OPTN/UNOS Membership and Professional Standards Committee

Changes to Transplant Program Key Personnel Procurement Requirements

Committee Liaison:
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UNOS Member Quality Department

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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.[1] The group did not think it

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

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

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

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

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

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

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

B. Clinical Experience Pathway

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

1. The surgeon has performed 45 or more kidney transplants over a 2 to 5-year period as primary surgeon or first assistant at a designated kidney transplant program, or its foreign equivalent. The 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. The log should be signed by the program director, division chief, or department chair from the program where the experience was gained. Each year of the surgeon's experience must be substantive and relevant and include pre-operative assessment of kidney transplant candidates, performance of transplants as primary surgeon or first assistant, and post-operative care of kidney recipients.
2. The surgeon has performed at least 15 kidney procurements as primary surgeon or first assistant. At least ~~3 of these procurements must be multiple organ procurements and at least~~ 10 of these procurements must be from deceased donors. These cases 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. The following letters are submitted directly to the OPTN Contractor:
    a. A letter from the director of the transplant program and Chairman of the department or hospital credentialing committee verifying that the surgeon has met the above qualifications and is qualified to direct a kidney transplant program.
    b. A letter of recommendation from the primary surgeon and transplant program director at the transplant program last served by the surgeon outlining the surgeon's overall qualifications to act as a primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
    c. A letter from the surgeon that details the training and experience the surgeon has gained in kidney transplantation.

E.3 Primary Kidney Transplant Physician Requirements

A. Twelve-month Transplant Nephrology Fellowship Pathway

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

1. The physician has current board certification in nephrology by the American Board of Internal Medicine or the foreign equivalent.
2. The physician completed 12 consecutive months of specialized training in transplantation under the direct supervision of a qualified kidney transplant physician and along with a kidney transplant surgeon at a kidney transplant program that performs 30 or more transplants each year. The training must have included at least 6 months of clinical transplant service. The remaining time must have consisted of transplant-related experience, such as experience in a tissue typing laboratory, on another solid organ transplant service, or conducting basic or clinical transplant research.
3. During the fellowship period, the physician was directly involved in the primary care of 30 or more newly transplanted kidney recipients and continued to follow these recipients for a minimum of 3 months from the time of transplant. The care must be documented in a log that includes the date of transplant and the recipient medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log must be signed by the director of the training program or the transplant program's primary transplant physician.
4. The physician has maintained a current working knowledge of kidney transplantation, defined as direct involvement in kidney transplant care in the last 2 years. This includes the management of patients with end stage renal disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate postoperative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long term outpatient care. The curriculum for obtaining this knowledge should be approved by the Residency Review Committee for Internal Medicine (RRC-IM) of the Accreditation Council for Graduate Medical Education (ACGME).
5. 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.
6. 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.
~~6~~7. The following letters are submitted directly to the OPTN Contractor:
    a. A letter from the director of the training program and the supervising qualified kidney transplant physician verifying that the physician has met the above requirements and is qualified to direct a kidney transplant program.
    b. A letter of recommendation from the fellowship training program's primary physician and transplant program director outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and

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

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

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

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

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

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

C. Three-year Pediatric Nephrology Fellowship Pathway

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

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

6. The physician must have observed at least 3 kidney transplants involving a pediatric recipient. The observation of these transplants must be documented in a log that includes the transplant date, donor type, and medical record number or other unique identifier that can be verified by the OPTN Contractor.
~~6~~7. The following letters are submitted directly to the OPTN Contractor:
   a. A letter from the director and the supervising qualified transplant physician and surgeon of the fellowship training program verifying that the physician has met the above requirements and is qualified to direct a kidney transplant program.
   b. A letter of recommendation from the fellowship training program's primary physician and transplant program director outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
   c. A letter from the physician that details the training and experience the physician has gained in kidney transplantation.

D. Twelve-month Pediatric Transplant Nephrology Fellowship Pathway

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

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

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

5. The physician ~~should~~ must have observed at least 3 ~~organ~~ kidney procurements, including at least 1 deceased donor and 1 living donor. ~~and 3 pediatric 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.
6. The physician must have observed at least 3 kidney transplants involving a pediatric recipient. The observation of these transplants must be documented in a log that includes the transplant date, donor type, and medical record number or other unique identifier that can be verified by the OPTN Contractor.
~~6~~7. The following letters are submitted directly to the OPTN Contractor:
    a. A letter from the director and the supervising qualified transplant physician and surgeon of the fellowship training program verifying that the physician has met the above requirements and is qualified to become the primary transplant physician of a designated kidney transplant program.
    b. A letter of recommendation from the fellowship training program's primary physician and transplant program director outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
    c. A letter from the physician that details the training and experience the physician has gained in kidney transplantation.

E. Combined Pediatric Nephrology Training and Experience Pathway

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

1. The physician has current board certification in pediatric nephrology by the American Board of Pediatrics or the foreign equivalent, or is approved by the American Board of Pediatrics to take the certifying exam.
2. The physician gained a minimum of 2 years of experience during or after fellowship, or accumulated during both periods, at a kidney transplant program.
3. During the 2 or more years of accumulated experience, the physician was directly involved in the primary care of 10 or more newly transplanted kidney recipients and followed 30 newly transplanted kidney recipients for at least 6 months from the time of transplant, under the direct supervision of a qualified kidney transplant physician, along with a qualified kidney transplant surgeon. This care must be documented in a recipient log that includes the date of transplant, and the recipient medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the training program director or the primary physician of the transplant program.

4. The physician has maintained a current working knowledge of kidney transplantation, defined as direct involvement in kidney transplant patient care during the past 2 years. This includes the management of pediatric patients with end-stage renal disease, the selection of appropriate pediatric recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative care including those issues of management unique to the pediatric recipient, fluid and electrolyte management, the use of immunosuppressive therapy in the pediatric recipient including side-effects of drugs and complications of immunosuppression, the effects of transplantation and immunosuppressive agents on growth and development, differential diagnosis of renal dysfunction in the allograft recipient, manifestation of rejection in the pediatric patient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long-term outpatient care of pediatric allograft recipients including management of hypertension, nutritional support, and drug dosage, including antibiotics, in the pediatric patient. The curriculum for obtaining this knowledge must be approved by the Residency Review Committee (RRC) -Ped of the ACGME or a Residency Review Committee.
5. The physician ~~should~~ must have observed at least 3 ~~organ~~ kidney procurements, including at least 1 deceased donor and 1 living donor. ~~and 3 pediatric 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.
6. The physician must have observed at least 3 kidney transplants involving a pediatric recipient. The observation of these transplants must be documented in a log that includes the transplant date, donor type, and medical record number or other unique identifier that can be verified by the OPTN Contractor.
~~6~~7. The following letters are submitted directly to the OPTN Contractor:
    a. A letter from the supervising qualified transplant physician and surgeon who were directly involved with the physician documenting the physician's experience and competence.
    b. A letter of recommendation from the fellowship training program's primary physician and transplant program director outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, Director, or others affiliated with any transplant program previously served by the physician, at its discretion.
    c. A letter from the physician that details the training and experience the physician has gained in kidney transplantation.

G. Conditional Approval for Primary Transplant Physician

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

1. The physician has current board certification in nephrology 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 23 or more newly transplanted kidney 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 kidney transplantation, defined as direct involvement in kidney transplant patient care during 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.
4. The physician has 12 months experience on an active kidney transplant service as the primary kidney transplant physician or under the direct supervision of a qualified kidney transplant physician and in conjunction with a kidney transplant surgeon at a designated kidney 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~~ 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.
6. 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.

~~6~~7. The program has established and documented a consulting relationship with counterparts at another kidney transplant program.

~~7~~8. 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 45 or more kidney transplant recipients, or that the program is making sufficient progress in recruiting a physician who meets all requirements for primary kidney 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.

~~8~~9. The following letters are submitted directly to the OPTN Contractor:

a. A letter from the supervising qualified transplant physician and surgeon who were directly involved with the physician documenting the physician's experience and competence.
b. A letter of recommendation from the primary physician and director at the transplant program last served by the physician outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, 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 12-month conditional approval period begins on the initial approval date granted to the personnel change application, whether it is interim approval granted by the MPSC subcommittee, or approval granted by the full MPSC. The conditional approval period ends 12 months after the first approval date of the personnel change application.

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

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

Appendix F: Membership and Personnel Requirements for Liver Transplant Programs

F.3 Primary Liver Transplant Surgeon Requirements

A. Formal 2-year Transplant Fellowship Pathway

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

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

interpretation of allograft biopsies, interpretation of ancillary tests for liver dysfunction, and long term outpatient care.

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

B. Clinical Experience Pathway

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

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

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

F.4 Primary Liver Transplant Physician Requirements

A. 12-month Transplant Hepatology Fellowship Pathway

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

1. The physician completed 12 consecutive months of specialized training in transplantation under the direct supervision of a qualified liver transplant physician and in conjunction with a liver transplant surgeon at a liver transplant program. The training must have included at least 3 months of clinical transplant service. The remaining time must have consisted of transplant-related experience, such as experience in a tissue typing laboratory, on another solid organ transplant service, or conducting basic or clinical transplant research.
2. During the fellowship period, the physician was directly involved in the primary care of 30 or more newly transplanted liver recipients, and continued to follow these recipients for a minimum of 3 months from the time of transplant. The care must be documented in a log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the director of the training program or the transplant program's primary transplant physician.
3. The physician has maintained a current working knowledge of liver transplantation, defined as direct involvement in liver transplant patient care within the last 2 years. This includes the management of patients with end stage liver disease, 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 ~~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 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.
5. 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.

~~5~~6. The following letters are submitted directly to the OPTN Contractor:
   a. A letter from the director of the training program and the supervising liver transplant physician verifying that the physician has met the above requirements and is qualified to direct a liver transplant program.
   b. A letter of recommendation from the fellowship training program's primary physician and transplant program director outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
   c. A letter from the physician writes that details the training and experience the physician gained in liver transplantation.

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

B. Clinical Experience Pathway

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

1. The physician has been directly involved in the primary care of 50 or more newly transplanted liver 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 liver transplant service as the primary liver transplant physician or under the direct supervision of a qualified liver transplant physician and in conjunction with a liver transplant surgeon at a liver transplant program or the foreign equivalent. This care must be documented in a log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log 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 liver transplantation, defined as direct involvement in liver transplant patient care within the last 2 years. This includes the management of patients with end stage liver disease, 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.
3. 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 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, the location of the donor, and Donor ID.
4. 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.

4. The following letters are submitted directly to the OPTN Contractor:
   a. A letter from the qualified transplant physician or the liver 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 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.

C. Three-year Pediatric Gastroenterology Fellowship Pathway

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

1. The physician has current board certification in gastroenterology by the American Board of Pediatrics, or the foreign equivalent.
2. During the 3-year training period 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 3 months from the time of transplant, under the direct supervision of a qualified liver transplant physician along with a qualified liver transplant surgeon. The physician was also directly involved in the preoperative, peri-operative and post-operative care of 10 or more liver transplants in pediatric patients. The pediatric gastroenterology program director may elect to have a portion of the transplant experience carried out at another transplant service, to meet these requirements. This care must be documented in a log that includes the date of transplant, 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's primary transplant physician.
3. The experience caring for pediatric patients occurred at a liver transplant program with a qualified liver transplant physician and a qualified liver transplant surgeon that performs an average of at least 10 liver transplants on pediatric patients per year.
4. 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.
5. 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.

~~5~~6. The physician 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 acute liver failure, the selection of appropriate pediatric recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate postoperative 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.

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

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

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

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

D. Pediatric Transplant Hepatology Fellowship Pathway

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

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

3. The experience in caring for pediatric liver patients occurred at a liver transplant program with a qualified liver transplant physician and surgeon that performs an average of at least 10 pediatric liver transplants a year.
4. The physician 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, acute liver failure, the selection of appropriate pediatric recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate postoperative 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.
~~6~~7. The following letters are submitted directly to the OPTN Contractor:
    a. A letter from the director of the pediatric transplant hepatology training program, and the qualified liver transplant physician and surgeon of the fellowship training program verifying that the physician has met the above requirements, and is qualified to act as a liver transplant physician and direct a liver transplant program.
    b. A letter of recommendation from the fellowship training program's primary physician and transplant program director outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
    c. A letter from the physician that details the training and experience the physician gained in liver transplantation.

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

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

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

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.
~~6~~7. 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.

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.
7. 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.
8. The program has established and documented a consulting relationship with counterparts at another liver transplant program.
9. The following letters are submitted directly to the OPTN Contractor:

a. A letter from the qualified liver transplant physician and surgeon who were directly involved with the physician verifying that the physician has satisfactorily met the above requirements to become the primary transplant physician of a liver transplant program.
b. A letter of recommendation from the primary physician and transplant program director at the transplant program last served by the physician outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, 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 sends that details the training and experience the physician gained in liver transplantation.

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

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

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

Appendix G: Membership and Personnel Requirements for Pancreas and Pancreatic Islet Transplant Programs

G.2 Primary Pancreas Transplant Surgeon Requirements

A. Formal 2-year Transplant Fellowship Pathway

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

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

These cases must be documented in a log that includes the date of procurement, location of the donor, and Donor ID. This log must be signed by the director of the training program.

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

G.3 Primary Pancreas Transplant Physician Requirements

A. Twelve-month Transplant Medicine Fellowship Pathway

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

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

by the OPTN Contractor. This recipient log must be signed by the director of the training program or the transplant program's primary transplant physician.

3. The physician has maintained a current working knowledge of pancreas transplantation, defined as direct involvement in pancreas transplant patient care within the last 2 years. This includes the management of patients with end stage pancreas disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of pancreas dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for pancreas dysfunction, and long term outpatient care.
4. The physician ~~should~~ must have observed at least 3 ~~organ~~ pancreas procurements ~~and 3 pancreas transplants~~. 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 pancreas. If the physician completed these observations, they~~ These observations must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
5. The physician must have observed at least 3 pancreas transplants. The observation of these transplants must be documented in a log that includes the transplant date and medical record number or other unique identifier that can be verified by the OPTN Contractor.

~~5~~6. The curriculum of this transplant medicine fellowship should be approved by the Residency Review Committee for Internal Medicine (RRC-IM) of the Accreditation Council for Graduate Medical Education (ACGME).

~~6~~7. The following letters are submitted directly to the OPTN Contractor:
   a. A letter from director of the training program and supervising qualified pancreas transplant physician send a letter directly to the OPTN Contractor verifying that the fellow has met the above requirements and is qualified to direct a pancreas transplant program.
   b. A letter of recommendation from the fellowship training program's primary physician and transplant program director outlining the physician's overall qualifications to act as primary transplant physician as well as the physician's personal integrity, honesty, familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request similar letters of recommendation from the primary physician, primary surgeon, director, or others affiliated with any transplant program that the physician previously served, at its discretion.
   c. A letter from the physician that details the training and experience the physician has gained in pancreas transplantation.

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

B. Clinical Experience Pathway

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

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

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

2. The physician has maintained a current working knowledge of pancreas transplantation, defined as direct involvement in pancreas transplant patient care within the last 2 years. This includes the management of patients with end stage pancreas disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of pancreas dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for pancreas dysfunction, and long term outpatient care.
3. The physician ~~should~~ must have observed at least 3 ~~organ~~ pancreas procurements ~~and 3 pancreas transplants~~. The physician ~~should~~ must have ~~also~~ observed the organ allocation and procurement processes for these donors. ~~evaluation, the donation process, and management of at least 3 multiple organ donors who donated a pancreas. If the physician has completed these observations, they~~ These observations must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
4. The physician must have observed at least 3 pancreas transplants. The observation of these transplants must be documented in a log that includes the transplant date and medical record number or other unique identifier that can be verified by the OPTN Contractor.
45. The following letters are submitted directly to the OPTN Contractor:
    a. A letter from the qualified pancreas transplant physician or surgeon who has been directly involved with the physician documenting the physician's experience and competence.
    b. A letter of recommendation from the primary physician and director at the transplant program last served by the physician outlining the physician's overall qualifications to act as primary transplant physician as well as the physician's personal integrity, honesty, familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request similar letters of recommendation from the primary physician, primary surgeon, director, or others affiliated with any transplant program the physician previously served, at its discretion.
    c. A letter from the physician that details the training and experience the physician has gained in pancreas transplantation.

D. Conditional Approval for Primary Transplant Physician

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

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

OPTN Contractor. This log should be signed by the program director, division chief, or department chair from the transplant program where the experience was gained.

2. The physician has maintained a current working knowledge of pancreas transplantation, defined as direct involvement in pancreas transplant patient care within the last 2 years. This includes the management of patients with end stage pancreas disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of pancreas dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for pancreas dysfunction, and long term outpatient care.
3. The physician has 12 months experience on an active pancreas transplant service as the primary pancreas transplant physician or under the direct supervision of a qualified pancreas transplant physician along with a pancreas transplant surgeon at a designated pancreas transplant program, or its foreign equivalent. This 12-month period of experience on the transplant service must have been acquired over a maximum of 2 years.
4. The physician ~~should~~ must have observed at least 3 ~~organ~~ pancreas procurements ~~and 3 pancreas transplants~~. The physician ~~should also~~ must have observed the 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 pancreas. If the physician has completed these observations, they~~ These observations must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
5. The physician must have observed at least 3 pancreas transplants. The observation of these transplants must be documented in a log that includes the transplant date and medical record number or other unique identifier that can be verified by the OPTN Contractor.

~~5~~6. The program has established and documented a consulting relationship with counterparts at another pancreas transplant program.

~~6~~7. The transplant program submits activity reports to the OPTN Contractor every 2 months describing the transplant activity, transplant outcomes, physician recruitment efforts, and other operating conditions as required by the MPSC to demonstrate the ongoing quality and efficient patient care at the program. The activity reports must also demonstrate that the physician is making sufficient progress in meeting the required involvement in the primary care of 15 or more pancreas transplant recipients, or that the program is making sufficient progress in recruiting a physician who will be on site and approved by the MPSC to assume the role of Primary Physician by the end of the 12 month conditional approval period.

~~7~~8. The following letters are submitted directly to the OPTN Contractor:

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

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

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

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

Appendix H: Membership and Personnel Requirements for Heart Transplant Programs

H.2 Primary Heart Transplant Surgeon Requirements

A. Cardiothoracic Surgery Residency Pathway

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

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

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

B. Twelve-month Heart Transplant Fellowship Pathway

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

1. The surgeon performed at least 20 heart or heart/lung transplants as primary surgeon or first assistant during the 12-month heart transplant fellowship. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the director of the training program.
2. The surgeon performed at least 10 heart or heart/lung procurements as primary surgeon or first assistant under the supervision of a qualified heart transplant surgeon ~~during the 12-month heart transplant fellowship~~. 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. This log must be signed by the director of the training program.
3. The surgeon has maintained a current working knowledge of all aspects of heart transplantation, defined as a direct involvement in heart transplant patient care within the last 2 years. This includes performing the transplant operation, donor selection, the use of mechanical circulatory assist devices, recipient selection, post-operative hemodynamic care, postoperative immunosuppressive therapy, and outpatient follow-up.
4. This training was completed at a hospital with a cardiothoracic surgery training program approved by the American Board of Thoracic Surgery, or its foreign equivalent, as accepted by the MPSC with a recommendation from the Thoracic Organ Transplantation Committee.
5. The following letters are submitted directly to the OPTN Contractor:
   a. A letter from the director of the training program verifying that the surgeon has met the above requirements and is qualified to direct a heart transplant program.
   b. A letter of recommendation from the training program's primary surgeon and transplant program director outlining the individual's overall qualifications to act as primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
   c. A letter from the surgeon that details the training and experience the surgeon has gained in heart transplantation.

H.3 Primary Heart Transplant Physician Requirements

A. Twelve-month Transplant Cardiology Fellowship Pathway

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

1. During the fellowship period, the physician was directly involved in the primary care of at least 20 newly transplanted heart or heart/lung recipients. This training will have been under the direct supervision of a qualified heart transplant physician and in conjunction with a heart transplant surgeon. This care must be documented in a log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log must be signed by the director of the training program or the primary transplant physician at the transplant program.
2. The physician has maintained a current working knowledge of heart transplantation, defined as direct involvement in heart transplant patient care within the last 2 years. This includes the care of acute and chronic heart failure, donor selection, the use of mechanical circulatory support devices, recipient selection, pre- and post-operative hemodynamic care, post-operative immunosuppressive therapy, histological interpretation and grading of myocardial biopsies for rejection, and long-term outpatient follow-up.
3. The physician ~~should~~ 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.
5. This training was completed at a hospital with an American Board of Internal Medicine certified fellowship training program in adult cardiology or American Board of Pediatrics certified fellowship training program in pediatric cardiology or its foreign equivalent, as accepted by the MPSC.
6. The following letters are submitted directly to the OPTN Contractor:
    a. A letter from the director of the training program and the supervising qualified heart transplant physician verifying that the physician has met the above requirements and is qualified to direct a heart transplant program.
    b. A letter of recommendation from the training program's primary physician and transplant program director outlining the physician's overall qualifications to act as primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the Primary Physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
    c. A letter from the physician that details the training and experience the physician has gained in heart transplantation.

B. Clinical Experience Pathway

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

1. The physician has been directly involved in the primary care of 20 or more newly transplanted heart or heart/lung recipients and continued to follow these recipients for a minimum of 3 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.
5. The following letters are submitted directly to the OPTN Contractor:
    a. A letter from the heart transplant physician or the heart transplant surgeon who has been directly involved with the physician at the transplant program verifying the physician's competence.
    b. A letter of recommendation from the primary physician and transplant program director at the transplant program last served by the physician outlining the physician's overall qualifications to act as primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
    c. A letter from the physician that details the training and experience the physician has gained in heart transplantation.

D. Conditional Approval for Primary Transplant Physician

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

1. The physician has current board certification in cardiology by the American Board of Internal Medicine, the American Board of Pediatrics, or the foreign equivalent.
2. The physician has 12 months experience 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 designated heart transplant program. These 12 months of experience must be acquired within a 2-year period.
3. 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 knowledge of acute and chronic heart failure, donor selection, the use of mechanical circulatory support devices, recipient selection, pre- and post-operative hemodynamic care, post-operative immunosuppressive therapy, histological interpretation in grading of myocardial biopsies for rejection, and long-term outpatient follow-up.
4. The physician has been involved in the primary care of 10 or more newly transplanted heart or heart/lung transplant recipients as the heart transplant physician or under the direct supervision of a qualified heart transplant physician or in conjunction with a heart transplant surgeon. The physician will have followed these patients for a minimum of 3 months from the time of transplant. This care must be documented in a log that includes the date of transplant and medical record or other unique identifier that can be verified by the OPTN Contractor. This recipient log should be signed by the program director or the primary transplant physician at the transplant program where the physician gained experience.
5. 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 at least 3 multiple organ donors who donated 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.
6. 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.

~~6~~7. The program has established and documented a consulting relationship with counterparts at another heart transplant program.

~~7~~8. 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 20 or more heart transplant recipients, or that the program is making sufficient progress in recruiting a physician who meets all requirements for primary heart transplant physician by the end of the 12 month conditional approval period.

~~8~~9. 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 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.

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

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

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

Appendix I: Membership and Personnel Requirements for Lung Transplant Programs

I.2 Primary Lung Transplant Surgeon Requirements

A. Cardiothoracic Surgery Residency Pathway

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

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

donor selection, recipient selection, pre- and postoperative ventilator care, postoperative immunosuppressive therapy, histological interpretation and grading of lung biopsies for rejection, and long-term outpatient follow-up. This training must also include the other clinical requirements for thoracic surgery

4. This training was completed at a hospital with a cardiothoracic training program approved by the American Board of Thoracic Surgery, or its foreign equivalent. Foreign programs must have a recommendation from the Thoracic Organ Transplantation Committee and be accepted as equivalent by the MPSC.
5. The following letters are submitted directly to the OPTN Contractor:
    a. A letter from the director of the training program verifying that the surgeon has met the above requirements and is qualified to direct a lung transplant program.
    b. A letter of recommendation from the program's primary surgeon and transplant program director outlining the individual's overall qualifications to act as primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.
    c. A letter from the surgeon that details the training and experience the surgeon has gained in lung transplantation.

B. Twelve-month Lung Transplant Fellowship Pathway

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

1. The surgeon has performed at least 15 lung or heart/lung transplants under the direct supervision of a qualified lung transplant surgeon and in conjunction with a qualified lung transplant physician as primary surgeon or first assistant during the 12-month lung transplant fellowship. At least half of these transplants must be lung procedures. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the director of the program.
2. The surgeon has performed at least 10 lung procurements as primary surgeon or first assistant under the supervision of a qualified lung transplant surgeon ~~during the 12-month lung transplant fellowship~~. These 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 all aspects of lung transplantation, defined as a direct involvement in lung transplant patient care within the last 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass, donor selection, recipient selection, pre- and postoperative ventilator care, postoperative immunosuppressive therapy, histological interpretation and grading of lung biopsies for rejection, and long-term outpatient follow-up.
4. This training was completed at a hospital with a cardiothoracic training program approved by the American Board of Thoracic Surgery, or its foreign equivalent. Foreign programs must have a recommendation from the Thoracic Organ Transplantation Committee and be accepted as equivalent by the MPSC.

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

I.3 Primary Lung Transplant Physician Requirements

A. Twelve-month Transplant Pulmonary Fellowship Pathway

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

1. The physician was directly involved in the primary and follow-up care of at least 15 newly transplanted lung or heart/lung recipients. This training will have been under the direct supervision of a qualified lung transplant physician and in conjunction with a lung transplant surgeon. At least half of these patients must be single or double-lung transplant recipients. This care must be documented in a log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log must be signed by the director of the training program or the primary transplant physician at the transplant program.
2. The physician has maintained a current working knowledge of all aspects of lung transplantation, defined as a direct involvement in lung transplant patient care within the last 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass, donor selection, recipient selection, pre- and postoperative ventilator care, postoperative immunosuppressive therapy, histological interpretation and grading of lung biopsies for rejection, and long-term outpatient follow-up.
3. The physician ~~should~~ must have observed at least 3 lung or heart/lung procurements ~~and 3 lung 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 lung 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 lung 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.
~~4~~5. This training was completed at a hospital with an American Board of Internal Medicine certified fellowship training program in adult pulmonary medicine, an American Board of Pediatrics-certified fellowship training program in pediatric medicine, or its foreign equivalent. Foreign programs must have a recommendation from the Thoracic Organ Transplantation Committee and be accepted as equivalent by the MPSC.

~~5~~6. The following letters are submitted directly to the OPTN Contractor:
   a. A letter from the director of the training program verifying that the physician has met the above requirements and is qualified to direct a lung transplant program.
   b. A letter of recommendation from the training program's primary physician and transplant program director outlining the physician's overall qualifications to act as primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
   c. A letter from the physician that details the training and experience the physician has gained in lung transplantation.

B. Clinical Experience Pathway

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

1. The physician has been directly involved in the primary care of 15 or more newly transplanted lung or heart/lung recipients and continued to follow these recipients for a minimum of 3 months from the time of transplant. At least half of these transplant must be lung transplants. This patient care must have been provided over a 2 to 5-year period on an active lung transplant program or its foreign equivalent. This care must have been provided as the lung transplant physician or directly supervised by a qualified lung transplant physician along with a lung transplant surgeon. This care must be documented in a log that includes the date of transplant and medical record number or other unique identifier that can be verified by the OPTN Contractor. This recipient log should be signed by the director or the primary transplant physician at the transplant program where the physician gained this experience.
2. The physician has maintained a current working knowledge of all aspects of lung transplantation, defined as a direct involvement in lung transplant patient care within the last 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass, donor selection, recipient selection, pre- and postoperative ventilator care, postoperative immunosuppressive therapy, histological interpretation and grading of lung biopsies for rejection, and long-term outpatient follow-up.
3. The physician ~~should~~ must observe at least 3 lung or heart/lung procurements ~~and 3 lung 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 lung 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 lung 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.

~~4~~5. The following letters are submitted directly to the OPTN Contractor:
   a. A letter from the lung transplant physician or surgeon of the training program who has been directly involved with the physician documenting the physician's competence.
   b. A letter of recommendation from the primary physician and transplant program director at the transplant program last served by the physician outlining the physician's overall qualifications to act as primary transplant physician, as well as the physician's personal

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

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

D. Conditional Approval for Primary Transplant Physician

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

1. The physician is a pulmonologist with current board certification in pulmonary medicine by the American Board of Internal Medicine, the American Board of Pediatrics, or the foreign equivalent.
2. The physician has 12 months of experience on an active lung transplant service as the primary lung transplant physician or under the direct supervision of a qualified lung transplant physician and in conjunction with a lung transplant surgeon at a designated lung transplant program. These 12 months of experience must be acquired within a 2-year period.
3. The physician has been involved in the primary care of 8 or more newly transplanted lung or heart/lung transplant recipients as the lung transplant physician or under the direct supervision of a qualified lung transplant physician and in conjunction with a lung transplant surgeon. At least half of these patients must be lung transplant recipients. This care must be documented in a recipient log that includes the date of transplant and medical record or other unique identifier that can be verified by the OPTN Contractor. This log should be signed by the program director or the primary transplant physician at the transplant program where the physician gained experience.
4. The physician has maintained a current working knowledge of all aspects of lung transplantation, defined as a direct involvement in lung transplant patient care within the last 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass, donor selection, recipient selection, pre- and postoperative ventilator care, postoperative immunosuppressive therapy, histological interpretation and grading of lung biopsies for rejection, and long-term outpatient follow-up.
5. The physician ~~should~~ must have observed at least 3 lung or heart/lung procurements ~~and 3 lung 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 lung 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.
6. The physician must have observed at least 3 lung transplants. The observation of these transplants must be documented in a log that includes the transplant date and medical record number or other unique identifier that can be verified by the OPTN Contractor.
~~6~~7. The program has established and documented a consulting relationship with counterparts at another lung transplant program.
~~7~~8. 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 20 or more lung transplant recipients, or that the program is making sufficient progress in recruiting a physician who meets all requirements for primary lung transplant physician by the end of the 12 month conditional approval period.

~~8~~9. The following letters are submitted directly to the OPTN Contractor:
   a. A letter from the supervising lung transplant physician or surgeon of the training program documenting the physician's competence.
   b. A letter of recommendation from the training program's primary physician and director outlining the physician's overall qualifications to act as primary transplant physician of the transplant program last served by the physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
   c. A letter from the physician that details the training and experience the physician has gained in lung transplantation.

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

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

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

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ROCKVILLE POLICY DEVELOPMENT DISCUSSION

APRIL 9, 2010

ROCKVILLE POLICY DEVELOPMENT DISCUSSION

ATTENDANCE

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

SUMMARY

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

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

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

PROCESS

The general process will proceed as follows:

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

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

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

UNOS support staff will also attend in order to set up the calls, facilitate the presentations, and document the proceedings. Approximately 2 weeks after each quarterly call, the Steering Group will reconvene to 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 OTPN/UNOS committee by the Working Group chair.

c. The Working Group Chair will then participate in subsequent meetings of the sponsoring OPTN/UNOS committee as it continues the policy development process (e.g., policy formulation, public comment, and Board review).

d. The Working Group chair will not be a member of the OPTN/UNOS committee and will not have a vote.

e. In the event that the OPTN/UNOS committee disagrees with a substantial number of the Working Group's recommendations, discussion between the 2 groups will occur in an attempt to arrive at consensus.

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

PILOTING THE PROCESS

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