year.

- 891 4. The physician has maintained a current working knowledge of liver transplantation, defined
 892 as direct involvement in liver transplant patient care within the last 2 years. This includes the
 893 management of pediatric patients with end-stage liver disease, acute liver failure, the
 894 selection of appropriate pediatric recipients for transplantation, donor selection,
 895 histocompatibility and tissue typing, immediate postoperative care including those issues of
 896 management unique to the pediatric recipient, fluid and electrolyte management, the use of
 897 immunosuppressive therapy in the pediatric recipient including side-effects of drugs and
 898 complications of immunosuppression, the effects of transplantation and immunosuppressive
 899 agents on growth and development, differential diagnosis of liver dysfunction in the allograft
 900 recipient, manifestation of rejection in the pediatric patient, histological interpretation of
 901 allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long-term
 902 outpatient care of pediatric allograft recipients including management of hypertension,
 903 nutritional support, and drug dosage, including antibiotics, in the pediatric patient.
- 904 5. The physician should have observed at least 3 organ procurements and 3 liver transplants. In
 905 addition, the physician should have observed the evaluation, the donation process, and the
 906 care of at least 3 multiple organ donors who donated a liver. If the physician has completed
 907 these observations, they must be documented in a log that includes the date of procurement,
 908 location of the donor and Donor ID.
- 909 6. The following letters are submitted directly to the OPTN Contractor:
- 910 a. A letter from the director of the pediatric transplant hepatology training program, and the
 911 qualified liver transplant physician and surgeon of the fellowship training program
 912 verifying that the physician has met the above requirements, and is qualified to act as a
 913 liver transplant physician and direct a liver transplant program.
- 914 b. A letter of recommendation from the fellowship training program's primary physician and
 915 transplant program director outlining the physician's overall qualifications to act as a
 916 primary transplant physician, as well as the physician's personal integrity, honesty, and
 917 familiarity with and experience in adhering to OPTN obligations, and any other matters
 918 judged appropriate. The MPSC may request additional recommendation letters from the
 919 primary physician, primary surgeon, director, or others affiliated with any transplant
 920 program previously served by the physician, at its discretion.
- 921 c. A letter from the physician that details the training and experience the physician gained in
 922 liver transplantation.

924 **E. Combined Pediatric Gastroenterology/Transplant Hepatology**

925 **Training and Experience Pathway**

926 A physician can meet the requirements for primary liver transplant physician if the following
 927 conditions are met:

- 928
- 929 1. The physician has current board certification in pediatric gastroenterology by the American
 930 Board of Pediatrics, the Royal College of Physicians and Surgeons of Canada, or the foreign
 931 equivalent, or is approved by the American Board of Pediatrics to take the certifying exam.
- 932 2. The physician gained a minimum of 2 years of experience during or after fellowship, or
 933 accumulated during both periods, at a liver transplant program.
- 934 3. During the 2 or more years of accumulated experience, the physician was directly involved in
 935 the primary care of 10 or more newly transplanted pediatric liver recipients and followed 20
 936 newly transplanted liver recipients for a minimum of 6 months from the time of transplant,
 937 under the direct supervision of a qualified liver transplant physician and along with a qualified
 938 liver transplant surgeon. The physician must have been directly involved in the pre-operative,

939 peri-operative and post-operative care of 10 or more pediatric liver transplant recipients.
 940 This care must be documented in a log that includes at the date of transplant and the medical
 941 record number or other unique identifier that can be verified by the OPTN Contractor. This
 942 recipient log must be signed by the training program director or the transplant program
 943 primary transplant physician.

- 944 4. The individual has maintained a current working knowledge of liver transplantation, defined
 945 as direct involvement in liver transplant patient care within the last 2 years. This includes the
 946 management of pediatric patients with end-stage liver disease, the selection of appropriate
 947 pediatric recipients for transplantation, donor selection, histocompatibility and tissue typing,
 948 immediate post-operative care including those issues of management unique to the pediatric
 949 recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the
 950 pediatric recipient including side-effects of drugs and complications of immunosuppression,
 951 the effects of transplantation and immunosuppressive agents on growth and development,
 952 differential diagnosis of liver dysfunction in the allograft recipient, manifestation of rejection in
 953 the pediatric patient, histological interpretation of allograft biopsies, interpretation of ancillary
 954 tests for liver dysfunction, and long-term outpatient care of pediatric allograft recipients
 955 including management of hypertension, nutritional support, and drug dosage, including
 956 antibiotics, in the pediatric patient.
- 957 5. The physician should have observed at least 3 organ procurements and 3 liver transplants. In
 958 addition, the physician should have observed the evaluation of donor, the donation process,
 959 and the management of at least 3 multiple organ donors who donated a liver. If the physician
 960 has completed these observations, they must be documented in a log that includes the date
 961 of procurement, location of the donor, and Donor ID.
- 962 6. The following letters are submitted directly to the OPTN Contractor:
- 963 a. A letter from the qualified liver transplant physician and surgeon who have been directly
 964 involved with the physician documenting the physician's experience and competence.
- 965 b. A letter of recommendation from the primary physician and transplant program director at
 966 the fellowship training program or transplant program last served by the physician
 967 outlining the physician's overall qualifications to act as a primary transplant physician, as
 968 well as the physician's personal integrity, honesty, and familiarity with and experience in
 969 adhering to OPTN obligations, and any other matters judged appropriate. The MPSC
 970 may request additional recommendation letters from the primary physician, primary
 971 surgeon, director, or others affiliated with any transplant program previously served by
 972 the physician, at its discretion.
- 973 c. A letter from the physician that details the training and experience the physician gained in
 974 liver transplantation.
- 975

976 **G. Conditional Approval for Primary Transplant Physician**

977 If the primary liver transplant physician changes at an approved liver transplant program, a
 978 physician can serve as the primary liver transplant physician for a maximum of 12 months if the
 979 following conditions are met:

- 980 ~~1. The physician has current board certification in gastroenterology by the American Board of~~
 981 ~~Internal Medicine, the American Board of Pediatrics, or the foreign equivalent.~~
- 982 21. The physician has been involved in the primary care of 25 or more newly transplanted liver
 983 recipients, and has followed these patients for at least 3 months from the time of their
 984 transplant. This care must be documented in a recipient log that includes the date of
 985 transplant and the medical record number or other unique identifier that can be verified by the

- 986 OPTN Contractor. This log must be signed by the program director, division chief, or
 987 department chair from the transplant program where the experience was gained.
- 988 32. The physician has maintained a current working knowledge of liver transplantation, defined as
 989 direct involvement in liver transplant patient care during the last 2 years. This includes the
 990 management of patients with end stage liver disease, acute liver failure, the selection of
 991 appropriate recipients for transplantation, donor selection, histocompatibility and tissue
 992 typing, immediate post-operative patient care, the use of immunosuppressive therapy
 993 including side effects of the drugs and complications of immunosuppression, differential
 994 diagnosis of liver allograft dysfunction, histologic interpretation of allograft biopsies,
 995 interpretation of ancillary tests for liver dysfunction, and long term outpatient care.
- 996 43. The physician has 12 months experience on an active liver transplant service as the primary
 997 liver transplant physician or under the direct supervision of a qualified liver transplant
 998 physician along with a liver transplant surgeon at a designated liver transplant program ~~or the~~
 999 ~~foreign equivalent~~. These 12 months of experience must be acquired within a 2-year period.
- 1000 54. The physician should have observed at least 3 organ procurements and 3 liver transplants.
 1001 The physician should also have observed the evaluation, the donation process, and
 1002 management of at least 3 multiple organ donors who are donating a liver. If the physician has
 1003 completed these observations, they must be documented in a log that includes the date of
 1004 procurement, location of the donor, and Donor ID.
- 1005 65. The transplant program submits activity reports to the OPTN Contractor every 2 months
 1006 describing the transplant activity, transplant outcomes, physician recruitment efforts, and
 1007 other operating conditions as required by the MPSC to demonstrate the ongoing quality and
 1008 efficient patient care at the program. The activity reports must also demonstrate that the
 1009 physician is making sufficient progress to meet the required involvement in the primary care
 1010 of 50 or more liver transplant recipients, or that the program is making sufficient progress in
 1011 recruiting a physician who meets all requirements for primary liver transplant physician and
 1012 who will be on site and approved by the MPSC to assume the role of primary physician by the
 1013 end of the 12 month conditional approval period.
- 1014 76. The program has established and documented a consulting relationship with counterparts at
 1015 another liver transplant program.
- 1016 87. The following letters are submitted directly to the OPTN Contractor:
- 1017 a. A letter from the qualified liver transplant physician and surgeon who were directly
 1018 involved with the physician verifying that the physician has satisfactorily met the above
 1019 requirements to become the primary transplant physician of a liver transplant program.
- 1020 b. A letter of recommendation from the primary physician and transplant program director at
 1021 the transplant program last served by the physician outlining the physician's overall
 1022 qualifications to act as a primary transplant physician, as well as the physician's personal
 1023 integrity, honesty, and familiarity with and experience in adhering to OPTN obligations,
 1024 and any other matters judged appropriate. The MPSC may request additional
 1025 recommendation letters from the primary physician, primary surgeon, director, or others
 1026 affiliated with any transplant program previously served by the physician, at its discretion.
- 1027 c. A letter from the physician sends that details the training and experience the physician
 1028 gained in liver transplantation.
- 1029

1030 **F.4 Requirements for Director of Liver Transplant Anesthesia**

1031 Liver transplant programs must designate a director of liver transplant anesthesia who has expertise in
 1032 the area of peri-operative care of liver transplant patients and can serve as an advisor to other members
 1033 of the team.

- 1034 1. The director of liver transplant anesthesia must be a Diplomate of the American Board of
 1035 Anesthesiology, ~~or the foreign equivalent.~~
 1036 2. In place of current certification by the American Board of Anesthesiology, the director of liver
 1037 transplant anesthesia must provide to the OPTN Contractor two letters of recommendation from
 1038 current directors of liver transplant anesthesia at a designated liver program who are not employed
 1039 by the applying member. These letters must address:
 1040 a. Why an exception is reasonable.
 1041 b. The anesthesiologist's overall qualifications to act as a director of liver transplant
 1042 anesthesiology.
 1043 c. Any other matters judged appropriate.
 1044

1045 F.10 Primary Intestine Transplant Surgeon Requirements

1046 A designated intestine transplant program must have a primary surgeon who meets *all* of the following
 1048 requirements:

- 1049
 1050 1. The surgeon must have an M.D., D.O., or equivalent degree from another country, with a current
 1051 license to practice medicine in the hospital's state or jurisdiction.
 1052 2. The surgeon must be accepted onto the hospital's medical staff, and be on site at this hospital.
 1053 3. The surgeon must have documentation from the hospital credentialing committee that it has verified
 1054 the surgeon's state license, board certification, training, and transplant continuing medical education,
 1055 and that the surgeon is currently a member in good standing on the hospital's medical staff.
 1056 4. The surgeon must have current certification by the American Board of Surgery, the American Board
 1057 of Osteopathic Surgery, or the Royal College of Physicians and Surgeons of Canada ~~foreign~~
 1058 ~~equivalent.~~
 1059

1060 In place of current certification by the American Board of Surgery, the American Board of Osteopathic
 1061 Surgery, or the Royal College of Physicians and Surgeons of Canada, the surgeon must:

- 1062 a. Be ineligible for American board certification.
 1063 b. Provide a plan for continuing education that is comparable to American board maintenance of
 1064 certification. This plan must at least require that the surgeon obtains 60 hours of Category I
 1065 continuing medical education (CME) credits with self-assessment that are relevant to the
 1066 individual's practice every three years. Self-assessment is defined as a written or electronic
 1067 question-and-answer exercise that assesses understanding of the material in the CME program.
 1068 A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve
 1069 an acceptable self-assessment score are allowed. The transplant hospital must document
 1070 completion of this continuing education.
 1071 c. Provide to the OPTN Contractor two letters of recommendation from directors of designated
 1072 transplant programs not employed by the applying hospital. These letters must address:
 1073 i. Why an exception is reasonable.
 1074 ii. The surgeon's overall qualifications to act as a primary intestine transplant surgeon.
 1075 iii. The surgeon's personal integrity, honesty, and familiarity with and experience in adhering to
 1076 OPTN obligations and compliance protocols.
 1077 iv. Any other matters judged appropriate.
 1078

1079 If the surgeon has not adhered to the plan for maintaining continuing education or has not obtained
 1080 the necessary CME credits with self-assessment, the transplant program will have a six-month grace
 1081 period to address these deficiencies. If the surgeon has not fulfilled the requirements after the six-
 1082 month grace period, and a key personnel change application has not been submitted, then the
 1083 transplant program will be referred to the MPSC for appropriate action according to Appendix L of

1084 these Bylaws. If the OPTN Contractor becomes aware that a primary surgeon has not been compliant
 1085 for 12 months or more and deficiencies still exist, then the transplant program will not be given any
 1086 grace period and will be referred to the MPSC for appropriate action according to Appendix L of these
 1087 Bylaws.

1088
 1089 5. ~~In addition, t~~ The primary transplant surgeon must have completed at least one of the training or
 1090 experience pathways listed below:

- 1091 • a. The primary intestine transplant surgeon full approval pathway, as described in *Section F.10.A*
- 1092 below.
- 1093 • b. The primary intestine transplant surgeon conditional pathway, as described in *Section F.10.B*
- 1094 below.

1095
 1096 **A. Full Intestine Surgeon Approval Pathway**

1097
 1098 Surgeons can be fully approved as a primary intestine transplant surgeon by completing a formal
 1099 transplant fellowship or by completing clinical experience at an intestine transplant program if *all*
 1100 of the following conditions are met:

- 1101 1. The surgeon performed 7 or more intestine transplants at a designated intestine transplant
 1102 program, to include the isolated bowel and composite grafts, as primary surgeon or first
 1103 assistant within the last 10 years. These transplants must be documented in a log that
 1104 includes the date of transplant, the role of the surgeon in the procedure, and the medical
 1105 record number or other unique identifier that can be verified by the OPTN Contractor. This log
 1106 must be signed by the program director, division chief, or department chair from the program
 1107 where the experience or training was gained.
- 1108 2. The surgeon performed 3 or more intestine procurements as primary surgeon or first
 1109 assistant. These procurements must include selection and evaluation of the donor. These
 1110 procurements must include 1 or more organ recovery that includes a liver. These procedures
 1111 must be documented in a log that includes the date of procurement, location of the donor,
 1112 and Donor ID. This log must be signed by the program director, division chief, or department
 1113 chair from the program where the experience or training was gained.
- 1114 3. The surgeon has maintained a current working knowledge of intestine transplantation,
 1115 defined as direct involvement in intestine transplant patient care within the last 5 years. This
 1116 includes the management of patients with short bowel syndrome or intestinal failure, the
 1117 selection of appropriate recipients for transplantation, donor selection, histocompatibility and
 1118 tissue typing, performing the transplant operation, immediate postoperative and continuing
 1119 inpatient care, the use of immunosuppressive therapy including side effects of the drugs and
 1120 complications of immunosuppression, differential diagnosis of intestine allograft dysfunction,
 1121 histologic interpretation of allograft biopsies, interpretation of ancillary tests for intestine
 1122 dysfunction, and long term outpatient care.
- 1123 4. The training was completed at a hospital with a transplant training program approved by the
 1124 American Society of Transplant Surgeons (ASTS) or accepted by the OPTN Contractor as
 1125 described in *Section F.13 Approved Intestine Transplant Surgeon Fellowship Training*
 1126 *Programs* that follows. ~~Foreign training programs must be accepted as equivalent by the~~
 1127 ~~Membership and Professional Standards Committee (MPSC).~~
- 1128 5. The following letters are submitted to the OPTN Contractor:
 1129 a. A letter from the qualified intestine transplant physician and surgeon who have been
 1130 directly involved with the surgeon documenting the surgeon's experience and
 1131 competence.
 1132 b. A letter of recommendation from the primary surgeon and transplant program director at
 1133 the fellowship training program or transplant program last served by the surgeon outlining
 1134 the surgeon's overall qualifications to act as a primary transplant surgeon, as well as the
 1135 surgeon's personal integrity, honesty, and familiarity with and experience in adhering to
 1136 OPTN obligations, and any other matters judged appropriate. The MPSC may request
 1137 additional recommendation letters from the primary surgeon, primary physician surgeon,
 1138

- 1139 director, or others affiliated with any transplant program previously served by the
 1140 physician, at its discretion.
 1141 c. A letter from the surgeon that details the training and experience the surgeon gained in
 1142 intestine transplantation.
 1143

1144 **B. Conditional Intestine Surgeon Approval Pathway**
 1145

1146 Surgeons can meet the requirements for conditional approval as primary intestine transplant
 1147 surgeon through experience gained during or post-fellowship, if *all* of the following conditions are
 1148 met:
 1149

- 1150 1. The surgeon has performed at least 4 intestine transplants that include the isolated bowel
 1151 and composite grafts and must perform 3 or more intestine transplants over the next 3
 1152 consecutive years as primary surgeon or first assistant at a designated intestine transplant
 1153 program, ~~or its foreign equivalent~~. These transplants must be documented in a log that
 1154 includes the date of transplant, the role of the surgeon in the procedure, and medical record
 1155 number or other unique identifier that can be verified by the OPTN Contractor. This log must
 1156 be signed by the program director, division chief, or department chair from the program
 1157 where the experience or training was gained. Each year of the surgeon’s experience must be
 1158 substantive and relevant and include pre-operative assessment of intestine transplant
 1159 candidates, transplants performed as primary surgeon or first assistant and post-operative
 1160 management of intestine recipients.
- 1161 2. The surgeon has performed at least 3 intestine procurements as primary surgeon or first
 1162 assistant. These procurements must include at least 1 procurement of a graft that includes a
 1163 liver, and selection and evaluation of the donor. This procedure must be documented in a log
 1164 that includes the date of procurement, location of the donor, and Donor ID.
- 1165 3. The surgeon has maintained a current working knowledge of intestine transplantation,
 1166 defined as direct involvement in intestine transplant patient care within the last 5 years. This
 1167 includes the management of patients with short bowel syndrome or intestinal failure, the
 1168 selection of appropriate recipients for transplantation, donor selection, histocompatibility and
 1169 tissue typing, performing the transplant operation, immediate postoperative and continuing
 1170 inpatient care, the use of immunosuppressive therapy including side effects of the drugs and
 1171 complications of immunosuppression, differential diagnosis of intestine dysfunction in the
 1172 allograft recipient, histologic interpretation of allograft biopsies, interpretation of ancillary tests
 1173 for intestine dysfunction, and long term outpatient care.
- 1174 4. The surgeon develops a formal mentor relationship with a primary intestine transplant
 1175 surgeon at another approved intestine transplant program. The mentor will discuss program
 1176 requirements, patient and donor selection, recipient management, and be available for
 1177 consultation as required until full approval conditions are all met.
- 1178 5. The following letters are sent to the OPTN Contractor:
 1179 a. A letter from the director of the transplant program and chair of the department or hospital
 1180 credentialing committee verifying that the surgeon has met the above requirements and
 1181 is qualified to direct an intestine transplant program.
 1182 b. A letter of recommendation from the primary surgeon and transplant program director at
 1183 the transplant program last served by the surgeon, outlining the surgeon’s overall
 1184 qualifications to act as primary transplant surgeon, as well as the surgeon’s personal
 1185 integrity, honesty, familiarity with and experience in adhering to OPTN obligations, and
 1186 other matters judged appropriate. The MPSC may request additional recommendation
 1187 letters from the primary surgeon, primary physician, director, or others affiliated with any
 1188 transplant program previously served by the surgeon, at its discretion.
 1189 c. A letter from the surgeon that details the training and experience the surgeon gained in
 1190 intestine transplantation as well as detailing the plan for obtaining full approval within the
 1191 3-year conditional approval period.
 1192 d. A letter of commitment from the surgeon’s mentor supporting the detailed plan developed
 1193 by the surgeon to obtain full approval.
 1194

F.11 Primary Intestine Transplant Physician Requirements

A designated intestine transplant program must have a primary physician who meets *all* the following requirements:

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

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

- a. Be ineligible for American board certification.
- b. Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that the physician obtains 60 hours of Category I continuing medical education (CME) credits with self-assessment that are relevant to the individual’s practice every three years. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program. A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve an acceptable self-assessment score are allowed. The transplant hospital must document completion of this continuing education.
- c. Provide to the OPTN Contractor two letters of recommendation from directors of designated transplant programs not employed by the applying hospital. These letters must address:
 - i. Why an exception is reasonable.
 - ii. The physician’s overall qualifications to act as a primary intestine transplant physician.
 - iii. The physician’s personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
 - iv. Any other matters judged appropriate.

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

5. ~~In addition, t~~ The primary physician must have completed at least one of the training or experience pathways listed below:
 - a. The primary intestine transplant physician full approval pathway, as described in Section F.11.A below.
 - b. The primary intestine transplant physician conditional pathway, as described in Section F.11.B below.

1246
 1247 Any physician who meets the criteria as a primary intestine transplant physician can function as the
 1248 primary intestine transplant physician for a program that serves predominantly pediatric patients, if a
 1249 pediatric gastroenterologist is also involved in the care of the transplant recipients.
 1250

1251 **A. Full Intestine Physician Approval Pathway**

1252
 1253 Physicians can meet the requirements for a primary intestine transplant physician during the
 1254 physician's adult gastroenterology fellowship, pediatric gastroenterology fellowship, or through
 1255 acquired clinical experience (including accumulated training during any fellowships) if all of the
 1256 following conditions are met:
 1257

- 1258 1. The physician has been directly involved within the last 10 years in the primary care of 7 or
 1259 more newly transplanted intestine recipients and continued to follow these recipients for a
 1260 minimum of 3 months from the time of transplant. This clinical experience must be gained as
 1261 the primary intestine transplant physician or under the direct supervision of a intestine
 1262 transplant physician and in conjunction with an intestine transplant surgeon at a designated
 1263 intestine transplant program. This care must be documented in a log that includes the date of
 1264 transplant and the medical record number or other unique identifier that can be verified by the
 1265 OPTN Contractor. This log must be signed by the program director, division chief, or
 1266 department chair from the program where the experience or training was gained.
- 1267 2. The physician has maintained a current working knowledge of intestine transplantation,
 1268 defined as direct involvement in intestine transplant patient care within the last 5 years. This
 1269 includes the management of patients with intestinal failure, the selection of appropriate
 1270 recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate
 1271 post-operative patient care, the use of immunosuppressive therapy including side effects of
 1272 the drugs and complications of immunosuppression, differential diagnosis of intestine
 1273 allograft dysfunction, histologic interpretation of allograft biopsies, interpretation of ancillary
 1274 tests for intestine dysfunction, and long term outpatient care.
- 1275 3. The physician must have observed at least 1 isolated intestine transplant and at least 1
 1276 combined liver-intestine or multi-visceral transplant.
- 1277 4. The following letters are submitted to the OPTN Contractor:
 1278 a. A letter from the transplant program director documenting the physician's experience and
 1279 training.
 1280 b. A letter of recommendation from the primary physician and transplant program director at
 1281 the fellowship training program or transplant program last served by the physician
 1282 outlining the physician's overall qualifications to act as a primary transplant physician, as
 1283 well as the physician's personal integrity, honesty, and familiarity with and experience in
 1284 adhering to OPTN obligations, and any other matters judged appropriate. The MPSC
 1285 may request additional recommendation letters from the primary physician, primary
 1286 surgeon, director, or others affiliated with any transplant program previously served by
 1287 the physician, at its discretion.
 1288 c. A letter from the physician that details the training and experience the physician gained in
 1289 intestine transplantation.
 1290

1291 **B. Conditional Intestine Physician Approval Pathway**

1292
 1293 Physicians can meet the requirements for approval as primary intestine transplant physician
 1294 through a conditional approval pathway if *all* of the following conditions are met:
 1295

- 1296 ~~1. The physician has current board certification in gastroenterology by the American Board of~~
 1297 ~~Internal Medicine, the American Board of Pediatrics, or the foreign equivalent.~~
- 1298 2~~1~~. The physician has been involved in the primary care of at least 4 newly transplanted intestine
 1299 recipients, and has followed these patients for at least 3 months from the time of their
 1300 transplant. Additionally, the physician must become involved in the care of 3 or more intestine

- 1301 recipients over the next 3 consecutive years. This clinical experience must be gained as the
 1302 primary intestine transplant physician or under the direct supervision of a intestine transplant
 1303 physician and in conjunction with an intestine transplant surgeon at a designated intestine
 1304 transplant program. This care must be documented in a recipient log that includes the date of
 1305 transplant and the medical record number or other unique identifier that can be verified by the
 1306 OPTN Contractor. This log must be signed by the program director, division chief, or
 1307 department chair from the program where the experience or training was gained.
- 1308 32. The physician has maintained a current working knowledge of intestine transplantation,
 1309 defined as direct involvement in intestine transplant patient care within the last 5 years. This
 1310 includes the management of patients with intestine failure, the selection of appropriate
 1311 recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate
 1312 post-operative patient care, the use of immunosuppressive therapy including side effects of
 1313 the drugs and complications of immunosuppression, differential diagnosis of intestine
 1314 allograft dysfunction, histologic interpretation of allograft biopsies, interpretation of ancillary
 1315 tests for intestine dysfunction, and long term outpatient care.
- 1316 43. The physician has 12 months experience as the primary intestine transplant physician or
 1317 under the direct supervision of a qualified intestine transplant physician along with an
 1318 intestine transplant surgeon at a designated intestine transplant program, ~~or the foreign~~
 1319 ~~equivalent.~~ These 12 months of experience must be acquired within a 2-year period.
- 1320 54. The physician develops a formal mentor relationship with a primary intestine transplant
 1321 physician at another approved designated intestine transplant program. The mentor will
 1322 discuss program requirements, patient and donor selection, recipient management, and be
 1323 available for consultation as required.
- 1324 65. The following letters are submitted to the OPTN Contractor:
- 1325 a. A letter from the qualified intestine transplant physician and surgeon who were directly
 1326 involved with the physician verifying that the physician has satisfactorily met the above
 1327 requirements to become the primary transplant physician of an intestine transplant
 1328 program.
- 1329 b. A letter of recommendation from the primary physician and transplant program director at
 1330 the transplant program last served by the physician outlining the physician's overall
 1331 qualifications to act as a primary transplant physician, as well as the physician's personal
 1332 integrity, honesty, and familiarity with and experience in adhering to OPTN obligations,
 1333 and any other matters judged appropriate. The MPSC may request additional
 1334 recommendation letters from the primary physician, primary surgeon, director, or others
 1335 affiliated with any transplant program previously served by the physician, at its discretion.
- 1336 c. A letter from the physician that details the training and experience the physician gained in
 1337 intestine transplantation as well as a detailed plan for obtaining full approval.
- 1338 d. A letter of commitment from the physician's mentor supporting the detailed plan
 1339 developed by the physician to obtain full approval.
- 1340

1341 **Appendix G:**

1342 **Membership and Personnel Requirements for** 1343 **Pancreas and Pancreatic Islet Transplant Programs**

1344 1345 **G.2 Primary Pancreas Transplant Surgeon Requirements**

1346 A designated pancreas transplant program must have a primary surgeon who meets *all* the following
 1347 requirements:

- 1348
- 1349 1. The surgeon must have an M.D., D.O., or equivalent degree from another country, with a current
 1350 license to practice medicine in the hospital's state or jurisdiction.

- 1351 2. The surgeon must be accepted onto the hospital’s medical staff, and be on site at this hospital.
 1352 3. The surgeon must have documentation from the hospital credentialing committee that it has verified
 1353 the surgeon’s state license, board certification, training, and transplant continuing medical education,
 1354 and that the surgeon is currently a member in good standing of the hospital’s medical staff.
 1355 4. The surgeon must have current certification by the American Board of Surgery, the American Board
 1356 of Urology, the American Board of Osteopathic Surgery, or the Royal College of Physicians and
 1357 Surgeons of Canada, ~~foreign equivalent~~ In the case of a surgeon who has just completed training and
 1358 whose ~~board American Board of Urology certification in urology~~ certification is pending, the Membership and
 1359 Professional Standards Committee (MPSC) may grant conditional approval for ~~42~~16 months to allow
 1360 time for the surgeon to complete board certification, with the possibility of ~~renewal for~~ one additional
 1361 12~~16~~-month ~~period~~ extension.
 1362

1363 In place of current certification by the American Board of Surgery, the American Board of Urology, the
 1364 American Board of Osteopathic Surgery, the Royal College of Physicians and Surgeons of Canada,
 1365 or pending certification by the American Board of Urology, the surgeon must:

- 1366 a. Be ineligible for American board certification.
 1367 b. Provide a plan for continuing education that is comparable to American board maintenance of
 1368 certification. This plan must at least require that the surgeon obtains 60 hours of Category I
 1369 continuing medical education (CME) credits with self-assessment that are relevant to the
 1370 individual’s practice every three years. Self-assessment is defined as a written or electronic
 1371 question-and-answer exercise that assesses understanding of the material in the CME program.
 1372 A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve
 1373 an acceptable self-assessment score are allowed. The transplant hospital must document
 1374 completion of this continuing education.
 1375 c. Provide to the OPTN Contractor two letters of recommendation from directors of designated
 1376 transplant programs not employed by the applying hospital. These letters must address:
 1377 i. Why an exception is reasonable.
 1378 ii. The surgeon’s overall qualifications to act as a primary pancreas transplant surgeon.
 1379 iii. The surgeon’s personal integrity, honesty, and familiarity with and experience in adhering to
 1380 OPTN obligations and compliance protocols.
 1381 iv. Any other matters judged appropriate.
 1382

1383 If the surgeon has not adhered to the plan for maintaining continuing education or has not obtained
 1384 the necessary CME credits with self-assessment, the transplant program will have a six-month grace
 1385 period to address these deficiencies. If the surgeon has not fulfilled the requirements after the six-
 1386 month grace period, and a key personnel change application has not been submitted, then the
 1387 transplant program will be referred to the MPSC for appropriate action according to Appendix L of
 1388 these Bylaws. If the OPTN Contractor becomes aware that a primary surgeon has not been compliant
 1389 for 12 months or more and deficiencies still exist, then the transplant program will not be given any
 1390 grace period and will be referred to the MPSC for appropriate action according to Appendix L of these
 1391 Bylaws.

- 1392 5. In addition, t The primary transplant surgeon must have completed at least one of the training or
 1393 experience pathways listed below:
 1394 ■ a. The formal 2-year transplant fellowship pathway, as described in Section G.2.A. Formal 2-year
 1395 Transplant Fellowship Pathway below.
 1396 ■ b. The pancreas transplant program clinical experience pathway, as described in Section G.2.B.
 1397 Clinical Experience Pathway below.

- 1398 ■ c. The alternative pathway for predominantly pediatric programs, as described in Section G.2.C.
- 1399 Alternative Pathway for Predominantly Pediatric Programs below.
- 1400

A. Formal 2-year Transplant Fellowship Pathway

1402 Surgeons can meet the training requirements for primary pancreas transplant surgeon by

1403 completing a 2-year transplant fellowship if the following conditions are met:

1404

- 1405 1. The surgeon performed at least 15 pancreas transplants as primary surgeon or first assistant
- 1406 during the 2-year fellowship period. These transplants must be documented in a log that
- 1407 includes the date of transplant, the role of the surgeon in the procedure, and medical record
- 1408 number or other unique identifier that can be verified by the OPTN Contractor. This log must
- 1409 be signed by the director of the training program.
- 1410 2. The surgeon performed at least 10 pancreas procurements as primary surgeon or first
- 1411 assistant during the 2-year period. These cases must be documented in a log that includes
- 1412 the date of procurement, location of the donor, and Donor ID. This log must be signed by the
- 1413 director of the training program.
- 1414 3. The surgeon has maintained a current working knowledge of pancreas transplantation,
- 1415 defined as direct involvement in patient care within the last 2 years. This includes the
- 1416 management of patients with diabetes mellitus, the selection of appropriate recipients for
- 1417 transplantation, donor selection, histocompatibility and tissue typing, performing the
- 1418 transplant operation, immediate postoperative and continuing inpatient care, the use of
- 1419 immunosuppressive therapy including side effects of the drugs and complications of
- 1420 immunosuppression, differential diagnosis of pancreas dysfunction in the allograft recipient,
- 1421 histological interpretation of allograft biopsies, interpretation of ancillary tests for pancreatic
- 1422 dysfunction, and long term outpatient care.
- 1423 4. The training was completed at a hospital with a pancreas transplant training program
- 1424 approved by the Fellowship Training Committee of the American Society of Transplant
- 1425 Surgeons, the Royal College of Physicians and Surgeons of Canada, or accepted by the
- 1426 OPTN Contractor as described in *Section G.7. Approved Pancreas Transplant Surgeon*
- 1427 *Fellowship Training Programs* that follows. ~~Foreign training programs will be reviewed by the~~
- 1428 ~~MPSC and only those programs that are accepted as equivalent will be granted approval.~~
- 1429 5. The following letters are submitted directly to the OPTN Contractor:
- 1430 a. A letter from the director of the training program and chairman of the department or
- 1431 hospital credentialing committee verifying that the fellow has met the above requirements
- 1432 and is qualified to direct a pancreas transplant program.
- 1433 b. A letter of recommendation from the fellowship training program’s primary surgeon and
- 1434 transplant program director outlining the surgeon’s overall qualifications to act as primary
- 1435 transplant surgeon as well as the surgeon’s personal integrity, honesty, familiarity with
- 1436 and experience in adhering to OPTN obligations, and any other matters judged
- 1437 appropriate. The MPSC may request similar letters of recommendation from the primary
- 1438 physician, primary surgeon, director, or others affiliated with any transplant program
- 1439 previously served by the surgeon, at its discretion.
- 1440 c. A letter from the surgeon that details the training and experience the surgeon has gained
- 1441 in pancreas transplantation.
- 1442

B. Clinical Experience Pathway

1444 Surgeons can meet the requirements for primary pancreas transplant surgeon through clinical

1445 experience gained post-fellowship if the following conditions are met:

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1. The surgeon has performed 20 or more pancreas transplants over a 2 to 5-year period as primary surgeon or first assistant, at a designated pancreas transplant program ~~or its foreign equivalent~~. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and medical record number or other unique identifier that can be verified by the OPTN Contractor. This log should be signed by the program director, division chief, or department chair from the program where the experience was gained. Each year of the surgeon’s experience must be substantive and relevant and include pre-operative assessment of pancreas transplant candidates, transplants performed as primary surgeon or first assistant, and post-operative care of pancreas recipients.
 2. The surgeon has performed at least 10 pancreas procurements as primary surgeon or first assistant. These procurements must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
 3. The surgeon 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 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 pancreatic dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for pancreatic dysfunction, and long term outpatient care.
 4. The following letters are submitted directly to the OPTN Contractor:
 - a. A letter from the director of the transplant 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 pancreas transplant program.
 - b. A letter of recommendation from the primary surgeon and director at the transplant program last served by the surgeon 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 individual, at its discretion.
 - c. A letter from the surgeon that details the training and experience the surgeon has gained in pancreas transplantation.

1483 **G.3 Primary Pancreas Transplant Physician Requirements**

1484 A designated pancreas transplant program must have a primary physician who meets *all* the following

1485 requirements:

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

1493 4. The physician must have current board certification in nephrology, endocrinology, or diabetology by
 1494 the American Board of Internal Medicine, the American Board of Pediatrics, or the Royal College of
 1495 Physicians and Surgeons of Canada ~~foreign equivalent~~.

1496
 1497 In place of current certification in nephrology, endocrinology, or diabetology by the American Board of
 1498 Internal Medicine, the American Board of Pediatrics, or the Royal College of Physicians and
 1499 Surgeons of Canada, the physician must:

- 1500 a. Be ineligible for American board certification.
- 1501 b. Provide a plan for continuing education that is comparable to American board maintenance of
 1502 certification. This plan must at least require that the physician obtains 60 hours of Category I
 1503 continuing medical education (CME) credits with self-assessment that are relevant to the
 1504 individual's practice every three years. Self-assessment is defined as a written or electronic
 1505 question-and-answer exercise that assesses understanding of the material in the CME program.
 1506 A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve
 1507 an acceptable self-assessment score are allowed. The transplant hospital must document
 1508 completion of this continuing education.
- 1509 c. Provide to the OPTN Contractor two letters of recommendation from directors of designated
 1510 transplant programs not employed by the applying hospital. These letters must address:
 - 1511 i. Why an exception is reasonable.
 - 1512 ii. The physician's overall qualifications to act as a primary pancreas transplant physician.
 - 1513 iii. The physician's personal integrity, honesty, and familiarity with and experience in adhering to
 1514 OPTN obligations and compliance protocols.
 - 1515 iv. Any other matters judged appropriate.

1516
 1517 If the physician has not adhered to the plan for maintaining continuing education or has not obtained
 1518 the necessary CME credits with self-assessment, the transplant program will have a six-month grace
 1519 period to address these deficiencies. If the physician has not fulfilled the requirements after the six-
 1520 month grace period, and a key personnel change application has not been submitted, then the
 1521 transplant program will be referred to the MPSC for appropriate action according to Appendix L of
 1522 these Bylaws. If the OPTN Contractor becomes aware that a primary physician has not been
 1523 compliant for 12 months or more and deficiencies still exist, then the transplant program will not be
 1524 given any grace period and will be referred to the MPSC for appropriate action according to Appendix
 1525 L of these Bylaws.

- 1526 5. ~~In addition, t~~ The primary transplant physician must have completed at least one of the training or
 1527 ~~experience~~ pathways listed below:
- 1528 ■ a. The 12-month pancreas transplant fellowship pathway, as described in Section G.3.A. Twelve-
 1529 month Transplant Medicine Fellowship Pathway below.
 - 1530 ■ b. The clinical experience pathway, as described in Section G.3.B. Clinical Experience Pathway
 1531 below.
 - 1532 ■ c. The alternative pathway for predominantly pediatric programs, as described in Section G.3.C.
 1533 Alternative Pathway for Predominantly Pediatric Programs below.
 - 1534 ■ d. The conditional approval pathway, as described in Section G.3.D. Conditional Approval for
 1535 Primary Transplant Physician below, if the primary pancreas transplant physician changes at an
 1536 approved pancreas transplant program.

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1538

B. Clinical Experience Pathway

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

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1. The physician has been directly involved in the primary care of 15 or more newly transplanted pancreas recipients and continued to follow these recipients for a minimum of 3 months from the time of transplant. This patient care must have been provided over a 2 to 5-year period on an active pancreas transplant service as the primary pancreas transplant physician or under the direct supervision of a qualified pancreas transplant physician along with a pancreas transplant surgeon at a designated pancreas transplant program, ~~or the foreign equivalent.~~

1543

The 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 recipient log should be signed by the program director, division chief, or department chair from the program where the physician gained this experience.

1548

2. 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.

1550

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

1553

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

1554

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

1555

b. A letter of recommendation from the primary physician and director at the transplant program last served by the physician outlining the physician's overall qualifications to act as 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 the physician previously served, at its discretion.

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

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D. Conditional Approval for Primary Transplant Physician

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

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1583

1584

- 1585 1. The physician has been involved in the primary care of 8 or more newly transplanted
1586 pancreas recipients, and has followed these patients for at least 3 months from the time of
1587 their transplant. This care must be documented in a recipient log that includes the date of
1588 transplant and the medical record number or other unique identifier that can be verified by the
1589 OPTN Contractor. This log should be signed by the program director, division chief, or
1590 department chair from the transplant program where the experience was gained.
- 1591 2. The physician has maintained a current working knowledge of pancreas transplantation,
1592 defined as direct involvement in pancreas transplant patient care within the last 2 years. This
1593 includes the management of patients with end stage pancreas disease, the selection of
1594 appropriate recipients for transplantation, donor selection, histocompatibility and tissue
1595 typing, immediate post-operative patient care, the use of immunosuppressive therapy
1596 including side effects of the drugs and complications of immunosuppression, differential
1597 diagnosis of pancreas dysfunction in the allograft recipient, histological interpretation of
1598 allograft biopsies, interpretation of ancillary tests for pancreas dysfunction, and long term
1599 outpatient care.
- 1600 3. The physician has 12 months experience on an active pancreas transplant service as the
1601 primary pancreas transplant physician or under the direct supervision of a qualified pancreas
1602 transplant physician along with a pancreas transplant surgeon at a designated pancreas
1603 transplant program, ~~or the foreign equivalent~~. This 12-month period of experience on the
1604 transplant service must have been acquired over a maximum of 2 years.
- 1605 4. The physician should have observed at least 3 organ procurements and 3 pancreas
1606 transplants. The physician should also have observed the evaluation, the donation process,
1607 and management of at least 3 multiple organ donors who are donating a pancreas. If the
1608 physician has completed these observations, they must be documented in a log that includes
1609 the date of procurement, location of the donor, and Donor ID.
- 1610 5. The program has established and documented a consulting relationship with counterparts at
1611 another pancreas transplant program.
- 1612 6. The transplant program submits activity reports to the OPTN Contractor every 2 months
1613 describing the transplant activity, transplant outcomes, physician recruitment efforts, and
1614 other operating conditions as required by the MPSC to demonstrate the ongoing quality and
1615 efficient patient care at the program. The activity reports must also demonstrate that the
1616 physician is making sufficient progress in meeting the required involvement in the primary
1617 care of 15 or more pancreas transplant recipients, or that the program is making sufficient
1618 progress in recruiting a physician who will be on site and approved by the MPSC to assume
1619 the role of Primary Physician by the end of the 12 month conditional approval period.
- 1620 7. The following letters are submitted directly to the OPTN Contractor:
- 1621 a. A letter from the qualified pancreas transplant physician and surgeon who were directly
1622 involved with the physician documenting the physician's experience and competence.
- 1623 b. A letter of recommendation from the primary physician and director at the transplant
1624 program last served by the physician outlining the physician's overall qualifications to act
1625 as a primary transplant physician, as well as the physician's personal integrity, honesty,
1626 and familiarity with and experience in adhering to OPTN obligations, and any other
1627 matters judged appropriate. The MPSC may request additional recommendation letters
1628 from the primary physician, primary surgeon, director, or others affiliated with any
1629 transplant program previously served by the physician, at its discretion.
- 1630 c. A letter from the physician that details the training and experience the physician has
1631 gained in pancreas transplantation.
- 1632

1633 The 12-month conditional approval period begins on the initial approval date granted to the
 1634 personnel change application, whether it is interim approval granted by the MPSC subcommittee,
 1635 or approval granted by the full MPSC. The conditional approval period ends 12 months after the
 1636 first approval date of the personnel change application.

1637
 1638 If the transplant program is unable to demonstrate that it has an individual on site who can meet
 1639 the requirements as described in *Sections G.3.A through G.3.C* above at the end of the 12-month
 1640 conditional approval period, it must inactivate. The requirements for program inactivation are
 1641 described in *Appendix K: Transplant Program Inactivity, Withdrawal and Termination* of these
 1642 Bylaws.

1643
 1644 The MPSC may consider on a case-by-case basis and grant a 6-month extension to a transplant
 1645 program that provides substantial evidence of progress toward fulfilling the requirements but is
 1646 unable to complete the requirements within one year.
 1647

1648 **Appendix H:**

1649 **Membership and Personnel Requirements for Heart**

1650 **Transplant Programs**

1651 **H.2 Primary Heart Transplant Surgeon Requirements**

1652 A designated heart transplant program must have a primary surgeon who meets *all* the following
 1653 requirements:

- 1655 1. The surgeon must have an M.D., D.O., or equivalent degree from another country, with a current
 1656 license to practice medicine in the hospital's state or jurisdiction.
- 1657 2. The surgeon must be accepted onto the hospital's medical staff, and be on site at this hospital.
- 1658 3. The surgeon must have documentation from the hospital credentialing committee that it has verified
 1659 the surgeon's state license, board certification, training, and transplant continuing medical education,
 1660 and that the surgeon is currently a member in good standing of the hospital's medical staff.
- 1661 4. The surgeon must have current certification by the American Board of Thoracic Surgery or current
 1662 certification in thoracic surgery by the Royal College of Physicians and Surgeons of Canada ~~its~~
 1663 ~~foreign equivalent~~. In the case of a surgeon who has just completed training and whose ~~board~~
 1664 certification by the American Board of Thoracic Surgery in thoracic surgery is pending, the
 1665 Membership and Professional Standards Committee (MPSC) may grant conditional approval for 24
 1666 months to allow time for the surgeon to complete board certification, with the possibility of renewal for
 1667 one additional 24-month period.

1668
 1669 In place of current certification by the American Board of Thoracic Surgery, current certification in
 1670 thoracic surgery by the Royal College of Physicians and Surgeons of Canada, or pending certification
 1671 by the American Board of Thoracic Surgery, the surgeon must:

- 1672 a. Be ineligible for American board certification.
- 1673 b. Provide a plan for continuing education that is comparable to American board maintenance of
 1674 certification. This plan must at least require that the surgeon obtains 60 hours of Category I
 1675 continuing medical education (CME) credits with self-assessment that are relevant to the
 1676 individual's practice every three years. Self-assessment is defined as a written or electronic
 1677 question-and-answer exercise that assesses understanding of the material in the CME program.

1678 A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve
 1679 an acceptable self-assessment score are allowed. The transplant hospital must document
 1680 completion of this continuing education.

- 1681 c. Provide to the OPTN Contractor two letters of recommendation from directors of designated
 1682 transplant programs not employed by the applying hospital. These letters must address:
 1683 i. Why an exception is reasonable.
 1684 ii. The surgeon’s overall qualifications to act as a primary heart transplant surgeon.
 1685 iii. The surgeon’s personal integrity, honesty, and familiarity with and experience in adhering to
 1686 OPTN obligations and compliance protocols.
 1687 iv. Any other matters judged appropriate.
 1688

1689 If the surgeon has not adhered to the plan for maintaining continuing education or has not obtained
 1690 the necessary CME credits with self-assessment, the transplant program will have a six-month grace
 1691 period to address these deficiencies. If the surgeon has not fulfilled the requirements after the six-
 1692 month grace period, and a key personnel change application has not been submitted, then the
 1693 transplant program will be referred to the MPSC for appropriate action according to Appendix L of
 1694 these Bylaws. If the OPTN Contractor becomes aware that a primary surgeon has not been compliant
 1695 for 12 months or more and deficiencies still exist, then the transplant program will not be given any
 1696 grace period and will be referred to the MPSC for appropriate action according to Appendix L of these
 1697 Bylaws.

1698 5. In addition, t ~~The primary transplant~~ he primary transplant surgeon must have completed at least one of the training or
 1699 experience pathways listed below:

- 1700 ■ a. The formal cardiothoracic surgery residency pathway, as described in Section H.2.A.
 1701 Cardiothoracic Surgery Residency Pathway below.
- 1702 ■ b. The 12-month heart transplant fellowship pathway, as described in Section H.2.B. Twelve-
 1703 month Heart Transplant Fellowship Pathway below.
- 1704 ■ c. The heart transplant program clinical experience pathway, as described in Section H.2.C.
 1705 Clinical Experience Pathway below.
- 1706 ■ d. The alternative pathway for predominantly pediatric programs, as described in Section H.2.D.
 1707 Alternative Pathway for Predominantly Pediatric Programs below.
 1708

1709 **A. Cardiothoracic Surgery Residency Pathway**

1710 Surgeons can meet the training requirements for primary heart transplant surgeon by completing
 1711 a cardiothoracic surgery residency if *all* the following conditions are met:
 1712

- 1713 1. The surgeon performed at least 20 heart or heart/lung transplants as primary surgeon or first
 1714 assistant during the cardiothoracic surgery residency. These transplants must be
 1715 documented in a log that includes the date of transplant, role of the surgeon in the procedure,
 1716 and medical record number or other unique identifier that can be verified by the OPTN
 1717 Contractor. This log must be signed by the director of the training program.
- 1718 2. The surgeon performed at least 10 heart or heart/lung procurements as primary surgeon or
 1719 first assistant under the supervision of a qualified heart transplant surgeon during the
 1720 cardiothoracic surgery residency. These procedures must be documented in a log that
 1721 includes the date of procurement, location of the donor, and Donor ID. This log must be
 1722 signed by the director of the training program.
- 1723 3. The surgeon has maintained a current working knowledge of all aspects of heart
 1724 transplantation, defined as a direct involvement in heart transplant patient care within the last

- 1725 2 years. This includes performing the transplant operation, donor selection, use of
 1726 mechanical assist devices, recipient selection, post-operative hemodynamic care,
 1727 postoperative immunosuppressive therapy, and outpatient follow-up.
- 1728 4. This training was completed at a hospital with a cardiothoracic surgery training program
 1729 approved by the American Board of Thoracic Surgery, or the Royal College of Physicians and
 1730 Surgeons of Canada, its foreign equivalent, as accepted by the MPSC with a
 1731 recommendation from the Thoracic Organ Transplantation Committee.
- 1732 5. The following letters are submitted directly to the OPTN Contractor:
- 1733 a. A letter from the director of the training program verifying that the surgeon has met the
 1734 above requirements and is qualified to direct a heart transplant program.
- 1735 b. A letter of recommendation from the training program’s primary surgeon and transplant
 1736 program director outlining the individual’s overall qualifications to act as primary
 1737 transplant surgeon, as well as the surgeon’s personal integrity, honesty, and familiarity
 1738 with and experience in adhering to OPTN obligations, and any other matters judged
 1739 appropriate. The MPSC may request additional recommendation letters from the primary
 1740 physician, primary surgeon, director, or others affiliated with any transplant program
 1741 previously served by the surgeon, at its discretion.
- 1742 c. A letter from the surgeon that details the training and experience the surgeon has gained
 1743 in heart transplantation.

1744
 1745 **B. Twelve-month Heart Transplant Fellowship Pathway**

- 1746 Surgeons can meet the training requirements for primary heart transplant surgeon by completing
 1747 a 12-month heart transplant fellowship if the following conditions are met:
- 1748
- 1749 1. The surgeon performed at least 20 heart or heart/lung transplants as primary surgeon or first
 1750 assistant during the 12-month heart transplant fellowship. These transplants must be
 1751 documented in a log that includes the date of transplant, the role of the surgeon in the
 1752 procedure, and the medical record number or other unique identifier that can be verified by
 1753 the OPTN Contractor. This log must be signed by the director of the training program.
- 1754 2. The surgeon performed at least 10 heart or heart/lung procurements as primary surgeon or
 1755 first assistant under the supervision of a qualified heart transplant surgeon during the 12-
 1756 month heart transplant fellowship. These procedures must be documented in a log that
 1757 includes the date of procurement, location of the donor, and Donor ID. This log must be
 1758 signed by the director of the training program.
- 1759 3. The surgeon has maintained a current working knowledge of all aspects of heart
 1760 transplantation, defined as a direct involvement in heart transplant patient care within the last
 1761 2 years. This includes performing the transplant operation, donor selection, the use of
 1762 mechanical circulatory assist devices, recipient selection, post-operative hemodynamic care,
 1763 postoperative immunosuppressive therapy, and outpatient follow-up.
- 1764 4. This training was completed at a hospital with a cardiothoracic surgery training program
 1765 approved by the American Board of Thoracic Surgery, or the Royal College of Physicians and
 1766 Surgeons of Canada, or its foreign equivalent, as accepted by the MPSC with a
 1767 recommendation from the Thoracic Organ Transplantation Committee.
- 1768 5. The following letters are submitted directly to the OPTN Contractor:
- 1769 a. A letter from the director of the training program verifying that the surgeon has met the
 1770 above requirements and is qualified to direct a heart transplant program.
- 1771 b. A letter of recommendation from the training program’s primary surgeon and transplant
 1772 program director outlining the individual’s overall qualifications to act as primary

1773 transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity
 1774 with and experience in adhering to OPTN obligations, and any other matters judged
 1775 appropriate. The MPSC may request additional recommendation letters from the primary
 1776 physician, primary surgeon, director, or others affiliated with any transplant program
 1777 previously served by the surgeon, at its discretion.

1778 c. A letter from the surgeon that details the training and experience the surgeon has gained
 1779 in heart transplantation.

1780

1781 **C. Clinical Experience Pathway**

1782 Surgeons can meet the requirements for primary heart transplant surgeon through clinical
 1783 experience gained post-fellowship if the following conditions are met:

1784

1785 1. The surgeon has performed 20 or more heart or heart/lung transplants as primary surgeon or
 1786 first assistant at a designated heart transplant program ~~or the foreign equivalent~~. These
 1787 transplants must have been completed over a 2 to 5-year period and include at least 15 of
 1788 these procedures performed as the primary surgeon. These transplants must be documented
 1789 in a log that includes the date of transplant, the role of the surgeon in the procedure, and
 1790 medical record number or other unique identifier that can be verified by the OPTN Contractor.
 1791 This log should be signed by the program director, division chief, or department chair from
 1792 program where the experience was gained. Transplants performed during board qualifying
 1793 surgical residency or fellowship do not count.

1794 2. The surgeon has performed at least 10 heart or heart/lung procurements as primary surgeon
 1795 or first assistant under the supervision of a qualified heart transplant surgeon. These
 1796 procedures must be documented in a log that includes the date of procurement, location of
 1797 the donor, and Donor ID.

1798 3. The surgeon has maintained a current working knowledge of all aspects of heart
 1799 transplantation, defined as a direct involvement in heart transplant patient care within the last
 1800 2 years. This includes performing the transplant operation, donor selection, the use of
 1801 mechanical assist devices, recipient selection, post-operative hemodynamic care,
 1802 postoperative immunosuppressive therapy, and outpatient follow-up.

1803 4. The following letters are submitted directly to the OPTN Contractor:

1804 a. A letter from the director of the program where the surgeon acquired transplant
 1805 experience verifying that the surgeon has met the above requirements and is qualified to
 1806 direct a heart transplant program.

1807 b. A letter of recommendation from the primary surgeon and transplant program director at
 1808 the transplant program last served by the surgeon outlining the surgeon's overall
 1809 qualifications to act as primary transplant surgeon, as well as the surgeon's personal
 1810 integrity, honesty, and familiarity with and experience in adhering to OPTN obligations,
 1811 and any other matters judged appropriate. The MPSC may request additional
 1812 recommendation letters from the primary physician, primary surgeon, director, or others
 1813 affiliated with any transplant program previously served by the surgeon, at its discretion.

1814 c. A letter from the surgeon that details the training and experience the surgeon has gained
 1815 in heart transplantation.

1816

1817 **H.3 Primary Heart Transplant Physician Requirements**

1818 A designated heart transplant program must have a primary physician who meets *all* the following
 1819 requirements:

- 1820
- 1821 1. The physician must have an M.D., D.O., or equivalent degree from another country, with a current
- 1822 license to practice medicine in the hospital's state or jurisdiction.
- 1823 2. The physician must be accepted onto the hospital's medical staff, and be practicing on site at this
- 1824 hospital.
- 1825 3. The physician must have documentation from the hospital credentialing committee that it has verified
- 1826 the physician's state license, board certification, training, and transplant continuing medical education
- 1827 and that the physician is currently a member in good standing of the hospital's medical staff.
- 1828 4. The physician must have current certification in adult or pediatric cardiology by the American Board of
- 1829 Internal Medicine, the American Board of Pediatrics, or the Royal College of Physicians and
- 1830 Surgeons of Canada ~~foreign equivalent~~.

1831

1832 In place of current board certification in adult or pediatric cardiology by the American Board of Internal

1833 Medicine, the American Board of Pediatrics, or the Royal College of Physicians and Surgeons of

1834 Canada, the physician must:

- 1835 a. Be ineligible for American board certification.
- 1836 b. Provide a plan for continuing education that is comparable to American board maintenance of
- 1837 certification. This plan must at least require that the physician obtains 60 hours of Category I
- 1838 continuing medical education (CME) credits with self-assessment that are relevant to the
- 1839 individual's practice every three years. Self-assessment is defined as a written or electronic
- 1840 question-and-answer exercise that assesses understanding of the material in the CME program.
- 1841 A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve
- 1842 an acceptable self-assessment score are allowed. The transplant hospital must document
- 1843 completion of this continuing education.
- 1844 c. Provide to the OPTN Contractor two letters of recommendation from directors of designated
- 1845 transplant programs not employed by the applying hospital. These letters must address:
- 1846 i. Why an exception is reasonable.
- 1847 ii. The physician's overall qualifications to act as a primary heart transplant physician.
- 1848 iii. The physician's personal integrity, honesty, and familiarity with and experience in adhering to
- 1849 OPTN obligations and compliance protocols.
- 1850 iv. Any other matters judged appropriate.

1851

1852 If the physician has not adhered to the plan for maintaining continuing education or has not obtained

1853 the necessary CME credits with self-assessment, the transplant program will have a six-month grace

1854 period to address these deficiencies. If the physician has not fulfilled the requirements after the six-

1855 month grace period, and a key personnel change application has not been submitted, then the

1856 transplant program will be referred to the MPSC for appropriate action according to Appendix L of

1857 these Bylaws. If the OPTN Contractor becomes aware that a primary physician has not been

1858 compliant for 12 months or more and deficiencies still exist, then the transplant program will not be

1859 given any grace period and will be referred to the MPSC for appropriate action according to Appendix

1860 L of these Bylaws.

- 1861 5. ~~In addition,~~ The primary transplant physician must have completed at least one of the training or
- 1862 experience pathways listed below:
- 1863 ■ a. The 12-month transplant cardiology fellowship pathway, as described in Section H.3.A. Twelve-
- 1864 month Transplant Cardiology Fellowship Pathway below.
- 1865 ■ b. The clinical experience pathway, as described in Section H.3.B. Clinical Experience Pathway
- 1866 below.

- 1867 ■ c. The alternative pathway for predominantly pediatric programs, as described in Section H.3.C.
 1868 Alternative Pathway for Predominantly Pediatric Programs below.
- 1869 ■ d. The conditional approval pathway, as described in Section H.3.D. Conditional Approval for
 1870 Primary Transplant Physician below, if the primary heart transplant physician changes at an
 1871 approved heart transplant program.

1872

1873 **A. Twelve-month Transplant Cardiology Fellowship Pathway**

1874 Physicians can meet the training requirements for primary heart transplant physician during a 12-
 1875 month transplant cardiology fellowship if the following conditions are met:

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- 1877 1. During the fellowship period, the physician was directly involved in the primary care of at least
 1878 20 newly transplanted heart or heart/lung recipients. This training will have been under the
 1879 direct supervision of a qualified heart transplant physician and in conjunction with a heart
 1880 transplant surgeon. This care must be documented in a log that includes the date of
 1881 transplant and the medical record number or other unique identifier that can be verified by the
 1882 OPTN Contractor. This recipient log must be signed by the director of the training program or
 1883 the primary transplant physician at the transplant program.
- 1884 2. The physician has maintained a current working knowledge of heart transplantation, defined
 1885 as direct involvement in heart transplant patient care within the last 2 years. This includes the
 1886 care of acute and chronic heart failure, donor selection, the use of mechanical circulatory
 1887 support devices, recipient selection, pre- and post-operative hemodynamic care, post-
 1888 operative immunosuppressive therapy, histological interpretation and grading of myocardial
 1889 biopsies for rejection, and long-term outpatient follow-up.
- 1890 3. The physician should have observed at least 3 organ procurements and 3 heart transplants.
 1891 The physician should also have observed the evaluation, the donation process, and
 1892 management of 3 multiple organ donors who are donating a heart or heart/lungs. If the
 1893 physician has completed these observations, they must be documented in a log that includes
 1894 the date of procurement, location of the donor, and Donor ID.
- 1895 4. This training was completed at a hospital with an American Board of Internal Medicine
 1896 certified fellowship training program in adult cardiology, ~~or an~~ an American Board of Pediatrics
 1897 certified fellowship training program in pediatric cardiology, or a cardiology training program
 1898 approved by the Royal College of Physicians and Surgeons of Canada. or its foreign
 1899 equivalent, as accepted by the MPSC.
- 1900 5. The following letters are submitted directly to the OPTN Contractor:
- 1901 a. A letter from the director of the training program and the supervising qualified heart
 1902 transplant physician verifying that the physician has met the above requirements and is
 1903 qualified to direct a heart transplant program.
- 1904 b. A letter of recommendation from the training program's primary physician and transplant
 1905 program director outlining the physician's overall qualifications to act as primary
 1906 transplant physician, as well as the physician's personal integrity, honesty, and familiarity
 1907 with and experience in adhering to OPTN obligations, and any other matters judged
 1908 appropriate. The MPSC may request additional recommendation letters from the Primary
 1909 Physician, primary surgeon, director, or others affiliated with any transplant program
 1910 previously served by the physician, at its discretion.
- 1911 c. A letter from the physician that details the training and experience the physician has
 1912 gained in heart transplantation.
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B. Clinical Experience Pathway

A physician can meet the requirements for primary heart transplant physician through acquired clinical experience if the following conditions are met.

1. The physician has been directly involved in the primary care of 20 or more newly transplanted heart or heart/lung recipients and continued to follow these recipients for a minimum of 3 months from transplant. This patient care must have been provided over a 2 to 5-year period on an active heart transplant service as the primary heart transplant physician or under the direct supervision of a qualified heart transplant physician and in conjunction with a heart transplant surgeon at a heart transplant program ~~or the foreign equivalent~~. This care must be documented in a log that includes the date of transplant and medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log should be signed by the director or the primary transplant physician at the transplant program where the physician gained this experience.
2. The physician has maintained a current working knowledge of heart transplantation, defined as direct involvement in heart transplant patient care within the last 2 years. This includes the 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.
3. The physician should have observed at least 3 organ procurements and 3 heart transplants. The physician should also have observed the evaluation, the donation process, and management of 3 multiple organ donors who are donating a heart or heart/lungs. If the physician has completed these observations, they must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
4. The following letters are submitted directly to the OPTN Contractor:
 - a. A letter from the heart transplant physician or the heart transplant surgeon who has been directly involved with the physician at the transplant program verifying the physician’s competence.
 - b. A letter of recommendation from the primary physician and transplant program director at the transplant program last served by the physician outlining the physician’s overall qualifications to act as 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 heart transplantation.

D. Conditional Approval for Primary Transplant Physician

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

- ~~1. The physician has current board certification in cardiology by the American Board of Internal Medicine, the American Board of Pediatrics, or the foreign equivalent.~~

- 1960 21. The physician has 12 months experience on an active heart transplant service as the primary
- 1961 heart transplant physician or under the direct supervision of a qualified heart transplant
- 1962 physician and in conjunction with a heart transplant surgeon at a designated heart transplant
- 1963 program. These 12 months of experience must be acquired within a 2-year period.
- 1964 32. The physician has maintained a current working knowledge of heart transplantation, defined
- 1965 as direct involvement in heart transplant patient care within the last 2 years. This includes
- 1966 knowledge of acute and chronic heart failure, donor selection, the use of mechanical
- 1967 circulatory support devices, recipient selection, pre- and post-operative hemodynamic care,
- 1968 post-operative immunosuppressive therapy, histological interpretation in grading of
- 1969 myocardial biopsies for rejection, and long-term outpatient follow-up.
- 1970 43. The physician has been involved in the primary care of 10 or more newly transplanted heart
- 1971 or heart/lung transplant recipients as the heart transplant physician or under the direct
- 1972 supervision of a qualified heart transplant physician or in conjunction with a heart transplant
- 1973 surgeon at a designated heart transplant program. The physician will have followed these
- 1974 patients for a minimum of 3 months from the time of transplant. This care must be
- 1975 documented in a log that includes the date of transplant and medical record or other unique
- 1976 identifier that can be verified by the OPTN Contractor. This recipient log should be signed by
- 1977 the program director or the primary transplant physician at the transplant program where the
- 1978 physician gained experience.
- 1979 54. The physician should have observed at least 3 organ procurements and 3 heart transplants.
- 1980 The physician should also have observed the evaluation, the donation process, and
- 1981 management of at least 3 multiple organ donors who donated a heart or heart/lungs. If the
- 1982 physician has completed these observations, they must be documented in a log that includes
- 1983 the date of procurement, location of the donor, and Donor ID.
- 1984 65. The program has established and documented a consulting relationship with counterparts at
- 1985 another heart transplant program.
- 1986 76. The transplant program submits activity reports to the OPTN Contractor every 2 months
- 1987 describing the transplant activity, transplant outcomes, physician recruitment efforts, and
- 1988 other operating conditions as required by the MPSC to demonstrate the ongoing quality and
- 1989 efficient patient care at the program. The activity reports must also demonstrate that the
- 1990 physician is making sufficient progress to meet the required involvement in the primary care
- 1991 of 20 or more heart transplant recipients, or that the program is making sufficient progress in
- 1992 recruiting a physician who meets all requirements for primary heart transplant physician by
- 1993 the end of the 12 month conditional approval period.
- 1994 87. The following letters are submitted directly to the OPTN Contractor:
- 1995 a. A letter from the heart transplant physician or the heart transplant surgeon who has been
- 1996 directly involved with the physician at the transplant program verifying the physician's
- 1997 competence.
- 1998 b. A letter of recommendation from the primary physician and director at the transplant
- 1999 program last served by the physician outlining the physician's overall qualifications to act
- 2000 as primary transplant physician, as well as the physician's personal integrity, honesty,
- 2001 and familiarity with and experience in adhering to OPTN obligations, and any other
- 2002 matters judged appropriate. The MPSC may request additional recommendation letters
- 2003 from the primary physician, primary surgeon, director, or others affiliated with any
- 2004 transplant program previously served by the physician, at its discretion.
- 2005 c. A letter from the physician that details the training and experience the physician has
- 2006 gained in heart transplantation.
- 2007

2008 The 12-month conditional approval period begins on the first approval date granted to the
 2009 personnel change application, whether it is an interim approval granted by the MPSC
 2010 subcommittee, or an approval granted by the full MPSC. The conditional approval period ends
 2011 exactly 12 months after this first approval date of the personnel change application.
 2012

2013 If the program is unable to demonstrate that it has an individual on site who can meet the
 2014 requirements as described in *Sections H.3.A through H.3.C* above at the end of the 12-month
 2015 conditional approval period, it must inactivate. The requirements for program inactivation are
 2016 described in *Appendix K: Transplant Program Inactivity, Withdrawal and Termination* of these
 2017 Bylaws.
 2018

2019 The MPSC may consider on a case-by-case basis and grant a 6-month extension to a transplant
 2020 program that provides substantial evidence of progress toward fulfilling the requirements but is
 2021 unable to complete the requirements within one year.
 2022

2023 **Appendix I:**

2024 **Membership and Personnel Requirements for Lung**

2025 **Transplant Programs**

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2027 **I.2 Primary Lung Transplant Surgeon Requirements**

2028 A designated lung transplant program must have a primary surgeon who meets *all* the following
 2029 requirements:
 2030

- 2031 1. The surgeon must have an M.D., D.O., or equivalent degree from another country, with a current
 2032 license to practice medicine in the hospital's state or jurisdiction.
- 2033 2. The surgeon must be accepted onto the hospital's medical staff, and be practicing on site at this
 2034 hospital.
- 2035 3. The surgeon must have documentation from the hospital credentialing committee that it has verified
 2036 the surgeon's state license, board certification, training, and transplant continuing medical education,
 2037 and that the surgeon is currently a member in good standing of the hospital's medical staff.
- 2038 4. The surgeon must have current certification by the American Board of Thoracic Surgery or current
 2039 certification in thoracic surgery by the Royal College of Physicians and Surgeons of Canada ~~its~~
 2040 ~~foreign equivalent~~. In the case of a surgeon who has just completed training and whose board
 2041 certification by the American Board of Thoracic Surgery in thoracic surgery is pending, the
 2042 Membership and Professional Standards Committee (MPSC) may grant conditional approval for 24
 2043 months to allow time for the surgeon to complete board certification, with the possibility of renewal for
 2044 one additional 24-month period.
 2045

2046 In place of current certification by the American Board of Thoracic Surgery, current certification in
 2047 thoracic surgery by the Royal College of Physicians and Surgeons of Canada, or pending board
 2048 certification by the American Board of Thoracic Surgery, the surgeon must:

- 2049 a. Be ineligible for American board certification.
- 2050 b. Provide a plan for continuing education that is comparable to American board maintenance of
 2051 certification. This plan must at least require that the surgeon obtains 60 hours of Category I
 2052 continuing medical education (CME) credits with self-assessment that are relevant to the

2053 individual's practice every three years. Self-assessment is defined as a written or electronic
 2054 question-and-answer exercise that assesses understanding of the material in the CME program.
 2055 A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve
 2056 an acceptable self-assessment score are allowed. The transplant hospital must document
 2057 completion of this continuing education.

- 2058 c. Provide to the OPTN Contractor two letters of recommendation from directors of designated
 2059 transplant programs not employed by the applying hospital. These letters must address:
 2060 i. Why an exception is reasonable.
 2061 ii. The surgeon's overall qualifications to act as a primary lung transplant surgeon.
 2062 iii. The surgeon's personal integrity, honesty, and familiarity with and experience in adhering to
 2063 OPTN obligations and compliance protocols.
 2064 iv. Any other matters judged appropriate.
 2065

2066 If the surgeon has not adhered to the plan for maintaining continuing education or has not obtained
 2067 the necessary CME credits with self-assessment, the transplant program will have a six-month grace
 2068 period to address these deficiencies. If the surgeon has not fulfilled the requirements after the six-
 2069 month grace period, and a key personnel change application has not been submitted, then the
 2070 transplant program will be referred to the MPSC for appropriate action according to Appendix L of
 2071 these Bylaws. If the OPTN Contractor becomes aware that a primary surgeon has not been compliant
 2072 for 12 months or more and deficiencies still exist, then the transplant program will not be given any
 2073 grace period and will be referred to the MPSC for appropriate action according to Appendix L of these
 2074 Bylaws.
 2075

2076 5. ~~In addition, t~~ The primary transplant surgeon must have completed at least one of the training or
 2077 experience pathways listed below:

- 2078 ■ a. The formal cardiothoracic surgery residency pathway, as described in Section 1.2.A.
 2079 Cardiothoracic Surgery Residency Pathway below.
- 2080 ■ b. The 12-month lung transplant fellowship pathway, as described in Section 1.2.B. Twelve-month
 2081 Lung Transplant Fellowship Pathway below.
- 2082 ■ c. The lung transplant program clinical experience pathway, as described in Section 1.2.C. Clinical
 2083 Experience Pathway below.
- 2084 ■ d. The alternative pathway for predominantly pediatric programs, as described in Section 1.2.D.
 2085 Alternative Pathway for Predominantly Pediatric Programs below.
 2086

2087 **A. Cardiothoracic Surgery Residency Pathway**

2088 Surgeons can meet the training requirements for primary lung transplant surgeon by completing a
 2089 cardiothoracic surgery residency if the following conditions are met:
 2090

- 2091 1. During the cardiothoracic surgery residency, the surgeon has performed at least 15 lung or
 2092 heart/lung transplants as primary surgeon or first assistant under the direct supervision of a
 2093 qualified lung transplant surgeon and in conjunction with a lung transplant physician at a lung
 2094 transplant program. At least half of these transplants must be lung procedures. These
 2095 transplants must be documented in a log that includes the date of transplant, role of the
 2096 surgeon in the procedure, and medical record number or other unique identifier that can be
 2097 verified by the OPTN Contractor. This log must be signed by the director of the training
 2098 program.

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2. The surgeon performed at least 10 lung procurements as primary surgeon or first assistant under the supervision of a qualified lung transplant surgeon. These procedures must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
 3. The surgeon has maintained a current working knowledge of all aspects of lung transplantation, defined as a direct involvement in lung transplant patient care within the last 2 years. This includes the 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. This training must also include the other clinical requirements for thoracic surgery.
 4. This training was completed at a hospital with a cardiothoracic training program approved by the American Board of Thoracic Surgery or the Royal College of Physicians and Surgeons of Canada, ~~or its foreign equivalent. Foreign programs must have a recommendation from the Thoracic Organ Transplantation Committee and be accepted as equivalent by the MPSC.~~
 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 lung transplant program.
 - b. A letter of recommendation from the program's primary surgeon and transplant program director outlining the individual's overall qualifications to act as primary transplant surgeon, as well as the surgeon'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 surgeon, at its discretion.
 - c. A letter from the surgeon that details the training and experience the surgeon has gained in lung transplantation.

2127 **B. Twelve-month Lung Transplant Fellowship Pathway**

2128 Surgeons can meet the training requirements for primary lung transplant surgeon by completing a
2129 12-month lung transplant fellowship if the following conditions are met:
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1. The surgeon has performed at least 15 lung or heart/lung transplants under the direct supervision of a qualified lung transplant surgeon and in conjunction with a qualified lung transplant physician as primary surgeon or first assistant during the 12-month lung transplant fellowship. At least half of these transplants must be lung procedures. 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 director of the program.
 2. The surgeon has performed at least 10 lung procurements as primary surgeon or first assistant under the supervision of a qualified lung transplant surgeon during the 12-month lung transplant fellowship. These procedures must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
 3. The surgeon has maintained a current working knowledge of all aspects of lung transplantation, defined as a direct involvement in lung transplant patient care within the last 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass, donor selection, recipient selection, pre- and postoperative ventilator care, postoperative

- 2146 immunosuppressive therapy, histological interpretation and grading of lung biopsies for
 2147 rejection, and long-term outpatient follow-up.
- 2148 4. This training was completed at a hospital with a cardiothoracic training program approved by
 2149 the American Board of Thoracic Surgery or the Royal College of Physicians and Surgeons of
 2150 Canada, or its foreign equivalent. Foreign programs must have a recommendation from the
 2151 Thoracic Organ Transplantation Committee and be accepted as equivalent by the MPSC.
- 2152 5. The following letters are submitted directly to the OPTN Contractor:
- 2153 a. A letter from the director of the training program verifying that the surgeon has met the
 2154 above requirements and is qualified to direct a lung transplant program.
- 2155 b. A letter of recommendation from the training program's primary surgeon and transplant
 2156 program director outlining the individual's overall qualifications to act as primary
 2157 transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity
 2158 with and experience in adhering to OPTN obligations, and any other matters judged
 2159 appropriate. The MPSC may request additional recommendation letters from the primary
 2160 physician, primary surgeon, director, or others affiliated with any transplant program
 2161 previously served by the surgeon, at its discretion.
- 2162 c. A letter from the surgeon that details the training and experience the surgeon has gained
 2163 in lung transplantation.

2164 **C. Clinical Experience Pathway**

2166 Surgeons can meet the requirements for primary lung transplant surgeon through clinical
 2167 experience gained post-fellowship if the following conditions are met:

- 2168
- 2169 1. The surgeon has performed 15 or more lung or heart/lung transplants over a 2 to 5-year
 2170 period as primary surgeon or first assistant at a designated lung transplant program, ~~or the~~
 2171 ~~foreign equivalent.~~ At least half of these transplants must be lung procedures, and at least
 2172 10 must be performed as the primary surgeon. The surgeon must also have been actively
 2173 involved with cardiothoracic surgery. These transplants must be documented in a log that
 2174 includes the date of transplant, the role of the surgeon in the procedure, and medical record
 2175 number or other unique identifier that can be verified by the OPTN Contractor. This recipient
 2176 log should be signed by the program director, division chief, or department chair from
 2177 program where the experience was gained.
- 2178 2. The surgeon has performed at least 10 lung procurements. These procedures must be
 2179 documented in a log that includes the date of procurement, location of the donor, and Donor
 2180 ID.
- 2181 3. The surgeon has maintained a current working knowledge of all aspects of lung
 2182 transplantation, defined as a direct involvement in lung transplant patient care within the last
 2183 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass,
 2184 donor selection, recipient selection, pre- and postoperative ventilator care, postoperative
 2185 immunosuppressive therapy, histological interpretation and grading of lung biopsies for
 2186 rejection, and long-term outpatient follow-up.
- 2187 4. The following letters are submitted directly to the OPTN Contractor:
- 2188 a. A letter from the director of the program where the surgeon gained experience verifying
 2189 that the surgeon has met the above requirements and is qualified to direct a lung
 2190 transplant program.
- 2191 b. A letter of recommendation from the primary surgeon and director at the transplant
 2192 program last served by the surgeon outlining the surgeon's overall qualifications to act
 2193 as primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and

- 2194 familiarity with and experience in adhering to OPTN obligations, and any other matters
 2195 judged appropriate. The MPSC may request additional recommendation letters from the
 2196 primary physician, primary surgeon, director, or others affiliated with any transplant
 2197 program previously served by the surgeon, at its discretion.
 2198 c. A letter from the surgeon that details the training and experience the surgeon has
 2199 gained in lung transplantation.
 2200

2201 I.3 Primary Lung Transplant Physician Requirements

2202 A designated lung transplant program must have a primary physician who meets *all* the following
 2203 requirements:

- 2204
- 2205 1. The physician must have an M.D., D.O., or equivalent degree from another country, with a current
 2206 license to practice medicine in the hospital's state or jurisdiction.
 - 2207 2. The physician must be accepted onto the hospital's medical staff, and be practicing on site at this
 2208 hospital.
 - 2209 3. The physician must have documentation from the hospital credentialing committee that it has verified
 2210 the physician's state license, board certification, training, and transplant continuing medical education
 2211 and that the physician is currently a member in good standing of the hospital's medical staff.
 - 2212 4. The lung transplant physician must have current board certification or have achieved eligibility in adult
 2213 or pediatric pulmonary medicine by the American Board of Internal Medicine, the American Board of
 2214 Pediatrics, or the Royal College of Physicians and Surgeons of Canada ~~their foreign equivalent~~.

2215
 2216 In place of current board certification or achieved eligibility in adult or pediatric pulmonary medicine by
 2217 the American Board of Internal Medicine, the American Board of Pediatrics, or the Royal College of
 2218 Physicians and Surgeons of Canada, the physician must:

- 2219 a. Be ineligible for American board certification.
- 2220 b. Provide a plan for continuing education that is comparable to American board maintenance of
 2221 certification. This plan must at least require that the physician obtains 60 hours of Category I
 2222 continuing medical education (CME) credits with self-assessment that are relevant to the
 2223 individual's practice every three years. Self-assessment is defined as a written or electronic
 2224 question-and-answer exercise that assesses understanding of the material in the CME program.
 2225 A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve
 2226 an acceptable self-assessment score are allowed. The hospital must document completion of this
 2227 continuing education.
- 2228 c. Provide to the OPTN Contractor two letters of recommendation from directors of designated
 2229 transplant programs not employed by the applying hospital. These letters must address:
 - 2230 i. Why an exception is reasonable.
 - 2231 ii. The physician's overall qualifications to act as a primary lung transplant physician.
 - 2232 iii. The physician's personal integrity, honesty, and familiarity with and experience in adhering to
 2233 OPTN obligations and compliance protocols.
 - 2234 iv. Any other matters judged appropriate.

2235
 2236 If the physician has not adhered to the plan for maintaining continuing education or has not obtained
 2237 the necessary CME credits with self-assessment, the transplant program will have a six-month grace
 2238 period to address these deficiencies. If the physician has not fulfilled the requirements after the six-
 2239 month grace period, and a key personnel change application has not been submitted, then the
 2240 transplant program will be referred to the MPSC for appropriate action according to Appendix L of
 2241 these Bylaws. If the OPTN Contractor becomes aware that a primary physician has not been

2242 compliant for 12 months or more and deficiencies still exist, then the transplant program will not be
 2243 given any grace period and will be referred to the MPSC for appropriate action according to Appendix
 2244 L of these Bylaws.

2245

2246 5. In addition, the primary transplant physician must have completed at least one of the training or
 2247 experience pathways listed below:

2248 ■ a. The 12-month transplant pulmonary fellowship pathway, as described in Section I.3.A. Twelve-
 2249 month Transplant Pulmonary Fellowship Pathway below.

2250 ■ b. The clinical experience pathway, as described in Section I.3.B. Clinical Experience Pathway
 2251 below.

2252 ■ c. The alternative pathway for predominantly pediatric programs, as described in Section I.3.C.
 2253 Alternative Pathway for Predominantly Pediatric Programs below.

2254 ■ d. The conditional approval pathway, as described in Section I.3.D. Conditional Approval for
 2255 Primary Transplant Physician below, if the primary lung transplant physician changes at an
 2256 approved lung transplant program.

2257

2258

A. Twelve-month Transplant Pulmonary Fellowship Pathway

2259 Physicians can meet the training requirements for primary lung transplant physician during a 12-
 2260 month transplant pulmonary fellowship if the following conditions are met:

2261 1. The physician was directly involved in the primary and follow-up care of at least 15 newly
 2262 transplanted lung or heart/lung recipients. This training will have been under the direct
 2263 supervision of a qualified lung transplant physician and in conjunction with a lung transplant
 2264 surgeon. At least half of these patients must be single or double-lung transplant recipients.
 2265 This care must be documented in a log that includes the date of transplant and the medical
 2266 record number or other unique identifier that can be verified by the OPTN Contractor. This
 2267 recipient log must be signed by the director of the training program or the primary transplant
 2268 physician at the transplant program.

2269 2. The physician has maintained a current working knowledge of all aspects of lung
 2270 transplantation, defined as a direct involvement in lung transplant patient care within the last
 2271 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass,
 2272 donor selection, recipient selection, pre- and postoperative ventilator care, postoperative
 2273 immunosuppressive therapy, histological interpretation and grading of lung biopsies for
 2274 rejection, and long-term outpatient follow-up.

2275 3. The physician should have observed at least 3 lung or heart/lung procurements and 3 lung
 2276 transplants. The physician should also have observed the evaluation, the donation process,
 2277 and management of 3 multiple organ donors who are donating a lung or heart/lungs. If the
 2278 physician has completed these observations, they must be documented in a log that includes
 2279 the date of procurement, location of the donor, and Donor ID.

2280 4. This training was completed at a hospital with an American Board of Internal Medicine
 2281 certified fellowship training program in adult pulmonary medicine, an American Board of
 2282 Pediatrics-certified fellowship training program in pediatric medicine, or a pulmonary medicine
 2283 training program approved by the Royal College of Physicians and Surgeons of Canada, or
 2284 its foreign equivalent. Foreign programs must have a recommendation from the Thoracic
 2285 Organ Transplantation Committee and be accepted as equivalent by the MPSC.

2286 5. The following letters are submitted directly to the OPTN Contractor:
 2287 a. A letter from the director of the training program verifying that the physician has met the
 2288 above requirements and is qualified to direct a lung transplant program.

- 2289 b. A letter of recommendation from the training program’s primary physician and transplant
 2290 program director outlining the physician’s overall qualifications to act as primary
 2291 transplant physician, as well as the physician’s personal integrity, honesty, and familiarity
 2292 with and experience in adhering to OPTN obligations, and any other matters judged
 2293 appropriate. The MPSC may request additional recommendation letters from the primary
 2294 physician, primary surgeon, director, or others affiliated with any transplant program
 2295 previously served by the physician, at its discretion.
 2296 c. A letter from the physician that details the training and experience the physician has
 2297 gained in lung transplantation.
 2298

2299 **B. Clinical Experience Pathway**

2300 A physician can meet the requirements for primary lung transplant physician through acquired
 2301 clinical experience if the following conditions are met.
 2302

- 2303 1. The physician has been directly involved in the primary care of 15 or more newly transplanted
 2304 lung or heart/lung recipients and continued to follow these recipients for a minimum of 3
 2305 months from the time of transplant. At least half of these transplant must be lung transplants.
 2306 This patient care must have been provided over a 2 to 5-year period ~~on an active at a~~
 2307 designated lung transplant program ~~or the foreign equivalent~~. This care must have been
 2308 provided as the lung transplant physician or directly supervised by a qualified lung transplant
 2309 physician along with a lung transplant surgeon. This care must be documented in a log that
 2310 includes the date of transplant and medical record number or other unique identifier that can
 2311 be verified by the OPTN Contractor. This recipient log should be signed by the director or the
 2312 primary transplant physician at the transplant program where the physician gained this
 2313 experience.
 2314 2. The physician has maintained a current working knowledge of all aspects of lung
 2315 transplantation, defined as a direct involvement in lung transplant patient care within the last
 2316 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass,
 2317 donor selection, recipient selection, pre- and postoperative ventilator care, postoperative
 2318 immunosuppressive therapy, histological interpretation and grading of lung biopsies for
 2319 rejection, and long-term outpatient follow-up.
 2320 3. The physician should have observed at least 3 lung or heart/lung procurements and 3 lung
 2321 transplants. The physician should also have observed the evaluation, the donation process,
 2322 and management of 3 multiple organ donors who are donating a lung or heart/lungs. If the
 2323 physician has completed these observations, they must be documented in a log that includes
 2324 the date of procurement, location of the donor, and Donor ID.
 2325 4. The following letters are submitted directly to the OPTN Contractor:
 2326 a. A letter from the lung transplant physician or surgeon of the training program who has
 2327 been directly involved with the physician documenting the physician’s competence.
 2328 b. A letter of recommendation from the primary physician and transplant program director at
 2329 the transplant program last served by the physician outlining the physician’s overall
 2330 qualifications to act as primary transplant physician, as well as the physician’s personal
 2331 integrity, honesty, and familiarity with and experience in adhering to OPTN obligations,
 2332 and any other matters judged appropriate. The MPSC may request additional
 2333 recommendation letters from the primary physician, primary surgeon, director, or others
 2334 affiliated with any transplant program previously served by the physician, at its discretion.
 2335 c. A letter from the physician that details the training and experience the physician has
 2336 gained in lung transplantation.

2337
2338

D. Conditional Approval for Primary Transplant Physician

2339 If the primary lung transplant physician changes at an approved lung transplant program, a
2340 physician can serve as the primary lung transplant physician for a maximum of 12 months if the
2341 following conditions are met:

2342

2343 ~~1. The physician is a pulmonologist with current board certification in pulmonary medicine by the~~
2344 ~~American Board of Internal Medicine, the American Board of Pediatrics, or the foreign~~
2345 ~~equivalent.~~

2346 21. The physician has 12 months of experience on an active lung transplant service as the
2347 primary lung transplant physician or under the direct supervision of a qualified lung transplant
2348 physician and in conjunction with a lung transplant surgeon at a designated lung transplant
2349 program. These 12 months of experience must be acquired within a 2-year period.

2350 32. The physician has been involved in the primary care of 8 or more newly transplanted lung or
2351 heart/lung transplant recipients as the lung transplant physician or under the direct
2352 supervision of a qualified lung transplant physician and in conjunction with a lung transplant
2353 surgeon. At least half of these patients must be lung transplant recipients. This care must be
2354 documented in a recipient log that includes the date of transplant and medical record or other
2355 unique identifier that can be verified by the OPTN Contractor. This log should be signed by
2356 the program director or the primary transplant physician at the transplant program where the
2357 physician gained experience.

2358 43. The physician has maintained a current working knowledge of all aspects of lung
2359 transplantation, defined as a direct involvement in lung transplant patient care within the last
2360 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass,
2361 donor selection, recipient selection, pre- and postoperative ventilator care, postoperative
2362 immunosuppressive therapy, histological interpretation and grading of lung biopsies for
2363 rejection, and long-term outpatient follow-up.

2364 54. The physician should have observed at least 3 lung or heart/lung procurements and 3 lung
2365 transplants. The physician should also have observed the evaluation, the donation process,
2366 and management of 3 multiple organ donors who are donating a lung or heart/lungs. If the
2367 physician has completed these observations, they must be documented in a log that includes
2368 the date of procurement, location of the donor, and Donor ID.

2369 65. The program has established and documented a consulting relationship with counterparts at
2370 another lung transplant program.

2371 76. The transplant program submits activity reports to the OPTN Contractor every 2 months
2372 describing the transplant activity, transplant outcomes, physician recruitment efforts, and
2373 other operating conditions as required by the MPSC to demonstrate the ongoing quality and
2374 efficient patient care at the program. The activity reports must also demonstrate that the
2375 physician is making sufficient progress to meet the required involvement in the primary care
2376 of 20 or more lung transplant recipients, or that the program is making sufficient progress in
2377 recruiting a physician who meets all requirements for primary lung transplant physician by the
2378 end of the 12 month conditional approval period.

2379 87. The following letters are submitted directly to the OPTN Contractor:

2380 a. A letter from the supervising lung transplant physician or surgeon of the training program
2381 documenting the physician's competence.

2382 b. A letter of recommendation from the training program's primary physician and director
2383 outlining the physician's overall qualifications to act as primary transplant physician of the
2384 transplant program last served by the physician, as well as the physician's personal

2385 integrity, honesty, and familiarity with and experience in adhering to OPTN obligations,
2386 and any other matters judged appropriate. The MPSC may request additional
2387 recommendation letters from the primary physician, primary surgeon, director, or others
2388 affiliated with any transplant program previously served by the physician, at its discretion.
2389 c. A letter from the physician that details the training and experience the physician has
2390 gained in lung transplantation.

2391
2392 The 12-month conditional approval period begins on the first approval date granted to the
2393 personnel change application, whether it is an interim approval granted by the MPSC
2394 subcommittee, or approval granted by the full MPSC. The conditional approval period ends
2395 exactly 12 months after this first approval date of the personnel change application.

2396
2397 If the program is unable to demonstrate that it has an individual practicing on site who can meet
2398 the requirements as described in *Sections 1.3.A through 1.3.C* above at the end of the 12-month
2399 conditional approval period, it must inactivate. The requirements for transplant program
2400 inactivation are described in *Appendix K: Transplant Program Inactivity, Withdrawal, and*
2401 *Termination* of these Bylaws.

2402
2403 The MPSC may consider on a case-by-case basis and grant a 6-month extension to a transplant
2404 program that provides substantial evidence of progress toward fulfilling the requirements but is
2405 unable to complete the requirements within one year.

2406
2407 #

OPTN/UNOS Membership and Professional Standards Committee

Remove Reference to Time Frames from Bylaws regarding Inactivation after Conditional Approval

*Committee Liaison
Sally Aungier
UNOS Member Quality Department*

Executive Summary 2

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Remove Reference to Time Frames from Bylaws regarding Inactivation after Conditional Approval

Mini-Brief

Executive Summary

The Bylaws regarding program inactivation after a period of conditional approval are currently misleading. Conditional approval of transplant program key personnel can be granted for an initial period (either 12 or 36 months, depending on the program type), and may be extended for up to an additional 6 months or year depending on the type of program. In the language that requires a program to inactivate after their conditional approval ends, the Bylaws reference a specific length (either 12 months, 2 years or 36 months) for the conditional approval period. Since this period can change depending on whether or not it is extended, this proposal would remove the reference to the specific length of time in the inactivation sections so that they simply refer to the end of conditional approval.

Additionally, the paragraph regarding extension or conditional approval currently follows the paragraph regarding inactivation after conditional approval ends. This proposal would switch the order of these paragraphs where applicable so that it is in chronological and logical order.

Remove Reference to Time Frames from Bylaws regarding Inactivation after Conditional Approval

Affected Bylaws: Bylaws Appendixes E.3.G Conditional Approval for Primary Transplant Physician, F.3.G Conditional Approval for Primary Transplant Physician, F.7.F Rejection of Conditional Approval, F.12.B. Rejection of Conditional Approval, G.3.D Conditional Approval for Primary Transplant Physician, H.3.D Conditional Approval for Primary Transplant Physician, I.3.D Conditional Approval for Primary Transplant Physician

Sponsoring Committee: Membership and Professional Standards Committee

What problem will this proposal solve?

The Bylaws regarding inactivation after a period of conditional approval is currently misleading. There are two main things contributing to this.

1. The Bylaws stating that the program must inactivate after a fixed length of time are counter to the Bylaws stating that the approval period may vary depending on whether or not the conditional approval is extended at the discretion of the MPSC. The periods of time vary by program type.

Program Type	Initial Approval Period	Possible Extention Period	Inactivation-Referenced Period
Kidney	12 months	6 months	12 months
Liver	12 months	6 months	12 months
Living Donor Liver	1 year	1 year	2 years
Intestine	36 months		36 month
Pancreas	12 months	6 months	12 months
Heart	12 months	6 months	12 months
Lung	12 months	6 months	12 months

2. The paragraph in each section that explains extension of a conditional approval is after the paragraph that requires the transplant program to inactivate if it does not receive full approval at the end of its conditional approval period. It is neither in chronological nor logical order.

These two factors may lead a transplant program to think that it needs to inactivate where the language specifies inactivation at the end of the 12-month period, even if the MPSC is willing to grant an extension. It may also lead a program to believe that it is not required to inactivate when it reaches the end of a 12-month approval which is not extended, where the inactivation section refers to inactivation only after a 2-year conditional approval period ends.

Why should you support this proposal?

Changing the language to make it consistent provides more transparency about what may happen if a conditionally approved transplant program is unable to meet the full requirements for program approval by the end of its conditional approval period. It also provides clear guidance for the actions of the OPTN regarding decisions about conditionally approved transplant programs and components. During its meeting on October 27, 2015, the Membership and Professional Standards Committee (MPSC) voted in favor of sending this proposal to the Board of Directors for its consideration (29 yes, 0 no, 0 abstentions).

How does this proposal support the OPTN Strategic Plan?

Please state how this will affect the five goals in the OPTN Strategic Plan. Mention both positive and negative effects. If there is no known impact, then write, "There is no impact to this goal." This can be copied from the committee project form.

1. *Increase the number of transplants:* There is no impact on this goal.
2. *Improve equity in access to transplants:* There is no impact on this goal.
3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* This specific proposal has no impact on this goal. These underlying Bylaw sections improve patient outcomes by creating minimum requirements for transplant programs and components.
4. *Promote living donor and transplant recipient safety:* There is no impact on this goal.
5. *Promote the efficient management of the OPTN:* Making the Bylaws language more consistent will prevent unnecessary arguments over which section is accurate and will make the expectations clearer to members.

How will the OPTN implement this proposal?

There are no additional education or programming efforts required for the OPTN to implement this proposal. There are no changes to the Membership and Professional Standards Committee's processes required to implement this proposal. Once these changes are approved by the Board of Directors, staff will distribute a policy notice to membership that details these changes.

How will members implement this proposal?

This will not represent a change to the members. Members with conditional approval, including those that have been granted a conditional approval extension by the MPSC, will still be expected to inactivate at the end of their conditional approval period if they do not meet the requirements for full approval. Members who print out copies of their Policies or Bylaws as reference should print the updated versions.

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?

Members with conditional approval, including those that have been granted a conditional approval extension by the MPSC, will still be expected to inactivate at the end of their conditional approval period if they do not meet the requirements for full approval.

Policy or Bylaw Language

During its October meeting, the Committee reviewed the proposed bylaw language and unanimously approved the language for consideration by the Board of Directors (29 For, 0 Against, 0 Abstentions).

RESOLVED, that Bylaws Appendixes E.3.G (Conditional Approval for Primary Transplant Physician), F.3.G (Conditional Approval for Primary Transplant Physician), F.7.F (Rejection of Conditional Approval), F.12.B. (Rejection of Conditional Approval), G.3.D (Conditional Approval for Primary Transplant Physician), H.3.D (Conditional Approval for Primary Transplant Physician), I.3.D (Conditional Approval for Primary Transplant Physician) as set forth in Exhibit C, are hereby approved effective March 1, 2016.

New language is underlined and revised language is ~~stricken through~~.

1 **Appendix E.3.G Conditional Approval for Primary Transplant Physician**

2 If the primary kidney transplant physician changes at an approved Kidney transplant program, a physician
 3 can serve as the primary kidney transplant physician for a maximum of 12 months if the following
 4 conditions are met:

- 5 1. The physician has current board certification in nephrology by the American Board of Internal
 6 Medicine, the American Board of Pediatrics, or the foreign equivalent.
- 7 2. The physician has been involved in the primary care of 23 or more newly transplanted kidney
 8 recipients, and has followed these patients for at least 3 months from the time of their transplant.
 9 This care must be documented in a recipient log that includes the date of transplant and the
 10 medical record number or other unique identifier that can be verified by the OPTN Contractor.
 11 This log must be signed by the program director, division chief, or department chair from the
 12 transplant program where the experience was gained.
- 13 3. The physician has maintained a current working knowledge of kidney transplantation, defined as
 14 direct involvement in kidney transplant patient care during the last 2 years. This includes the
 15 management of patients with end stage renal disease, the selection of appropriate recipients for
 16 transplantation, donor selection, histocompatibility and tissue typing, immediate postoperative
 17 patient care, the use of immunosuppressive therapy including side effects of the drugs and
 18 complications of immunosuppression, differential diagnosis of renal dysfunction in the allograft
 19 recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal
 20 dysfunction, and long-term outpatient care.
- 21 4. The physician has 12 months experience on an active kidney transplant service as the primary
 22 kidney transplant physician or under the direct supervision of a qualified kidney transplant
 23 physician and in conjunction with a kidney transplant surgeon at a designated kidney transplant
 24 program or the foreign equivalent. These 12 months of experience must be acquired within a 2-
 25 year period.
- 26 5. The physician should have observed at least 3 organ procurements and 3 kidney transplants. The
 27 physician should also have observed the evaluation, the donation process, and management of
 28 at least 3 multiple organ donors who donated a kidney. If the physician has completed these
 29 observations, they must be documented in a log that includes the date of procurement, location of
 30 the donor, and Donor ID.
- 31 6. The program has established and documented a consulting relationship with counterparts at
 32 another kidney transplant program.
- 33 7. The transplant program submits activity reports to the OPTN Contractor every 2 months
 34 describing the transplant activity, transplant outcomes, physician recruitment efforts, and other

35 operating conditions as required by the MPSC to demonstrate the ongoing quality and efficient
 36 patient care at the program. The activity reports must also demonstrate that the physician is
 37 making sufficient progress to meet the required involvement in the primary care of 45 or more
 38 kidney transplant recipients, or that the program is making sufficient progress in recruiting a
 39 physician who meets all requirements for primary kidney transplant physician and who will be on
 40 site and approved by the MPSC to assume the role of primary physician by the end of the 12
 41 month conditional approval period.

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

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

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

61 If the program is unable to demonstrate that it has an individual on site who can meet the requirements as
 62 described in *Sections E.3.A through E.3.F* above at the end of the ~~12-month~~ conditional approval period,
 63 it must inactivate. The requirements for program inactivation are described in **Error! Reference source**
 64 **not found. Error! Reference source not found.** of these Bylaws.

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

68 **Appendix F.3.G. Conditional Approval for Primary Transplant Physician**

69 If the primary liver transplant physician changes at an approved liver transplant program, a physician can
 70 serve as the primary liver transplant physician for a maximum of 12 months if the following conditions are
 71 met:

- 72 1. The physician has current board certification in gastroenterology by the American Board of Internal
 73 Medicine, the American Board of Pediatrics, or the foreign equivalent.
- 74 2. The physician has been involved in the primary care of 25 or more newly transplanted liver recipients,
 75 and has followed these patients for at least 3 months from the time of their transplant. This care must
 76 be documented in a recipient log that includes the date of transplant and the medical record number
 77 or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the

78 program director, division chief, or department chair from the transplant program where the
 79 experience was gained.

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

87 4. The physician has 12 months experience on an active liver transplant service as the primary liver
 88 transplant physician or under the direct supervision of a qualified liver transplant physician along with
 89 a liver transplant surgeon at a designated liver transplant program, or the foreign equivalent. These
 90 12 months of experience must be acquired within a 2-year period.

91 5. The physician should have observed at least 3 organ procurements and 3 liver transplants. The
 92 physician should also have observed the evaluation, the donation process, and management of at
 93 least 3 multiple organ donors who are donating a liver. If the physician has completed these
 94 observations, they must be documented in a log that includes the date of procurement, location of the
 95 donor, and Donor ID.

96 6. The transplant program submits activity reports to the OPTN Contractor every 2 months describing
 97 the transplant activity, transplant outcomes, physician recruitment efforts, and other operating
 98 conditions as required by the MPSC to demonstrate the ongoing quality and efficient patient care at
 99 the program. The activity reports must also demonstrate that the physician is making sufficient
 100 progress to meet the required involvement in the primary care of 50 or more liver transplant
 101 recipients, or that the program is making sufficient progress in recruiting a physician who meets all
 102 requirements for primary liver transplant physician and who will be on site and approved by the
 103 MPSC to assume the role of primary physician by the end of the 12 month conditional approval
 104 period.

105 7. The program has established and documented a consulting relationship with counterparts at another
 106 liver transplant program.

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

108 a. A letter from the qualified liver transplant physician and surgeon who were directly involved with
 109 the physician verifying that the physician has satisfactorily met the above requirements to
 110 become the primary transplant physician of a liver transplant program.

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

118 c. A letter from the physician sends that details the training and experience the physician gained in
 119 liver transplantation.

120 The 12-month conditional approval period begins on the first approval date granted to the personnel
 121 change application, whether it is interim approval granted by the MPSC subcommittee, or approval

122 granted by the full MPSC. The conditional approval period ends 12 months after the first approval date of
 123 the personnel change application.

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

127

128 If the program is unable to demonstrate that it has an individual on site who can meet the requirements
 129 as described in *Sections F.3.A through F.3.F* above at the end of the ~~12-month~~ conditional approval
 130 period, it must inactivate. The requirements for program inactivation are described in *Appendix K:*
 131 *Transplant Program Inactivity, Withdrawal, and Termination* of these Bylaws.
 132 ~~The MPSC may consider on a case-by-case basis and grant a 6-month extension to a transplant program~~
 133 ~~that provides substantial evidence of progress toward fulfilling the requirements but is unable to complete~~
 134 ~~the requirements within one year.~~

135 **Appendix F.7.F Rejection of Conditional Approval**

136 If the program is unable to demonstrate that it has 2 designated surgeons on site who can fully meet the
 137 primary living donor liver surgeon requirements as described above at the end of the ~~2-year~~ conditional
 138 approval period, it must stop performing living donor liver recoveries by *either*:

- 139 1. Inactivating the living donor component of the program for a period up to 12 months.
- 140 2. Relinquishing the living donor component of the liver transplant program until it can meet the
 141 requirements for full approval.

142 **Appendix F.12.B. Rejection of Conditional Approval**

143 If the program is unable to demonstrate that it has a designated surgeon and physician on site who can
 144 fully meet the primary surgeon and primary physician requirements as described above at the end of the
 145 ~~36-month~~ conditional approval period, it must stop performing intestine transplants and *either*:

- 146 ■ Inactivate the intestine transplant program for a period up to 12 months
- 147 ■ Withdraw the intestine transplant program until it can meet the requirements for full approval

148 The requirements for program inactivation and withdrawal are described in *Appendix K: Transplant*
 149 *Program Inactivity, Withdrawal, and Termination* of these Bylaws.

150 **Appendix G.3.D. Conditional Approval for Primary Transplant Physician**

151 If the primary pancreas transplant physician changes at an approved pancreas transplant program, a
 152 physician can serve as the primary pancreas transplant physician for a maximum of 12 months if the
 153 following conditions are met:

- 154 1. The physician has been involved in the primary care of 8 or more newly transplanted pancreas
 155 recipients, and has followed these patients for at least 3 months from the time of their transplant. This
 156 care must be documented in a recipient log that includes the date of transplant and the medical
 157 record number or other unique identifier that can be verified by the OPTN Contractor. This log should
 158 be signed by the program director, division chief, or department chair from the transplant program
 159 where the experience was gained.
- 160 2. The physician has maintained a current working knowledge of pancreas transplantation, defined as
 161 direct involvement in pancreas transplant patient care within the last 2 years. This includes the
 162 management of patients with end stage pancreas disease, the selection of appropriate recipients for
 163 transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative patient

164 care, the use of immunosuppressive therapy including side effects of the drugs and complications of
 165 immunosuppression, differential diagnosis of pancreas dysfunction in the allograft recipient,
 166 histological interpretation of allograft biopsies, interpretation of ancillary tests for pancreas
 167 dysfunction, and long term outpatient care.

168 3. The physician has 12 months experience on an active pancreas transplant service as the primary
 169 pancreas transplant physician or under the direct supervision of a qualified pancreas transplant
 170 physician along with a pancreas transplant surgeon at a designated pancreas transplant program, or
 171 its foreign equivalent. This 12-month period of experience on the transplant service must have been
 172 acquired over a maximum of 2 years.

173 4. The physician should have observed at least 3 organ procurements and 3 pancreas transplants. The
 174 physician should also have observed the evaluation, the donation process, and management of at
 175 least 3 multiple organ donors who are donating a pancreas. If the physician has completed these
 176 observations, they must be documented in a log that includes the date of procurement, location of the
 177 donor, and Donor ID.

178 5. The program has established and documented a consulting relationship with counterparts at another
 179 pancreas transplant program.

180 6. The transplant program submits activity reports to the OPTN Contractor every 2 months describing
 181 the transplant activity, transplant outcomes, physician recruitment efforts, and other operating
 182 conditions as required by the MPSC to demonstrate the ongoing quality and efficient patient care at
 183 the program. The activity reports must also demonstrate that the physician is making sufficient
 184 progress in meeting the required involvement in the primary care of 15 or more pancreas transplant
 185 recipients, or that the program is making sufficient progress in recruiting a physician who will be on
 186 site and approved by the MPSC to assume the role of Primary Physician by the end of the 12 month
 187 conditional approval period.

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

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

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

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

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

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

207 If the transplant program is unable to demonstrate that it has an individual on site who can meet the
 208 requirements as described in *Sections G.3.A through G.3.C* above at the end of the ~~12-month~~ conditional

209 approval period, it must inactivate. The requirements for program inactivation are described in *Appendix*
 210 *K: Transplant Program Inactivity, Withdrawal and Termination* of these Bylaws.

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

214 **Appendix H.3.D. Conditional Approval for Primary Transplant Physician**

215 If the primary heart transplant physician changes at an approved heart transplant program, a physician
 216 can serve as the primary heart transplant physician for a maximum of 12 months if the following
 217 conditions are met:

- 218 1. The physician has current board certification in cardiology by the American Board of Internal
 219 Medicine, the American Board of Pediatrics, or the foreign equivalent.
- 220 2. The physician has 12 months experience on an active heart transplant service as the primary heart
 221 transplant physician or under the direct supervision of a qualified heart transplant physician and in
 222 conjunction with a heart transplant surgeon at a designated heart transplant program. These 12
 223 months of experience must be acquired within a 2-year period.
- 224 3. The physician has maintained a current working knowledge of heart transplantation, defined as direct
 225 involvement in heart transplant patient care within the last 2 years. This includes knowledge of acute
 226 and chronic heart failure, donor selection, the use of mechanical circulatory support devices, recipient
 227 selection, pre- and post-operative hemodynamic care, post-operative immunosuppressive therapy,
 228 histological interpretation in grading of myocardial biopsies for rejection, and long-term outpatient
 229 follow-up.
- 230 4. The physician has been involved in the primary care of 10 or more newly transplanted heart or
 231 heart/lung transplant recipients as the heart transplant physician or under the direct supervision of a
 232 qualified heart transplant physician or in conjunction with a heart transplant surgeon. The physician
 233 will have followed these patients for a minimum of 3 months from the time of transplant. This care
 234 must be documented in a log that includes the date of transplant and medical record or other unique
 235 identifier that can be verified by the OPTN Contractor. This recipient log should be signed by the
 236 program director or the primary transplant physician at the transplant program where the physician
 237 gained experience.
- 238 5. The physician should have observed at least 3 organ procurements and 3 heart transplants. The
 239 physician should also have observed the evaluation, the donation process, and management of at
 240 least 3 multiple organ donors who donated a heart or heart/lungs. If the physician has completed
 241 these observations, they must be documented in a log that includes the date of procurement, location
 242 of the donor, and Donor ID.
- 243 6. The program has established and documented a consulting relationship with counterparts at another
 244 heart transplant program.
- 245 7. The transplant program submits activity reports to the OPTN Contractor every 2 months describing
 246 the transplant activity, transplant outcomes, physician recruitment efforts, and other operating
 247 conditions as required by the MPSC to demonstrate the ongoing quality and efficient patient care at
 248 the program. The activity reports must also demonstrate that the physician is making sufficient
 249 progress to meet the required involvement in the primary care of 20 or more heart transplant
 250 recipients, or that the program is making sufficient progress in recruiting a physician who meets all
 251 requirements for primary heart transplant physician by the end of the 12 month conditional approval
 252 period.
- 253 8. The following letters are submitted directly to the OPTN Contractor:

- 254 a. A letter from the heart transplant physician or the heart transplant surgeon who has been directly
255 involved with the physician at the transplant program verifying the physician's competence.
- 256 b. A letter of recommendation from the primary physician and director at the transplant program last
257 served by the physician outlining the physician's overall qualifications to act as primary transplant
258 physician, as well as the physician's personal integrity, honesty, and familiarity with and
259 experience in adhering to OPTN obligations, and any other matters judged appropriate. The
260 MPSC may request additional recommendation letters from the primary physician, primary
261 surgeon, director, or others affiliated with any transplant program previously served by the
262 physician, at its discretion.
- 263 c. A letter from the physician that details the training and experience the physician has gained in
264 heart transplantation.

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

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

272 If the program is unable to demonstrate that it has an individual on site who can meet the requirements
273 as described in *Sections H.3.A through H.3.C* above at the end of the ~~12-month~~ conditional approval
274 period, it must inactivate. The requirements for program inactivation are described in *Appendix K:*
275 *Transplant Program Inactivity, Withdrawal, and Termination* of these Bylaws.
276 ~~The MPSC may consider on a case-by-case basis and grant a 6-month extension to a transplant program~~
277 ~~that provides substantial evidence of progress toward fulfilling the requirements but is unable to complete~~
278 ~~the requirements within one year.~~

279 **Appendix I.3.D. Conditional Approval for Primary Transplant Physician**

280 If the primary lung transplant physician changes at an approved lung transplant program, a physician can
281 serve as the primary lung transplant physician for a maximum of 12 months if the following conditions are
282 met:

- 283 1. The physician is a pulmonologist with current board certification in pulmonary medicine by the
284 American Board of Internal Medicine, the American Board of Pediatrics, or the foreign equivalent.
- 285 2. The physician has 12 months of experience on an active lung transplant service as the primary lung
286 transplant physician or under the direct supervision of a qualified lung transplant physician and in
287 conjunction with a lung transplant surgeon at a designated lung transplant program. These 12 months
288 of experience must be acquired within a 2-year period.
- 289 3. The physician has been involved in the primary care of 8 or more newly transplanted lung or
290 heart/lung transplant recipients as the lung transplant physician or under the direct supervision of a
291 qualified lung transplant physician and in conjunction with a lung transplant surgeon. At least half of
292 these patients must be lung transplant recipients. This care must be documented in a recipient log
293 that includes the date of transplant and medical record or other unique identifier that can be verified
294 by the OPTN Contractor. This log should be signed by the program director or the primary transplant
295 physician at the transplant program where the physician gained experience.
- 296 4. The physician has maintained a current working knowledge of all aspects of lung transplantation,
297 defined as a direct involvement in lung transplant patient care within the last 2 years. This includes
298 the care of acute and chronic lung failure, cardiopulmonary bypass, donor selection, recipient

299 selection, pre- and postoperative ventilator care, postoperative immunosuppressive therapy,
300 histological interpretation and grading of lung biopsies for rejection, and long-term outpatient follow-
301 up.

302 5. The physician should have observed at least 3 lung or heart/lung procurements and 3 lung
303 transplants. The physician should also have observed the evaluation, the donation process, and
304 management of 3 multiple organ donors who are donating a lung or heart/lungs. If the physician has
305 completed these observations, they must be documented in a log that includes the date of
306 procurement, location of the donor, and Donor ID.

307 6. The program has established and documented a consulting relationship with counterparts at another
308 lung transplant program.

309 7. The transplant program submits activity reports to the OPTN Contractor every 2 months describing
310 the transplant activity, transplant outcomes, physician recruitment efforts, and other operating
311 conditions as required by the MPSC to demonstrate the ongoing quality and efficient patient care at
312 the program. The activity reports must also demonstrate that the physician is making sufficient
313 progress to meet the required involvement in the primary care of 20 or more lung transplant
314 recipients, or that the program is making sufficient progress in recruiting a physician who meets all
315 requirements for primary lung transplant physician by the end of the 12 month conditional approval
316 period.

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

318 a. A letter from the supervising lung transplant physician or surgeon of the training program
319 documenting the physician's competence.

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

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

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

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

336 If the program is unable to demonstrate that it has an individual practicing on site who can meet the
337 requirements as described in *Sections 1.3.A through 1.3.C* above at the end of the ~~12-month~~ conditional
338 approval period, it must inactivate. The requirements for transplant program inactivation are described in
339 *Appendix K: Transplant Program Inactivity, Withdrawal, and Termination* of these Bylaws.
340 ~~The MPSC may consider on a case-by-case basis and grant a 6-month extension to a transplant program~~
341 ~~that provides substantial evidence of progress toward fulfilling the requirements but is unable to complete~~
342 ~~the requirements within one year##~~

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