OPTN | UNOS Public Comment Proposal

Consider Primary Transplant Surgeon Requirement- Primary or First Assistant on Transplant Cases

OPTN/UNOS Membership and Professional Standards Committee

Prepared by: Chad Waller
UNOS Member Quality Department

Executive Summary 1
Is the sponsoring Committee requesting specific feedback or input about the proposal? 1
What problem will this proposal solve? 2
Why should you support this proposal? 2
Which populations are impacted by this proposal? 4
How does this proposal impact the OPTN Strategic Plan? 4
How will the OPTN implement this proposal? 5
How will members implement this proposal? 5
How will members be evaluated for compliance with this proposal? 5
How will the sponsoring Committee evaluate whether this proposal was successful post implementation? 6
Policy or Bylaws Language 7

Consider Primary Transplant Surgeon Requirement- Primary or First Assistant on Transplant Cases

Affected Bylaws: OPTN Bylaws Appendices E.2.A (Formal 2-year Transplant Fellowship Pathway), E.2.B (Clinical Experience Pathway), E.6.D (Primary Open Living Donor Kidney Surgeon), E.6.E (Primary Laparoscopic Living Donor Kidney Surgeon), F.3.A (Formal 2-year Transplant Fellowship Pathway), F.3.B (Clinical Experience Pathway), F.8.A (Living Donor Surgeon Requirements), G.2.A (Formal 2-year Transplant Fellowship Pathway), G.2.B (Clinical Experience Pathway), H.2.A (Cardiothoracic Surgery Residency Pathway), H.2.A (Cardiothoracic Surgery Residency Pathway), H.2.B (Twelve-month Heart Transplant Fellowship Pathway), 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)

Sponsoring Committee: *Membership and Professional Standards*

Public Comment Period: *August 15, 2016 – October 15, 2016*

Executive Summary

Primary transplant surgeons are required to have performed a set number of transplants and procurements as the “primary surgeon or first assistant.” Primary thoracic transplant surgeons must perform a certain number of these procedures as the primary surgeon, but the Bylaws do not specify this for abdominal surgeons. Considering this, and that the responsibilities of a surgical first assistant are not consistent across institutions, the MPSC has raised concerns that surgeons could qualify as a transplant program’s primary surgeon though they may have never performed critical surgical transplant functions that would be expected of a primary transplant surgeon leading a designated program. This proposal recommends that an abdominal surgeon applying through the clinical experience pathway must have performed at least half of the required transplants and procurements as the primary or co-surgeon. Additionally, this proposal recommends that all cases accepted towards transplant training program requirements should also count towards OPTN/UNOS Bylaws requirements for all surgeons applying through training pathways. Requiring all primary transplant surgeons applying through clinical experience pathways to have performed a certain number of transplants and procurements as the primary surgeon is intended to promote patient safety and improve outcomes by assuring that each transplant program is led by individuals who have sufficient training and experience in organ transplantation.

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

- Should the recommendations in this proposal also apply to the primary intestine surgeon Bylaws requirements adopted by the OPTN/UNOS Board of Directors in June 2015?
- Should the recommendations in this proposal also apply to the surgeon requirements of the pediatric component Bylaws adopted by the OPTN/UNOS Board of Directors in December 2015?

What problem will this proposal solve?

The Bylaws require that primary transplant surgeons are to have performed a set number of transplants and procurements as the "primary surgeon or first assistant." Primary thoracic transplant surgeons must perform a certain number of these procedures as the primary surgeon, but the Bylaws do not specify this for abdominal surgeons. As such, abdominal surgeons could qualify as a transplant program's primary surgeon though they may have never performed critical surgical transplant functions that would be expected of a primary transplant surgeon leading a designated program.

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.

There are two primary components to the changes recommended in this proposal regarding the required case experience for primary transplant surgeons: what is required when applying through a training pathway, and what is required of abdominal surgeons applying through the clinical experience pathway. The JSWG stated it was necessary to look at this problem from those two perspectives considering billing implications of the primary surgeon/first assistant designation for residents and fellows. The JSWG recommended that the MPSC focus on training operative logs when evaluating the experience of surgeons applying through fellowship or residency pathways. This decision was guided by the rationale that if a surgeon's involvement in a transplant or procurement is accepted by the fellowship program towards completion of their training, then the OPTN should also accept these cases towards key personnel Bylaws requirements. For abdominal surgeons applying through a clinical experience pathway, the JSWG indicated it was unreasonable that someone could qualify without some transplant and procurement experience as the primary surgeon. To rectify this, the JSWG recommended that at least 50% of the transplants and procurements reported by abdominal primary transplant surgeon applicants must have been performed as the primary surgeon.

The proposed fellowship pathway changes should simplify the MPSC's evaluation of experience reported by surgeons applying through this pathway, which will yield more efficient reviews of these applications. Similarly, these changes should clarify this process for members when trying to assess if certain staff (or potential staff) meet Bylaws requirements, and when completing the membership applications for surgeons applying through residency or training pathways. Also, the proposed changes to the abdominal primary transplant surgeon clinical experience pathways establish more consistent standards for abdominal primary transplant surgeons.

How was this proposal developed?

In 2013 the MPSC created a working group to address a number of issues in the Bylaws' key personnel requirements that it had repeatedly noted as ambiguous, unenforceable, or that had prompted repeated questions from members of the MPSC. Included in the topics assigned to this working group was a review of primary transplant surgeon requirements in the Bylaws that state transplants and procurements cited on a key personnel application must have been performed as a "primary surgeon or first assistant." 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 Joint Societies Working Group (JSWG) to address the key personnel Bylaws projects being worked on by the MPSC.

When presented with this topic, the JSWG believed that the primary surgeon/first assistant requirements in primary transplant surgeon Bylaws needed to be reconsidered from two perspectives- what is required when applying through a training pathway, and what is required when applying through the clinical experience pathway.

The JSWG first focused on these requirements as they pertain to primary transplant surgeon training pathways (e.g., OPTN Bylaws Appendix E.2.A (Formal 2-year Transplant Fellowship Pathway); OPTN Bylaws Appendix H.2A (Cardiothoracic Surgery Residency Pathway)). The JSWG stated that fellows are always noted as assisting surgeons on hospital billing records, so differentiating between primary surgeon or first assistant experience during a surgeon's fellowship is not the best way to assess that they have the requisite training and experience that would be expected of a primary transplant surgeon. The JSWG also acknowledged that training pathways for primary transplant surgeons rely on quality training and experience gained during fellowship or residency, and the Bylaws requirements in these pathways generally reflect standards that must be met to complete one's fellowship or residency training. As such, the JSWG suggested that if the transplant or procurement experience has been accepted to count towards the completion of training program requirements, then the OPTN should also allow those cases to count towards the primary surgeon requirements found in the Bylaws in each respective training pathway. To evaluate this, primary transplant surgeon applicants applying through the fellowship pathway will be required to provide a copy of their residency or fellowship operative log. The JSWG confirmed that this should apply to all of the residency and fellowship pathways currently in the Bylaws for primary transplant surgeons.

The JSWG proceeded to consider these requirements for primary transplant surgeons applying through the clinical experience pathways (e.g., OPTN Bylaws Appendix F.2.B (Clinical Experience Pathway); OPTN Bylaws Appendix I.2.C (Clinical Experience Pathway)). To initiate the discussions, it was noted that primary heart transplant surgeons applying through the clinical experience pathway must have performed at least 15 (of a required 20) heart transplants as the primary surgeon, and that primary lung transplant surgeons must have performed at least 10 (of a required 15) transplants as the primary surgeon. The JSWG suggested that key personnel Bylaws for abdominal primary transplant surgeons should similarly include a set number of procedures that must have been performed as the primary surgeon. Further discussion yielded the recommendation that at least 50% of the procurements and transplants required of primary transplant surgeons who apply through a clinical experience pathway must have been performed as the primary surgeon. The JSWG discussed other possible thresholds, and expressed some concern about the arbitrary nature of the percentage to be included in this proposal. The JSWG was unable to determine a less arbitrary means to determine an appropriate threshold, and agreed to proceed with 50% of cases as the primary surgeon. Although the JSWG accepted that the arbitrariness of this decision as a weakness of this proposal, it believed that this solution was reasonable and the simplest way to address this problem.

The JSWG also considered if this recommendation should apply to the thoracic primary transplant surgeon clinical experience pathways. Unaware of any explicit problems that have resulted from the current requirements in the primary heart and primary lung transplant surgeon Bylaws, the JSWG indicated it was hesitant to recommend modifications to these sections. Although this would result in some inconsistency in the primary transplant surgeon requirements across all organs, the JSWG opted not to recommend applying these proposed changes to the clinical experience pathways for thoracic organ transplant programs unless feedback from the thoracic transplant community clearly indicates that this change is necessary.

The JSWG presented these recommendations to the MPSC and the Joint Societies Policy Steering Committee, and both groups endorsed proposed changes with no concerns raised. Upon the MPSC's endorsement, it drafted proposed Bylaws modifications to accommodate these recommendations (as presented in this proposal). An additional consideration raised by the MPSC while drafting this proposal is the inclusion of cases performed as co-surgeon. The MPSC noted that this designation is fairly common in abdominal surgery transplants, and that the experience is meaningful relative to the intent of these primary transplant surgeon requirements. Thoracic surgeons on the MPSC indicated this designation is not commonly used in heart or lung transplantation. Accordingly, the MPSC agreed that the term "co-surgeon" should be included for abdominal transplant surgeons applying through clinical experience pathways, and that cases reported as "co-surgeon" should be viewed, for the purposes of these Bylaws,

as equivalent to primary surgeon cases. The JSWG obtained an update on this approach during a subsequent teleconference, and did not express any objections.

How well does this proposal address the problem statement?

Requiring abdominal organ primary transplant surgeons to have performed at least 50% of their reported transplants and procurements as the primary surgeon further standardizes what is expected of all primary transplant surgeons at abdominal organ transplant programs across the country. These proposed changes should eliminate any concerns about the potential approval of a primary transplant surgeon who has not performed critical surgical transplant functions that would be expected of a primary transplant surgeon leading a designated program.

In addition to addressing these concerns, the proposed changes for acceptable case experience when applying through a residency or fellowship pathway should simplify the MPSC's evaluation of these applicants, and similarly, member determination of which staff could meet the primary transplant surgeon requirements through the training pathways.

The JSWG and MPSC realize that the recommended 50% primary surgeon threshold was reached arbitrarily. Nevertheless, both groups believe this is a reasonable and necessary requirement to include in the Bylaws. The MPSC would welcome any feedback on this 50% threshold, and any reasons why it should be raised or lowered.

Which populations are impacted by this proposal?

As primary transplant surgeons are required at every transplant program, and as these proposed changes address primary transplant surgeon requirements, these 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 as these changes are primarily operational in nature.

How does this proposal impact the OPTN Strategic Plan?

Increase the number of transplants: There is no impact to this goal.

Improve equity in access to transplants: Additional Bylaws requirements always have the potential to impact transplant access. Additional requirements may not be attainable for certain programs, which could eventually result in the approval of fewer transplant programs. Ultimately, the MPSC believes it would be unlikely that these changes pose a significant burden on transplant programs, and thus expects that these changes will have negligible impact on patient access.

Improve waitlisted patient, living donor, and transplant recipient outcomes: The primary purpose of key personnel Bylaws is to establish a standard that each transplant program is led by individuals who have sufficient training and experience in organ transplantation. Expanding the requirements for abdominal organ primary transplant surgeons applying through the clinical experience pathways further standardizes what is expected of all primary transplant surgeons at abdominal organ transplant programs across the country. A higher level of required experience should promote improved outcomes for patients on the waiting list, living donors, and transplant recipients.

Promote living donor and transplant recipient safety: The primary purpose of key personnel Bylaws is to establish a standard that each transplant program is led by individuals who have sufficient training and experience in organ transplantation. Expanding the requirements for abdominal organ primary transplant surgeons applying through the clinical experience pathways further standardizes what is expected of all primary transplant surgeons at abdominal organ transplant programs across the country. A higher level of required experience should promote living donor and transplant recipient safety.

Promote the efficient management of the OPTN: The proposed fellowship pathway changes should simplify the MPSC's evaluation of experience reported by surgeons applying through this pathway, which will yield more efficient reviews of these applications. Similarly, these changes should simplify this process for members when trying to assess if certain staff (or potential staff) meet Bylaws requirements, and when completing the membership applications for surgeons applying through residency or training pathways.

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 2016 meeting. Assuming the Board adopts these changes, members will be alerted through a policy notice. Necessary updates to the membership application prompted by these changes would require approval by the Office of Management and Budget (OMB) prior to the implementation of these Bylaws. After application changes have been approved by OMB, the OPTN will notify the membership of the implementation date for these Bylaws. All applications received on or after this implementation date would be evaluated by the MPSC considering these new Bylaws.

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.

Transplant Hospitals

With the adoption of the changes provided in this proposal, transplant hospitals that are proposing primary transplant surgeons through one of the OPTN Bylaws fellowship or residency pathways will be required to submit with their application the proposed primary transplant surgeon's operative log from their training.

Will this proposal require members to submit additional data?

This proposal does not necessitate the collection of any new data; however, there are additional considerations that members should be mindful of when submitting primary transplant surgeon key personnel applications. If the primary transplant surgeon applicant is qualifying through a training pathway, then the applicant will need to supply a copy of their training operative log. Cases included on these operative logs that have been accepted towards meeting the training program's requirements will also be accepted by the OPTN towards primary transplant surgeon training pathway requirements. Primary kidney, liver, and pancreas transplant surgeon applicants applying through the respective clinical experience pathways must make sure that at least half of the cases cited on their application were performed as the primary surgeon or co-surgeon.

How will members be evaluated for compliance with this proposal?

All membership and key personnel applications proposing a primary transplant surgeon that are received by UNOS on or after the implementation date of these changes would be evaluated against these new requirements. All primary transplant surgeon applicants applying through a residency or fellowship pathway will be required to provide a copy of their training operative log to document their involvement in the requisite number of transplants and procurements. All cases included on the training operative log that are accepted towards fellowship completion will also be accepted by the OPTN. Abdominal organ

primary transplant surgeon applicants applying through the clinical experience pathway will be required to have performed at least half of their reported transplants and procurements as primary surgeon or co-surgeon.

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

These proposed changes will necessarily prevent surgeons at abdominal organ programs from qualifying as the primary transplant surgeon without having performed critical surgical transplant functions that would be expected of a primary transplant surgeon leading a designated program. The impact of these changes will be evaluated as the MPSC receives primary kidney, liver, and pancreas transplant surgeon key personnel applications. The MPSC will assess primary transplant surgeon application deficiencies, as well as the type and frequency of questions raised about these new requirements. The MPSC will monitor if these changes yield a trend of negative consequences that it did not anticipate.

Policy or Bylaws Language

Proposed new language is underlined (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 the surgeon's fellowship operative log. ~~a log that includes~~ T~~t~~he 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, and the fellowship director's signature must be provided with this log. ~~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. At least 10 of these procurements must be from deceased donors. These procurements must have been performed anytime during the surgeon's fellowship and the two years immediately following fellowship completion. These procedures must be documented in the surgeon's fellowship operative log. ~~a log that includes t~~The date of procurement, location of the donor, and Donor ID must be provided with this log.
3. The surgeon has maintained a current working knowledge of kidney transplantation, defined as direct involvement in kidney transplant patient care in the last 2 years. This includes the management of patients with end stage renal disease, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, performing the transplant operation, immediate postoperative and continuing inpatient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of renal dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for renal dysfunction, and long term outpatient care.
4. This training was completed at a hospital with a kidney transplant training program approved by the Fellowship Training Committee of the American Society of Transplant Surgeons, the Royal College of Physicians and Surgeons of Canada, or accepted by the OPTN Contractor as described in the *Section E.4 Approved Kidney Transplant Surgeon and Physician Fellowship Training Programs* that follows.
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, co-surgeon, or first assistant at a designated kidney transplant program. Of these 45 kidney transplants, 23 or more must have been performed as primary surgeon or co-surgeon. 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, co-surgeon, or first assistant. Of these 15 kidney procurements, at least 8 must have been performed as primary surgeon or co-surgeon. 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.6 Kidney Transplant Programs that Perform Living Donor Recovery

D. Primary Open Living Donor Kidney Surgeon

A ~~K~~kidney donor surgeon who performs open living donor nephrectomies must be on site and must meet *one* of the following criteria:

- Completion of an accredited American Society of Transplant Surgeons (ASTS) fellowship with kidney certification.
- Completion of at least 10 open nephrectomies, including deceased donor nephrectomies or the removal of diseased kidneys, as primary surgeon, co-surgeon, or ~~F~~first ~~A~~assistant. At least 5 of these open nephrectomies must have been performed as the primary surgeon or co-surgeon. The open nephrectomies must be documented in a log that includes the date of recovery, the role of the surgeon in the procedure, the type of procedure (open or laparoscopic), and the medical record number or Donor ID.

E. Primary Laparoscopic Living Donor Kidney Surgeon

A surgeon who performs laparoscopic living donor kidney recoveries must be on site and must have completed at least 15 laparoscopic nephrectomies in the last 5 years as primary surgeon, co-surgeon, or first assistant. Seven of these nephrectomies must have been performed as ~~the~~ primary surgeon or co-surgeon, and this role should be documented by a letter from the fellowship program director, program director, division chief, or department chair from the program where the surgeon gained this experience. The laparoscopic nephrectomies must be documented in a log that includes the date of the surgery, the role of the surgeon in the procedure, the type of procedure (open or laparoscopic), and the medical record number or Donor ID.

Appendix F: Membership and Personnel Requirements for Liver Transplant Programs and Intestine 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 the surgeon's fellowship operative log. ~~a log that includes~~ T~~t~~he 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, and the fellowship director's signature must be provided with this log. ~~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. These procurements must have been performed anytime during the surgeon's fellowship and the two years immediately following fellowship completion. These procedures must be documented in the surgeon's fellowship operative log. ~~a log that includes t~~The date of procurement, location of the donor, and Donor ID must be provided with this log. ~~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 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, the Royal College of Physicians and Surgeons of Canada, or accepted by the OPTN Contractor as described in *Section F.6. Approved Liver Surgeon Transplant Fellowship Programs* that follows.
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, co-surgeon, or first assistant at a designated liver transplant program. Of these 60 liver transplants, 30 or more must have been performed as primary surgeon or co-surgeon. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and medical record number or other unique identifier that can be verified by the OPTN Contractor. This log should be signed by the program director, division chief, or department chair from 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, co-surgeon, or first assistant. Of these 30 liver procurements, at least 15 must have been performed as primary surgeon or co-surgeon. These procedures must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
3. The surgeon has maintained a current working knowledge of 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.8 Liver Transplant Programs that Perform Living Donor Recovery

A. Living Donor Surgeon Requirements

A liver recovery hospital must have on site *at least* 2 surgeons who:

1. Meet the primary liver transplant surgeon requirements as outlined in *Section F.3* above.
2. Have demonstrated experience as the primary surgeon, co-surgeon, or first assistant by completion of at least 20 major liver resection surgeries, including living donor procedures, splits, reductions, and resections, within the past 5 years. Of these 20 major liver resection surgeries, ~~S~~seven ~~of these procedures~~ must have been live donor procedures, and at least 10 must have been performed as the primary surgeon or co-surgeon. These procedures must be documented in a log that includes the date of the surgery, 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.

In the case of pediatric living donor transplantation, it may be necessary that the live organ recovery occurs at a hospital that is distinct from the approved liver transplant program.

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. These transplants must be documented in the surgeon's fellowship operative log. ~~a log that includes t~~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, and the fellowship director's signature must be provided with this log. ~~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. These procurements must have been performed anytime during the surgeon's fellowship and the two years immediately following fellowship completion. These cases must be documented in the surgeon's fellowship operative log. ~~a log that includes the~~The date of procurement, location of the donor, ~~and~~ Donor ID, and the fellowship director's signature must be provided with this log. ~~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, the Royal College of Physicians and Surgeons of Canada, or accepted by the OPTN Contractor as described in *Section G.7. Approved Pancreas Transplant Surgeon Fellowship Training Programs* that follows.
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.

B. Clinical Experience Pathway

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

1. The surgeon has performed 20 or more pancreas transplants over a 2 to 5-year period as primary surgeon, co-surgeon, or first assistant, at a designated pancreas transplant program. Of these 20 pancreas transplants, 10 or more must have been performed as primary surgeon or co-surgeon. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and medical record number or other unique identifier that can be verified by the OPTN Contractor. This log should be signed by the program director, division chief, or department chair from the program where the experience was gained. Each year of the surgeon's experience must be substantive and relevant and include pre-operative assessment of pancreas transplant candidates, transplants performed as primary surgeon or first assistant, and post-operative care of pancreas recipients.
2. The surgeon has performed at least 10 pancreas procurements as primary surgeon, co-surgeon, or first assistant. Of these 10 pancreas procurements, at least 5 must have been performed as primary surgeon or co-surgeon. These procurements must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
3. The surgeon has maintained a current working knowledge of pancreas transplantation, defined as direct involvement in pancreas transplant patient care within the last 2 years. This includes the management of patients with diabetes mellitus, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, performing the transplant operation, immediate postoperative and continuing inpatient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of pancreatic dysfunction in the allograft recipient, histological interpretation of allograft biopsies, interpretation of ancillary tests for pancreatic dysfunction, and long term outpatient care.
4. The following letters are submitted directly to the OPTN Contractor:
    a. A letter from the director of the transplant program and chairman of the department or hospital credentialing committee verifying that the surgeon has met the above requirements and is qualified to direct a pancreas transplant program.
    b. A letter of recommendation from the primary surgeon and director at the transplant program last served by the surgeon outlining the surgeon's overall qualifications to act as primary transplant surgeon as well as the surgeon's personal integrity, honesty, familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request similar letters of recommendation from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the individual, at its discretion.
    c. A letter from the surgeon that details the training and experience the surgeon has gained in pancreas transplantation.

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 the surgeon's cardiothoracic surgery residency operative log. ~~in a log that includes t~~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, and the training program director's signature must be provided with this log. ~~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. These procurements must have been performed anytime during the surgeon's cardiothoracic surgery residency and the two years immediately following cardiothoracic surgery residency completion. These procedures must be documented in the surgeon's cardiothoracic surgery residency operative log. ~~a log that includes t~~The date of procurement, location of the donor, ~~and~~ Donor ID, and the training program director's signature must be provided with this log. ~~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 the Royal College of Physicians and Surgeons of Canada.
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 the surgeon's fellowship operative log. ~~a log that includes t~~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, and the fellowship director's signature must be provided with this log. ~~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. These procurements must have been performed anytime during the surgeon's fellowship and the two years immediately following fellowship completion. These procedures must be documented in the surgeon's fellowship operative log. ~~a log that includes t~~The date of procurement, location of the donor, ~~and~~ Donor ID, and the training program director's signature must be provided with this log. ~~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 the Royal College of Physicians and Surgeons of Canada.
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.

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 the surgeon's cardiothoracic surgery residency operative log. ~~a log that includes t~~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, and the training program director's signature must be provided with this log. ~~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. These procedures must be documented in the surgeon's cardiothoracic surgery residency operative log. ~~a log that includes t~~The date of procurement, location of the donor, and Donor ID must be provided with this log.
3. The surgeon has maintained a current working knowledge of all aspects of lung transplantation, defined as a direct involvement in lung transplant patient care within the last 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass, donor selection, recipient selection, pre- and postoperative ventilator care, postoperative immunosuppressive therapy, histological interpretation and grading of lung biopsies for rejection, and long-term outpatient follow-up. This training must also include the other clinical requirements for thoracic surgery
4. This training was completed at a hospital with a cardiothoracic training program approved by the American Board of Thoracic Surgery, or the Royal College of Physicians and Surgeons of Canada.
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 the surgeon's fellowship operative log. ~~a log that includes t~~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, and the fellowship director's signature must be provided with this log. ~~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. These procurements must have been performed anytime during the surgeon's fellowship and the two years immediately following fellowship completion. These procedures must be documented in the surgeon's fellowship operative log. ~~a log that includes t~~The date of procurement, location of the donor, and Donor ID must be provided with this log.
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 the Royal College of Physicians and Surgeons of Canada.
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.

#