

OPTN/UNOS Membership and Professional Standards Committee

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

*Committee Liaison:
Chad Waller
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, 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), 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.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 – October 14

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 Membership and Professional Standards Committee (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 in situations when 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 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 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. Applicability of the term "foreign equivalent" in the VCA transplant program membership requirements is a matter that should 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 who had never practiced in the United States. The JSWG believed some 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, but that it is the transplant program’s responsibility to

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>

monitor 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 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 special individuals and this is an uncommon scenario. Accordingly, the JSWG reasoned that these “special” 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, they may also improve living donor and transplant patient safety. 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 that is included on an application must 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

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>.

a Joint Societies Working Group (JSWG) to address this topic, along with other key personnel Bylaws 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 are 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 2200 programs in total). 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, nor would such a task be something that the OPTN should venture into. 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 should 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 special individuals and this is an uncommon scenario. Accordingly, the JSWG reasoned that these "special" 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 come from 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.

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

Designated Transplant Program or the Foreign Equivalent

In addition to focusing on “foreign equivalent” 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” is 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 should 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, it 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 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 this term 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.

One potential unintended consequence of these proposed changes should be 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 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. 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.

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.

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

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?

If public comment on this proposal is favorable, the MPSC would likely present these changes for the OPTN/UNOS Board of Directors' consideration at its December 2015 meeting. Assuming the Board adopts these changes, they would be effective on February 1, 2016. These changes do not require programming to implement. All applications received on or after February 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.

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

Appendix E: Membership and Personnel Requirements for Kidney Transplant Programs

E.2 Primary Kidney Transplant Surgeon Requirements

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

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

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

- a. Meet all requirements described in Section E.2.B below.
- b. Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that the surgeon obtains 40 hours of Category I continuing medical education (CME) credits with self-assessment that are relevant to the individual's practice every two 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 transplant program directors not employed by the applying hospital. These letters must address:
 - i. Why an exception to Section E.2.4 above is reasonable.
 - ii. The surgeon's overall qualifications to act as a primary kidney transplant surgeon.
 - iii. The surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
 - iv. Any other matters judged appropriate.

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

51
52 In addition, the primary transplant surgeon must have completed at least one of the training or
53 experience pathways listed below:

- 54
55 ■ The formal 2-year transplant fellowship pathway, as described in *Section E.2.A. Formal 2-year*
56 *Transplant Fellowship Pathway* below.
- 57 ■ The kidney transplant program clinical experience pathway, as described in *Section E.2.B.*
58 *Clinical Experience Pathway* below.

59 60 **A. Formal 2-year Transplant Fellowship Pathway**

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

- 63
64 1. The surgeon performed at least 30 kidney transplants as the primary surgeon or first
65 assistant during the 2-year fellowship period. These transplants must be documented in a log
66 that includes the date of transplant, the role of the surgeon in the procedure, and medical
67 record number or other unique identifier that can be verified by the OPTN Contractor. This log
68 must be signed by the director of the training program.
- 69 2. The surgeon performed at least 15 kidney procurements as primary surgeon or first assistant
70 over the 2-year period. At least 3 of these procurements must be multiple organ
71 procurements and at least 10 must be from deceased donors. These procedures must be
72 documented in a log that includes the date of procurement, location of the donor, and Donor
73 ID.
- 74 3. The surgeon has maintained a current working knowledge of kidney transplantation, defined
75 as direct involvement in kidney transplant patient care in the last 2 years. This includes the
76 management of patients with end stage renal disease, the selection of appropriate recipients
77 for transplantation, donor selection, histocompatibility and tissue typing, performing the
78 transplant operation, immediate postoperative and continuing inpatient care, the use of
79 immunosuppressive therapy including side effects of the drugs and complications of
80 immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient,
81 histological interpretation of allograft biopsies, interpretation of ancillary tests for renal
82 dysfunction, and long term outpatient care.
- 83 4. This training was completed at a hospital with a kidney transplant training program approved
84 by the Fellowship Training Committee of the American Society of Transplant Surgeons, the
85 Royal College of Physicians and Surgeons of Canada, or accepted by the OPTN Contractor
86 as described in the *Section E.4 Approved Kidney Transplant Surgeon and Physician*
87 *Fellowship Training Programs* that follows. ~~Foreign training programs must be accepted as~~
88 ~~equivalent by the Membership and Professional Standards Committee (MPSC).~~
- 89 5. The following letters are submitted directly to the OPTN Contractor:

- 90 a. A letter from the director of the training program and chairman of the department or
91 hospital credentialing committee verifying that the surgeon has met the above
92 requirements and is qualified to direct a kidney transplant program.
- 93 b. A letter of recommendation from the fellowship training program's primary surgeon and
94 transplant program director outlining the surgeon's overall qualifications to act as a
95 primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and
96 familiarity with and experience in adhering to OPTN obligations, and any other matters
97 judged appropriate. The MPSC may request additional recommendation letters from the
98 primary physician, primary surgeon, director, or others affiliated with any transplant
99 program previously served by the surgeon, at its discretion.
- 100 c. A letter from the surgeon that details the training and experience the surgeon has gained
101 in kidney transplantation.
- 102

103 **B. Clinical Experience Pathway**

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

106

- 107 1. The surgeon has performed 45 or more kidney transplants over a 2 to 5-year period as
108 primary surgeon or first assistant at a designated kidney transplant program, ~~or its foreign~~
109 ~~equivalent~~. The transplants must be documented in a log that includes the date of transplant,
110 the role of the surgeon in the procedure, and medical record number or other unique identifier
111 that can be verified by the OPTN Contractor. The log should be signed by the program
112 director, division chief, or department chair from the program where the experience was
113 gained. Each year of the surgeon's experience must be substantive and relevant and include
114 pre-operative assessment of kidney transplant candidates, performance of transplants as
115 primary surgeon or first assistant, and post-operative care of kidney recipients.
- 116 2. The surgeon has performed at least 15 kidney procurements as primary surgeon or first
117 assistant. At least 3 of these procurements must be multiple organ procurements and at least
118 10 must be from deceased donors. These cases must be documented in a log that includes
119 the date of procurement, location of the donor, and Donor ID.
- 120 3. The surgeon has maintained a current working knowledge of kidney transplantation, defined
121 as direct involvement in kidney transplant patient care in the last 2 years. This includes the
122 management of patients with end stage renal disease, the selection of appropriate recipients
123 for transplantation, donor selection, histocompatibility and tissue typing, performing the
124 transplant operation, immediate postoperative and continuing inpatient care, the use of
125 immunosuppressive therapy including side effects of the drugs and complications of
126 immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient,
127 histological interpretation of allograft biopsies, interpretation of ancillary tests for renal
128 dysfunction, and long term outpatient care.
- 129 4. The following letters are submitted directly to the OPTN Contractor:
 - 130 a. A letter from the director of the transplant program and Chairman of the department or
131 hospital credentialing committee verifying that the surgeon has met the above
132 qualifications and is qualified to direct a kidney transplant program.
 - 133 b. A letter of recommendation from the primary surgeon and transplant program director at
134 the transplant program last served by the surgeon outlining the surgeon's overall
135 qualifications to act as a primary transplant surgeon, as well as the surgeon's personal
136 integrity, honesty, and familiarity with and experience in adhering to OPTN obligations
137 and compliance protocols, and any other matters judged appropriate. The MPSC may

- 138 request additional recommendation letters from the primary physician, primary surgeon,
139 director, or others affiliated with any transplant program previously served by the
140 surgeon, at its discretion.
- 141 c. A letter from the surgeon that details the training and experience the surgeon has gained
142 in kidney transplantation.
143

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

145 A designated kidney transplant program must have a primary physician who meets *all* the following
146 requirements:
147

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

157
158 In place of current certification in nephrology by the American Board of Internal Medicine, the
159 American Board of Pediatrics, or the Royal College of Physicians and Surgeons of Canada, the
160 physician must:

- 161 a. Meet all the requirements described in Section E.3.B below, or, if the primary kidney transplant
162 physician changes at an approved kidney transplant program, Section E.3.G below.
- 163 b. Provide a plan for continuing education that is comparable to American board maintenance of
164 certification. This plan must at least require that the physician obtains 40 hours of Category I
165 continuing medical education (CME) credits with self-assessment that are relevant to the
166 individual's practice every two years. Self-assessment is defined as a written or electronic
167 question-and-answer exercise that assesses understanding of the material in the CME program.
168 A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve
169 an acceptable self-assessment score are allowed. The transplant hospital must document
170 completion of this continuing education.
- 171 c. Provide to the OPTN Contractor two letters of recommendation from transplant program directors
172 not employed by the applying hospital. These letters must address:
 - 173 i. Why an exception to Section E.3.4 above is reasonable.
 - 174 ii. The physician's overall qualifications to act as a primary kidney transplant physician.
 - 175 iii. The physician's personal integrity, honesty, and familiarity with and experience in adhering to
176 OPTN obligations and compliance protocols.
 - 177 iv. Any other matters judged appropriate.

178
179 If the physician has not adhered to the plan for maintaining continuing education or has not obtained
180 the necessary CME credits with self-assessment, the transplant program will have a six-month grace
181 period to address these deficiencies. If the physician has not fulfilled the requirements after the six-
182 month grace period, and a key personnel change application has not been submitted, then the
183 transplant program will be referred to the MPSC for appropriate action according to Appendix L of
184 these Bylaws. If the OPTN Contractor becomes aware that a primary physician has not been
185 compliant for 12 months or more and deficiencies still exist, then the transplant program will not be

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

188
189 In addition, the primary transplant physician must have completed at least one of the training or
190 experience pathways listed below:

- 191
- 192 ■ The 12-month transplant nephrology fellowship pathway, as described in *Section E.3.A. Twelve-*
193 *month Transplant Nephrology Fellowship* Pathway below.
- 194 ■ The clinical experience pathway, as described in *Section E.3.B. Clinical Experience Pathway*
195 below.
- 196 ■ The 3-year pediatric nephrology fellowship pathway, as described in *Section E.3.C. Three-year*
197 *Pediatric Nephrology Fellowship* Pathway below.
- 198 ■ The 12-month pediatric transplant nephrology fellowship pathway, as described in *Section*
199 *E.3.D. Twelve-month Pediatric Transplant Nephrology Fellowship* Pathway below.
- 200 ■ The combined pediatric nephrology training and experience pathway, as described in *Section*
201 *E.3.E. Combined Pediatric Nephrology Training and Experience* Pathway below.
- 202 ■ The conditional approval pathway, as described in *Section E.3.G. Conditional Approval for*
203 *Primary Transplant Physician* below, if the primary kidney transplant physician changes at an
204 approved kidney transplant program.
- 205

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

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

- 209
- 210 ~~1. The physician has current board certification in nephrology by the American Board of Internal~~
211 ~~Medicine or the foreign equivalent.~~
- 212 21. The physician completed 12 consecutive months of specialized training in transplantation
213 under the direct supervision of a qualified kidney transplant physician and along with a kidney
214 transplant surgeon at a kidney transplant program that performs 30 or more transplants each
215 year. The training must have included at least 6 months of clinical transplant service. The
216 remaining time must have consisted of transplant-related experience, such as experience in a
217 tissue typing laboratory, on another solid organ transplant service, or conducting basic or
218 clinical transplant research.
- 219 32. During the fellowship period, the physician was directly involved in the primary care of 30 or
220 more newly transplanted kidney recipients and continued to follow these recipients for a
221 minimum of 3 months from the time of transplant. The care must be documented in a log that
222 includes the date of transplant and the recipient medical record number or other unique
223 identifier that can be verified by the OPTN Contractor. This recipient log must be signed by
224 the director of the training program or the transplant program's primary transplant physician.
- 225 43. The physician has maintained a current working knowledge of kidney transplantation, defined
226 as direct involvement in kidney transplant care in the last 2 years. This includes the
227 management of patients with end stage renal disease, the selection of appropriate recipients
228 for transplantation, donor selection, histocompatibility and tissue typing, immediate
229 postoperative patient care, the use of immunosuppressive therapy including side effects of
230 the drugs and complications of immunosuppression, differential diagnosis of renal
231 dysfunction in the allograft recipient, histological interpretation of allograft biopsies,

232 interpretation of ancillary tests for renal dysfunction, and long term outpatient care. The
233 curriculum for obtaining this knowledge should be approved by the Residency Review
234 Committee for Internal Medicine (RRC-IM) of the Accreditation Council for Graduate Medical
235 Education (ACGME).

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

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

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

254
255 The training requirements outlined above are in addition to other clinical requirements for general
256 nephrology training.

257

258 **B. Clinical Experience Pathway**

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

261

262 1. The physician has been directly involved in the primary care of 45 or more newly transplanted
263 kidney recipients and continued to follow these recipients for a minimum of 3 months from the
264 time of transplant. This patient care must have been provided over a 2 to 5-year period on an
265 active kidney transplant service as the primary kidney transplant physician or under the direct
266 supervision of a qualified transplant physician and in conjunction with a kidney transplant
267 surgeon at a designated kidney ~~Kidney~~ transplant program ~~or the foreign equivalent~~. The
268 care must be documented in a log that includes the date of transplant and recipient medical
269 record number or other unique identifier that can be verified by the OPTN Contractor. The
270 recipient log should be signed by the program director, division Chief, or department Chair
271 from the program where the physician gained this experience.

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

- 280 3. The physician should have observed at least 3 organ procurements and 3 kidney transplants.
281 The physician should also have observed the evaluation, the donation process, and
282 management of at least 3 multiple organ donors who donated a kidney. If the physician has
283 completed these observations, they must be documented in a log that includes the date of
284 procurement, location of the donor, and Donor ID.
- 285 4. The following letters are submitted directly to the OPTN Contractor:
- 286 a. A letter from the qualified transplant physician or the kidney transplant surgeon who has
287 been directly involved with the proposed physician documenting the physician's
288 experience and competence.
- 289 b. A letter of recommendation from the primary physician and transplant program director at
290 the transplant program last served by the physician outlining the physician's overall
291 qualifications to act as a primary transplant physician, as well as the physician's personal
292 integrity, honesty, and familiarity with and experience in adhering to OPTN obligations
293 and compliance protocols, and any other matters judged appropriate. The MPSC may
294 request additional recommendation letters from the primary physician, primary surgeon,
295 director, or others affiliated with any transplant program previously served by the
296 physician, at its discretion.
- 297 c. A letter from the physician that details the training and experience the physician has
298 gained in kidney transplantation.
299

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

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

- 306
- 307 ~~1. The physician has current board certification in nephrology by the American Board of~~
308 ~~Pediatrics, or the foreign equivalent.~~
- 309 21. During the 3-year training period the physician was directly involved in the primary care of 10
310 or more newly transplanted kidney recipients and followed 30 newly transplanted kidney
311 recipients for at least 6 months from the time of transplant, under the direct supervision of a
312 qualified kidney transplant physician and in conjunction with a qualified kidney transplant
313 surgeon. The pediatric nephrology program director may elect to have a portion of the
314 transplant experience completed at another kidney transplant program in order to meet these
315 requirements. This care must be documented in a log that includes the date of transplant,
316 and the recipient medical record number or other unique identifier that can be verified by the
317 OPTN Contractor. This recipient log must be signed by the training program's director or the
318 primary physician of the transplant program.
- 319 32. The experience caring for pediatric patients occurred with a qualified kidney transplant
320 physician and surgeon at a kidney transplant program that performs an average of at least 10
321 pediatric kidney transplants a year.
- 322 43. The physician has maintained a current working knowledge of kidney transplantation, defined
323 as direct involvement in kidney transplant patient care over the last 2 years. This includes the
324 management of pediatric patients with end-stage renal disease, the selection of appropriate
325 pediatric recipients for transplantation, donor selection, histocompatibility and tissue typing,
326 immediate post-operative care including those issues of management unique to the pediatric
327 recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the

328 pediatric recipient including side-effects of drugs and complications of immunosuppression,
329 the effects of transplantation and immunosuppressive agents on growth and development,
330 differential diagnosis of renal dysfunction in the allograft recipient, manifestation of rejection
331 in the pediatric patient, histological interpretation of allograft biopsies, interpretation of
332 ancillary tests for renal dysfunction, and long-term outpatient care of pediatric allograft
333 recipients including management of hypertension, nutritional support, and drug dosage,
334 including antibiotics, in the pediatric patient. The curriculum for obtaining this knowledge must
335 be approved by the Residency Review Committee (RRC) -Ped of the ACGME.

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

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

- 342 a. A letter from the director and the supervising qualified transplant physician and surgeon
343 of the fellowship training program verifying that the physician has met the above
344 requirements and is qualified to direct a kidney transplant program.
- 345 b. A letter of recommendation from the fellowship training program's primary physician and
346 transplant program director outlining the physician's overall qualifications to act as a
347 primary transplant physician, as well as the physician's personal integrity, honesty, and
348 familiarity with and experience in adhering to OPTN obligations, and any other matters
349 judged appropriate. The MPSC may request additional recommendation letters from the
350 primary physician, primary surgeon, director, or others affiliated with any transplant
351 program previously served by the physician, at its discretion.
- 352 c. A letter from the physician that details the training and experience the physician has
353 gained in kidney transplantation.

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

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

- 358
- 359 1. The physician has current board certification in pediatric nephrology by the American Board
360 of Pediatrics, the Royal College of Physicians and Surgeons of Canada, ~~or the foreign~~
361 ~~equivalent~~, or is approved by the American Board of Pediatrics to take the certifying exam.
 - 362 2. During the fellowship, the physician was directly involved in the primary care of 10 or more
363 newly transplanted kidney recipients and followed 30 newly transplanted kidney recipients for
364 at least 6 months from the time of transplant, under the direct supervision of a qualified
365 kidney transplant physician and in conjunction with a qualified kidney transplant surgeon. The
366 pediatric nephrology program director may elect to have a portion of the transplant
367 experience completed at another Kidney transplant program in order to meet these
368 requirements. This care must be documented in a recipient log that includes the date of
369 transplant, and the recipient medical record number or other unique identifier that can be
370 verified by the OPTN Contractor. This log must be signed by the training program director or
371 the primary physician of the transplant program.
 - 372 3. The experience in caring for pediatric patients occurred at a kidney transplant program with a
373 qualified kidney transplant physician and surgeon that performs an average of at least 10
374 pediatric kidney transplants a year.

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4. The physician has maintained a current working knowledge of kidney transplantation, defined as direct involvement in kidney transplant patient care in the past 2 years. This includes the management of pediatric patients with end-stage renal disease, the selection of appropriate pediatric recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative care including those issues of management unique to the pediatric recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the pediatric recipient including side-effects of drugs and complications of immunosuppression, the effects of transplantation and immunosuppressive agents on growth and development, differential diagnosis of renal dysfunction in the allograft recipient, manifestation of rejection in the pediatric patient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long-term outpatient care of pediatric allograft recipients including management of hypertension, nutritional support, and drug dosage, including antibiotics, in the pediatric patient. The curriculum for obtaining this knowledge must be approved by the Residency Review Committee (RRC) -Ped of the ACGME.
 5. The physician should have observed at least 3 organ procurements and 3 pediatric kidney transplants. The physician should also have observed the evaluation, the donation process, and management of at least 3 multiple organ donors who donated a kidney. If the physician has completed these observations, they must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
 6. The following letters are submitted directly to the OPTN Contractor:
 - a. A letter from the director and the supervising qualified transplant physician and surgeon of the fellowship training program verifying that the physician has met the above requirements and is qualified to become the primary transplant physician of a designated kidney transplant program.
 - b. A letter of recommendation from the fellowship training program's primary physician and transplant program director outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
 - c. A letter from the physician that details the training and experience the physician has gained in kidney transplantation.

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

410 A physician can meet the requirements for primary kidney transplant physician if the following
411 conditions are met:
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1. The physician has current board certification in pediatric nephrology by the American Board of Pediatrics, the Royal College of Physicians and Surgeons of Canada, or the foreign equivalent, or is approved by the American Board of Pediatrics to take the certifying exam.
 2. The physician gained a minimum of 2 years of experience during or after fellowship, or accumulated during both periods, at a kidney transplant program.
 3. During the 2 or more years of accumulated experience, the physician was directly involved in the primary care of 10 or more newly transplanted kidney recipients and followed 30 newly transplanted kidney recipients for at least 6 months from the time of transplant, under the direct supervision of a qualified kidney transplant physician, along with a qualified kidney transplant surgeon. This care must be documented in a recipient log that includes the date of

423 transplant, and the recipient medical record number or other unique identifier that can be
424 verified by the OPTN Contractor. This log must be signed by the training program director or
425 the primary physician of the transplant program.

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

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

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

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

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

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

465 1. The physician has been involved in the primary care of 23 or more newly transplanted kidney
466 recipients, and has followed these patients for at least 3 months from the time of their
467 transplant. This care must be documented in a recipient log that includes the date of
468 transplant and the medical record number or other unique identifier that can be verified by the
469 OPTN Contractor. This log must be signed by the program director, division chief, or
470 department chair from the transplant program where the experience was gained.

- 471 32. The physician has maintained a current working knowledge of kidney transplantation, defined
472 as direct involvement in kidney transplant patient care during the last 2 years. This includes
473 the management of patients with end stage renal disease, the selection of appropriate
474 recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate
475 postoperative patient care, the use of immunosuppressive therapy including side effects of
476 the drugs and complications of immunosuppression, differential diagnosis of renal
477 dysfunction in the allograft recipient, histological interpretation of allograft biopsies,
478 interpretation of ancillary tests for renal dysfunction, and long-term outpatient care.
- 479 43. The physician has 12 months experience on an active kidney transplant service as the
480 primary kidney transplant physician or under the direct supervision of a qualified kidney
481 transplant physician and in conjunction with a kidney transplant surgeon at a designated
482 kidney transplant program ~~or the foreign equivalent~~. These 12 months of experience must be
483 acquired within a 2-year period.
- 484 54. The physician should have observed at least 3 organ procurements and 3 kidney transplants.
485 The physician should also have observed the evaluation, the donation process, and
486 management of at least 3 multiple organ donors who donated a kidney. If the physician has
487 completed these observations, they must be documented in a log that includes the date of
488 procurement, location of the donor, and Donor ID.
- 489 65. The program has established and documented a consulting relationship with counterparts at
490 another kidney transplant program.
- 491 76. The transplant program submits activity reports to the OPTN Contractor every 2 months
492 describing the transplant activity, transplant outcomes, physician recruitment efforts, and
493 other operating conditions as required by the MPSC to demonstrate the ongoing quality and
494 efficient patient care at the program. The activity reports must also demonstrate that the
495 physician is making sufficient progress to meet the required involvement in the primary care
496 of 45 or more kidney transplant recipients, or that the program is making sufficient progress in
497 recruiting a physician who meets all requirements for primary kidney transplant physician and
498 who will be on site and approved by the MPSC to assume the role of primary physician by the
499 end of the 12 month conditional approval period.
- 500 87. The following letters are submitted directly to the OPTN Contractor:
- 501 a. A letter from the supervising qualified transplant physician and surgeon who were directly
502 involved with the physician documenting the physician's experience and competence.
- 503 b. A letter of recommendation from the primary physician and director at the transplant
504 program last served by the physician outlining the physician's overall qualifications to act
505 as a primary transplant physician, as well as the physician's personal integrity, honesty,
506 and familiarity with and experience in adhering to OPTN obligations, and any other
507 matters judged appropriate. The MPSC may request additional recommendation letters
508 from the primary physician, primary surgeon, director, or others affiliated with any
509 transplant program previously served by the physician, at its discretion.
- 510 c. A letter from the physician that details the training and experience the physician has
511 gained in kidney transplantation.

512
513 The 12-month conditional approval period begins on the initial approval date granted to the
514 personnel change application, whether it is interim approval granted by the MPSC subcommittee,
515 or approval granted by the full MPSC. The conditional approval period ends 12 months after the
516 first approval date of the personnel change application.

517
518 If the program is unable to demonstrate that it has an individual on site who can meet the
519 requirements as described in *Sections E.3.A through E.3.F* above at the end of the 12-month

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

523
524 The MPSC may consider on a case-by-case basis and grant a 6-month extension to a transplant
525 program that provides substantial evidence of progress toward fulfilling the requirements but is
526 unable to complete the requirements within one year.

527
528 **Appendix F:**
529 **Membership and Personnel Requirements for Liver**
530 **Transplant Programs**

531
532 **F.2 Primary Liver Transplant Surgeon Requirements**

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

- 535
536 1. The surgeon must have an M.D., D.O., or equivalent degree from another country, with a current
537 license to practice medicine in the hospital's state or jurisdiction.
538 2. The surgeon must be accepted onto the hospital's medical staff, and be on site at this hospital.
539 3. The surgeon must have documentation from the hospital credentialing committee that it has verified
540 the surgeon's state license, board certification, training, and transplant continuing medical education,
541 and that the surgeon is currently a member in good standing of the hospital's medical staff.
542 4. The surgeon must have current certification by the American Board of Surgery, the American Board
543 of Urology, the American Board of Osteopathic Surgery, or the Royal College of Physicians and
544 Surgeons of Canada ~~foreign equivalent~~. In the case of a surgeon who has just completed training and
545 whose ~~board American Board of Urology~~ certification in urology is pending, the Membership and
546 Professional Standards Committee (MPSC) may grant conditional approval for ~~12~~16 months to allow
547 time for the surgeon to complete board certification, with the possibility of ~~renewal for~~ one additional
548 ~~12~~16-month ~~period~~ extension.

549
550 In place of current certification by the American Board of Surgery, the American Board of Urology, the
551 American Board of Osteopathic Surgery, the Royal College of Physicians and Surgeons of Canada,
552 or pending certification by the American Board of Urology, the surgeon must:

- 553
554 a. Meet all requirements described in Section F.2.B below.
555 b. Provide a plan for continuing education that is comparable to American board maintenance of
556 certification. This plan must at least require that the surgeon obtains 40 hours of Category I
557 continuing medical education (CME) credits with self-assessment that are relevant to the
558 individual's practice every two years. Self-assessment is defined as a written or electronic
559 question-and-answer exercise that assesses understanding of the material in the CME program.
560 A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve
561 an acceptable self-assessment score are allowed. The transplant hospital must document
562 completion of this continuing education.
563 c. Provide to the OPTN Contractor two letters of recommendation from transplant program directors
564 not employed by the applying hospital. These letters must address:

- 565 i. Why an exception to Section F.2.4 above is reasonable.
566 ii. The surgeon's overall qualifications to act as a primary liver transplant surgeon.
567 iii. The surgeon's personal integrity, honesty, and familiarity with and experience in adhering to
568 OPTN obligations and compliance protocols.
569 iv. Any other matters judged appropriate.
570

571 If the surgeon has not adhered to the plan for maintaining continuing education or has not
572 obtained the necessary CME credits with self-assessment, the transplant program will have a six-
573 month grace period to address these deficiencies. If the surgeon has not fulfilled the requirements
574 after the six-month grace period, and a key personnel change application has not been
575 submitted, then the transplant program will be referred to the MPSC for appropriate action
576 according to Appendix L of these Bylaws. If the OPTN Contractor becomes aware that a primary
577 surgeon has not been compliant for 12 months or more and deficiencies still exist, then the
578 transplant program will not be given any grace period and will be referred to the MPSC for
579 appropriate action according to Appendix L of these Bylaws.
580

581 In addition, the primary transplant surgeon must have completed at least one of the training or
582 experience pathways listed below:
583

- 584 ■ The formal 2-year transplant fellowship pathway, as described in *Section F.2.A. Formal 2-year*
585 *Transplant Fellowship Pathway* below.
586 ■ The liver transplant program clinical experience pathway, as described in *Section F.2.B. Clinical*
587 *Experience Pathway* below.
588

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

590 Surgeons can meet the training requirements for primary liver transplant surgeon by completing a
591 2-year transplant fellowship if the following conditions are met:
592

- 593 1. The surgeon performed at least 45 liver transplants as primary surgeon or first assistant
594 during the 2-year fellowship period. These transplants must be documented in a log that
595 includes the date of transplant, the role of the surgeon in the procedure, and the medical
596 record number or other unique identifier that can be verified by the OPTN Contractor. This log
597 must be signed by the director of the training program.
598 2. The surgeon performed at least 20 liver procurements as primary surgeon or first assistant
599 during the 2-year period. At least 3 of these procurements must include selection and
600 management of the donor. These procedures must be documented in a log that includes the
601 date of procurement, location of the donor, and Donor ID. This log must be signed by the
602 director of the training program.
603 3. The surgeon has maintained a current working knowledge of liver transplantation, defined as
604 direct involvement in liver transplant patient care within the last 2 years. This includes the
605 management of patients with end stage liver disease, the selection of appropriate recipients
606 for transplantation, donor selection, histocompatibility and tissue typing, performing the
607 transplant operation, immediate postoperative and continuing inpatient care, the use of
608 immunosuppressive therapy including side effects of the drugs and complications of
609 immunosuppression, differential diagnosis of liver allograft dysfunction, histologic
610 interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and
611 long term outpatient care.

- 612 4. The training was completed at a hospital with a transplant training program approved by the
613 Fellowship Training Committee of the American Society of Transplant Surgeons, the Royal
614 College of Physicians and Surgeons of Canada, or accepted by the OPTN Contractor as
615 described in *Section F.5. Approved Liver Surgeon Transplant Fellowship Programs* that
616 follows. ~~Foreign training programs must be accepted as equivalent by the Membership and~~
617 ~~Professional Standards Committee (MPSC).~~
- 618 5. The following letters are submitted directly to the OPTN Contractor:
- 619 a. A letter from the director of the training program verifying that the surgeon has met the
620 above requirements, and is qualified to direct a liver transplant program.
- 621 b. A letter of recommendation from the fellowship training program's primary surgeon and
622 transplant program director outlining the surgeon's overall qualifications to act as primary
623 transplant surgeon, as well as the surgeon's personal integrity, honesty, familiarity with
624 and experience in adhering to OPTN obligations, and other matters judged appropriate.
625 The MPSC may request additional recommendation letters from the primary physician,
626 primary surgeon, director, or others affiliated with any transplant program previously
627 served by the surgeon, at its discretion.
- 628 c. A letter from the surgeon that details his or her training and experience in liver
629 transplantation.

630 **B. Clinical Experience Pathway**

631 Surgeons can meet the requirements for primary liver transplant surgeon through clinical
632 experience gained post-fellowship, if the following conditions are met:
633

- 634
- 635 1. The surgeon has performed 60 or more liver transplants over a 2 to 5-year period as primary
636 surgeon or first assistant at a designated liver transplant program ~~or the foreign equivalent~~.
637 These transplants must be documented in a log that includes the date of transplant, the role
638 of the surgeon in the procedure, and medical record number or other unique identifier that
639 can be verified by the OPTN Contractor. This log should be signed by the program director,
640 division chief, or department chair from the program where the experience was gained. Each
641 year of the surgeon's experience must be substantive and relevant and include pre-operative
642 assessment of liver transplant candidates, transplants performed as primary surgeon or first
643 assistant, and post-operative management of liver recipients.
- 644 2. The surgeon has performed at least 30 liver procurements as primary surgeon or first
645 assistant. At least 3 of these procurements must include selection and management of the
646 donor. These procedures must be documented in a log that includes the date of procurement,
647 location of the donor, and Donor ID.
- 648 3. The surgeon has maintained a current working knowledge of liver transplantation, defined as
649 direct involvement in liver transplant patient care within the last 2 years. This includes the
650 management of patients with end stage liver disease, the selection of appropriate recipients
651 for transplantation, donor selection, histocompatibility and tissue typing, performing the
652 transplant operation, immediate postoperative and continuing inpatient care, the use of
653 immunosuppressive therapy including side effects of the drugs and complications of
654 immunosuppression, differential diagnosis of liver dysfunction in the allograft recipient,
655 histologic interpretation of allograft biopsies, interpretation of ancillary tests for liver
656 dysfunction, and long term outpatient care.
- 657 4. The following letters are sent directly to the OPTN Contractor:

- 658 a. A letter from the director of the transplant program and chairman of the department or
659 hospital credentialing committee verifying that the surgeon has met the above
660 requirements, and is qualified to direct a liver transplant program.
- 661 b. A letter of recommendation from the primary surgeon and transplant program director at
662 the transplant program last served by the surgeon outlining the surgeon's overall
663 qualifications to act as primary transplant surgeon, as well as the surgeon's personal
664 integrity, honesty, familiarity with and experience in adhering to OPTN obligations, and
665 other matters judged appropriate. The MPSC may request additional recommendation
666 letters from the primary physician, primary surgeon, director, or others affiliated with any
667 transplant program previously served by the surgeon, at its discretion.
- 668 c. A letter from the surgeon that details the training and experience the surgeon gained in
669 liver transplantation.
- 670

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

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

674

- 675 1. The physician must have an M.D., D.O., or equivalent degree from another country, with a current
676 license to practice medicine in the hospital's state or jurisdiction.
 - 677 2. The physician must be accepted onto the hospital's medical staff, and be on site at this hospital.
 - 678 3. The physician must have documentation from the hospital credentialing committee that it has verified
679 the physician's state license, board certification, training, and transplant continuing medical education
680 and that the physician is currently a member in good standing of the hospital's medical staff.
 - 681 4. The physician must have current board certification in gastroenterology by the American Board of
682 Internal Medicine, the American Board of Pediatrics, or the Royal College of Physicians and
683 Surgeons of Canada ~~foreign equivalent~~.
- 684

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

- 688 a. Meet all the requirements described in Section F.3.B below, or, if the primary liver transplant
689 physician changes at an approved liver transplant program, Section F.3.G below.
 - 690 b. Provide a plan for continuing education that is comparable to American board maintenance of
691 certification. This plan must at least require that the physician obtains 40 hours of Category I
692 continuing medical education (CME) credits with self-assessment that are relevant to the
693 individual's practice every two years. Self-assessment is defined as a written or electronic
694 question-and-answer exercise that assesses understanding of the material in the CME program.
695 A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve
696 an acceptable self-assessment score are allowed. The transplant hospital must document
697 completion of this continuing education.
 - 698 c. Provide to the OPTN Contractor two letters of recommendation from transplant program directors
699 not employed by the applying hospital. These letters must address:
 - 700 i. Why an exception to Section F.3.4 above is reasonable.
 - 701 ii. The physician's overall qualifications to act as a primary liver transplant physician.
 - 702 iii. The physician's personal integrity, honesty, and familiarity with and experience in adhering to
703 OPTN obligations and compliance protocols.
 - 704 iv. Any other matters judged appropriate.
- 705

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

715
716 In addition, the primary transplant physician must have completed at least one of the training or
717 experience pathways listed below:

- 718
- 719 ■ The 12-month transplant hepatology fellowship pathway, as described in *Section F.3.A. 12-month*
720 *Transplant Hepatology Fellowship Pathway* below.
 - 721 ■ The clinical experience pathway, as described in *Section F.3.B. Clinical Experience Pathway* below.
 - 722 ■ The 3-year pediatric gastroenterology fellowship pathway, as described in *Section F.3.C. Three-year*
723 *Pediatric Gastroenterology Fellowship Pathway* below.
 - 724 ■ The 12-month pediatric transplant hepatology fellowship pathway, as described in *Section F.3.D.*
725 *Pediatric Transplant Hepatology Fellowship Pathway* below.
 - 726 ■ The combined pediatric gastroenterology or transplant hepatology training and experience pathway,
727 as described in *Section F.3.E. Combined Pediatric Gastroenterology/Transplant Hepatology Training*
728 *and Experience Pathway* below.
 - 729 ■ The conditional approval pathway, as described in Section F.3.G. Conditional Approval for Primary
730 Transplant Physician below, if the primary liver transplant physician changes at an approved liver
731 transplant program.
- 732

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

738 **B. Clinical Experience Pathway**

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

- 742
- 743 1. The physician has been directly involved in the primary care of 50 or more newly transplanted
744 liver recipients and continued to follow these recipients for a minimum of 3 months from the
745 time of transplant. This patient care must have been provided over a 2 to 5-year period on an
746 active liver transplant service as the primary liver transplant physician or under the direct
747 supervision of a qualified liver transplant physician and in conjunction with a liver transplant
748 surgeon at a designated liver transplant program ~~or the foreign equivalent~~. This care must be
749 documented in a log that includes the date of transplant and the medical record number or
750 other unique identifier that can be verified by the OPTN Contractor. This recipient log should
751 be signed by the program director, division chief, or department chair from the program
752 where the physician gained this experience.

- 753 2. The physician has maintained a current working knowledge of liver transplantation, defined
754 as direct involvement in liver transplant patient care within the last 2 years. This includes the
755 management of patients with end stage liver disease, acute liver failure, the selection of
756 appropriate recipients for transplantation, donor selection, histocompatibility and tissue
757 typing, immediate post-operative patient care, the use of immunosuppressive therapy
758 including side effects of the drugs and complications of immunosuppression, differential
759 diagnosis of liver allograft dysfunction, histologic interpretation of allograft biopsies,
760 interpretation of ancillary tests for liver dysfunction, and long term outpatient care.
- 761 3. The physician should have observed at least 3 organ procurements and 3 liver transplants.
762 The physician should also have observed the evaluation, the donation process, and
763 management of at least 3 multiple organ donors who donated a liver. If the physician has
764 completed these observations, they must be documented in a log that includes the date of
765 procurement, the location of the donor, and Donor ID.
- 766 4. The following letters are submitted directly to the OPTN Contractor:
- 767 a. A letter from the qualified transplant physician or the liver transplant surgeon who has
768 been directly involved with the proposed physician documenting the physician's
769 experience and competence.
- 770 b. A letter of recommendation from the primary physician and transplant program director at
771 the transplant program last served by the physician outlining the physician's overall
772 qualifications to act as a primary transplant physician, as well as the physician's personal
773 integrity, honesty, and familiarity with and experience in adhering to OPTN obligations,
774 and any other matters judged appropriate. The MPSC may request additional
775 recommendation letters from the primary physician, primary surgeon, director, or others
776 affiliated with any transplant program previously served by the physician, at its discretion.
- 777 c. A letter from the physician that details the training and experience the physician gained in
778 liver transplantation.
779

780 C. Three-year Pediatric Gastroenterology Fellowship Pathway

781 A physician can meet the requirements for primary liver transplant physician by completion of 3
782 years of pediatric gastroenterology fellowship training as required by the American Board of
783 Pediatrics in a program accredited by the Residency Review Committee for Pediatrics (RRC-Ped)
784 of the Accreditation Council for Graduate Medical Education (ACGME). The training must contain
785 at least 6 months of clinical care for transplant patients, and meet the following conditions:
786

- 787 1. The physician has current board certification in pediatric gastroenterology by the American
788 Board of Pediatrics, or ~~the foreign equivalent~~ the Royal College of Physicians and Surgeons
789 of Canada.
- 790 2. During the 3-year training period the physician was directly involved in the primary care of 10
791 or more newly transplanted pediatric liver recipients and followed 20 newly transplanted liver
792 recipients for a minimum of 3 months from the time of transplant, under the direct supervision
793 of a qualified liver transplant physician along with a qualified liver transplant surgeon. The
794 physician was also directly involved in the preoperative, peri-operative and post-operative
795 care of 10 or more liver transplants in pediatric patients. The pediatric gastroenterology
796 program director may elect to have a portion of the transplant experience carried out at
797 another transplant service, to meet these requirements. This care must be documented in a
798 log that includes the date of transplant, the medical record number or other unique identifier
799 that can be verified by the OPTN Contractor. This recipient log must be signed by the training
800 program director or the transplant program's primary transplant physician.

- 801 3. The experience caring for pediatric patients occurred at a liver transplant program with a
802 qualified liver transplant physician and a qualified liver transplant surgeon that performs an
803 average of at least 10 liver transplants on pediatric patients per year.
- 804 4. The physician should have observed at least 3 organ procurements and 3 liver transplants. In
805 addition, the physician should have observed the evaluation, the donation process, and the
806 care of at least 3 multiple organ donors who donated a liver. If the physician has completed
807 these observations, they must be documented in a log that includes the date of procurement,
808 location of the donor and Donor ID.
- 809 5. The physician has maintained a current working knowledge of liver transplantation, defined
810 as direct involvement in liver transplant patient care within the last 2 years. This includes the
811 management of pediatric patients with end-stage liver disease acute liver failure, the
812 selection of appropriate pediatric recipients for transplantation, donor selection,
813 histocompatibility and tissue typing, immediate postoperative care including those issues of
814 management unique to the pediatric recipient, fluid and electrolyte management, the use of
815 immunosuppressive therapy in the pediatric recipient including side-effects of drugs and
816 complications of immunosuppression, the effects of transplantation and immunosuppressive
817 agents on growth and development, differential diagnosis of liver dysfunction in the allograft
818 recipient, manifestation of rejection in the pediatric patient, histological interpretation of
819 allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long-term
820 outpatient care of pediatric allograft recipients including management of hypertension,
821 nutritional support, and drug dosage, including antibiotics, in the pediatric patient.
- 822 6. The following letters are submitted directly to the OPTN Contractor:
- 823 a. A letter from the director of the pediatric gastroenterology training program, and the
824 qualified liver transplant physician and surgeon of the fellowship training program
825 verifying that the physician has met the above requirements, and is qualified to act as a
826 liver transplant physician and direct a liver transplant program.
- 827 b. A letter of recommendation from the fellowship training program's primary physician and
828 transplant program director outlining the physician's overall qualifications to act as a
829 primary transplant physician, as well as the physician's personal integrity, honesty, and
830 familiarity with and experience in adhering to OPTN obligations, and any other matters
831 judged appropriate. The MPSC may request additional recommendation letters from the
832 primary physician, primary surgeon, director, or others affiliated with any transplant
833 program previously served by the physician, at its discretion.
- 834 c. A letter from the physician that details the training and experience the physician gained in
835 liver transplantation.
- 836

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

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

840

- 841 1. The physician has current board certification in pediatric gastroenterology by the American
842 Board of Pediatrics, the Royal College of Physicians and Surgeons of Canada, or the foreign
843 equivalent, or is approved by the American Board of Pediatrics to take the certifying exam.
- 844 2. During the fellowship, the physician was directly involved in the primary care of 10 or more
845 newly transplanted pediatric liver recipients and followed 20 newly transplanted liver
846 recipients for at least 3 months from the time of transplant, under the direct supervision of a
847 qualified liver transplant physician and in conjunction with a qualified liver transplant surgeon.
848 The physician must have been directly involved in the pre-operative, peri-operative and post-

849 operative care of 10 or more liver transplants in pediatric patients. The pediatric
850 gastroenterology program director may elect to have a portion of the transplant experience
851 completed at another liver transplant program in order to meet these requirements. This care
852 must be documented in a log that includes the date of transplant and the medical record
853 number or other unique identifier that can be verified by the OPTN Contractor. This recipient
854 log must be signed by the training program director or the transplant program primary
855 transplant physician.

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

859 4. The physician has maintained a current working knowledge of liver transplantation, defined
860 as direct involvement in liver transplant patient care within the last 2 years. This includes the
861 management of pediatric patients with end-stage liver disease, acute liver failure, the
862 selection of appropriate pediatric recipients for transplantation, donor selection,
863 histocompatibility and tissue typing, immediate postoperative care including those issues of
864 management unique to the pediatric recipient, fluid and electrolyte management, the use of
865 immunosuppressive therapy in the pediatric recipient including side-effects of drugs and
866 complications of immunosuppression, the effects of transplantation and immunosuppressive
867 agents on growth and development, differential diagnosis of liver dysfunction in the allograft
868 recipient, manifestation of rejection in the pediatric patient, histological interpretation of
869 allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long-term
870 outpatient care of pediatric allograft recipients including management of hypertension,
871 nutritional support, and drug dosage, including antibiotics, in the pediatric patient.

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

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

878 a. A letter from the director of the pediatric transplant hepatology training program, and the
879 qualified liver transplant physician and surgeon of the fellowship training program
880 verifying that the physician has met the above requirements, and is qualified to act as a
881 liver transplant physician and direct a liver transplant program.

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

889 c. A letter from the physician that details the training and experience the physician gained in
890 liver transplantation.

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892 **E. Combined Pediatric Gastroenterology/Transplant Hepatology**
893 **Training and Experience Pathway**

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

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1. The physician has current board certification in pediatric gastroenterology by the American Board of Pediatrics, the Royal College of Physicians and Surgeons of Canada, or the foreign equivalent, or is approved by the American Board of Pediatrics to take the certifying exam.
 2. The physician gained a minimum of 2 years of experience during or after fellowship, or accumulated during both periods, at a liver transplant program.
 3. During the 2 or more years of accumulated experience, the physician was directly involved in the primary care of 10 or more newly transplanted pediatric liver recipients and followed 20 newly transplanted liver recipients for a minimum of 6 months from the time of transplant, under the direct supervision of a qualified liver transplant physician and along 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 pediatric liver transplants recipients. This care must be documented in a log that includes at 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.
 4. The individual 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 pediatric patients with end-stage liver disease, the selection of appropriate pediatric recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative care including those issues of management unique to the pediatric recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the pediatric recipient including side-effects of drugs and complications of immunosuppression, the effects of transplantation and immunosuppressive agents on growth and development, differential diagnosis of liver dysfunction in the allograft recipient, manifestation of rejection in the pediatric patient, histological interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long-term outpatient care of pediatric allograft recipients including management of hypertension, nutritional support, and drug dosage, including antibiotics, in the pediatric patient.
 5. The physician should have observed at least 3 organ procurements and 3 liver transplants. In addition, the physician should have observed the evaluation of donor, the donation process, and the management of at least 3 multiple organ donors who donated a liver. 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.
 6. The following letters are submitted directly to the OPTN Contractor:
 - a. A letter from the qualified liver transplant physician and surgeon who have been directly involved with the physician documenting the physician's experience and competence.
 - b. A letter of recommendation from the primary physician and transplant program director at the fellowship training program or transplant program last served by the physician outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
 - c. A letter from the physician that details the training and experience the physician gained in liver transplantation.

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G. Conditional Approval for Primary Transplant Physician

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

- ~~1. The physician has current board certification in gastroenterology by the American Board of Internal Medicine, the American Board of Pediatrics, or the foreign equivalent.~~
21. The physician has been involved in the primary care of 25 or more newly transplanted liver 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 must be signed by the program director, division chief, or department chair from the transplant program where the experience was gained.
- ~~32.~~ 32. The physician has maintained a current working knowledge of liver transplantation, defined as direct involvement in liver transplant patient care during the last 2 years. This includes the management of patients with end stage liver disease, acute liver failure, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of liver allograft dysfunction, histologic interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long term outpatient care.
- ~~43.~~ 43. The physician has 12 months experience on an active liver transplant service as the primary liver transplant physician or under the direct supervision of a qualified liver transplant physician along with a liver transplant surgeon at a designated liver transplant program ~~or the foreign equivalent.~~ These 12 months of experience must be acquired within a 2-year period.
- ~~54.~~ 54. The physician should have observed at least 3 organ procurements and 3 liver transplants. The physician should also have observed the evaluation, the donation process, and management of at least 3 multiple organ donors who are donating a liver. 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.
- ~~65.~~ 65. The transplant program submits activity reports to the OPTN Contractor every 2 months describing the transplant activity, transplant outcomes, physician recruitment efforts, and other operating conditions as required by the MPSC to demonstrate the ongoing quality and efficient patient care at the program. The activity reports must also demonstrate that the physician is making sufficient progress to meet the required involvement in the primary care of 50 or more liver transplant recipients, or that the program is making sufficient progress in recruiting a physician who meets all requirements for primary liver transplant physician and who will be on site and approved by the MPSC to assume the role of primary physician by the end of the 12 month conditional approval period.
- ~~76.~~ 76. The program has established and documented a consulting relationship with counterparts at another liver transplant program.
- ~~87.~~ 87. The following letters are submitted directly to the OPTN Contractor:
 - a. A letter from the qualified liver transplant physician and surgeon who were directly involved with the physician verifying that the physician has satisfactorily met the above requirements to become the primary transplant physician of a liver transplant program.
 - b. A letter of recommendation from the primary physician and transplant program director at the transplant program last served by the physician outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations,

992 and any other matters judged appropriate. The MPSC may request additional
993 recommendation letters from the primary physician, primary surgeon, director, or others
994 affiliated with any transplant program previously served by the physician, at its discretion.
995 c. A letter from the physician sends that details the training and experience the physician
996 gained in liver transplantation.
997

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

999 Liver transplant programs must designate a director of liver transplant anesthesia who has expertise in
1000 the area of peri-operative care of liver transplant patients and can serve as an advisor to other members
1001 of the team.

- 1002 1. The director of liver transplant anesthesia must be a Diplomate of the American Board of
1003 Anesthesiology, ~~or the foreign equivalent.~~
- 1004 2. In place of current certification by the American Board of Anesthesiology, the director of liver
1005 transplant anesthesia must provide to the OPTN Contractor two letters of recommendation from
1006 current directors of liver transplant anesthesia not employed by the applying member. These letters
1007 must address:
- 1008 a. Why an exception to Section F.4.1 above is reasonable.
- 1009 b. The anesthesiologist's overall qualifications to act as a director of liver transplant
1010 anesthesiology.
- 1011 c. Any additional supportive information judged appropriate.
1012

1013 **Appendix G:**

1014 **Membership and Personnel Requirements for**

1015 **Pancreas and Pancreatic Islet Transplant Programs**

1016

1017 **G.2 Primary Pancreas Transplant Surgeon Requirements**

1018 A designated pancreas transplant program must have a primary surgeon who meets *all* the following
1019 requirements:
1020

- 1021 1. The surgeon must have an M.D., D.O., or equivalent degree from another country, with a current
1022 license to practice medicine in the hospital's state or jurisdiction.
- 1023 2. The surgeon must be accepted onto the hospital's medical staff, and be on site at this hospital.
- 1024 3. The surgeon must have documentation from the hospital credentialing committee that it has verified
1025 the surgeon's state license, board certification, training, and transplant continuing medical education,
1026 and that the surgeon is currently a member in good standing of the hospital's medical staff.
- 1027 4. The surgeon must have current certification by the American Board of Surgery, the American Board
1028 of Urology, the American Board of Osteopathic Surgery, or the Royal College of Physicians and
1029 Surgeons of Canada, foreign equivalent In the case of a surgeon who has just completed training and
1030 whose ~~board American Board of Urology certification in urology~~ is pending, the Membership and
1031 Professional Standards Committee (MPSC) may grant conditional approval for ~~42~~16 months to allow
1032 time for the surgeon to complete board certification, with the possibility of ~~renewal for~~ one additional
1033 ~~42~~16-month ~~period~~ extension.
1034

1035 In place of current certification by the American Board of Surgery, the American Board of Urology, the
1036 American Board of Osteopathic Surgery, the Royal College of Physicians and Surgeons of Canada,
1037 or pending certification by the American Board of Urology, the surgeon must:

- 1038 a. Meet all requirements described in *Section G.2.B* below
1039 b. Provide a plan for continuing education that is comparable to American board maintenance of
1040 certification. This plan must at least require that the surgeon obtains 40 hours of Category I
1041 continuing medical education (CME) credits with self-assessment that are relevant to the
1042 individual's practice every two years. Self-assessment is defined as a written or electronic
1043 question-and-answer exercise that assesses understanding of the material in the CME program.
1044 A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve
1045 an acceptable self-assessment score are allowed. The transplant hospital must document
1046 completion of this continuing education.
1047 c. Provide to the OPTN Contractor two letters of recommendation from transplant program directors
1048 not employed by the applying hospital. These letters must address:
1049 i. Why an exception to *Section G.2.4* above is reasonable.
1050 ii. The surgeon's overall qualifications to act as a primary pancreas transplant surgeon.
1051 iii. The surgeon's personal integrity, honesty, and familiarity with and experience in adhering to
1052 OPTN obligations and compliance protocols.
1053 iv. Any other matters judged appropriate.
1054

1055 If the surgeon has not adhered to the plan for maintaining continuing education or has not obtained
1056 the necessary CME credits with self-assessment, the transplant program will have a six-month grace
1057 period to address these deficiencies. If the surgeon has not fulfilled the requirements after the six-
1058 month grace period, and a key personnel change application has not been submitted, then the
1059 transplant program will be referred to the MPSC for appropriate action according to *Appendix L* of
1060 these Bylaws. If the OPTN Contractor becomes aware that a primary surgeon has not been compliant
1061 for 12 months or more and deficiencies still exist, then the transplant program will not be given any
1062 grace period and will be referred to the MPSC for appropriate action according to *Appendix L* of these
1063 Bylaws.
1064

1065 In addition, the primary transplant physician must have completed at least one of the training or
1066 experience pathways listed below:
1067

- 1068 ■ The 12-month pancreas transplant fellowship pathway, as described in *Section G.3.A.*
1069 *Twelve-month Transplant Medicine Fellowship Pathway* below.
1070 ■ The clinical experience pathway, as described in *Section G.3.B. Clinical Experience Pathway*
1071 below.
1072

1073 **A. Formal 2-year Transplant Fellowship Pathway**

1074 Surgeons can meet the training requirements for primary pancreas transplant surgeon by
1075 completing a 2-year transplant fellowship if the following conditions are met:
1076

- 1077 1. The surgeon performed at least 15 pancreas transplants as primary surgeon or first assistant
1078 during the 2-year fellowship period. These transplants must be documented in a log that
1079 includes the date of transplant, the role of the surgeon in the procedure, and medical record
1080 number or other unique identifier that can be verified by the OPTN Contractor. This log must
1081 be signed by the director of the training program.

- 1082 2. The surgeon performed at least 10 pancreas procurements as primary surgeon or first
1083 assistant during the 2-year period. These cases must be documented in a log that includes
1084 the date of procurement, location of the donor, and Donor ID. This log must be signed by the
1085 director of the training program.
- 1086 3. The surgeon has maintained a current working knowledge of pancreas transplantation,
1087 defined as direct involvement in patient care within the last 2 years. This includes the
1088 management of patients with diabetes mellitus, the selection of appropriate recipients for
1089 transplantation, donor selection, histocompatibility and tissue typing, performing the
1090 transplant operation, immediate postoperative and continuing inpatient care, the use of
1091 immunosuppressive therapy including side effects of the drugs and complications of
1092 immunosuppression, differential diagnosis of pancreas dysfunction in the allograft recipient,
1093 histological interpretation of allograft biopsies, interpretation of ancillary tests for pancreatic
1094 dysfunction, and long term outpatient care.
- 1095 4. The training was completed at a hospital with a pancreas transplant training program
1096 approved by the Fellowship Training Committee of the American Society of Transplant
1097 Surgeons, the Royal College of Physicians and Surgeons of Canada, or accepted by the
1098 OPTN Contractor as described in *Section G.7. Approved Pancreas Transplant Surgeon*
1099 *Fellowship Training Programs* that follows. ~~Foreign training programs will be reviewed by the~~
1100 ~~MPSC and only those programs that are accepted as equivalent will be granted approval.~~
- 1101 5. The following letters are submitted directly to the OPTN Contractor:
- 1102 a. A letter from the director of the training program and chairman of the department or
1103 hospital credentialing committee verifying that the fellow has met the above requirements
1104 and is qualified to direct a pancreas transplant program.
- 1105 b. A letter of recommendation from the fellowship training program's primary surgeon and
1106 transplant program director outlining the surgeon's overall qualifications to act as primary
1107 transplant surgeon as well as the surgeon's personal integrity, honesty, familiarity with
1108 and experience in adhering to OPTN obligations, and any other matters judged
1109 appropriate. The MPSC may request similar letters of recommendation from the primary
1110 physician, primary surgeon, director, or others affiliated with any transplant program
1111 previously served by the surgeon, at its discretion.
- 1112 c. A letter from the surgeon that details the training and experience the surgeon has gained
1113 in pancreas transplantation.
- 1114
- 1115

B. Clinical Experience Pathway

1116 Surgeons can meet the requirements for primary pancreas transplant surgeon through clinical
1117 experience gained post-fellowship if the following conditions are met:

1118

- 1119 1. The surgeon has performed 20 or more pancreas transplants over a 2 to 5-year period as
1120 primary surgeon or first assistant, at a designated pancreas transplant program ~~or its foreign~~
1121 ~~equivalent~~. These transplants must be documented in a log that includes the date of
1122 transplant, the role of the surgeon in the procedure, and medical record number or other
1123 unique identifier that can be verified by the OPTN Contractor. This log should be signed by
1124 the program director, division chief, or department chair from the program where the
1125 experience was gained. Each year of the surgeon's experience must be substantive and
1126 relevant and include pre-operative assessment of pancreas transplant candidates,
1127 transplants performed as primary surgeon or first assistant, and post-operative care of
1128 pancreas recipients.

- 1129 2. The surgeon has performed at least 10 pancreas procurements as primary surgeon or first
 1130 assistant. These procurements must be documented in a log that includes the date of
 1131 procurement, location of the donor, and Donor ID.
- 1132 3. The surgeon has maintained a current working knowledge of pancreas transplantation,
 1133 defined as direct involvement in pancreas transplant patient care within the last 2 years. This
 1134 includes the management of patients with diabetes mellitus, the selection of appropriate
 1135 recipients for transplantation, donor selection, histocompatibility and tissue typing, performing
 1136 the transplant operation, immediate postoperative and continuing inpatient care, the use of
 1137 immunosuppressive therapy including side effects of the drugs and complications of
 1138 immunosuppression, differential diagnosis of pancreatic dysfunction in the allograft recipient,
 1139 histological interpretation of allograft biopsies, interpretation of ancillary tests for pancreatic
 1140 dysfunction, and long term outpatient care.
- 1141 4. The following letters are submitted directly to the OPTN Contractor:
- 1142 a. A letter from the director of the transplant program and chairman of the department or
 1143 hospital credentialing committee verifying that the surgeon has met the above
 1144 requirements and is qualified to direct a pancreas transplant program.
- 1145 b. A letter of recommendation from the primary surgeon and director at the transplant
 1146 program last served by the surgeon outlining the surgeon's overall qualifications to act as
 1147 primary transplant surgeon as well as the surgeon's personal integrity, honesty, familiarity
 1148 with and experience in adhering to OPTN obligations, and any other matters judged
 1149 appropriate. The MPSC may request similar letters of recommendation from the primary
 1150 physician, primary surgeon, director, or others affiliated with any transplant program
 1151 previously served by the individual, at its discretion.
- 1152 c. A letter from the surgeon that details the training and experience the surgeon has gained
 1153 in pancreas transplantation.
- 1154
- 1155

G.3 Primary Pancreas Transplant Physician Requirements

1156 A designated pancreas transplant program must have a primary physician who meets *all* the
 1157 following requirements:

1158

- 1159 1. The physician must have an M.D., D.O., or equivalent degree from another country, with a
 1160 current license to practice medicine in the hospital's state or jurisdiction.
- 1161 2. The physician must be accepted onto the hospital's medical staff, and be on site at this
 1162 hospital.
- 1163 3. The physician must have documentation from the hospital credentialing committee that it has
 1164 verified the physician's state license, board certification, training, and transplant continuing
 1165 medical education and that the physician is currently a member in good standing of the
 1166 hospital's medical staff.
- 1167 4. The physician must have current board certification in nephrology, endocrinology, or
 1168 diabetology by the American Board of Internal Medicine, the American Board of Pediatrics, or
 1169 the Royal College of Physicians and Surgeons of Canada ~~foreign equivalent~~.
- 1170

1171 In place of current certification in nephrology, endocrinology, or diabetology by the American
 1172 Board of Internal Medicine, the American Board of Pediatrics, or the Royal College of
 1173 Physicians and Surgeons of Canada, the physician must:

- 1174 a. Meet all the requirements described in Section G.3.B below, or, if the primary pancreas
 1175 transplant physician changes at an approved pancreas transplant program, Section
 1176 G.3.D below.

- 1177 b. Provide a plan for continuing education that is comparable to American board
1178 maintenance of certification. This plan must at least require that the physician obtains 40
1179 hours of Category I continuing medical education (CME) credits with self-assessment that
1180 are relevant to the individual's practice every two years. Self-assessment is defined as a
1181 written or electronic question-and-answer exercise that assesses understanding of the
1182 material in the CME program. A score of 75% or higher must be obtained on self-
1183 assessments. Repeated attempts to achieve an acceptable self-assessment score are
1184 allowed. The transplant hospital must document completion of this continuing education.
1185 c. Provide to the OPTN Contractor two letters of recommendation from transplant program
1186 directors not employed by the applying hospital. These letters must address:
1187 i. Why an exception to *Section G.3.4* above is reasonable.
1188 ii. The physician's overall qualifications to act as a primary pancreas transplant
1189 physician.
1190 iii. The physician's personal integrity, honesty, and familiarity with and experience in
1191 adhering to OPTN obligations and compliance protocols.
1192 iv. Any other matters judged appropriate.
1193

1194 If the physician has not adhered to the plan for maintaining continuing education or has not
1195 obtained the necessary CME credits with self-assessment, the transplant program will have a
1196 six-month grace period to address these deficiencies. If the physician has not fulfilled the
1197 requirements after the six-month grace period, and a key personnel change application has
1198 not been submitted, then the transplant program will be referred to the MPSC for appropriate
1199 action according to *Appendix L* of these Bylaws. If the OPTN Contractor becomes aware that
1200 a primary physician has not been compliant for 12 months or more and deficiencies still exist,
1201 then the transplant program will not be given any grace period and will be referred to the
1202 MPSC for appropriate action according to *Appendix L* of these Bylaws.
1203

1204 In addition, the primary transplant physician must have completed at least one of the training or
1205 experience pathways listed below:
1206

- 1207 ■ The 12-month pancreas transplant fellowship pathway, as described in *Section G.3.A.*
1208 *Twelve-month Transplant Medicine Fellowship Pathway* below.
- 1209 ■ The clinical experience pathway, as described in *Section G.3.B. Clinical Experience Pathway*
1210 below.
- 1211 ■ The conditional approval pathway, as described in *Section G.3.D. Conditional Approval for*
1212 *Primary Transplant Physician* below, if the primary pancreas transplant physician changes at
1213 an approved pancreas transplant program.
1214

1215 **B. Clinical Experience Pathway**

1216 A physician can meet the requirements for a primary transplant physician through acquired
1217 clinical experience if the following conditions are met:
1218

- 1219 1. The physician has been directly involved in the primary care of 15 or more newly transplanted
1220 pancreas recipients and continued to follow these recipients for a minimum of 3 months from
1221 the time of transplant. This patient care must have been provided over a 2 to 5-year period on
1222 an active pancreas transplant service as the primary pancreas transplant physician or under
1223 the direct supervision of a qualified pancreas transplant physician along with a pancreas

- 1224 transplant surgeon at a designated pancreas transplant program, ~~or the foreign equivalent~~.
- 1225 The care must be documented in a log that includes the date of transplant and the medical
- 1226 record number or other unique identifier that can be verified by the OPTN Contractor. This
- 1227 recipient log should be signed by the program director, division chief, or department chair
- 1228 from the program where the physician gained this experience.
- 1229 2. The physician has maintained a current working knowledge of pancreas transplantation,
- 1230 defined as direct involvement in pancreas transplant patient care within the last 2 years. This
- 1231 includes the management of patients with end stage pancreas disease, the selection of
- 1232 appropriate recipients for transplantation, donor selection, histocompatibility and tissue
- 1233 typing, immediate post-operative patient care, the use of immunosuppressive therapy
- 1234 including side effects of the drugs and complications of immunosuppression, differential
- 1235 diagnosis of pancreas dysfunction in the allograft recipient, histological interpretation of
- 1236 allograft biopsies, interpretation of ancillary tests for pancreas dysfunction, and long term
- 1237 outpatient care.
- 1238 3. The physician should have observed at least 3 organ procurements and 3 pancreas
- 1239 transplants. The physician should have also observed the evaluation of the donor, the
- 1240 donation process, and the management of at least 3 multiple organ donors who donated a
- 1241 pancreas. If the physician has completed these observations, they must be documented in a
- 1242 log that includes the date of procurement, location of the donor, and Donor ID.
- 1243 4. The following letters are submitted directly to the OPTN Contractor:
- 1244 a. A letter from the qualified pancreas transplant physician or surgeon who has been
- 1245 directly involved with the physician documenting the physician's experience and
- 1246 competence.
- 1247 b. A letter of recommendation from the primary physician and director at the transplant
- 1248 program last served by the physician outlining the physician's overall qualifications to act
- 1249 as primary transplant physician as well as the physician's personal integrity, honesty,
- 1250 familiarity with and experience in adhering to OPTN obligations, and any other matters
- 1251 judged appropriate. The MPSC may request similar letters of recommendation from the
- 1252 primary physician, primary surgeon, director, or others affiliated with any transplant
- 1253 program the physician previously served, at its discretion.
- 1254 c. A letter from the physician that details the training and experience the physician has
- 1255 gained in pancreas transplantation.
- 1256

1257 **D. Conditional Approval for Primary Transplant Physician**

1258 If the primary pancreas transplant physician changes at an approved pancreas transplant

1259 program, a physician can serve as the primary pancreas transplant physician for a maximum of

1260 12 months if the following conditions are met:

1261

- 1262 1. The physician has been involved in the primary care of 8 or more newly transplanted
- 1263 pancreas recipients, and has followed these patients for at least 3 months from the time of
- 1264 their transplant. This care must be documented in a recipient log that includes the date of
- 1265 transplant and the medical record number or other unique identifier that can be verified by the
- 1266 OPTN Contractor. This log should be signed by the program director, division chief, or
- 1267 department chair from the transplant program where the experience was gained.
- 1268 2. The physician has maintained a current working knowledge of pancreas transplantation,
- 1269 defined as direct involvement in pancreas transplant patient care within the last 2 years. This
- 1270 includes the management of patients with end stage pancreas disease, the selection of
- 1271 appropriate recipients for transplantation, donor selection, histocompatibility and tissue

- 1272 typing, immediate post-operative patient care, the use of immunosuppressive therapy
1273 including side effects of the drugs and complications of immunosuppression, differential
1274 diagnosis of pancreas dysfunction in the allograft recipient, histological interpretation of
1275 allograft biopsies, interpretation of ancillary tests for pancreas dysfunction, and long term
1276 outpatient care.
- 1277 3. The physician has 12 months experience on an active pancreas transplant service as the
1278 primary pancreas transplant physician or under the direct supervision of a qualified pancreas
1279 transplant physician along with a pancreas transplant surgeon at a designated pancreas
1280 transplant program, ~~or the foreign equivalent~~. This 12-month period of experience on the
1281 transplant service must have been acquired over a maximum of 2 years.
 - 1282 4. The physician should have observed at least 3 organ procurements and 3 pancreas
1283 transplants. The physician should also have observed the evaluation, the donation process,
1284 and management of at least 3 multiple organ donors who are donating a pancreas. If the
1285 physician has completed these observations, they must be documented in a log that includes
1286 the date of procurement, location of the donor, and Donor ID.
 - 1287 5. The program has established and documented a consulting relationship with counterparts at
1288 another pancreas transplant program.
 - 1289 6. The transplant program submits activity reports to the OPTN Contractor every 2 months
1290 describing the transplant activity, transplant outcomes, physician recruitment efforts, and
1291 other operating conditions as required by the MPSC to demonstrate the ongoing quality and
1292 efficient patient care at the program. The activity reports must also demonstrate that the
1293 physician is making sufficient progress in meeting the required involvement in the primary
1294 care of 15 or more pancreas transplant recipients, or that the program is making sufficient
1295 progress in recruiting a physician who will be on site and approved by the MPSC to assume
1296 the role of Primary Physician by the end of the 12 month conditional approval period.
 - 1297 7. The following letters are submitted directly to the OPTN Contractor:
 - 1298 a. A letter from the qualified pancreas transplant physician and surgeon who were directly
1299 involved with the physician documenting the physician's experience and competence.
 - 1300 b. A letter of recommendation from the primary physician and director at the transplant
1301 program last served by the physician outlining the physician's overall qualifications to act
1302 as a primary transplant physician, as well as the physician's personal integrity, honesty,
1303 and familiarity with and experience in adhering to OPTN obligations, and any other
1304 matters judged appropriate. The MPSC may request additional recommendation letters
1305 from the primary physician, primary surgeon, director, or others affiliated with any
1306 transplant program previously served by the physician, at its discretion.
 - 1307 c. A letter from the physician that details the training and experience the physician has
1308 gained in pancreas transplantation.

1309
1310 The 12-month conditional approval period begins on the initial approval date granted to the
1311 personnel change application, whether it is interim approval granted by the MPSC subcommittee,
1312 or approval granted by the full MPSC. The conditional approval period ends 12 months after the
1313 first approval date of the personnel change application.

1314
1315 If the transplant program is unable to demonstrate that it has an individual on site who can meet
1316 the requirements as described in *Sections G.3.A through G.3.C* above at the end of the 12-month
1317 conditional approval period, it must inactivate. The requirements for program inactivation are
1318 described in *Appendix K: Transplant Program Inactivity, Withdrawal and Termination* of these
1319 Bylaws.

1321 The MPSC may consider on a case-by-case basis and grant a 6-month extension to a transplant
1322 program that provides substantial evidence of progress toward fulfilling the requirements but is
1323 unable to complete the requirements within one year.
1324

1325 **Appendix H:** 1326 **Membership and Personnel Requirements for Heart** 1327 **Transplant Programs**

1328

1329 **H.2 Primary Heart Transplant Surgeon Requirements**

1330 A designated heart transplant program must have a primary surgeon who meets *all* the following
1331 requirements:
1332

- 1333 1. The surgeon must have an M.D., D.O., or equivalent degree from another country, with a current
1334 license to practice medicine in the hospital's state or jurisdiction.
- 1335 2. The surgeon must be accepted onto the hospital's medical staff, and be on site at this hospital.
- 1336 3. The surgeon must have documentation from the hospital credentialing committee that it has verified
1337 the surgeon's state license, board certification, training, and transplant continuing medical education,
1338 and that the surgeon is currently a member in good standing of the hospital's medical staff.
- 1339 4. The surgeon must have current certification by the American Board of Thoracic Surgery or current
1340 certification in thoracic surgery by the Royal College of Physicians and Surgeons of Canada ~~its~~
1341 ~~foreign equivalent~~. In the case of a surgeon who has just completed training and whose ~~board~~
1342 certification by the American Board of Thoracic Surgery in thoracic surgery is pending, the
1343 Membership and Professional Standards Committee (MPSC) may grant conditional approval for 24
1344 months to allow time for the surgeon to complete board certification, with the possibility of renewal for
1345 one additional 24-month period.
1346

1347 In place of current certification by the American Board of Thoracic Surgery, current certification in
1348 thoracic surgery by the Royal College of Physicians and Surgeons of Canada, or pending certification
1349 by the American Board of Thoracic Surgery, the surgeon must:

- 1350 a. Meet all requirements described in Section H.2.C below.
- 1351 b. Provide a plan for continuing education that is comparable to American board maintenance of
1352 certification. This plan must at least require that the surgeon obtains 40 hours of Category I
1353 continuing medical education (CME) credits with self-assessment that are relevant to the
1354 individual's practice every two years. Self-assessment is defined as a written or electronic
1355 question-and-answer exercise that assesses understanding of the material in the CME program.
1356 A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve
1357 an acceptable self-assessment score are allowed. The transplant hospital must document
1358 completion of this continuing education.
- 1359 c. Provide to the OPTN Contractor two letters of recommendation from transplant program directors
1360 not employed by the applying hospital. These letters must address:
 - 1361 i. Why an exception to Section H.2.4 above is reasonable.
 - 1362 ii. The surgeon's overall qualifications to act as a primary heart transplant surgeon.
 - 1363 iii. The surgeon's personal integrity, honesty, and familiarity with and experience in adhering to
1364 OPTN obligations and compliance protocols.
 - 1365 iv. Any other matters judged appropriate.

1366
1367 If the surgeon has not adhered to the plan for maintaining continuing education or has not obtained
1368 the necessary CME credits with self-assessment, the transplant program will have a six-month grace
1369 period to address these deficiencies. If the surgeon has not fulfilled the requirements after the six-
1370 month grace period, and a key personnel change application has not been submitted, then the
1371 transplant program will be referred to the MPSC for appropriate action according to Appendix L of
1372 these Bylaws. If the OPTN Contractor becomes aware that a primary surgeon has not been compliant
1373 for 12 months or more and deficiencies still exist, then the transplant program will not be given any
1374 grace period and will be referred to the MPSC for appropriate action according to Appendix L of these
1375 Bylaws.

1376
1377 In addition, the primary transplant surgeon must have completed at least one of the training or experience
1378 pathways listed below:

- 1379
- 1380 ■ The formal cardiothoracic surgery residency pathway, as described in *Section H.2.A. Cardiothoracic*
1381 *Surgery Residency Pathway* below.
 - 1382 ■ The 12-month heart transplant fellowship pathway, as described in *Section H.2.B. Twelve-month*
1383 *Heart Transplant Fellowship Pathway* below.
 - 1384 ■ The heart transplant program clinical experience pathway, as described in *Section H.2.C. Clinical*
1385 *Experience Pathway* below.
- 1386

1387 **A. Cardiothoracic Surgery Residency Pathway**

1388 Surgeons can meet the training requirements for primary heart transplant surgeon by completing
1389 a cardiothoracic surgery residency if ~~all~~ the following conditions are met:

- 1390
- 1391 1. The surgeon performed at least 20 heart or heart/lung transplants as primary surgeon or first
1392 assistant during the cardiothoracic surgery residency. These transplants must be
1393 documented in a log that includes the date of transplant, role of the surgeon in the procedure,
1394 and medical record number or other unique identifier that can be verified by the OPTN
1395 Contractor. This log must be signed by the director of the training program.
 - 1396 2. The surgeon performed at least 10 heart or heart/lung procurements as primary surgeon or
1397 first assistant under the supervision of a qualified heart transplant surgeon during the
1398 cardiothoracic surgery residency. These procedures must be documented in a log that
1399 includes the date of procurement, location of the donor, and Donor ID. This log must be
1400 signed by the director of the training program.
 - 1401 3. The surgeon has maintained a current working knowledge of all aspects of heart
1402 transplantation, defined as a direct involvement in heart transplant patient care within the last
1403 2 years. This includes performing the transplant operation, donor selection, use of
1404 mechanical assist devices, recipient selection, post-operative hemodynamic care,
1405 postoperative immunosuppressive therapy, and outpatient follow-up.
 - 1406 4. This training was completed at a hospital with a cardiothoracic surgery training program
1407 approved by the American Board of Thoracic Surgery, or the Royal College of Physicians and
1408 Surgeons of Canada. ~~its foreign equivalent, as accepted by the MPSC with a~~
1409 ~~recommendation from the Thoracic Organ Transplantation Committee.~~
 - 1410 5. The following letters are submitted directly to the OPTN Contractor:
 - 1411 a. A letter from the director of the training program verifying that the surgeon has met the
1412 above requirements and is qualified to direct a heart transplant program.

- 1413 b. A letter of recommendation from the training program’s primary surgeon and transplant
1414 program director outlining the individual’s overall qualifications to act as primary
1415 transplant surgeon, as well as the surgeon’s personal integrity, honesty, and familiarity
1416 with and experience in adhering to OPTN obligations, and any other matters judged
1417 appropriate. The MPSC may request additional recommendation letters from the primary
1418 physician, primary surgeon, director, or others affiliated with any transplant program
1419 previously served by the surgeon, at its discretion.
1420 c. A letter from the surgeon that details the training and experience the surgeon has gained
1421 in heart transplantation.
1422

1423 **B. Twelve-month Heart Transplant Fellowship Pathway**

1424 Surgeons can meet the training requirements for primary heart transplant surgeon by completing
1425 a 12-month heart transplant fellowship if the following conditions are met:
1426

- 1427 1. The surgeon performed at least 20 heart or heart/lung transplants as primary surgeon or first
1428 assistant during the 12-month heart transplant fellowship. These transplants must be
1429 documented in a log that includes the date of transplant, the role of the surgeon in the
1430 procedure, and the medical record number or other unique identifier that can be verified by
1431 the OPTN Contractor. This log must be signed by the director of the training program.
1432 2. The surgeon performed at least 10 heart or heart/lung procurements as primary surgeon or
1433 first assistant under the supervision of a qualified heart transplant surgeon during the 12-
1434 month heart transplant fellowship. These procedures must be documented in a log that
1435 includes the date of procurement, location of the donor, and Donor ID. This log must be
1436 signed by the director of the training program.
1437 3. The surgeon has maintained a current working knowledge of all aspects of heart
1438 transplantation, defined as a direct involvement in heart transplant patient care within the last
1439 2 years. This includes performing the transplant operation, donor selection, the use of
1440 mechanical circulatory assist devices, recipient selection, post-operative hemodynamic care,
1441 postoperative immunosuppressive therapy, and outpatient follow-up.
1442 4. This training was completed at a hospital with a cardiothoracic surgery training program
1443 approved by the American Board of Thoracic Surgery, or the Royal College of Physicians and
1444 Surgeons of Canada, or its foreign equivalent, as accepted by the MPSC with a
1445 recommendation from the Thoracic Organ Transplantation Committee.
1446 5. The following letters are submitted directly to the OPTN Contractor:
1447 a. A letter from the director of the training program verifying that the surgeon has met the
1448 above requirements and is qualified to direct a heart transplant program.
1449 b. A letter of recommendation from the training program’s primary surgeon and transplant
1450 program director outlining the individual’s overall qualifications to act as primary
1451 transplant surgeon, as well as the surgeon’s personal integrity, honesty, and familiarity
1452 with and experience in adhering to OPTN obligations, and any other matters judged
1453 appropriate. The MPSC may request additional recommendation letters from the primary
1454 physician, primary surgeon, director, or others affiliated with any transplant program
1455 previously served by the surgeon, at its discretion.
1456 c. A letter from the surgeon that details the training and experience the surgeon has gained
1457 in heart transplantation.
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C. Clinical Experience Pathway

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

1. The surgeon has performed 20 or more heart or heart/lung transplants as primary surgeon or first assistant at a designated heart transplant program ~~or the foreign equivalent~~. These transplants must have been completed over a 2 to 5-year period and include at least 15 of these procedures performed as the primary surgeon. 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 program where the experience was gained. Transplants performed during board qualifying surgical residency or fellowship do not count.
2. The surgeon has performed at least 10 heart or heart/lung procurements as primary surgeon or first assistant under the supervision of a qualified heart 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 heart transplantation, defined as a direct involvement in heart transplant patient care within the last 2 years. This includes performing the transplant operation, donor selection, the use of mechanical assist devices, recipient selection, post-operative hemodynamic care, postoperative immunosuppressive therapy, and outpatient follow-up.
4. The following letters are submitted directly to the OPTN Contractor:
 - a. A letter from the director of the program where the surgeon acquired transplant experience verifying that the surgeon has met the above requirements and is qualified to direct a heart transplant program.
 - b. A letter of recommendation from the primary surgeon and transplant program 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, 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 heart transplantation.

H.3 Primary Heart Transplant Physician Requirements

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

1. The physician must have an M.D., D.O., or equivalent degree from another country, with a current license to practice medicine in the hospital's state or jurisdiction.
2. The physician must be accepted onto the hospital's medical staff, and be practicing 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.

1506 4. The physician must have current certification in adult or pediatric cardiology by the American Board of
1507 Internal Medicine, the American Board of Pediatrics, or the Royal College of Physicians and
1508 Surgeons of Canada ~~foreign equivalent~~.

1509
1510 In place of current board certification in adult or pediatric cardiology by the American Board of Internal
1511 Medicine, the American Board of Pediatrics, or the Royal College of Physicians and Surgeons of
1512 Canada, the physician must:

- 1513 a. Meet all the requirements described in Section H.3.B below, or, if the primary heart transplant
1514 physician changes at an approved heart transplant program, Section G.3.D below.
1515 b. Provide a plan for continuing education that is comparable to American board maintenance of
1516 certification. This plan must at least require that the physician obtains 40 hours of Category I
1517 continuing medical education (CME) credits with self-assessment that are relevant to the
1518 individual's practice every two years. Self-assessment is defined as a written or electronic
1519 question-and-answer exercise that assesses understanding of the material in the CME program.
1520 A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve
1521 an acceptable self-assessment score are allowed. The transplant hospital must document
1522 completion of this continuing education.
1523 c. Provide to the OPTN Contractor two letters of recommendation from transplant program directors
1524 not employed by the applying hospital. These letters must address:
1525 i. Why an exception to Section H.3.4 above is reasonable.
1526 ii. The physician's overall qualifications to act as a primary heart transplant physician.
1527 iii. The physician's personal integrity, honesty, and familiarity with and experience in adhering to
1528 OPTN obligations and compliance protocols.
1529 iv. Any other matters judged appropriate.

1530
1531 If the physician has not adhered to the plan for maintaining continuing education or has not obtained
1532 the necessary CME credits with self-assessment, the transplant program will have a six-month grace
1533 period to address these deficiencies. If the physician has not fulfilled the requirements after the six-
1534 month grace period, and a key personnel change application has not been submitted, then the
1535 transplant program will be referred to the MPSC for appropriate action according to Appendix L of
1536 these Bylaws. If the OPTN Contractor becomes aware that a primary physician has not been
1537 compliant for 12 months or more and deficiencies still exist, then the transplant program will not be
1538 given any grace period and will be referred to the MPSC for appropriate action according to Appendix
1539 L of these Bylaws.

1540
1541 In addition, the primary transplant physician must have completed at least *one* of the training or
1542 experience pathways listed below:

- 1543
1544 ■ The 12-month transplant cardiology fellowship pathway, as described in Section H.3.A. Twelve-month
1545 Transplant Cardiology Fellowship Pathway below.
1546 ■ The clinical experience pathway, as described in Section H.3.B. Clinical Experience Pathway below.
1547 ■ The conditional approval pathway, as described in Section H.3.D. Conditional Approval for Primary
1548 Transplant Physician below, if the primary heart transplant physician changes at an approved heart
1549 transplant program.

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A. Twelve-month Transplant Cardiology Fellowship Pathway

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

1. During the fellowship period, the physician was directly involved in the primary care of at least 20 newly transplanted heart or heart/lung recipients. This training will have been under the direct supervision of a qualified heart transplant physician and in conjunction with a heart transplant surgeon. 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 director of the training program or the primary transplant physician at the transplant program.
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, the 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. This training was completed at a hospital with an American Board of Internal Medicine certified fellowship training program in adult cardiology, ~~or an~~ American Board of Pediatrics certified fellowship training program in pediatric cardiology, or a cardiology training program approved by the Royal College of Physicians and Surgeons of Canada. ~~or its foreign equivalent, as accepted by the MPSC.~~
5. The following letters are submitted directly to the OPTN Contractor:
 - a. A letter from the director of the training program and the supervising qualified heart transplant physician verifying that the physician has met the above requirements and is qualified to direct a heart transplant program.
 - b. A letter of recommendation from the training program's primary physician and transplant program director outlining the physician's overall qualifications to act as primary transplant physician, as well as the physician's personal integrity, honesty, 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.

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

1598 months from transplant. This patient care must have been provided over a 2 to 5-year period
1599 on an active heart transplant service as the primary heart transplant physician or under the
1600 direct supervision of a qualified heart transplant physician and in conjunction with a heart
1601 transplant surgeon at a heart transplant program ~~or the foreign equivalent~~. This care must be
1602 documented in a log that includes the date of transplant and medical record number or other
1603 unique identifier that can be verified by the OPTN Contractor. This recipient log should be
1604 signed by the director or the primary transplant physician at the transplant program where the
1605 physician gained this experience.

1606 2. The physician has maintained a current working knowledge of heart transplantation, defined
1607 as direct involvement in heart transplant patient care within the last 2 years. This includes the
1608 care of acute and chronic heart failure, donor selection, use of mechanical circulatory support
1609 devices, recipient selection, pre- and post-operative hemodynamic care, post-operative
1610 immunosuppressive therapy, histological interpretation and grading of myocardial biopsies for
1611 rejection, and long-term outpatient follow-up.

1612 3. The physician should have observed at least 3 organ procurements and 3 heart transplants.
1613 The physician should also have observed the evaluation, the donation process, and
1614 management of 3 multiple organ donors who are donating a heart or heart/lungs. If the
1615 physician has completed these observations, they must be documented in a log that includes
1616 the date of procurement, location of the donor, and Donor ID.

1617 4. The following letters are submitted directly to the OPTN Contractor:
1618 a. A letter from the heart transplant physician or the heart transplant surgeon who has been
1619 directly involved with the physician at the transplant program verifying the physician's
1620 competence.
1621 b. A letter of recommendation from the primary physician and transplant program director
1622 at the transplant program last served by the physician outlining the physician's overall
1623 qualifications to act as primary transplant physician, as well as the physician's personal
1624 integrity, honesty, and familiarity with and experience in adhering to OPTN obligations,
1625 and any other matters judged appropriate. The MPSC may request additional
1626 recommendation letters from the primary physician, primary surgeon, director, or others
1627 affiliated with any transplant program previously served by the physician, at its discretion.
1628 c. A letter from the physician that details the training and experience the physician has
1629 gained in heart transplantation.

1630
1631

D. Conditional Approval for Primary Transplant Physician

1632 If the primary heart transplant physician changes at an approved heart transplant program, a
1633 physician can serve as the primary heart transplant physician for a maximum of 12 months if the
1634 following conditions are met:

1635
1636 ~~1. The physician has current board certification in cardiology by the American Board of Internal
1637 Medicine, the American Board of Pediatrics, or the foreign equivalent.~~

1638 21. The physician has 12 months experience on an active heart transplant service as the primary
1639 heart transplant physician or under the direct supervision of a qualified heart transplant
1640 physician and in conjunction with a heart transplant surgeon at a designated heart transplant
1641 program. These 12 months of experience must be acquired within a 2-year period.

1642 32. The physician has maintained a current working knowledge of heart transplantation, defined
1643 as direct involvement in heart transplant patient care within the last 2 years. This includes
1644 knowledge of acute and chronic heart failure, donor selection, the use of mechanical
1645 circulatory support devices, recipient selection, pre- and post-operative hemodynamic care,

- 1646 post-operative immunosuppressive therapy, histological interpretation in grading of
1647 myocardial biopsies for rejection, and long-term outpatient follow-up.
- 1648 43. The physician has been involved in the primary care of 10 or more newly transplanted heart
1649 or heart/lung transplant recipients as the heart transplant physician or under the direct
1650 supervision of a qualified heart transplant physician or in conjunction with a heart transplant
1651 surgeon at a designated heart transplant program. The physician will have followed these
1652 patients for a minimum of 3 months from the time of transplant. This care must be
1653 documented in a log that includes the date of transplant and medical record or other unique
1654 identifier that can be verified by the OPTN Contractor. This recipient log should be signed by
1655 the program director or the primary transplant physician at the transplant program where the
1656 physician gained experience.
- 1657 54. The physician should have observed at least 3 organ procurements and 3 heart transplants.
1658 The physician should also have observed the evaluation, the donation process, and
1659 management of at least 3 multiple organ donors who donated a heart or heart/lungs. If the
1660 physician has completed these observations, they must be documented in a log that includes
1661 the date of procurement, location of the donor, and Donor ID.
- 1662 65. The program has established and documented a consulting relationship with counterparts at
1663 another heart transplant program.
- 1664 76. The transplant program submits activity reports to the OPTN Contractor every 2 months
1665 describing the transplant activity, transplant outcomes, physician recruitment efforts, and
1666 other operating conditions as required by the MPSC to demonstrate the ongoing quality and
1667 efficient patient care at the program. The activity reports must also demonstrate that the
1668 physician is making sufficient progress to meet the required involvement in the primary care
1669 of 20 or more heart transplant recipients, or that the program is making sufficient progress in
1670 recruiting a physician who meets all requirements for primary heart transplant physician by
1671 the end of the 12 month conditional approval period.
- 1672 87. The following letters are submitted directly to the OPTN Contractor:
- 1673 a. A letter from the heart transplant physician or the heart transplant surgeon who has been
1674 directly involved with the physician at the transplant program verifying the physician's
1675 competence.
- 1676 b. A letter of recommendation from the primary physician and director at the transplant
1677 program last served by the physician outlining the physician's overall qualifications to act
1678 as primary transplant physician, as well as the physician's personal integrity, honesty,
1679 and familiarity with and experience in adhering to OPTN obligations, and any other
1680 matters judged appropriate. The MPSC may request additional recommendation letters
1681 from the primary physician, primary surgeon, director, or others affiliated with any
1682 transplant program previously served by the physician, at its discretion.
- 1683 c. A letter from the physician that details the training and experience the physician has
1684 gained in heart transplantation.

1685
1686 The 12-month conditional approval period begins on the first approval date granted to the
1687 personnel change application, whether it is an interim approval granted by the MPSC
1688 subcommittee, or an approval granted by the full MPSC. The conditional approval period ends
1689 exactly 12 months after this first approval date of the personnel change application.

1690
1691 If the program is unable to demonstrate that it has an individual on site who can meet the
1692 requirements as described in *Sections H.3.A through H.3.C* above at the end of the 12-month
1693 conditional approval period, it must inactivate. The requirements for program inactivation are

1694 described in **Error! Reference source not found. Error! Reference source not found.** of these
1695 Bylaws.

1696
1697 The MPSC may consider on a case-by-case basis and grant a 6-month extension to a transplant
1698 program that provides substantial evidence of progress toward fulfilling the requirements but is
1699 unable to complete the requirements within one year.

1700

1701 **Appendix I:**

1702 **Membership and Personnel Requirements for Lung**

1703 **Transplant Programs**

1704

1705 **I.2 Primary Lung Transplant Surgeon Requirements**

1706 A designated lung transplant program must have a primary surgeon who meets *all* the following
1707 requirements:

1708

- 1709 1. The surgeon must have an M.D., D.O., or equivalent degree from another country, with a current
1710 license to practice medicine in the hospital's state or jurisdiction.
- 1711 2. The surgeon must be accepted onto the hospital's medical staff, and be practicing on site at this
1712 hospital.
- 1713 3. The surgeon must have documentation from the hospital credentialing committee that it has verified
1714 the surgeon's state license, board certification, training, and transplant continuing medical education,
1715 and that the surgeon is currently a member in good standing of the hospital's medical staff.
- 1716 4. The surgeon must have current certification by the American Board of Thoracic Surgery or current
1717 certification in thoracic surgery by the Royal College of Physicians and Surgeons of Canada ~~its~~
1718 ~~foreign equivalent~~. In the case of a surgeon who has just completed training and whose ~~board~~
1719 certification by the American Board of Thoracic Surgery in thoracic surgery is pending, the
1720 Membership and Professional Standards Committee (MPSC) may grant conditional approval for 24
1721 months to allow time for the surgeon to complete board certification, with the possibility of renewal for
1722 one additional 24-month period.

1723

1724 In place of current certification by the American Board of Thoracic Surgery, current certification in
1725 thoracic surgery by the Royal College of Physicians and Surgeons of Canada, or pending board
1726 certification by the American Board of Thoracic Surgery, the surgeon must:

1727

- a. Meet all requirements described in Section 1.2.C below.
- b. Provide a plan for continuing education that is comparable to American board maintenance of
1729 certification. This plan must at least require that the surgeon obtains 40 hours of Category I
1730 continuing medical education (CME) credits with self-assessment that are relevant to the
1731 individual's practice every two years. Self-assessment is defined as a written or electronic
1732 question-and-answer exercise that assesses understanding of the material in the CME program.
1733 A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve
1734 an acceptable self-assessment score are allowed. The transplant hospital must document
1735 completion of this continuing education.
- c. Provide to the OPTN Contractor two letters of recommendation from transplant program directors
1737 not employed by the applying hospital. These letters must address:
 - 1738 i. Why an exception to Section 1.2.4 above is reasonable.

- 1739 ii. The surgeon's overall qualifications to act as a primary lung transplant surgeon.
- 1740 iii. The surgeon's personal integrity, honesty, and familiarity with and experience in adhering to
- 1741 OPTN obligations and compliance protocols.
- 1742 iv. Any other matters judged appropriate.

1743

1744 If the surgeon has not adhered to the plan for maintaining continuing education or has not obtained

1745 the necessary CME credits with self-assessment, the transplant program will have a six-month grace

1746 period to address these deficiencies. If the surgeon has not fulfilled the requirements after the six-

1747 month grace period, and a key personnel change application has not been submitted, then the

1748 transplant program will be referred to the MPSC for appropriate action according to Appendix L of

1749 these Bylaws. If the OPTN Contractor becomes aware that a primary surgeon has not been compliant

1750 for 12 months or more and deficiencies still exist, then the transplant program will not be given any

1751 grace period and will be referred to the MPSC for appropriate action according to Appendix L of these

1752 Bylaws.

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1754 In addition, the primary transplant surgeon must have completed at least one of the training or experience

1755 pathways listed below:

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- 1757 ■ The formal cardiothoracic surgery residency pathway, as described in *Section 1.2.A. Cardiothoracic*
- 1758 *Surgery Residency Pathway* below.
- 1759 ■ The 12-month lung transplant fellowship pathway, as described in *Section 1.2.B. Twelve-month Lung*
- 1760 *Transplant Fellowship Pathway* below.
- 1761 ■ The lung transplant program clinical experience pathway, as described in *Section 1.2.C. Clinical*
- 1762 *Experience Pathway* below.

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1764 **A. Cardiothoracic Surgery Residency Pathway**

1765 Surgeons can meet the training requirements for primary lung transplant surgeon by completing a

1766 cardiothoracic surgery residency if the following conditions are met:

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- 1768 1. During the cardiothoracic surgery residency, the surgeon has performed at least 15 lung or
- 1769 heart/lung transplants as primary surgeon or first assistant under the direct supervision of a
- 1770 qualified lung transplant surgeon and in conjunction with a lung transplant physician at a lung
- 1771 transplant program. At least half of these transplants must be lung procedures. These
- 1772 transplants must be documented in a log that includes the date of transplant, role of the
- 1773 surgeon in the procedure, and medical record number or other unique identifier that can be
- 1774 verified by the OPTN Contractor. This log must be signed by the director of the training
- 1775 program.
- 1776 2. The surgeon performed at least 10 lung procurements as primary surgeon or first assistant
- 1777 under the supervision of a qualified lung transplant surgeon. These procedures must be
- 1778 documented in a log that includes the date of procurement, location of the donor, and Donor
- 1779 ID.
- 1780 3. The surgeon has maintained a current working knowledge of all aspects of lung
- 1781 transplantation, defined as a direct involvement in lung transplant patient care within the last
- 1782 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass,
- 1783 donor selection, recipient selection, pre- and postoperative ventilator care, postoperative
- 1784 immunosuppressive therapy, histological interpretation and grading of lung biopsies for

- 1785 rejection, and long-term outpatient follow-up. This training must also include the other clinical
1786 requirements for thoracic surgery.
- 1787 4. This training was completed at a hospital with a cardiothoracic training program approved by
1788 the American Board of Thoracic Surgery or the Royal College of Physicians and Surgeons of
1789 Canada, ~~or its foreign equivalent. Foreign programs must have a recommendation from the~~
1790 ~~Thoracic Organ Transplantation Committee and be accepted as equivalent by the MPSC.~~
- 1791 5. The following letters are submitted directly to the OPTN Contractor:
- 1792 a. A letter from the director of the training program verifying that the surgeon has met the
1793 above requirements and is qualified to direct a lung transplant program.
- 1794 b. A letter of recommendation from the program's primary surgeon and transplant program
1795 director outlining the individual's overall qualifications to act as primary transplant
1796 surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and
1797 experience in adhering to OPTN obligations and compliance protocols, and any other
1798 matters judged appropriate. The MPSC may request additional recommendation letters
1799 from the primary physician, primary surgeon, director, or others affiliated with any
1800 transplant program previously served by the surgeon, at its discretion.
- 1801 c. A letter from the surgeon that details the training and experience the surgeon has gained
1802 in lung transplantation.
- 1803

1804 **B. Twelve-month Lung Transplant Fellowship Pathway**

1805 Surgeons can meet the training requirements for primary lung transplant surgeon by completing a
1806 12-month lung transplant fellowship if the following conditions are met:

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- 1808 1. The surgeon has performed at least 15 lung or heart/lung transplants under the direct
1809 supervision of a qualified lung transplant surgeon and in conjunction with a qualified lung
1810 transplant physician as primary surgeon or first assistant during the 12-month lung transplant
1811 fellowship. At least half of these transplants must be lung procedures. These transplants
1812 must be documented in a log that includes the date of transplant, the role of the surgeon in
1813 the procedure, and the medical record number or other unique identifier that can be verified
1814 by the OPTN Contractor. This log must be signed by the director of the program.
- 1815 2. The surgeon has performed at least 10 lung procurements as primary surgeon or first
1816 assistant under the supervision of a qualified lung transplant surgeon during the 12-month
1817 lung transplant fellowship. These procedures must be documented in a log that includes the
1818 date of procurement, location of the donor, and Donor ID.
- 1819 3. The surgeon has maintained a current working knowledge of all aspects of lung
1820 transplantation, defined as a direct involvement in lung transplant patient care within the last
1821 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass,
1822 donor selection, recipient selection, pre- and postoperative ventilator care, postoperative
1823 immunosuppressive therapy, histological interpretation and grading of lung biopsies for
1824 rejection, and long-term outpatient follow-up.
- 1825 4. This training was completed at a hospital with a cardiothoracic training program approved by
1826 the American Board of Thoracic Surgery or the Royal College of Physicians and Surgeons of
1827 Canada, ~~or its foreign equivalent. Foreign programs must have a recommendation from the~~
1828 ~~Thoracic Organ Transplantation Committee and be accepted as equivalent by the MPSC.~~
- 1829 5. The following letters are submitted directly to the OPTN Contractor:
- 1830 a. A letter from the director of the training program verifying that the surgeon has met the
1831 above requirements and is qualified to direct a lung transplant program.

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- b. A letter of recommendation from the training 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 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.

C. Clinical Experience Pathway

1843 Surgeons can meet the requirements for primary lung transplant surgeon through clinical
1844 experience gained post-fellowship if the following conditions are met:

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- 1. The surgeon has performed 15 or more lung or heart/lung transplants over a 2 to 5-year period as primary surgeon or first assistant at a designated lung transplant program, ~~or the foreign equivalent~~. At least half of these transplants must be lung procedures, and at least 10 must be performed as the primary surgeon. The surgeon must also have been actively involved with cardiothoracic surgery. 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 recipient log should be signed by the program director, division chief, or department chair from program where the experience was gained.
 - 2. The surgeon has performed at least 10 lung procurements. 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.
 - 4. The following letters are submitted directly to the OPTN Contractor:
 - a. A letter from the director of the program where the surgeon gained experience 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 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, 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 lung transplantation.

1878 **I.3 Primary Lung Transplant Physician Requirements**

1879 A designated lung transplant program must have a primary physician who meets *all* the following
1880 requirements:

- 1881
- 1882 1. The physician must have an M.D., D.O., or equivalent degree from another country, with a current
1883 license to practice medicine in the hospital's state or jurisdiction.
 - 1884 2. The physician must be accepted onto the hospital's medical staff, and be practicing on site at this
1885 hospital.
 - 1886 3. The physician must have documentation from the hospital credentialing committee that it has verified
1887 the physician's state license, board certification, training, and transplant continuing medical education
1888 and that the physician is currently a member in good standing of the hospital's medical staff.
 - 1889 4. The lung transplant physician must have current board certification or have achieved eligibility in adult
1890 or pediatric pulmonary medicine by the American Board of Internal Medicine, the American Board of
1891 Pediatrics, or the Royal College of Physicians and Surgeons of Canada ~~their foreign equivalent~~.
- 1892

1893 In place of current board certification or achieved eligibility in adult or pediatric pulmonary medicine by
1894 the American Board of Internal Medicine, the American Board of Pediatrics, or the Royal College of
1895 Physicians and Surgeons of Canada, the physician must:

- 1896 a. Meet all the requirements described in Section 1.3.B below, or, if the primary lung transplant
1897 physician changes at an approved lung transplant program, Section 1.3.D below.
 - 1898 b. Provide a plan for continuing education that is comparable to American board maintenance of
1899 certification. This plan must at least require that the physician obtains 40 hours of Category I
1900 continuing medical education (CME) credits with self-assessment that are relevant to the
1901 individual's practice every two years. Self-assessment is defined as a written or electronic
1902 question-and-answer exercise that assesses understanding of the material in the CME program.
1903 A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve
1904 an acceptable self-assessment score are allowed. The hospital must document completion of
1905 this continuing education.
 - 1906 c. Provide to the OPTN Contractor two letters of recommendation from transplant program directors
1907 not employed by the applying hospital. These letters must address:
 - 1908 i. Why an exception to Section 1.3.4 above is reasonable.
 - 1909 ii. The physician's overall qualifications to act as a primary lung transplant physician.
 - 1910 iii. The physician's personal integrity, honesty, and familiarity with and experience in adhering to
1911 OPTN obligations and compliance protocols.
 - 1912 iv. Any other matters judged appropriate.
- 1913

1914 If the physician has not adhered to the plan for maintaining continuing education or has not obtained
1915 the necessary CME credits with self-assessment, the transplant program will have a six-month grace
1916 period to address these deficiencies. If the physician has not fulfilled the requirements after the six-
1917 month grace period, and a key personnel change application has not been submitted, then the
1918 transplant program will be referred to the MPSC for appropriate action according to Appendix L of
1919 these Bylaws. If the OPTN Contractor becomes aware that a primary physician has not been
1920 compliant for 12 months or more and deficiencies still exist, then the transplant program will not be
1921 given any grace period and will be referred to the MPSC for appropriate action according to Appendix
1922 L of these Bylaws.

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1924 In addition, the primary transplant physician must have completed at least one of the training or
1925 experience pathways listed below:

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- The 12-month transplant pulmonary fellowship pathway, as described in *Section I.3.A. Twelve-month Transplant Pulmonary Fellowship Pathway* below.
- The clinical experience pathway, as described in *Section I.3.B. Clinical Experience Pathway* below.
- The conditional approval pathway, as described in *Section I.3.D. Conditional Approval for Primary Transplant Physician* below, if the primary lung transplant physician changes at an approved lung transplant program.

A. Twelve-month Transplant Pulmonary Fellowship Pathway

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

1. The physician was directly involved in the primary and follow-up care of at least 15 newly transplanted lung or heart/lung recipients. This training will have been under the direct supervision of a qualified lung transplant physician and in conjunction with a lung transplant surgeon. At least half of these patients must be single or double-lung transplant recipients. 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 director of the training program or the primary transplant physician at the transplant program.
2. The physician 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.
3. The physician should have observed at least 3 lung or heart/lung procurements and 3 lung transplants. The physician should also have observed the evaluation, the donation process, and management of 3 multiple organ donors who are donating a lung 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. This training was completed at a hospital with an American Board of Internal Medicine certified fellowship training program in adult pulmonary medicine, an American Board of Pediatrics-certified fellowship training program in pediatric medicine, or a pulmonary medicine training program approved by 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 physician has met the above requirements and is qualified to direct a lung transplant program.
 - b. A letter of recommendation from the training program's primary physician and transplant program director outlining the physician's overall qualifications to act as primary transplant physician, as well as the physician's personal integrity, honesty, 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.

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

B. Clinical Experience Pathway

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A physician can meet the requirements for primary lung 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 lung or heart/lung recipients and continued to follow these recipients for a minimum of 3 months from the time of transplant. At least half of these transplant must be lung transplants. This patient care must have been provided over a 2 to 5-year period ~~on an active at a designated~~ lung transplant program ~~or the foreign equivalent~~. This care must have been provided as the lung transplant physician or directly supervised by a qualified lung transplant physician along with a lung transplant surgeon. 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 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.
 3. The physician should have observed at least 3 lung or heart/lung procurements and 3 lung transplants. The physician should also have observed the evaluation, the donation process, and management of 3 multiple organ donors who are donating a lung 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 lung transplant physician or surgeon of the training program who has been directly involved with the physician documenting 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 lung transplantation.

D. Conditional Approval for Primary Transplant Physician

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

- 2020 1. ~~The physician is a pulmonologist with current board certification in pulmonary medicine by the~~
2021 ~~American Board of Internal Medicine, the American Board of Pediatrics, or the foreign~~
2022 ~~equivalent.~~
- 2023 21. The physician has 12 months of experience on an active lung transplant service as the
2024 primary lung transplant physician or under the direct supervision of a qualified lung transplant
2025 physician and in conjunction with a lung transplant surgeon at a designated lung transplant
2026 program. These 12 months of experience must be acquired within a 2-year period.
- 2027 32. The physician has been involved in the primary care of 8 or more newly transplanted lung or
2028 heart/lung transplant recipients as the lung transplant physician or under the direct
2029 supervision of a qualified lung transplant physician and in conjunction with a lung transplant
2030 surgeon. At least half of these patients must be lung transplant recipients. This care must be
2031 documented in a recipient log that includes the date of transplant and medical record or other
2032 unique identifier that can be verified by the OPTN Contractor. This log should be signed by
2033 the program director or the primary transplant physician at the transplant program where the
2034 physician gained experience.
- 2035 43. The physician has maintained a current working knowledge of all aspects of lung
2036 transplantation, defined as a direct involvement in lung transplant patient care within the last
2037 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass,
2038 donor selection, recipient selection, pre- and postoperative ventilator care, postoperative
2039 immunosuppressive therapy, histological interpretation and grading of lung biopsies for
2040 rejection, and long-term outpatient follow-up.
- 2041 54. The physician should have observed at least 3 lung or heart/lung procurements and 3 lung
2042 transplants. The physician should also have observed the evaluation, the donation process,
2043 and management of 3 multiple organ donors who are donating a lung or heart/lungs. If the
2044 physician has completed these observations, they must be documented in a log that includes
2045 the date of procurement, location of the donor, and Donor ID.
- 2046 65. The program has established and documented a consulting relationship with counterparts at
2047 another lung transplant program.
- 2048 76. The transplant program submits activity reports to the OPTN Contractor every 2 months
2049 describing the transplant activity, transplant outcomes, physician recruitment efforts, and
2050 other operating conditions as required by the MPSC to demonstrate the ongoing quality and
2051 efficient patient care at the program. The activity reports must also demonstrate that the
2052 physician is making sufficient progress to meet the required involvement in the primary care
2053 of 20 or more lung transplant recipients, or that the program is making sufficient progress in
2054 recruiting a physician who meets all requirements for primary lung transplant physician by the
2055 end of the 12 month conditional approval period.
- 2056 87. The following letters are submitted directly to the OPTN Contractor:
- 2057 a. A letter from the supervising lung transplant physician or surgeon of the training program
2058 documenting the physician's competence.
- 2059 b. A letter of recommendation from the training program's primary physician and director
2060 outlining the physician's overall qualifications to act as primary transplant physician of the
2061 transplant program last served by the physician, as well as the physician's personal
2062 integrity, honesty, and familiarity with and experience in adhering to OPTN obligations,
2063 and any other matters judged appropriate. The MPSC may request additional
2064 recommendation letters from the primary physician, primary surgeon, director, or others
2065 affiliated with any transplant program previously served by the physician, at its discretion.
- 2066 c. A letter from the physician that details the training and experience the physician has
2067 gained in lung transplantation.
- 2068

2069 The 12-month conditional approval period begins on the first approval date granted to the
2070 personnel change application, whether it is an interim approval granted by the MPSC
2071 subcommittee, or approval granted by the full MPSC. The conditional approval period ends
2072 exactly 12 months after this first approval date of the personnel change application.
2073

2074 If the program is unable to demonstrate that it has an individual practicing on site who can meet
2075 the requirements as described in *Sections 1.3.A through 1.3.C* above at the end of the 12-month
2076 conditional approval period, it must inactivate. The requirements for transplant program
2077 inactivation are described in *Appendix K: Transplant Program Inactivity, Withdrawal, and*
2078 *Termination* of these Bylaws.
2079

2080 The MPSC may consider on a case-by-case basis and grant a 6-month extension to a transplant
2081 program that provides substantial evidence of progress toward fulfilling the requirements but is
2082 unable to complete the requirements within one year.
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ROCKVILLE POLICY DEVELOPMENT DISCUSSION

APRIL 9, 2010

ROCKVILLE POLICY DEVELOPMENT DISCUSSION

ATTENDANCE

Chris McLaughlin (HRSA), Emily Levine (HRSA), Joyce Somsak (HRSA), Rich Durbin (HRSA), Jim Bowman (HRSA), Bernie Koslovsky (HRSA), Patricia Stroup (HRSA), Walter Graham (UNOS/OPTN), James Wynn (UNOS/OPTN), Charlie Alexander (UNOS/OPTN), Mary D. Ellison (UNOS/OPTN), Connie Davis (UNOS/OPTN), Maryl Johnson (AST), Joren Madsen (AST), Susan Nelson (AST), Katrina Crist (ASTS), Bob Merion (ASTS), Catherine Garvey (NATCO), Janene Dawson (NATCO)

SUMMARY

Representatives of the ASTS, the AST, NATCO, OPTN/UNOS, and HRSA met on April 9, 2010 to discuss and develop a new process for incorporating clinical input into developing OPTN/UNOS policies with the potential to direct or prescribe medical care. The need for such a process has been identified during the course of OPTN/UNOS's attempts to develop policies that are more specific and detailed regarding OPTN/UNOS member requirements in the area of living donor protections.

During the discussion, it was noted that early involvement of the societies in the OPTN/UNOS policy development process, for the purpose of identifying the appropriate medical requirements and the appropriate level of specificity of such requirements, would be an important advance. Hopefully, this will allow policies to be developed in a timelier manner and will foster their acceptance by the transplant community at large.

A general process was agreed upon, which will be piloted during OPTN/UNOS's continuing efforts to expand its current requirements in the area of living donor medical evaluation (including psychosocial evaluation), informed consent, and post-donation follow-up.

PROCESS

The general process will proceed as follows:

- I. Quarterly, the **Joint Society Policy Steering Group** will meet via conference call to review the current and planned policy agenda of OPTN/UNOS. OPTN/UNOS will host each call, using Microsoft Live Meeting. Specific policy development activities will be described so that each clinical society can determine, over a 2-week period after the call, whether any policy under development has the potential to prescribe medical care.

The Joint Society Policy Steering Group will comprise representatives of the AST, ASTS and NATCO as well as the OPTN/UNOS President or his/her designee. Each society will identify its standing representative on an annual

basis. The quarterly calls may be attended by the society and UNOS executive directors, as well as HRSA staff. Each member society may be represented by a substitute upon the agreement of its president or executive director.

UNOS support staff will also attend in order to set up the calls, facilitate the presentations, and document the proceedings. Approximately 2 weeks after each quarterly call, the Steering Group will reconvene in order to identify policies in development that have the potential to prescribe medical care. A vote of the non-OPTN/UNOS Steering Group members will be taken on each such policy under consideration. A majority approval vote of the three society representatives will be required to invoke the rest of the process.

In the event that 2 of the 3 clinical societies conclude that the special process does NOT need to be invoked for a particular policy issue, the dissenting society will pursue its own approach to ensuring input into the OPTN/UNOS policy process, through existing mechanisms in the OPTN/UNOS policy development process (e.g., attending OPTN/UNOS meetings, providing input through committee members, participating in OPTN/UNOS public comment, etc.).

- II. For any policy voted by the non-OPTN/UNOS members of the Steering Group to direct or prescribe medical care, a **Joint Society Policy Working Group** will be formed. The Working Group's charge (scope and goals for what is to be accomplished) will be defined by the Steering Group. The length of time each Working Group will have to complete its work will be determined by the Steering Committee with input from OPTN/UNOS and HRSA. Each Working Group will consist of up to 3 member representatives selected by each organization (AST, ASTS, NATCO, and OPTN/UNOS). The OPTN/UNOS representatives will be members of the OPTN/UNOS committee that is sponsoring the policy in question, and will regularly apprise the sponsoring OPTN/UNOS committee of the Working Group's progress. Although each organization will typically have an equal number of representatives, this may vary by mutual agreement of the organizations, and the Steering Group may ask representatives of other organizations to participate as needed. HRSA representatives may also attend conference calls and meetings of the Working Group. A UNOS staff member will arrange calls and meetings of the Working Group as requested and will provide reports of each meeting, to be approved by the Working Group chair.
 - a. The first item of business for each Working Group will be the election of a chair from among its non-OPTN/UNOS members. The non-OPTN/UNOS representatives participate in the vote. The Working Group will next consider whether persons with special expertise should be added to the group and will suggest either individuals or organizations that should be added or consulted, with input from the Steering Group and DoT/HRSA as appropriate. UNOS staff will assist the Working Group in contacting additional individuals or organizations and arranging their participation in the Working Group.
 - b. The Working Group will provide its perspectives on the scope and goals of the policy in development, as well as specific recommendations for policy content.

- c. The Working Group will also assure OPTN/UNOS that the input provided represents the opinions and views of the societies.
- d. Recommendations developed by the Working Group will include the following:
 - level of specificity to be required in the OPTN/UNOS policy;
 - specific policy provisions, differentiating between what would be required and what would be optional or recommended;
 - the evidence basis for each recommendation (which may consist not only of data and published literature, but also opinion on generally accepted medical practice);
 - the period of time within which requirements should be revisited for currency;
 - any pertinent comments on cost implications for members, patients, OPTN/UNOS.

The Working Group will also identify key policy components that it would recommend be used by OPTN/UNOS in assessing policy compliance by the members, and will consider how it envisions OPTN/UNOS would monitor member compliance, using information provided by UNOS staff about mechanisms available to OPTN/UNOS for this purpose.

Should disagreements regarding policy content arise, they will be decided by majority vote of the non-OPTN/UNOS members of the working group.

- III. Once the Working Group's final recommendations are available, the Group's input will be provided to the Steering Committee for review and endorsement.
 - a. After Steering Committee approval, the recommendations will be provided to the OPTN/UNOS Committee sponsoring the developing policy for incorporation into the OPTN/UNOS policy development process.
 - b. The recommendations will be presented to the OPTN/UNOS committee by the Working Group chair.
 - c. The Working Group Chair will then participate in subsequent meetings of the sponsoring OPTN/UNOS committee as it continues the policy development process (e.g., policy formulation, public comment, and Board review).
 - d. The Working Group chair will not be a member of the OPTN/UNOS committee and will not have a vote.
 - e. In the event that the OPTN/UNOS committee disagrees with a substantial number of the Working Group's recommendations, discussion between the 2 groups will occur in an attempt to arrive at consensus.

OPTN/UNOS committee reports, public comment documents, and Board reports describing policies developed with the aid of this new process will include a description of the whole process and the deliberations and considerations involved.

PILOTING THE PROCESS

To pilot this process during the further development of OPTN/UNOS living donor requirements, a Working Group will be formed immediately following the review and approval of this summary and as soon as UNOS can identify staff to support the new process. The Working Group will provide recommendations to OPTN/UNOS regarding appropriate requirements for the medical evaluation (including psycho-social evaluation) and informed consent of potential living kidney donors as well as post-donation follow-up and data submission. The Group must provide final recommendations to OPTN/UNOS within 12 months of its formation, or approximately June 2011. The OPTN/UNOS Living Donor Committee will then finalize a policy proposal, issue it for public comment, and continue any policy development and consensus building necessary for continued policy review and approval.