

OPTN/UNOS Membership and Professional Standards Committee

# Changes to Transplant Program Key Personnel Procurement Requirements

Committee Liaison:  
Chad Waller  
UNOS Member Quality Department

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# Changes to Transplant Program Key Personnel Procurement Requirements

## Executive Summary

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

## Is the sponsoring Committee requesting specific feedback or input about the proposal?

Should these proposed changes also apply to the new intestine transplant program in OPTN Bylaws Appendix F (Membership and Personnel Requirements for Liver Transplant Programs and Intestine Transplant Programs) that the OPTN/UNOS Board of Directors approved at its June 2015 meeting?

The new intestine transplant program requirements contain language similar to what this proposal recommends modifying. This proposal does include the new intestinal transplant program requirements only because the OPTN/UNOS Membership and Professional Standards Committee finalized the modified Bylaws language to be included in this proposal before the OPTN/UNOS Board of Directors June 2015 meeting.

# Changes to Transplant Program Key Personnel Procurement Requirements

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

*Sponsoring Committee:* Membership and Professional Standards Committee

*Public Comment Period:* August 14 – October 14

## What problem will this proposal solve?

The MPSC receives approximately 350 key personnel change applications annually. This proposal will solve numerous problems with the OPTN Bylaws pertaining to transplant program key personnel procurement requirements. Specifically:

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

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

## Why should you support this proposal?

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

The proposed Bylaws changes address a number of issues that have been noted by the MPSC:

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

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

## How was this proposal developed?

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

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

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

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

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

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

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

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



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

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

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

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

### How well does this proposal address the problem statement?

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

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

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

## Which populations are impacted by this proposal?

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

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

## How does this proposal support the OPTN Strategic Plan?

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

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



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

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

- Expanding the time to meet the procurement requirement for primary transplant surgeons applying through the fellowship pathway reduces barriers that could prevent program approval, potentially resulting in the approval of more transplant programs. This modification will likely have a small impact on this goal.

3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:*

- Key personnel Bylaws are intended to promote patient safety by assuring that each transplant program is led by individuals who have sufficient training and experience in organ transplantation. Modifying the Bylaws pertaining to procurement observations will assure that every primary transplant physicians has been directly exposed to the organ procurement process. Changing the Bylaws to better reflect the training and experience that would be expected of a primary transplant physician should help to improve outcomes of waitlisted patients, living donors, and transplant recipients.

4. *Promote living donor and transplant recipient safety:*

- Key personnel Bylaws are intended to promote patient safety by assuring that each transplant program is led by individuals who have sufficient training and experience in organ transplantation. Modifying the Bylaws pertaining to procurement observations will assure that every primary transplant physicians has been directly exposed to the organ procurement process. Changing the Bylaws to better reflect the training and experience that would be expected of a primary transplant physician should contribute positively to increased transplant recipient safety.

5. *Promote the efficient management of the OPTN:*

- Currently, OPTN Bylaws are inconsistent in requiring surgeons to perform a set number of multi-organ donor procurements. A consistent approach to this requirement will likely result in less confusion among the community, especially if the requirement is eliminated. Similarly, deleting the primary surgeon requirement to observe multi-organ donor procurements eliminates a point of potential confusion in the key personnel application process and would be one less set of data that needs to be provided by members, validated by UNOS staff, and reviewed by the MPSC.
- MPSC occasionally receives primary transplant surgeon applications that meet all requirements outlined in the respective fellowship pathway, except the individual did not perform the requisite number of procurements during their fellowship. Extending the time period will allow some flexibility for members, and will provide an updated position (that is seen as more reasonable) on these types of scenarios to guide the MPSC in future reviews of key personnel applications.
- Deleting the primary physician requirement to observe multi-organ donor procurements eliminates a point of potential confusion in the key personnel application process and would be one less set of data that needs to be provided by members, validated by UNOS staff, and reviewed by the MPSC. Conversely, clarifying that primary transplant physicians must

observe three procurements and three transplants will add to what needs to be provided and reviewed on applications proposing a primary transplant physician. Although these Bylaws modifications are also adding new requirements, this should not significantly increase the key personnel application process burden as this requirement is already routinely provided by members (and reviewed by UNOS staff and the MPSC). The proposed Bylaws additions are clarifications to prevent the approval of the occasional primary transplant physician applicant that does not report any organ procurement or transplant observations.

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

The impact of these changes will be evaluated as the MPSC receives applications proposing individuals as key personnel.

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

## How will members implement this proposal?

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

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

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

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

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

## Policy or Bylaw Language

Proposed new language is underlined 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. Formal 2-year Transplant Fellowship Pathway

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

1. The surgeon performed at least 30 kidney transplants as the primary surgeon or first assistant during the 2-year fellowship period. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the director of the training program.
2. The surgeon performed at least 15 kidney procurements as primary surgeon or first assistant ~~over the 2-year period~~. At least 3 of these procurements must be multiple organ procurements and at least 10 of these procurements must be from deceased donors. These procurements must have been performed during the surgeon's fellowship and the two years immediately following fellowship completion. These procedures must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
3. The surgeon has maintained a current working knowledge of kidney transplantation, defined as direct involvement in kidney transplant patient care in the last 2 years. This includes the management of patients with end stage renal disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, performing the transplant operation, immediate postoperative and continuing inpatient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long term outpatient care.
4. This training was completed at a hospital with a kidney transplant training program approved by the Fellowship Training Committee of the American Society of Transplant Surgeons or accepted by the OPTN Contractor as described in the *Section E.4 Approved Kidney Transplant Surgeon and Physician Fellowship Training Programs* that follows. Foreign training programs must be accepted as equivalent by the Membership and Professional Standards Committee (MPSC).
5. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the director of the training program and chairman of the department or hospital credentialing committee verifying that the surgeon has met the above requirements and is qualified to direct a kidney transplant program.
  - b. A letter of recommendation from the fellowship training program's primary surgeon and transplant program director outlining the surgeon's overall qualifications to act as a primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and

42 familiarity with and experience in adhering to OPTN obligations, and any other matters  
43 judged appropriate. The MPSC may request additional recommendation letters from the  
44 primary physician, primary surgeon, director, or others affiliated with any transplant  
45 program previously served by the surgeon, at its discretion.

- 46 c. A letter from the surgeon that details the training and experience the surgeon has gained  
47 in kidney transplantation.

## 48 **B. Clinical Experience Pathway**

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

- 51  
52
- 53 1. The surgeon has performed 45 or more kidney transplants over a 2 to 5-year period as  
54 primary surgeon or first assistant at a designated kidney transplant program, or its foreign  
55 equivalent. The transplants must be documented in a log that includes the date of transplant,  
56 the role of the surgeon in the procedure, and medical record number or other unique identifier  
57 that can be verified by the OPTN Contractor. The log should be signed by the program  
58 director, division chief, or department chair from the program where the experience was  
59 gained. Each year of the surgeon's experience must be substantive and relevant and include  
60 pre-operative assessment of kidney transplant candidates, performance of transplants as  
61 primary surgeon or first assistant, and post-operative care of kidney recipients.
  - 62 2. The surgeon has performed at least 15 kidney procurements as primary surgeon or first  
63 assistant. ~~At least 3 of these procurements must be multiple organ procurements and at least~~  
64 10 of these procurements must be from deceased donors. These cases must be documented  
65 in a log that includes the date of procurement, location of the donor, and Donor ID.
  - 66 3. The surgeon has maintained a current working knowledge of kidney transplantation, defined  
67 as direct involvement in kidney transplant patient care in the last 2 years. This includes the  
68 management of patients with end stage renal disease, the selection of appropriate recipients  
69 for transplantation, donor selection, histocompatibility and tissue typing, performing the  
70 transplant operation, immediate postoperative and continuing inpatient care, the use of  
71 immunosuppressive therapy including side effects of the drugs and complications of  
72 immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient,  
73 histological interpretation of allograft biopsies, interpretation of ancillary tests for renal  
74 dysfunction, and long term outpatient care.
  - 75 4. The following letters are submitted directly to the OPTN Contractor:
    - 76 a. A letter from the director of the transplant program and Chairman of the department or  
77 hospital credentialing committee verifying that the surgeon has met the above  
78 qualifications and is qualified to direct a kidney transplant program.
    - 79 b. A letter of recommendation from the primary surgeon and transplant program director at  
80 the transplant program last served by the surgeon outlining the surgeon's overall  
81 qualifications to act as a primary transplant surgeon, as well as the surgeon's personal  
82 integrity, honesty, and familiarity with and experience in adhering to OPTN obligations  
83 and compliance protocols, and any other matters judged appropriate. The MPSC may  
84 request additional recommendation letters from the primary physician, primary surgeon,  
85 director, or others affiliated with any transplant program previously served by the  
86 surgeon, at its discretion.
    - 87 c. A letter from the surgeon that details the training and experience the surgeon has gained  
88 in kidney transplantation.
- 89

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

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

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

- 94 1. The physician has current board certification in nephrology by the American Board of Internal  
95 Medicine or the foreign equivalent.
- 96 2. The physician completed 12 consecutive months of specialized training in transplantation  
97 under the direct supervision of a qualified kidney transplant physician and along with a kidney  
98 transplant surgeon at a kidney transplant program that performs 30 or more transplants each  
99 year. The training must have included at least 6 months of clinical transplant service. The  
100 remaining time must have consisted of transplant-related experience, such as experience in a  
101 tissue typing laboratory, on another solid organ transplant service, or conducting basic or  
102 clinical transplant research.
- 103 3. During the fellowship period, the physician was directly involved in the primary care of 30 or  
104 more newly transplanted kidney recipients and continued to follow these recipients for a  
105 minimum of 3 months from the time of transplant. The care must be documented in a log that  
106 includes the date of transplant and the recipient medical record number or other unique  
107 identifier that can be verified by the OPTN Contractor. This recipient log must be signed by  
108 the director of the training program or the transplant program's primary transplant physician.
- 109 4. The physician has maintained a current working knowledge of kidney transplantation, defined  
110 as direct involvement in kidney transplant care in the last 2 years. This includes the  
111 management of patients with end stage renal disease, the selection of appropriate recipients  
112 for transplantation, donor selection, histocompatibility and tissue typing, immediate  
113 postoperative patient care, the use of immunosuppressive therapy including side effects of  
114 the drugs and complications of immunosuppression, differential diagnosis of renal  
115 dysfunction in the allograft recipient, histological interpretation of allograft biopsies,  
116 interpretation of ancillary tests for renal dysfunction, and long term outpatient care. The  
117 curriculum for obtaining this knowledge should be approved by the Residency Review  
118 Committee for Internal Medicine (RRC-IM) of the Accreditation Council for Graduate Medical  
119 Education (ACGME).
- 120 5. The physician ~~should~~ must have observed at least 3 ~~organ~~ kidney procurements, including at  
121 least 1 deceased donor and 1 living donor, and 3 kidney transplants. The physician ~~should~~  
122 also must have observed the organ allocation and procurement processes for these donors.  
123 ~~evaluation, the donation process, and management of at least 3 multiple organ donors who~~  
124 ~~donated a kidney. If the physician has completed these observations, they~~ These  
125 observations must be documented in a log that includes the date of procurement, location of  
126 the donor, and Donor ID.
- 127 6. The physician must have observed at least 3 kidney transplants. The observation of these  
128 transplants must be documented in a log that includes the transplant date, donor type, and  
129 medical record number or other unique identifier that can be verified by the OPTN Contractor.
- 130 ~~6~~7. The following letters are submitted directly to the OPTN Contractor:
- 131 a. A letter from the director of the training program and the supervising qualified kidney  
132 transplant physician verifying that the physician has met the above requirements and is  
133 qualified to direct a kidney transplant program.
- 134 b. A letter of recommendation from the fellowship training program's primary physician and  
135 transplant program director outlining the physician's overall qualifications to act as a  
136 primary transplant physician, as well as the physician's personal integrity, honesty, and

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

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

## **B. Clinical Experience Pathway**

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

1. The physician has been directly involved in the primary care of 45 or more newly transplanted kidney recipients and continued to follow these recipients for a minimum of 3 months from the time of transplant. This patient care must have been provided over a 2 to 5-year period on an active kidney transplant service as the primary kidney transplant physician or under the direct supervision of a qualified transplant physician and in conjunction with a kidney transplant surgeon at a Kidney transplant program or the foreign equivalent. The care must be documented in a log that includes the date of transplant and recipient medical record number or other unique identifier that can be verified by the OPTN Contractor. The recipient log should be signed by the program director, division Chief, or department Chair from the program where the physician gained this experience.
2. The physician has maintained a current working knowledge of kidney transplantation, defined as direct involvement in kidney transplant patient care over the last 2 years. This includes the management of patients with end stage renal disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate postoperative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long term outpatient care.
3. The physician ~~should~~ must have observed at least 3 organ kidney procurements, including at least 1 deceased donor and 1 living donor, and 3 kidney transplants. The physician ~~should~~ also must have observed the organ allocation and procurement processes for these donors, 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 These observations must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
4. The physician must have observed at least 3 kidney transplants. The observation of these transplants must be documented in a log that includes the transplant date, donor type, and medical record number or other unique identifier that can be verified by the OPTN Contractor.
45. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the qualified transplant physician or the kidney transplant surgeon who has been directly involved with the proposed physician documenting the physician's experience and 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



185 qualifications to act as a primary transplant physician, as well as the physician's personal  
186 integrity, honesty, and familiarity with and experience in adhering to OPTN obligations  
187 and compliance protocols, and any other matters judged appropriate. The MPSC may  
188 request additional recommendation letters from the primary physician, primary surgeon,  
189 director, or others affiliated with any transplant program previously served by the  
190 physician, at its discretion.

- 191 c. A letter from the physician that details the training and experience the physician has  
192 gained in kidney transplantation.  
193

### 194 **C. Three-year Pediatric Nephrology Fellowship Pathway**

195 A physician can meet the requirements for primary kidney transplant physician by completion of 3  
196 years of pediatric nephrology fellowship training as required by the American Board of Pediatrics  
197 in a program accredited by the Residency Review Committee for Pediatrics (RRC-Ped) of the  
198 ACGME. The training must contain at least 6 months of clinical care for transplant patients, and  
199 the following conditions must be met:  
200

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

234 ~~donors who donated a kidney. If the physician has completed these observations, they~~ These  
235 observations must be documented in a log that includes the date of procurement, location of  
236 the donor, and Donor ID.

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

241 ~~6~~7. The following letters are submitted directly to the OPTN Contractor:

- 242 a. A letter from the director and the supervising qualified transplant physician and surgeon  
243 of the fellowship training program verifying that the physician has met the above  
244 requirements and is 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 any other matters  
249 judged appropriate. The MPSC may request additional recommendation letters from the  
250 primary physician, primary surgeon, director, or others affiliated with any transplant  
251 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 **D. Twelve-month Pediatric Transplant Nephrology Fellowship Pathway**

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

258

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

283 differential diagnosis of renal dysfunction in the allograft recipient, manifestation of rejection  
284 in the pediatric patient, histological interpretation of allograft biopsies, interpretation of  
285 ancillary tests for renal dysfunction, and long-term outpatient care of pediatric allograft  
286 recipients including management of hypertension, nutritional support, and drug dosage,  
287 including antibiotics, in the pediatric patient. The curriculum for obtaining this knowledge must  
288 be approved by the Residency Review Committee (RRC) -Ped of the ACGME.

289 5. The physician ~~should~~ must have observed at least 3 ~~organ~~ kidney procurements, including at  
290 least 1 deceased donor and 1 living donor. ~~and 3 pediatric kidney transplants.~~ The physician  
291 ~~should also~~ must have observed the organ allocation and procurement processes for these  
292 donors, evaluation, the donation process, and management of at least 3 multiple organ  
293 ~~donors who donated a kidney. If the physician has completed these observations, they~~ These  
294 observations must be documented in a log that includes the date of procurement, location of  
295 the donor, and Donor ID.

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

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

301 a. A letter from the director and the supervising qualified transplant physician and surgeon  
302 of the fellowship training program verifying that the physician has met the above  
303 requirements and is qualified to become the primary transplant physician of a designated  
304 kidney transplant program.

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

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

## 314 **E. Combined Pediatric Nephrology Training and Experience Pathway**

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

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

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

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

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

## 371 **G. Conditional Approval for Primary Transplant Physician**

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

- 375
- 376 1. The physician has current board certification in nephrology by the American Board of Internal  
377 Medicine, the American Board of Pediatrics, or the foreign equivalent.
  - 378 2. The physician has been involved in the primary care of 23 or more newly transplanted kidney  
379 recipients, and has followed these patients for at least 3 months from the time of their

380 transplant. This care must be documented in a recipient log that includes the date of  
381 transplant and the medical record number or other unique identifier that can be verified by the  
382 OPTN Contractor. This log must be signed by the program director, division chief, or  
383 department chair from the transplant program where the experience was gained.

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

392 4. The physician has 12 months experience on an active kidney transplant service as the  
393 primary kidney transplant physician or under the direct supervision of a qualified kidney  
394 transplant physician and in conjunction with a kidney transplant surgeon at a designated  
395 kidney transplant program or the foreign equivalent. These 12 months of experience must be  
396 acquired within a 2-year period.

397 5. The physician ~~should~~ must have observed at least 3 ~~organ kidney procurements, including at~~  
398 ~~least 1 deceased donor and 1 living donor. and 3 kidney transplants.~~ The physician ~~should~~  
399 ~~also~~ must have observed the organ allocation and procurement processes for these donors.  
400 evaluation, the donation process, and management of at least 3 multiple organ donors who  
401 donated a kidney. If the physician has completed these observations, they ~~These~~  
402 observations must be documented in a log that includes the date of procurement, location of  
403 the donor, and Donor ID.

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

407 ~~67.~~ The program has established and documented a consulting relationship with counterparts at  
408 another kidney transplant program.

409 ~~78.~~ The transplant program submits activity reports to the OPTN Contractor every 2 months  
410 describing the transplant activity, transplant outcomes, physician recruitment efforts, and  
411 other operating conditions as required by the MPSC to demonstrate the ongoing quality and  
412 efficient patient care at the program. The activity reports must also demonstrate that the  
413 physician is making sufficient progress to meet the required involvement in the primary care  
414 of 45 or more kidney transplant recipients, or that the program is making sufficient progress in  
415 recruiting a physician who meets all requirements for primary kidney transplant physician and  
416 who will be on site and approved by the MPSC to assume the role of primary physician by the  
417 end of the 12 month conditional approval period.

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

419 a. A letter from the supervising qualified transplant physician and surgeon who were directly  
420 involved with the physician documenting the physician's experience and competence.

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

428 c. A letter from the physician that details the training and experience the physician has  
429 gained in kidney transplantation.  
430

431 The 12-month conditional approval period begins on the initial approval date granted to the  
432 personnel change application, whether it is interim approval granted by the MPSC subcommittee,  
433 or approval granted by the full MPSC. The conditional approval period ends 12 months after the  
434 first approval date of the personnel change application.  
435

436 If the program is unable to demonstrate that it has an individual on site who can meet the  
437 requirements as described in *Sections E.3.A through E.3.F* above at the end of the 12-month  
438 conditional approval period, it must inactivate. The requirements for program inactivation are  
439 described in *Appendix K: Transplant Program Inactivity, Withdrawal, and Termination* of these  
440 Bylaws.  
441

442 The MPSC may consider on a case-by-case basis and grant a 6-month extension to a transplant  
443 program that provides substantial evidence of progress toward fulfilling the requirements but is  
444 unable to complete the requirements within one year.  
445

## 446 **Appendix F:** 447 **Membership and Personnel Requirements for Liver** 448 **Transplant Programs**

### 449 **F.3 Primary Liver Transplant Surgeon Requirements**

#### 450 **A. Formal 2-year Transplant Fellowship Pathway**

451 Surgeons can meet the training requirements for primary liver transplant surgeon by completing a  
452 2-year transplant fellowship if the following conditions are met:  
453

- 454 1. The surgeon performed at least 45 liver transplants as primary surgeon or first assistant during  
455 the 2-year fellowship period. These transplants must be documented in a log that includes the  
456 date of transplant, the role of the surgeon in the procedure, and the medical record number or  
457 other unique identifier that can be verified by the OPTN Contractor. This log must be signed by  
458 the director of the training program.
- 459 2. The surgeon performed at least 20 liver procurements as primary surgeon or first assistant  
460 ~~during the 2-year period. At least 3 of these procurements must include selection and~~  
461 ~~management of the donor. These procurements must have been performed during the~~  
462 surgeon's fellowship and the two years immediately following fellowship completion. These  
463 procedures must be documented in a log that includes the date of procurement, location of the  
464 donor, and Donor ID. This log must be signed by the director of the training program.
- 465 3. The surgeon has maintained a current working knowledge of liver transplantation, defined as  
466 direct involvement in liver transplant patient care within the last 2 years. This includes the  
467 management of patients with end stage liver disease, the selection of appropriate recipients  
468 for transplantation, donor selection, histocompatibility and tissue typing, performing the  
469 transplant operation, immediate postoperative and continuing inpatient care, the use of  
470 immunosuppressive therapy including side effects of the drugs and complications of  
471 immunosuppression, differential diagnosis of liver allograft dysfunction, histologic



- 472 interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and  
473 long term outpatient care.
- 474 4. The training was completed at a hospital with a transplant training program approved by the  
475 Fellowship Training Committee of the American Society of Transplant Surgeons or accepted  
476 by the OPTN Contractor as described in *Section F.5. Approved Liver Surgeon Transplant*  
477 *Fellowship Programs* that follows. Foreign training programs must be accepted as equivalent  
478 by the Membership and Professional Standards Committee (MPSC).
- 479 5. The following letters are submitted directly to the OPTN Contractor:
- 480 a. A letter from the director of the training program verifying that the surgeon has met the  
481 above requirements, and is qualified to direct a liver transplant program.
- 482 b. A letter of recommendation from the fellowship training program's primary surgeon and  
483 transplant program director outlining the surgeon's overall qualifications to act as primary  
484 transplant surgeon, as well as the surgeon's personal integrity, honesty, familiarity with  
485 and experience in adhering to OPTN obligations, and other matters judged appropriate.  
486 The MPSC may request additional recommendation letters from the primary physician,  
487 primary surgeon, director, or others affiliated with any transplant program previously  
488 served by the surgeon, at its discretion.
- 489 c. A letter from the surgeon that details his or her training and experience in liver  
490 transplantation.
- 491

## 492 **B. Clinical Experience Pathway**

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

495

- 496 1. The surgeon has performed 60 or more liver transplants over a 2 to 5-year period as primary  
497 surgeon or first assistant at a designated liver transplant program, or its foreign equivalent.  
498 These transplants must be documented in a log that includes the date of transplant, the role  
499 of the surgeon in the procedure, and medical record number or other unique identifier that  
500 can be verified by the OPTN Contractor. This log should be signed by the program director,  
501 division chief, or department chair from the program where the experience was gained. Each  
502 year of the surgeon's experience must be substantive and relevant and include pre-operative  
503 assessment of liver transplant candidates, transplants performed as primary surgeon or first  
504 assistant, and post-operative management of liver recipients.
- 505 2. The surgeon has performed at least 30 liver procurements as primary surgeon or first  
506 assistant. ~~At least 3 of these procurements must include selection and management of the~~  
507 ~~donor.~~ These procedures must be documented in a log that includes the date of procurement,  
508 location of the donor, and Donor ID.
- 509 3. The surgeon has maintained a current working knowledge of liver transplantation, defined as  
510 direct involvement in liver transplant patient care within the last 2 years. This includes the  
511 management of patients with end stage liver disease, the selection of appropriate recipients  
512 for transplantation, donor selection, histocompatibility and tissue typing, performing the  
513 transplant operation, immediate postoperative and continuing inpatient care, the use of  
514 immunosuppressive therapy including side effects of the drugs and complications of  
515 immunosuppression, differential diagnosis of liver dysfunction in the allograft recipient,  
516 histologic interpretation of allograft biopsies, interpretation of ancillary tests for liver  
517 dysfunction, and long term outpatient care.
- 518 4. The following letters are sent directly to the OPTN Contractor:

- 519 a. A letter from the director of the transplant program and chairman of the department or  
520 hospital credentialing committee verifying that the surgeon has met the above  
521 requirements, and is qualified to direct a liver transplant program.  
522 b. A letter of recommendation from the primary surgeon and transplant program director at  
523 the transplant program last served by the surgeon outlining the surgeon's overall  
524 qualifications to act as primary transplant surgeon, as well as the surgeon's personal  
525 integrity, honesty, familiarity with and experience in adhering to OPTN obligations, and  
526 other matters judged appropriate. The MPSC may request additional recommendation  
527 letters from the primary physician, primary surgeon, director, or others affiliated with any  
528 transplant program previously served by the surgeon, at its discretion.  
529 c. A letter from the surgeon that details the training and experience the surgeon gained in  
530 liver transplantation.  
531

## 532 F.4 Primary Liver Transplant Physician Requirements

### 533 A. 12-month Transplant Hepatology Fellowship Pathway

534 Physicians can meet the training requirements for a primary liver transplant physician during a  
535 separate 12-month transplant hepatology fellowship if the following conditions are met:  
536

- 537 1. The physician completed 12 consecutive months of specialized training in transplantation  
538 under the direct supervision of a qualified liver transplant physician and in conjunction with a  
539 liver transplant surgeon at a liver transplant program. The training must have included at least  
540 3 months of clinical transplant service. The remaining time must have consisted of transplant-  
541 related experience, such as experience in a tissue typing laboratory, on another solid organ  
542 transplant service, or conducting basic or clinical transplant research.  
543 2. During the fellowship period, the physician was directly involved in the primary care of 30 or  
544 more newly transplanted liver recipients, and continued to follow these recipients for a  
545 minimum of 3 months from the time of transplant. The care must be documented in a log that  
546 includes the date of transplant and the medical record number or other unique identifier that  
547 can be verified by the OPTN Contractor. This log must be signed by the director of the  
548 training program or the transplant program's primary transplant physician.  
549 3. The physician has maintained a current working knowledge of liver transplantation, defined  
550 as direct involvement in liver transplant patient care within the last 2 years. This includes the  
551 management of patients with end stage liver disease, acute liver failure, the selection of  
552 appropriate recipients for transplantation, donor selection, histocompatibility and tissue  
553 typing, immediate post-operative patient care, the use of immunosuppressive therapy  
554 including side effects of the drugs and complications of immunosuppression, differential  
555 diagnosis of liver allograft dysfunction, histologic interpretation of allograft biopsies,  
556 interpretation of ancillary tests for liver dysfunction, and long term outpatient care.  
557 4. The physician ~~should~~ must have observed at least 3 organ liver procurements and 3 liver  
558 transplants. The physician ~~should also~~ must have observed the organ allocation and  
559 procurement processes for these donors. ~~evaluation, the donation process, and management~~  
560 ~~of at least 3 multiple organ donors who donated a liver. If the physician has completed these~~  
561 ~~observations, they~~ These observations must be documented in a log that includes the date of  
562 procurement, location of the donor, and Donor ID.  
563 5. The physician must have observed at least 3 liver transplants. The observation of these  
564 transplants must be documented in a log that includes the transplant date, donor type, and  
565 medical record number or other unique identifier that can be verified by the OPTN Contractor.

- 566 56. The following letters are submitted directly to the OPTN Contractor:  
567 a. A letter from the director of the training program and the supervising liver transplant  
568 physician verifying that the physician has met the above requirements and is qualified  
569 to direct a liver transplant program.  
570 b. A letter of recommendation from the fellowship training program's primary physician  
571 and transplant program director outlining the physician's overall qualifications to act  
572 as a primary transplant physician, as well as the physician's personal integrity,  
573 honesty, and familiarity with and experience in adhering to OPTN obligations, and  
574 any other matters judged appropriate. The MPSC may request additional  
575 recommendation letters from the primary physician, primary surgeon, director, or  
576 others affiliated with any transplant program previously served by the physician, at its  
577 discretion.  
578 c. A letter from the physician writes that details the training and experience the  
579 physician gained in liver transplantation.  
580

581 The training requirements outlines above are in addition to other clinical requirements for general  
582 gastroenterology training.  
583

## 584 **B. Clinical Experience Pathway**

585 A physician can meet the requirements for a primary liver transplant physician through acquired  
586 clinical experience if the following conditions are met:  
587

- 588 1. The physician has been directly involved in the primary care of 50 or more newly transplanted  
589 liver recipients and continued to follow these recipients for a minimum of 3 months from the  
590 time of transplant. This patient care must have been provided over a 2 to 5-year period on an  
591 active liver transplant service as the primary liver transplant physician or under the direct  
592 supervision of a qualified liver transplant physician and in conjunction with a liver transplant  
593 surgeon at a liver transplant program or the foreign equivalent. This care must be  
594 documented in a log that includes the date of transplant and the medical record number or  
595 other unique identifier that can be verified by the OPTN Contractor. This recipient log should  
596 be signed by the program director, division chief, or department chair from the program  
597 where the physician gained this experience.
- 598 2. The physician has maintained a current working knowledge of liver transplantation, defined  
599 as direct involvement in liver transplant patient care within the last 2 years. This includes the  
600 management of patients with end stage liver disease, acute liver failure, the selection of  
601 appropriate recipients for transplantation, donor selection, histocompatibility and tissue  
602 typing, immediate post-operative patient care, the use of immunosuppressive therapy  
603 including side effects of the drugs and complications of immunosuppression, differential  
604 diagnosis of liver allograft dysfunction, histologic interpretation of allograft biopsies,  
605 interpretation of ancillary tests for liver dysfunction, and long term outpatient care.
- 606 3. The physician ~~should~~ must have observed at least 3 organ liver procurements and 3 liver  
607 transplants. The physician ~~should also~~ must have observed the organ allocation and  
608 procurement processes for these donors. ~~evaluation, the donation process, and~~  
609 ~~management of at least 3 multiple organ donors who donated a liver. If the physician has~~  
610 ~~completed these observations, they~~ These observations must be documented in a log that  
611 includes the date of procurement, the location of the donor, and Donor ID.
- 612 4. The physician must have observed at least 3 liver transplants. The observation of these  
613 transplants must be documented in a log that includes the transplant date, donor type, and

614 medical record number or other unique identifier that can be verified by the OPTN  
615 Contractor.

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

- 617 a. A letter from the qualified transplant physician or the liver transplant surgeon who has  
618 been directly involved with the proposed physician documenting the physician's  
619 experience and competence.
- 620 b. A letter of recommendation from the primary physician and transplant program director at  
621 the transplant program last served by the physician outlining the physician's overall  
622 qualifications to act as a primary transplant physician, as well as the physician's personal  
623 integrity, honesty, and familiarity with and experience in adhering to OPTN obligations,  
624 and any other matters judged appropriate. The MPSC may request additional  
625 recommendation letters from the primary physician, primary surgeon, director, or others  
626 affiliated with any transplant program previously served by the physician, at its discretion.
- 627 c. A letter from the physician that details the training and experience the physician gained in  
628 liver transplantation.

### 630 C. Three-year Pediatric Gastroenterology Fellowship Pathway

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

- 636
- 637 1. The physician has current board certification in gastroenterology by the American Board of  
638 Pediatrics, or the foreign equivalent.
  - 639 2. During the 3-year training period the physician was directly involved in the primary care of 10  
640 or more newly transplanted pediatric liver recipients and followed 20 newly transplanted liver  
641 recipients for a minimum of 3 months from the time of transplant, under the direct supervision  
642 of a qualified liver transplant physician along with a qualified liver transplant surgeon. The  
643 physician was also directly involved in the preoperative, peri-operative and post-operative  
644 care of 10 or more liver transplants in pediatric patients. The pediatric gastroenterology  
645 program director may elect to have a portion of the transplant experience carried out at  
646 another transplant service, to meet these requirements. This care must be documented in a  
647 log that includes the date of transplant, the medical record number or other unique identifier  
648 that can be verified by the OPTN Contractor. This recipient log must be signed by the training  
649 program director or the transplant program's primary transplant physician.
  - 650 3. The experience caring for pediatric patients occurred at a liver transplant program with a  
651 qualified liver transplant physician and a qualified liver transplant surgeon that performs an  
652 average of at least 10 liver transplants on pediatric patients per year.
  - 653 4. The physician ~~should~~ must have observed at least 3 organ liver procurements ~~and 3 liver~~  
654 ~~transplants. In addition, the~~ The physician should must have observed the organ allocation  
655 and procurement processes for these donors. evaluation, the donation process, and  
656 management of at least 3 multiple organ donors who donated a liver. If the physician has  
657 completed these observations, they These observations must be documented in a log that  
658 includes the date of procurement, location of the donor and Donor ID.
  - 659 5. The physician must have observed at least 3 liver transplants. The observation of these  
660 transplants must be documented in a log that includes the transplant date, donor type, and  
661 medical record number or other unique identifier that can be verified by the OPTN Contractor.

662 56. The physician has maintained a current working knowledge of liver transplantation, defined  
663 as direct involvement in liver transplant patient care within the last 2 years. This includes the  
664 management of pediatric patients with end-stage liver disease acute liver failure, the  
665 selection of appropriate pediatric recipients for transplantation, donor selection,  
666 histocompatibility and tissue typing, immediate postoperative care including those issues of  
667 management unique to the pediatric recipient, fluid and electrolyte management, the use of  
668 immunosuppressive therapy in the pediatric recipient including side-effects of drugs and  
669 complications of immunosuppression, the effects of transplantation and immunosuppressive  
670 agents on growth and development, differential diagnosis of liver dysfunction in the allograft  
671 recipient, manifestation of rejection in the pediatric patient, histological interpretation of  
672 allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long-term  
673 outpatient care of pediatric allograft recipients including management of hypertension,  
674 nutritional support, and drug dosage, including antibiotics, in the pediatric patient.

675 67. The following letters are submitted directly to the OPTN Contractor:  
676 a. A letter from the director of the pediatric gastroenterology training program, and the  
677 qualified liver transplant physician and surgeon of the fellowship training program  
678 verifying that the physician has met the above requirements, and is qualified to act as a  
679 liver transplant physician and direct a liver transplant program.  
680 b. A letter of recommendation from the fellowship training program's primary physician and  
681 transplant program director outlining the physician's overall qualifications to act as a  
682 primary transplant physician, as well as the physician's personal integrity, honesty, and  
683 familiarity with and experience in adhering to OPTN obligations, and any other matters  
684 judged appropriate. The MPSC may request additional recommendation letters from the  
685 primary physician, primary surgeon, director, or others affiliated with any transplant  
686 program previously served by the physician, at its discretion.  
687 c. A letter from the physician that details the training and experience the physician gained in  
688 liver transplantation.  
689

#### 690 **D. Pediatric Transplant Hepatology Fellowship Pathway**

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

693  
694 1. The physician has current board certification in pediatric gastroenterology by the American  
695 Board of Pediatrics or the foreign equivalent, or is approved by the American Board of  
696 Pediatrics to take the certifying exam.  
697 2. During the fellowship, the physician was directly involved in the primary care of 10 or more  
698 newly transplanted pediatric liver recipients and followed 20 newly transplanted liver  
699 recipients for at least 3 months from the time of transplant, under the direct supervision of a  
700 qualified liver transplant physician and in conjunction with a qualified liver transplant surgeon.  
701 The physician must have been directly involved in the pre-operative, peri-operative and post-  
702 operative care of 10 or more liver transplants in pediatric patients. The pediatric  
703 gastroenterology program director may elect to have a portion of the transplant experience  
704 completed at another liver transplant program in order to meet these requirements. This care  
705 must be documented in a log that includes the date of transplant and the medical record  
706 number or other unique identifier that can be verified by the OPTN Contractor. This recipient  
707 log must be signed by the training program director or the transplant program primary  
708 transplant physician.

- 709 3. The experience in caring for pediatric liver patients occurred at a liver transplant program with  
710 a qualified liver transplant physician and surgeon that performs an average of at least 10  
711 pediatric liver transplants a year.
- 712 4. The physician has maintained a current working knowledge of liver transplantation, defined  
713 as direct involvement in liver transplant patient care within the last 2 years. This includes the  
714 management of pediatric patients with end-stage liver disease, acute liver failure, the  
715 selection of appropriate pediatric recipients for transplantation, donor selection,  
716 histocompatibility and tissue typing, immediate postoperative care including those issues of  
717 management unique to the pediatric recipient, fluid and electrolyte management, the use of  
718 immunosuppressive therapy in the pediatric recipient including side-effects of drugs and  
719 complications of immunosuppression, the effects of transplantation and immunosuppressive  
720 agents on growth and development, differential diagnosis of liver dysfunction in the allograft  
721 recipient, manifestation of rejection in the pediatric patient, histological interpretation of  
722 allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long-term  
723 outpatient care of pediatric allograft recipients including management of hypertension,  
724 nutritional support, and drug dosage, including antibiotics, in the pediatric patient.
- 725 5. The physician ~~should~~ must have observed at least 3 ~~organ liver~~ procurements ~~and 3 liver~~  
726 ~~transplants. In addition, the~~ The physician should must have observed the organ allocation  
727 and procurement processes for these donors. evaluation, the donation process, and  
728 management of at least 3 multiple organ donors who donated a liver. If the physician has  
729 ~~completed these observations, they~~ These observations must be documented in a log that  
730 includes the date of procurement, location of the donor and Donor ID.
- 731 6. The physician must have observed at least 3 liver transplants. The observation of these  
732 transplants must be documented in a log that includes the transplant date, donor type, and  
733 medical record number or other unique identifier that can be verified by the OPTN Contractor.
- 734 67. The following letters are submitted directly to the OPTN Contractor:
- 735 a. A letter from the director of the pediatric transplant hepatology training program, and the  
736 qualified liver transplant physician and surgeon of the fellowship training program  
737 verifying that the physician has met the above requirements, and is qualified to act as a  
738 liver transplant physician and direct a liver transplant program.
- 739 b. A letter of recommendation from the fellowship training program's primary physician and  
740 transplant program director outlining the physician's overall qualifications to act as a  
741 primary transplant physician, as well as the physician's personal integrity, honesty, and  
742 familiarity with and experience in adhering to OPTN obligations, and any other matters  
743 judged appropriate. The MPSC may request additional recommendation letters from the  
744 primary physician, primary surgeon, director, or others affiliated with any transplant  
745 program previously served by the physician, at its discretion.
- 746 c. A letter from the physician that details the training and experience the physician gained in  
747 liver transplantation.
- 748

## 749 **E. Combined Pediatric Gastroenterology/Transplant Hepatology** 750 **Training and Experience Pathway**

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

753

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



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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~~ must have observed at least 3 ~~organ liver~~ procurements ~~and 3 liver transplants~~. ~~In addition, the~~ The physician should must have observed the organ allocation and procurement processes for these donors. evaluation, the donation process, and management of at least 3 multiple organ donors who donated a liver. If the physician has completed these observations, they These observations must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
  6. The physician must have observed at least 3 liver transplants. The observation of these transplants must be documented in a log that includes the transplant date, donor type, and medical record number or other unique identifier that can be verified by the OPTN Contractor.
  67. 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.
2. 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.
3. 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.
4. 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.
5. The physician ~~should~~ must have observed at least 3 ~~organ liver~~ procurements ~~and 3 liver transplants~~. The physician ~~should also~~ must have observed the organ allocation and procurement processes for these donors. ~~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~~ These observations must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
6. The physician must have observed at least 3 liver transplants. The observation of these transplants must be documented in a log that includes the transplant date, donor type, and medical record number or other unique identifier that can be verified by the OPTN Contractor.
67. The transplant program submits activity reports to the OPTN Contractor every 2 months describing the transplant activity, transplant outcomes, physician recruitment efforts, and other operating conditions as required by the MPSC to demonstrate the ongoing quality and efficient patient care at the program. The activity reports must also demonstrate that the physician is making sufficient progress 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.
78. The program has established and documented a consulting relationship with counterparts at another liver transplant program.
89. The following letters are submitted directly to the OPTN Contractor:

- 852 a. A letter from the qualified liver transplant physician and surgeon who were directly  
853 involved with the physician verifying that the physician has satisfactorily met the above  
854 requirements to become the primary transplant physician of a liver transplant program.  
855 b. A letter of recommendation from the primary physician and transplant program director at  
856 the transplant program last served by the physician outlining the physician's overall  
857 qualifications to act as a primary transplant physician, as well as the physician's personal  
858 integrity, honesty, and familiarity with and experience in adhering to OPTN obligations,  
859 and any other matters judged appropriate. The MPSC may request additional  
860 recommendation letters from the primary physician, primary surgeon, director, or others  
861 affiliated with any transplant program previously served by the physician, at its discretion.  
862 c. A letter from the physician sends that details the training and experience the physician  
863 gained in liver transplantation.  
864

865 The 12-month conditional approval period begins on the first approval date granted to the  
866 personnel change application, whether it is interim approval granted by the MPSC subcommittee,  
867 or approval granted by the full MPSC. The conditional approval period ends 12 months after the  
868 first approval date of the personnel change application.  
869

870 If the program is unable to demonstrate that it has an individual on site who can meet the  
871 requirements as described in *Sections F.3.A through F.3.F* above at the end of the 12 month  
872 conditional approval period, it must inactivate. The requirements for program inactivation are  
873 described in *Appendix K: Transplant Program Inactivity, Withdrawal, and Termination* of these  
874 Bylaws.  
875

876 The MPSC may consider on a case-by-case basis and grant a 6-month extension to a transplant  
877 program that provides substantial evidence of progress toward fulfilling the requirements but is  
878 unable to complete the requirements within one year.  
879

## 880 ***Appendix G:***

### 881 ***Membership and Personnel Requirements for***

### 882 ***Pancreas and Pancreatic Islet Transplant Programs***

#### 883 **G.2 Primary Pancreas Transplant Surgeon Requirements**

##### 884 **A. Formal 2-year Transplant Fellowship Pathway**

885 Surgeons can meet the training requirements for primary pancreas transplant surgeon by  
886 completing a 2-year transplant fellowship if the following conditions are met:  
887

- 888 1. The surgeon performed at least 15 pancreas transplants as primary surgeon or first assistant  
889 during the 2-year fellowship period. These transplants must be documented in a log that  
890 includes the date of transplant, the role of the surgeon in the procedure, and medical record  
891 number or other unique identifier that can be verified by the OPTN Contractor. This log must  
892 be signed by the director of the training program.
- 893 2. The surgeon performed at least 10 pancreas procurements as primary surgeon or first  
894 assistant during the 2-year period. These procurements must have been performed during  
895 the surgeon's fellowship and the two years immediately following fellowship completion.

- 896 These cases must be documented in a log that includes the date of procurement, location of  
897 the donor, and Donor ID. This log must be signed by the director of the training program.
- 898 3. The surgeon has maintained a current working knowledge of pancreas transplantation,  
899 defined as direct involvement in patient care within the last 2 years. This includes the  
900 management of patients with diabetes mellitus, the selection of appropriate recipients for  
901 transplantation, donor selection, histocompatibility and tissue typing, performing the  
902 transplant operation, immediate postoperative and continuing inpatient care, the use of  
903 immunosuppressive therapy including side effects of the drugs and complications of  
904 immunosuppression, differential diagnosis of pancreas dysfunction in the allograft recipient,  
905 histological interpretation of allograft biopsies, interpretation of ancillary tests for pancreatic  
906 dysfunction, and long term outpatient care.
- 907 4. The training was completed at a hospital with a pancreas transplant training program  
908 approved by the Fellowship Training Committee of the American Society of Transplant  
909 Surgeons or accepted by the OPTN Contractor as described in *Section G.7. Approved*  
910 *Pancreas Transplant Surgeon Fellowship Training Programs* that follows. Foreign training  
911 programs will be reviewed by the MPSC and only those programs that are accepted as  
912 equivalent will be granted approval.
- 913 5. The following letters are submitted directly to the OPTN Contractor:
- 914 a. A letter from the director of the training program and chairman of the department or  
915 hospital credentialing committee verifying that the fellow has met the above requirements  
916 and is qualified to direct a pancreas transplant program.
- 917 b. A letter of recommendation from the fellowship training program's primary surgeon and  
918 transplant program director outlining the surgeon's overall qualifications to act as primary  
919 transplant surgeon as well as the surgeon's personal integrity, honesty, familiarity with  
920 and experience in adhering to OPTN obligations, and any other matters judged  
921 appropriate. The MPSC may request similar letters of recommendation from the primary  
922 physician, primary surgeon, director, or others affiliated with any transplant program  
923 previously served by the surgeon, at its discretion.
- 924 c. A letter from the surgeon that details the training and experience the surgeon has gained  
925 in pancreas transplantation.
- 926

### 927 **G.3 Primary Pancreas Transplant Physician Requirements**

#### 928 **A. Twelve-month Transplant Medicine Fellowship Pathway**

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

- 931
- 932 1. The physician completed 12 consecutive months of specialized training in pancreas  
933 transplantation at a pancreas transplant program under the direct supervision of a qualified  
934 pancreas transplant physician along with a pancreas transplant surgeon. The training must  
935 have included at least 6 months on the clinical transplant service. The remaining time must  
936 have consisted of transplant-related experience, such as experience in a tissue typing  
937 laboratory, on another solid organ transplant service, or conducting basic or clinical transplant  
938 research.
- 939 2. During the fellowship period, the physician was directly involved in the primary care of 8 or  
940 more newly transplanted pancreas recipients and followed these recipients for a minimum of  
941 3 months from the time of transplant. The care must be documented in a log that includes the  
942 date of transplant and medical record number or other unique identifier that can be identified

- 943 by the OPTN Contractor. This recipient log must be signed by the director of the training  
944 program or the transplant program's primary transplant physician.
- 945 3. The physician has maintained a current working knowledge of pancreas transplantation,  
946 defined as direct involvement in pancreas transplant patient care within the last 2 years. This  
947 includes the management of patients with end stage pancreas disease, the selection of  
948 appropriate recipients for transplantation, donor selection, histocompatibility and tissue  
949 typing, immediate post-operative patient care, the use of immunosuppressive therapy  
950 including side effects of the drugs and complications of immunosuppression, differential  
951 diagnosis of pancreas dysfunction in the allograft recipient, histological interpretation of  
952 allograft biopsies, interpretation of ancillary tests for pancreas dysfunction, and long term  
953 outpatient care.
- 954 4. The physician ~~should~~ must have observed at least 3 ~~organ pancreas~~ procurements ~~and 3~~  
955 ~~pancreas transplants~~. The physician ~~should~~ must have observed the organ allocation and  
956 procurement processes for these donors. ~~evaluation, the donation process, and~~  
957 ~~management of at least 3 multiple organ donors who donated a pancreas. If the physician~~  
958 ~~completed these observations, they~~ These observations must be documented in a log that  
959 includes the date of procurement, location of the donor, and Donor ID.
- 960 5. The physician must have observed at least 3 pancreas transplants. The observation of these  
961 transplants must be documented in a log that includes the transplant date and medical record  
962 number or other unique identifier that can be verified by the OPTN Contractor.
- 963 56. The curriculum of this transplant medicine fellowship should be approved by the Residency  
964 Review Committee for Internal Medicine (RRC-IM) of the Accreditation Council for Graduate  
965 Medical Education (ACGME).
- 966 67. The following letters are submitted directly to the OPTN Contractor:
- 967 a. A letter from director of the training program and supervising qualified pancreas  
968 transplant physician send a letter directly to the OPTN Contractor verifying that the fellow  
969 has met the above requirements and is qualified to direct a pancreas transplant program.
- 970 b. A letter of recommendation from the fellowship training program's primary physician and  
971 transplant program director outlining the physician's overall qualifications to act as  
972 primary transplant physician as well as the physician's personal integrity, honesty,  
973 familiarity with and experience in adhering to OPTN obligations, and any other matters  
974 judged appropriate. The MPSC may request similar letters of recommendation from the  
975 primary physician, primary surgeon, director, or others affiliated with any transplant  
976 program that the physician previously served, at its discretion.
- 977 c. A letter from the physician that details the training and experience the physician has  
978 gained in pancreas transplantation.

979  
980 The above training is in addition to other clinical requirements for general nephrology,  
981 endocrinology, or diabetology training.

## 982 **B. Clinical Experience Pathway**

983  
984 A physician can meet the requirements for a primary transplant physician through acquired  
985 clinical experience if the following conditions are met:

- 986  
987 1. The physician has been directly involved in the primary care of 15 or more newly transplanted  
988 pancreas recipients and continued to follow these recipients for a minimum of 3 months from  
989 the time of transplant. This patient care must have been provided over a 2 to 5-year period on  
990 an active pancreas transplant service as the primary pancreas transplant physician or under

991 the direct supervision of a qualified pancreas transplant physician along with a pancreas  
992 transplant surgeon at a pancreas transplant program, or its foreign equivalent. The care must  
993 be documented in a log that includes the date of transplant and the medical record number or  
994 other unique identifier that can be verified by the OPTN Contractor. This recipient log should  
995 be signed by the program director, division chief, or department chair from the program  
996 where the physician gained this experience.

997 2. The physician has maintained a current working knowledge of pancreas transplantation,  
998 defined as direct involvement in pancreas transplant patient care within the last 2 years. This  
999 includes the management of patients with end stage pancreas disease, the selection of  
1000 appropriate recipients for transplantation, donor selection, histocompatibility and tissue  
1001 typing, immediate post-operative patient care, the use of immunosuppressive therapy  
1002 including side effects of the drugs and complications of immunosuppression, differential  
1003 diagnosis of pancreas dysfunction in the allograft recipient, histological interpretation of  
1004 allograft biopsies, interpretation of ancillary tests for pancreas dysfunction, and long term  
1005 outpatient care.

1006 3. The physician ~~should~~ must have observed at least 3 ~~organ pancreas~~ procurements ~~and 3~~  
1007 ~~pancreas transplants~~. The physician ~~should~~ must have ~~also~~ observed the organ allocation  
1008 and procurement processes for these donors. ~~evaluation, the donation process, and~~  
1009 ~~management of at least 3 multiple organ donors who donated a pancreas.~~ If the physician  
1010 ~~has completed these observations, they~~ These observations must be documented in a log  
1011 that includes the date of procurement, location of the donor, and Donor ID.

1012 4. The physician must have observed at least 3 pancreas transplants. The observation of these  
1013 transplants must be documented in a log that includes the transplant date and medical record  
1014 number or other unique identifier that can be verified by the OPTN Contractor.

1015 45. The following letters are submitted directly to the OPTN Contractor:

- 1016 a. A letter from the qualified pancreas transplant physician or surgeon who has been  
1017 directly involved with the physician documenting the physician's experience and  
1018 competence.
- 1019 b. A letter of recommendation from the primary physician and director at the transplant  
1020 program last served by the physician outlining the physician's overall qualifications to act  
1021 as primary transplant physician as well as the physician's personal integrity, honesty,  
1022 familiarity with and experience in adhering to OPTN obligations, and any other matters  
1023 judged appropriate. The MPSC may request similar letters of recommendation from the  
1024 primary physician, primary surgeon, director, or others affiliated with any transplant  
1025 program the physician previously served, at its discretion.
- 1026 c. A letter from the physician that details the training and experience the physician has  
1027 gained in pancreas transplantation.

1028

## 1029 **D. Conditional Approval for Primary Transplant Physician**

1030 If the primary pancreas transplant physician changes at an approved pancreas transplant  
1031 program, a physician can serve as the primary pancreas transplant physician for a maximum of  
1032 12 months if the following conditions are met:

1033

- 1034 1. The physician has been involved in the primary care of 8 or more newly transplanted  
1035 pancreas recipients, and has followed these patients for at least 3 months from the time of  
1036 their transplant. This care must be documented in a recipient log that includes the date of  
1037 transplant and the medical record number or other unique identifier that can be verified by the

- 1038 OPTN Contractor. This log should be signed by the program director, division chief, or  
1039 department chair from the transplant program where the experience was gained.
- 1040 2. The physician has maintained a current working knowledge of pancreas transplantation,  
1041 defined as direct involvement in pancreas transplant patient care within the last 2 years. This  
1042 includes the management of patients with end stage pancreas disease, the selection of  
1043 appropriate recipients for transplantation, donor selection, histocompatibility and tissue  
1044 typing, immediate post-operative patient care, the use of immunosuppressive therapy  
1045 including side effects of the drugs and complications of immunosuppression, differential  
1046 diagnosis of pancreas dysfunction in the allograft recipient, histological interpretation of  
1047 allograft biopsies, interpretation of ancillary tests for pancreas dysfunction, and long term  
1048 outpatient care.
- 1049 3. The physician has 12 months experience on an active pancreas transplant service as the  
1050 primary pancreas transplant physician or under the direct supervision of a qualified pancreas  
1051 transplant physician along with a pancreas transplant surgeon at a designated pancreas  
1052 transplant program, or its foreign equivalent. This 12-month period of experience on the  
1053 transplant service must have been acquired over a maximum of 2 years.
- 1054 4. The physician ~~should~~ must have observed at least 3 ~~organ pancreas~~ procurements ~~and 3~~  
1055 ~~pancreas transplants~~. The physician ~~should also~~ must have observed the organ allocation  
1056 and procurement processes for these donors, ~~evaluation, the donation process, and~~  
1057 ~~management of at least 3 multiple organ donors who are donating a pancreas~~. ~~If the~~  
1058 ~~physician has completed these observations, they~~ These observations must be documented  
1059 in a log that includes the date of procurement, location of the donor, and Donor ID.
- 1060 5. The physician must have observed at least 3 pancreas transplants. The observation of these  
1061 transplants must be documented in a log that includes the transplant date and medical record  
1062 number or other unique identifier that can be verified by the OPTN Contractor.
- 1063 ~~56.~~ The program has established and documented a consulting relationship with counterparts at  
1064 another pancreas transplant program.
- 1065 ~~67.~~ The transplant program submits activity reports to the OPTN Contractor every 2 months  
1066 describing the transplant activity, transplant outcomes, physician recruitment efforts, and  
1067 other operating conditions as required by the MPSC to demonstrate the ongoing quality and  
1068 efficient patient care at the program. The activity reports must also demonstrate that the  
1069 physician is making sufficient progress in meeting the required involvement in the primary  
1070 care of 15 or more pancreas transplant recipients, or that the program is making sufficient  
1071 progress in recruiting a physician who will be on site and approved by the MPSC to assume  
1072 the role of Primary Physician by the end of the 12 month conditional approval period.
- 1073 ~~78.~~ The following letters are submitted directly to the OPTN Contractor:
- 1074 a. A letter from the qualified pancreas transplant physician and surgeon who were directly  
1075 involved with the physician documenting the physician's experience and competence.
- 1076 b. A letter of recommendation from the primary physician and director at the transplant  
1077 program last served by the physician outlining the physician's overall qualifications to act  
1078 as a primary transplant physician, as well as the physician's personal integrity, honesty,  
1079 and familiarity with and experience in adhering to OPTN obligations, and any other  
1080 matters judged appropriate. The MPSC may request additional recommendation letters  
1081 from the primary physician, primary surgeon, director, or others affiliated with any  
1082 transplant program previously served by the physician, at its discretion.
- 1083 c. A letter from the physician that details the training and experience the physician has  
1084 gained in pancreas transplantation.
- 1085

1086 The 12-month conditional approval period begins on the initial approval date granted to the  
1087 personnel change application, whether it is interim approval granted by the MPSC subcommittee,  
1088 or approval granted by the full MPSC. The conditional approval period ends 12 months after the  
1089 first approval date of the personnel change application.

1090  
1091 If the transplant program is unable to demonstrate that it has an individual on site who can meet  
1092 the requirements as described in *Sections G.3.A through G.3.C* above at the end of the 12-month  
1093 conditional approval period, it must inactivate. The requirements for program inactivation are  
1094 described in *Appendix K: Transplant Program Inactivity, Withdrawal and Termination* of these  
1095 Bylaws.

1096  
1097 The MPSC may consider on a case-by-case basis and grant a 6-month extension to a transplant  
1098 program that provides substantial evidence of progress toward fulfilling the requirements but is  
1099 unable to complete the requirements within one year.  
1100

## 1101 **Appendix H:**

# 1102 **Membership and Personnel Requirements for Heart**

# 1103 **Transplant Programs**

## 1104 **H.2 Primary Heart Transplant Surgeon Requirements**

### 1105 **A. Cardiothoracic Surgery Residency Pathway**

1106 Surgeons can meet the training requirements for primary heart transplant surgeon by completing  
1107 a cardiothoracic surgery residency if *all* the following conditions are met:

- 1108  
1109 1. The surgeon performed at least 20 heart or heart/lung transplants as primary surgeon or first  
1110 assistant during the cardiothoracic surgery residency. These transplants must be  
1111 documented in a log that includes the date of transplant, role of the surgeon in the procedure,  
1112 and medical record number or other unique identifier that can be verified by the OPTN  
1113 Contractor. This log must be signed by the director of the training program.
- 1114 2. The surgeon performed at least 10 heart or heart/lung procurements as primary surgeon or  
1115 first assistant under the supervision of a qualified heart transplant surgeon ~~during the~~  
1116 cardiothoracic surgery residency. These procurements must have been performed during the  
1117 surgeon's cardiothoracic surgery residency and the two years immediately following  
1118 cardiothoracic surgery residency completion. These procedures must be documented in a log  
1119 that includes the date of procurement, location of the donor, and Donor ID. This log must be  
1120 signed by the director of the training program.
- 1121 3. The surgeon has maintained a current working knowledge of all aspects of heart  
1122 transplantation, defined as a direct involvement in heart transplant patient care within the last  
1123 2 years. This includes performing the transplant operation, donor selection, use of  
1124 mechanical assist devices, recipient selection, post-operative hemodynamic care,  
1125 postoperative immunosuppressive therapy, and outpatient follow-up.
- 1126 4. This training was completed at a hospital with a cardiothoracic surgery training program  
1127 approved by the American Board of Thoracic Surgery, or its foreign equivalent, as accepted  
1128 by the MPSC with a recommendation from the Thoracic Organ Transplantation Committee.
- 1129 5. The following letters are submitted directly to the OPTN Contractor:



- 1130 a. A letter from the director of the training program verifying that the surgeon has met the  
1131 above requirements and is qualified to direct a heart transplant program.  
1132 b. A letter of recommendation from the training program's primary surgeon and transplant  
1133 program director outlining the individual's overall qualifications to act as primary  
1134 transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity  
1135 with and experience in adhering to OPTN obligations, and any other matters judged  
1136 appropriate. The MPSC may request additional recommendation letters from the primary  
1137 physician, primary surgeon, director, or others affiliated with any transplant program  
1138 previously served by the surgeon, at its discretion.  
1139 c. A letter from the surgeon that details the training and experience the surgeon has gained  
1140 in heart transplantation.  
1141

## 1142 **B. Twelve-month Heart Transplant Fellowship Pathway**

1143 Surgeons can meet the training requirements for primary heart transplant surgeon by completing  
1144 a 12-month heart transplant fellowship if the following conditions are met:  
1145

- 1146 1. The surgeon performed at least 20 heart or heart/lung transplants as primary surgeon or first  
1147 assistant during the 12-month heart transplant fellowship. These transplants must be  
1148 documented in a log that includes the date of transplant, the role of the surgeon in the  
1149 procedure, and the medical record number or other unique identifier that can be verified by  
1150 the OPTN Contractor. This log must be signed by the director of the training program.
- 1151 2. The surgeon performed at least 10 heart or heart/lung procurements as primary surgeon or  
1152 first assistant under the supervision of a qualified heart transplant surgeon ~~during the 12-~~  
1153 ~~month heart transplant fellowship.~~ These procurements must have been performed during the  
1154 surgeon's fellowship and the two years immediately following fellowship completion. These  
1155 procedures must be documented in a log that includes the date of procurement, location of  
1156 the donor, and Donor ID. This log must be signed by the director of the training program.
- 1157 3. The surgeon has maintained a current working knowledge of all aspects of heart  
1158 transplantation, defined as a direct involvement in heart transplant patient care within the last  
1159 2 years. This includes performing the transplant operation, donor selection, the use of  
1160 mechanical circulatory assist devices, recipient selection, post-operative hemodynamic care,  
1161 postoperative immunosuppressive therapy, and outpatient follow-up.
- 1162 4. This training was completed at a hospital with a cardiothoracic surgery training program  
1163 approved by the American Board of Thoracic Surgery, or its foreign equivalent, as accepted  
1164 by the MPSC with a recommendation from the Thoracic Organ Transplantation Committee.
- 1165 5. The following letters are submitted directly to the OPTN Contractor:
  - 1166 a. A letter from the director of the training program verifying that the surgeon has met the  
1167 above requirements and is qualified to direct a heart transplant program.
  - 1168 b. A letter of recommendation from the training program's primary surgeon and transplant  
1169 program director outlining the individual's overall qualifications to act as primary  
1170 transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity  
1171 with and experience in adhering to OPTN obligations, and any other matters judged  
1172 appropriate. The MPSC may request additional recommendation letters from the primary  
1173 physician, primary surgeon, director, or others affiliated with any transplant program  
1174 previously served by the surgeon, at its discretion.
  - 1175 c. A letter from the surgeon that details the training and experience the surgeon has gained  
1176 in heart transplantation.  
1177

1178 **H.3 Primary Heart Transplant Physician Requirements**

1179 **A. Twelve-month Transplant Cardiology Fellowship Pathway**

1180 Physicians can meet the training requirements for primary heart transplant physician during a 12-  
1181 month transplant cardiology fellowship if the following conditions are met:

- 1182
- 1183 1. During the fellowship period, the physician was directly involved in the primary care of at least  
1184 20 newly transplanted heart or heart/lung recipients. This training will have been under the  
1185 direct supervision of a qualified heart transplant physician and in conjunction with a heart  
1186 transplant surgeon. This care must be documented in a log that includes the date of  
1187 transplant and the medical record number or other unique identifier that can be verified by the  
1188 OPTN Contractor. This recipient log must be signed by the director of the training program or  
1189 the primary transplant physician at the transplant program.
- 1190 2. The physician has maintained a current working knowledge of heart transplantation, defined  
1191 as direct involvement in heart transplant patient care within the last 2 years. This includes the  
1192 care of acute and chronic heart failure, donor selection, the use of mechanical circulatory  
1193 support devices, recipient selection, pre- and post-operative hemodynamic care, post-  
1194 operative immunosuppressive therapy, histological interpretation and grading of myocardial  
1195 biopsies for rejection, and long-term outpatient follow-up.
- 1196 3. The physician ~~should~~ must have observed at least 3 ~~organ heart~~ organ heart procurements ~~and 3 heart~~  
1197 ~~transplants~~. The physician ~~should also~~ must have observed the organ allocation and  
1198 procurement processes for these donors. ~~evaluation, the donation process, and management~~  
1199 ~~of 3 multiple organ donors who are donating a heart or heart/lungs. If the physician has~~  
1200 ~~completed these observations, they~~ These observations must be documented in a log that  
1201 includes the date of procurement, location of the donor, and Donor ID.
- 1202 4. The physician must have observed at least 3 heart transplants. The observation of these  
1203 transplants must be documented in a log that includes the transplant date and medical record  
1204 number or other unique identifier that can be verified by the OPTN Contractor.
- 1205 45. This training was completed at a hospital with an American Board of Internal Medicine  
1206 certified fellowship training program in adult cardiology or American Board of Pediatrics  
1207 certified fellowship training program in pediatric cardiology or its foreign equivalent, as  
1208 accepted by the MPSC.
- 1209 56. The following letters are submitted directly to the OPTN Contractor:
- 1210 a. A letter from the director of the training program and the supervising qualified heart  
1211 transplant physician verifying that the physician has met the above requirements and is  
1212 qualified to direct a heart transplant program.
- 1213 b. A letter of recommendation from the training program's primary physician and transplant  
1214 program director outlining the physician's overall qualifications to act as primary  
1215 transplant physician, as well as the physician's personal integrity, honesty, and familiarity  
1216 with and experience in adhering to OPTN obligations, and any other matters judged  
1217 appropriate. The MPSC may request additional recommendation letters from the Primary  
1218 Physician, primary surgeon, director, or others affiliated with any transplant program  
1219 previously served by the physician, at its discretion.
- 1220 c. A letter from the physician that details the training and experience the physician has  
1221 gained in heart transplantation.
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## **B. Clinical Experience Pathway**

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

1. The physician has been directly involved in the primary care of 20 or more newly transplanted heart or heart/lung recipients and continued to follow these recipients for a minimum of 3 months from transplant. This patient care must have been provided over a 2 to 5-year period on an active heart transplant service as the primary heart transplant physician or under the direct supervision of a qualified heart transplant physician and in conjunction with a heart transplant surgeon at a heart transplant program or its foreign equivalent. This care must be documented in a log that includes the date of transplant and medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log should be signed by the director or the primary transplant physician at the transplant program where the physician gained this experience.
2. The physician has maintained a current working knowledge of heart transplantation, defined as direct involvement in heart transplant patient care within the last 2 years. This includes the care of acute and chronic heart failure, donor selection, use of mechanical circulatory support devices, recipient selection, pre- and post-operative hemodynamic care, post-operative immunosuppressive therapy, histological interpretation and grading of myocardial biopsies for rejection, and long-term outpatient follow-up.
3. The physician ~~should~~ must have observed at least 3 ~~organ heart~~ procurements ~~and 3 heart transplants~~. The physician ~~should also~~ must have observed the organ allocation and procurement processes for these donors. 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 ~~These observations~~ must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
4. The physician must have observed at least 3 heart transplants. The observation of these transplants must be documented in a log that includes the transplant date and medical record number or other unique identifier that can be verified by the OPTN Contractor.
45. The following letters are submitted directly to the OPTN Contractor:
  - a. A letter from the heart transplant physician or the heart transplant surgeon who has been directly involved with the physician at the transplant program verifying the physician's competence.
  - b. A letter of recommendation from the primary physician and transplant program director at the transplant program last served by the physician outlining the physician's overall qualifications to act as primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
  - c. A letter from the physician that details the training and experience the physician has gained in heart transplantation.

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

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

- 1271 1. The physician has current board certification in cardiology by the American Board of Internal  
1272 Medicine, the American Board of Pediatrics, or the foreign equivalent.
- 1273 2. The physician has 12 months experience on an active heart transplant service as the primary  
1274 heart transplant physician or under the direct supervision of a qualified heart transplant  
1275 physician and in conjunction with a heart transplant surgeon at a designated heart transplant  
1276 program. These 12 months of experience must be acquired within a 2-year period.
- 1277 3. The physician has maintained a current working knowledge of heart transplantation, defined  
1278 as direct involvement in heart transplant patient care within the last 2 years. This includes  
1279 knowledge of acute and chronic heart failure, donor selection, the use of mechanical  
1280 circulatory support devices, recipient selection, pre- and post-operative hemodynamic care,  
1281 post-operative immunosuppressive therapy, histological interpretation in grading of  
1282 myocardial biopsies for rejection, and long-term outpatient follow-up.
- 1283 4. The physician has been involved in the primary care of 10 or more newly transplanted heart  
1284 or heart/lung transplant recipients as the heart transplant physician or under the direct  
1285 supervision of a qualified heart transplant physician or in conjunction with a heart transplant  
1286 surgeon. The physician will have followed these patients for a minimum of 3 months from the  
1287 time of transplant. This care must be documented in a log that includes the date of transplant  
1288 and medical record or other unique identifier that can be verified by the OPTN Contractor.  
1289 This recipient log should be signed by the program director or the primary transplant  
1290 physician at the transplant program where the physician gained experience.
- 1291 5. The physician ~~should~~ must have observed at least 3 ~~organ heart~~ procurements ~~and 3 heart~~  
1292 ~~transplants~~. The physician ~~should also~~ must have observed the organ allocation and  
1293 procurement processes for these donors. evaluation, the donation process, and management  
1294 ~~of at least 3 multiple organ donors who donated a heart or heart/lungs. If the physician has~~  
1295 ~~completed these observations, they~~ These observations must be documented in a log that  
1296 includes the date of procurement, location of the donor, and Donor ID.
- 1297 6. The physician must have observed at least 3 heart transplants. The observation of these  
1298 transplants must be documented in a log that includes the transplant date and medical record  
1299 number or other unique identifier that can be verified by the OPTN Contractor.
- 1300 ~~67.~~ The program has established and documented a consulting relationship with counterparts at  
1301 another heart transplant program.
- 1302 ~~78.~~ The transplant program submits activity reports to the OPTN Contractor every 2 months  
1303 describing the transplant activity, transplant outcomes, physician recruitment efforts, and  
1304 other operating conditions as required by the MPSC to demonstrate the ongoing quality and  
1305 efficient patient care at the program. The activity reports must also demonstrate that the  
1306 physician is making sufficient progress to meet the required involvement in the primary care  
1307 of 20 or more heart transplant recipients, or that the program is making sufficient progress in  
1308 recruiting a physician who meets all requirements for primary heart transplant physician by  
1309 the end of the 12 month conditional approval period.
- 1310 ~~89.~~ The following letters are submitted directly to the OPTN Contractor:
- 1311 a. A letter from the heart transplant physician or the heart transplant surgeon who has been  
1312 directly involved with the physician at the transplant program verifying the physician's  
1313 competence.
- 1314 b. A letter of recommendation from the primary physician and director at the transplant  
1315 program last served by the physician outlining the physician's overall qualifications to act  
1316 as primary transplant physician, as well as the physician's personal integrity, honesty,  
1317 and familiarity with and experience in adhering to OPTN obligations, and any other  
1318 matters judged appropriate. The MPSC may request additional recommendation letters

1319 from the primary physician, primary surgeon, director, or others affiliated with any  
1320 transplant program previously served by the physician, at its discretion.  
1321 c. A letter from the physician that details the training and experience the physician has  
1322 gained in heart transplantation.

1323  
1324 The 12-month conditional approval period begins on the first approval date granted to the  
1325 personnel change application, whether it is an interim approval granted by the MPSC  
1326 subcommittee, or an approval granted by the full MPSC. The conditional approval period ends  
1327 exactly 12 months after this first approval date of the personnel change application.

1328  
1329 If the program is unable to demonstrate that it has an individual on site who can meet the  
1330 requirements as described in *Sections H.3.A through H.3.C* above at the end of the 12-month  
1331 conditional approval period, it must inactivate. The requirements for program inactivation are  
1332 described in **Error! Reference source not found. Error! Reference source not found.** of these  
1333 Bylaws.

1334  
1335 The MPSC may consider on a case-by-case basis and grant a 6-month extension to a transplant  
1336 program that provides substantial evidence of progress toward fulfilling the requirements but is  
1337 unable to complete the requirements within one year.

1338

## 1339 ***Appendix I:*** 1340 ***Membership and Personnel Requirements for Lung*** 1341 ***Transplant Programs***

### 1342 **I.2 Primary Lung Transplant Surgeon Requirements**

#### 1343 **A. Cardiothoracic Surgery Residency Pathway**

1344 Surgeons can meet the training requirements for primary lung transplant surgeon by completing a  
1345 cardiothoracic surgery residency if the following conditions are met:

1346

- 1347 1. During the cardiothoracic surgery residency, the surgeon has performed at least 15 lung or  
1348 heart/lung transplants as primary surgeon or first assistant under the direct supervision of a  
1349 qualified lung transplant surgeon and in conjunction with a lung transplant physician at a lung  
1350 transplant program. At least half of these transplants must be lung procedures. These  
1351 transplants must be documented in a log that includes the date of transplant, role of the  
1352 surgeon in the procedure, and medical record number or other unique identifier that can be  
1353 verified by the OPTN Contractor. This log must be signed by the director of the training  
1354 program.
- 1355 2. The surgeon performed at least 10 lung procurements as primary surgeon or first assistant  
1356 under the supervision of a qualified lung transplant surgeon. These procurements must have  
1357 been performed during the surgeon's cardiothoracic surgery residency and the two years  
1358 immediately following cardiothoracic surgery residency completion. These procedures must  
1359 be documented in a log that includes the date of procurement, location of the donor, and  
1360 Donor ID.
- 1361 3. The surgeon has maintained a current working knowledge of all aspects of lung  
1362 transplantation, defined as a direct involvement in lung transplant patient care within the last  
1363 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass,

- 1364 donor selection, recipient selection, pre- and postoperative ventilator care, postoperative  
1365 immunosuppressive therapy, histological interpretation and grading of lung biopsies for  
1366 rejection, and long-term outpatient follow-up. This training must also include the other clinical  
1367 requirements for thoracic surgery
- 1368 4. This training was completed at a hospital with a cardiothoracic training program approved by  
1369 the American Board of Thoracic Surgery, or its foreign equivalent. Foreign programs must  
1370 have a recommendation from the Thoracic Organ Transplantation Committee and be  
1371 accepted as equivalent by the MPSC.
- 1372 5. The following letters are submitted directly to the OPTN Contractor:
- 1373 a. A letter from the director of the training program verifying that the surgeon has met the  
1374 above requirements and is qualified to direct a lung transplant program.
- 1375 b. A letter of recommendation from the program's primary surgeon and transplant program  
1376 director outlining the individual's overall qualifications to act as primary transplant  
1377 surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and  
1378 experience in adhering to OPTN obligations and compliance protocols, and any other  
1379 matters judged appropriate. The MPSC may request additional recommendation letters  
1380 from the primary physician, primary surgeon, director, or others affiliated with any  
1381 transplant program previously served by the surgeon, at its discretion.
- 1382 c. A letter from the surgeon that details the training and experience the surgeon has gained  
1383 in lung transplantation.
- 1384

## 1385 **B. Twelve-month Lung Transplant Fellowship Pathway**

1386 Surgeons can meet the training requirements for primary lung transplant surgeon by completing a  
1387 12-month lung transplant fellowship if the following conditions are met:

1388

- 1389 1. The surgeon has performed at least 15 lung or heart/lung transplants under the direct  
1390 supervision of a qualified lung transplant surgeon and in conjunction with a qualified lung  
1391 transplant physician as primary surgeon or first assistant during the 12-month lung transplant  
1392 fellowship. At least half of these transplants must be lung procedures. These transplants  
1393 must be documented in a log that includes the date of transplant, the role of the surgeon in  
1394 the procedure, and the medical record number or other unique identifier that can be verified  
1395 by the OPTN Contractor. This log must be signed by the director of the program.
- 1396 2. The surgeon has performed at least 10 lung procurements as primary surgeon or first  
1397 assistant under the supervision of a qualified lung transplant surgeon ~~during the 12-month~~  
1398 ~~lung transplant fellowship.~~ These procurements must have been performed during the  
1399 surgeon's fellowship and the two years immediately following fellowship completion. These  
1400 procedures must be documented in a log that includes the date of procurement, location of  
1401 the donor, and Donor ID.
- 1402 3. The surgeon has maintained a current working knowledge of all aspects of lung  
1403 transplantation, defined as a direct involvement in lung transplant patient care within the last  
1404 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass,  
1405 donor selection, recipient selection, pre- and postoperative ventilator care, postoperative  
1406 immunosuppressive therapy, histological interpretation and grading of lung biopsies for  
1407 rejection, and long-term outpatient follow-up.
- 1408 4. This training was completed at a hospital with a cardiothoracic training program approved by  
1409 the American Board of Thoracic Surgery, or its foreign equivalent. Foreign programs must  
1410 have a recommendation from the Thoracic Organ Transplantation Committee and be  
1411 accepted as equivalent by the MPSC.

- 1412 5. The following letters are submitted directly to the OPTN Contractor:  
1413 a. A letter from the director of the training program verifying that the surgeon has met the  
1414 above requirements and is qualified to direct a lung transplant program.  
1415 b. A letter of recommendation from the training program's primary surgeon and transplant  
1416 program director outlining the individual's overall qualifications to act as primary  
1417 transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity  
1418 with and experience in adhering to OPTN obligations, and any other matters judged  
1419 appropriate. The MPSC may request additional recommendation letters from the primary  
1420 physician, primary surgeon, director, or others affiliated with any transplant program  
1421 previously served by the surgeon, at its discretion.  
1422 c. A letter from the surgeon that details the training and experience the surgeon has gained  
1423 in lung transplantation.  
1424

### 1425 I.3 Primary Lung Transplant Physician Requirements

#### 1426 A. Twelve-month Transplant Pulmonary Fellowship Pathway

1427 Physicians can meet the training requirements for primary lung transplant physician during a 12-  
1428 month transplant pulmonary fellowship if the following conditions are met:  
1429

- 1430 1. The physician was directly involved in the primary and follow-up care of at least 15 newly  
1431 transplanted lung or heart/lung recipients. This training will have been under the direct  
1432 supervision of a qualified lung transplant physician and in conjunction with a lung transplant  
1433 surgeon. At least half of these patients must be single or double-lung transplant recipients.  
1434 This care must be documented in a log that includes the date of transplant and the medical  
1435 record number or other unique identifier that can be verified by the OPTN Contractor. This  
1436 recipient log must be signed by the director of the training program or the primary transplant  
1437 physician at the transplant program.
- 1438 2. The physician has maintained a current working knowledge of all aspects of lung  
1439 transplantation, defined as a direct involvement in lung transplant patient care within the last  
1440 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass,  
1441 donor selection, recipient selection, pre- and postoperative ventilator care, postoperative  
1442 immunosuppressive therapy, histological interpretation and grading of lung biopsies for  
1443 rejection, and long-term outpatient follow-up.
- 1444 3. The physician ~~should~~ must have observed at least 3 lung or heart/lung procurements ~~and 3~~  
1445 ~~lung transplants.~~ The physician ~~should also~~ must have observed the organ allocation and  
1446 procurement processes for these donors. ~~evaluation, the donation process, and management~~  
1447 ~~of 3 multiple organ donors who are donating a lung or heart/lungs. If the physician has~~  
1448 ~~completed these observations, they~~ These observations must be documented in a log that  
1449 includes the date of procurement, location of the donor, and Donor ID.
- 1450 4. The physician must have observed at least 3 lung transplants. The observation of these  
1451 transplants must be documented in a log that includes the transplant date and medical record  
1452 number or other unique identifier that can be verified by the OPTN Contractor.
- 1453 45. This training was completed at a hospital with an American Board of Internal Medicine  
1454 certified fellowship training program in adult pulmonary medicine, an American Board of  
1455 Pediatrics-certified fellowship training program in pediatric medicine, or its foreign equivalent.  
1456 Foreign programs must have a recommendation from the Thoracic Organ Transplantation  
1457 Committee and be accepted as equivalent by the MPSC.  
1458

- 1459 56. The following letters are submitted directly to the OPTN Contractor:  
1460 a. A letter from the director of the training program verifying that the physician has met the  
1461 above requirements and is qualified to direct a lung transplant program.  
1462 b. A letter of recommendation from the training program's primary physician and transplant  
1463 program director outlining the physician's overall qualifications to act as primary  
1464 transplant physician, as well as the physician's personal integrity, honesty, and familiarity  
1465 with and experience in adhering to OPTN obligations, and any other matters judged  
1466 appropriate. The MPSC may request additional recommendation letters from the primary  
1467 physician, primary surgeon, director, or others affiliated with any transplant program  
1468 previously served by the physician, at its discretion.  
1469 c. A letter from the physician that details the training and experience the physician has  
1470 gained in lung transplantation.  
1471

## 1472 B. Clinical Experience Pathway

1473 A physician can meet the requirements for primary lung transplant physician through acquired  
1474 clinical experience if the following conditions are met.  
1475

- 1476 1. The physician has been directly involved in the primary care of 15 or more newly transplanted  
1477 lung or heart/lung recipients and continued to follow these recipients for a minimum of 3  
1478 months from the time of transplant. At least half of these transplant must be lung transplants.  
1479 This patient care must have been provided over a 2 to 5-year period on an active lung  
1480 transplant program or its foreign equivalent. This care must have been provided as the lung  
1481 transplant physician or directly supervised by a qualified lung transplant physician along with  
1482 a lung transplant surgeon. This care must be documented in a log that includes the date of  
1483 transplant and medical record number or other unique identifier that can be verified by the  
1484 OPTN Contractor. This recipient log should be signed by the director or the primary  
1485 transplant physician at the transplant program where the physician gained this experience.
  - 1486 2. The physician has maintained a current working knowledge of all aspects of lung  
1487 transplantation, defined as a direct involvement in lung transplant patient care within the last  
1488 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass,  
1489 donor selection, recipient selection, pre- and postoperative ventilator care, postoperative  
1490 immunosuppressive therapy, histological interpretation and grading of lung biopsies for  
1491 rejection, and long-term outpatient follow-up.
  - 1492 3. The physician ~~should~~ must observe at least 3 lung or heart/lung procurements and 3 lung  
1493 ~~transplants~~. The physician ~~should also~~ must have observed the organ allocation and  
1494 procurement processes for these donors. ~~evaluation, the donation process, and management~~  
1495 ~~of 3 multiple organ donors who are donating a lung or heart/lungs. If the physician has~~  
1496 ~~completed these observations, they~~ These observations must be documented in a log that  
1497 includes the date of procurement, location of the donor, and Donor ID.
  - 1498 4. The physician must have observed at least 3 lung transplants. The observation of these  
1499 transplants must be documented in a log that includes the transplant date and medical record  
1500 number or other unique identifier that can be verified by the OPTN Contractor.
- 1501 45. The following letters are submitted directly to the OPTN Contractor:  
1502 a. A letter from the lung transplant physician or surgeon of the training program who has  
1503 been directly involved with the physician documenting the physician's competence.  
1504 b. A letter of recommendation from the primary physician and transplant program director at  
1505 the transplant program last served by the physician outlining the physician's overall  
1506 qualifications to act as primary transplant physician, as well as the physician's personal



1507 integrity, honesty, and familiarity with and experience in adhering to OPTN obligations,  
1508 and any other matters judged appropriate. The MPSC may request additional  
1509 recommendation letters from the primary physician, primary surgeon, director, or others  
1510 affiliated with any transplant program previously served by the physician, at its discretion.  
1511 c. A letter from the physician that details the training and experience the physician has  
1512 gained in lung transplantation.  
1513

#### 1514 **D. Conditional Approval for Primary Transplant Physician**

1515 If the primary lung transplant physician changes at an approved lung transplant program, a  
1516 physician can serve as the primary lung transplant physician for a maximum of 12 months if the  
1517 following conditions are met:  
1518

- 1519 1. The physician is a pulmonologist with current board certification in pulmonary medicine by the  
1520 American Board of Internal Medicine, the American Board of Pediatrics, or the foreign  
1521 equivalent.
- 1522 2. The physician has 12 months of experience on an active lung transplant service as the  
1523 primary lung transplant physician or under the direct supervision of a qualified lung transplant  
1524 physician and in conjunction with a lung transplant surgeon at a designated lung transplant  
1525 program. These 12 months of experience must be acquired within a 2-year period.
- 1526 3. The physician has been involved in the primary care of 8 or more newly transplanted lung or  
1527 heart/lung transplant recipients as the lung transplant physician or under the direct  
1528 supervision of a qualified lung transplant physician and in conjunction with a lung transplant  
1529 surgeon. At least half of these patients must be lung transplant recipients. This care must be  
1530 documented in a recipient log that includes the date of transplant and medical record or other  
1531 unique identifier that can be verified by the OPTN Contractor. This log should be signed by  
1532 the program director or the primary transplant physician at the transplant program where the  
1533 physician gained experience.
- 1534 4. The physician has maintained a current working knowledge of all aspects of lung  
1535 transplantation, defined as a direct involvement in lung transplant patient care within the last  
1536 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass,  
1537 donor selection, recipient selection, pre- and postoperative ventilator care, postoperative  
1538 immunosuppressive therapy, histological interpretation and grading of lung biopsies for  
1539 rejection, and long-term outpatient follow-up.
- 1540 5. The physician ~~should~~ must have observed at least 3 lung or heart/lung procurements ~~and 3~~  
1541 ~~lung transplants.~~ The physician ~~should also~~ must have observed the organ allocation and  
1542 procurement processes for these donors. ~~evaluation, the donation process, and management~~  
1543 ~~of 3 multiple organ donors who are donating a lung or heart/lungs. If the physician has~~  
1544 ~~completed these observations, they~~ These observations must be documented in a log that  
1545 includes the date of procurement, location of the donor, and Donor ID.
- 1546 6. The physician must have observed at least 3 lung transplants. The observation of these  
1547 transplants must be documented in a log that includes the transplant date and medical record  
1548 number or other unique identifier that can be verified by the OPTN Contractor.
- 1549 ~~6~~7. The program has established and documented a consulting relationship with counterparts at  
1550 another lung transplant program.
- 1551 ~~7~~8. The transplant program submits activity reports to the OPTN Contractor every 2 months  
1552 describing the transplant activity, transplant outcomes, physician recruitment efforts, and  
1553 other operating conditions as required by the MPSC to demonstrate the ongoing quality and  
1554 efficient patient care at the program. The activity reports must also demonstrate that the

1555 physician is making sufficient progress to meet the required involvement in the primary care  
1556 of 20 or more lung transplant recipients, or that the program is making sufficient progress in  
1557 recruiting a physician who meets all requirements for primary lung transplant physician by the  
1558 end of the 12 month conditional approval period.

- 1559 89. The following letters are submitted directly to the OPTN Contractor:
- 1560 a. A letter from the supervising lung transplant physician or surgeon of the training program  
1561 documenting the physician's competence.
  - 1562 b. A letter of recommendation from the training program's primary physician and director  
1563 outlining the physician's overall qualifications to act as primary transplant physician of the  
1564 transplant program last served by the physician, as well as the physician's personal  
1565 integrity, honesty, and familiarity with and experience in adhering to OPTN obligations,  
1566 and any other matters judged appropriate. The MPSC may request additional  
1567 recommendation letters from the primary physician, primary surgeon, director, or others  
1568 affiliated with any transplant program previously served by the physician, at its discretion.
  - 1569 c. A letter from the physician that details the training and experience the physician has  
1570 gained in lung transplantation.

1571

1572 The 12-month conditional approval period begins on the first approval date granted to the  
1573 personnel change application, whether it is an interim approval granted by the MPSC  
1574 subcommittee, or approval granted by the full MPSC. The conditional approval period ends  
1575 exactly 12 months after this first approval date of the personnel change application.

1576

1577 If the program is unable to demonstrate that it has an individual practicing on site who can meet  
1578 the requirements as described in *Sections 1.3.A through 1.3.C* above at the end of the 12-month  
1579 conditional approval period, it must inactivate. The requirements for transplant program  
1580 inactivation are described in *Appendix K: Transplant Program Inactivity, Withdrawal, and*  
1581 *Termination* of these Bylaws.

1582

1583 The MPSC may consider on a case-by-case basis and grant a 6-month extension to a transplant  
1584 program that provides substantial evidence of progress toward fulfilling the requirements but is  
1585 unable to complete the requirements within one year.

1586 #

# ROCKVILLE POLICY DEVELOPMENT DISCUSSION

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APRIL 9, 2010

# ROCKVILLE POLICY DEVELOPMENT DISCUSSION

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## ATTENDANCE

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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)

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## SUMMARY

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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.

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## PROCESS

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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.

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## PILOTING THE PROCESS

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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.