

At-a-Glance

Proposal to Establish Pediatric Training and Experience Requirements in the Bylaws

- **Affected Bylaws:** Appendix E.2 (Primary Kidney Transplant Surgeon Requirements), Appendix E.3 (Primary Kidney Transplant Physician Requirements), Appendix F.2 (Primary Liver Transplant Surgeon Requirements), Appendix F.3 (Primary Liver Transplant Physician Requirements), Appendix G.2 (Primary Pancreas Transplant Surgeon Requirements), Appendix G.3 (Primary Pancreas Transplant Physician Requirements), Appendix H.2 (Primary Heart Transplant Surgeon Requirements), Appendix H.3 (Primary Heart Transplant Physician Requirements), Appendix I.2 (Primary Lung Transplant Surgeon Requirements), Appendix I.3 (Primary Lung Transplant Physician Requirements)
- **Pediatric Transplantation Committee**

Pediatric transplantation is a subspecialty within the field of transplantation. In the current OPTN Bylaws, the primary surgeon and primary physician are not required to have pediatric training or experience in order to serve as key personnel at programs that perform pediatric transplants. The Bylaws' silence on pediatric program requirements means that there is not a universal standard of quality in pediatric care, which, in the most rare and serious of circumstances, could pose a risk to patient safety. In 2012, the Board of Directors included developing separate program requirements for pediatric programs as a key initiative under Goal 4: Promote Patient Safety of the OPTN/UNOS Strategic Plan and charged the Pediatric Transplantation Committee with developing Bylaws that fulfill this key initiative. The Committee proposes that a designated transplant program must have an approved pediatric component in order to perform transplants in patients less than 18 years old. To be approved for a pediatric component, a program must identify a qualified primary pediatric surgeon and a qualified primary pediatric physician to serve as key personnel.
- **Affected Groups**
 - Directors of Organ Procurement
 - OPO Executive Directors
 - OPO Medical Directors
 - OPO Coordinators
 - Transplant Administrators
 - Transplant Physicians/Surgeons
 - Transplant Program Directors
 - Organ Candidates
 - Organ Recipients
 - General Public
- **Number of Potential Candidates Affected**

As of December 12, 2014, there were 2,481 candidates added to the waiting list at the age of less than 18 years who were still waiting for transplant.
- **Compliance with OPTN Strategic Goals and Final Rule**

In 2012, the Board of Directors included developing separate program requirements for pediatric programs as a key initiative under Goal 4: Promote Patient Safety of the OPTN/UNOS Strategic Plan.

Proposal to Establish Pediatric Training and Experience Requirements in the Bylaws

Affected Bylaws:

Appendix E.2 (Primary Kidney Transplant Surgeon Requirements), Appendix E.3 (Primary Kidney Transplant Physician Requirements), Appendix F.2 (Primary Liver Transplant Surgeon Requirements), Appendix F.3 (Primary Liver Transplant Physician Requirements), Appendix G.2 (Primary Pancreas Transplant Surgeon Requirements), Appendix G.3 (Primary Pancreas Transplant Physician Requirements), Appendix H.2 (Primary Heart Transplant Surgeon Requirements), Appendix H.3 (Primary Heart Transplant Physician Requirements), Appendix I.2 (Primary Lung Transplant Surgeon Requirements), Appendix I.3 (Primary Lung Transplant Physician Requirements)

Pediatric Transplantation Committee

Public comment response period: January 27 – March 27, 2015

Summary and Goals of the Proposal:

Pediatric transplantation is a subspecialty within the field of transplantation. In the current OPTN Bylaws, the primary surgeon and primary physician are not required to have pediatric training or experience in order to serve as key personnel at programs that perform pediatric transplants. The Bylaws' silence on pediatric program requirements means that there is not a universal standard of quality in pediatric care, which, in the most rare and serious of circumstances, could pose a risk to patient safety. While the Pediatric Transplantation Committee (hereafter, the Committee), the MPSC, and others have attempted to establish pediatric requirements since 1993, the project has gained momentum since 2010, when the MPSC set an annual goal of developing qualification criteria for pediatric organ transplant approval. In 2012, the Board of Directors included developing separate program requirements for pediatric programs as a key initiative under Goal 4: Promote Patient Safety of the OPTN/UNOS Strategic Plan. To fulfill this key initiative, the Committee proposes that a designated transplant program must have an approved pediatric component in order to perform transplants in patients less than 18 years old. To be approved for a pediatric component, a program must identify a qualified primary pediatric surgeon and a qualified primary pediatric physician to serve as key personnel.

Background and Significance of the Proposal:

Purpose

Pediatric transplantation is a subspecialty within the field of transplantation, not unlike the 19 pediatric subspecialties recognized in other areas of medicine.¹ In the current OPTN Bylaws, the primary surgeon and primary physician are not required to have pediatric training or experience in order to serve as key personnel at programs that perform pediatric transplants. The Membership and Professional Standards Committee (MPSC) receives applications for key personnel at free-standing children's hospitals from applicants without pediatric transplantation training or experience. Since the current Bylaws do not define a pediatric program or require that applicants have pediatric training or experience to serve as key personnel, MPSC members have approved these applications despite their reservations. Programs that predominantly perform

¹ "Descriptions of Pediatric Subspecialties," Council of Pediatric Subspecialties, accessed January 5, 2015, <http://www.pedsubs.org>.

adult transplants are also not prohibited from performing the occasional pediatric transplant, regardless if key personnel have pediatric training or experience. The Bylaws' silence on pediatric program requirements means that there is not a universal standard of quality in pediatric care, which, in the most rare and serious of circumstances, could pose a risk to patient safety.

The Proposal

The Committee proposes that a designated transplant program must have an approved pediatric component in order to register or perform transplants in patients less than 18 years old. To be approved for a pediatric component, a program must identify a qualified primary pediatric surgeon and a qualified primary pediatric physician to serve as key personnel. The qualifications for these individuals are program-specific and are as follows:

Table 1. Pediatric Kidney Key Personnel Requirements

Primary Pediatric Kidney Surgeon	<ul style="list-style-type: none"> • Must meet current Bylaws for Primary Kidney Surgeon • Must have performed at least 12 kidney transplants in patients less than 18 years old • Must have maintained a current working knowledge of pediatric kidney transplantation, defined as direct involvement in pediatric kidney transplant patient care, in the last 2 years
Primary Pediatric Kidney Physician	<p>Must meet current Bylaws for Primary Kidney Physician and have completed at least one of the following training or experience pathways:</p> <ul style="list-style-type: none"> • 3-year Pediatric Nephrology Fellowship Pathway • 12-month Pediatric Transplant Nephrology Fellowship Pathway • Combined Pediatric Nephrology Training and Experience Pathway

Table 2. Pediatric Liver Key Personnel Requirements

Primary Pediatric Liver Surgeon	<ul style="list-style-type: none"> • Must meet current Bylaws for Primary Liver Surgeon • Must have performed at least 18 liver transplants in patients less than 18 years old • Must have maintained a current working knowledge of pediatric liver transplantation, defined as direct involvement in pediatric liver transplant patient care, in the last 2 years
Primary Pediatric Liver Physician	<p>Must meet current Bylaws for Primary Liver Physician and have completed at least one of the following training or experience pathways:</p> <ul style="list-style-type: none"> • 3-year Pediatric Gastroenterology Fellowship Pathway • Pediatric Transplant Hepatology Fellowship Pathway • Combined Pediatric Gastroenterology/Transplant Hepatology Training and Experience Pathway

Table 3. Pediatric Heart Key Personnel Requirements

Primary Pediatric Heart Surgeon	<ul style="list-style-type: none"> • Must meet current Bylaws for Primary Heart Surgeon • Must have performed at least 8 heart transplants in patients less than 18 years old • Must have maintained a current working knowledge of pediatric heart transplantation, defined as direct involvement in pediatric heart transplant patient care, in the last 2 years
Primary Pediatric Heart Physician	<ul style="list-style-type: none"> • Must meet current Bylaws for Primary Heart Physician

	<ul style="list-style-type: none"> • Must have current certification in pediatric cardiology by the American Board of Pediatrics • Must have been directly involved in the primary care of at least 8 heart transplant patients less than 18 years old
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Table 4. Pediatric Lung Key Personnel Requirements

Primary Pediatric Lung Surgeon	<ul style="list-style-type: none"> • Must meet current Bylaws for Primary Lung Surgeon • Must have performed at least 4 lung transplants in patients less than 18 years old • Must have maintained a current working knowledge of pediatric lung transplantation, defined as direct involvement in pediatric lung transplant patient care, in the last 2 years
Primary Pediatric Lung Physician	<ul style="list-style-type: none"> • Must meet current Bylaws for Primary Lung Physician • Either this individual or another member of the lung transplant program must have current certification or has achieved eligibility in pediatric pulmonary medicine by the American Board of Pediatrics

The proposed Bylaws also explicitly state that both the primary pediatric pancreas surgeon and physician must meet the current training and experience requirements for key personnel. This proposal does not impact programs that are currently designated as “active, approval not required.” For instance, designated liver programs will still be able to perform abdominal multivisceral transplants without separate pancreas transplant program approval.²

These new requirements replace the alternative pathways for predominantly pediatric programs that currently exist in the Bylaws. A program may qualify for conditional approval for a pediatric component for 24 months if either the primary pediatric surgeon or the primary pediatric physician meets the full requirements, and the other key personnel member meets conditional criteria. The MPSC may grant a 24 month extension to the conditional approval period if they determine substantial progress has been made toward satisfying the full requirements. Programs may take advantage of the conditional pathway when establishing a new pediatric component or to accommodate changes in key personnel at programs with an existing pediatric component.

The Development Process

The past two years of concerted effort have generated the first pediatric Bylaws proposal ever to be released for public comment. Since 1993, the MPSC, the Pediatric Transplantation Committee, and others have attempted to define a pediatric program. For 20 years, efforts have continually failed because of an inability to reach consensus on pediatric training and experience requirements.

In an effort to build consensus, the Committee has involved important stakeholders throughout the development of these proposed Bylaws, including the OPTN organ-specific committees, professional societies, and the community. In the spring of 2013, the Committee sent a formal memo to the OPTN organ-specific committees, the American Society of Transplantation (AST), the American Society of Transplant Surgeons (ASTS), and the International Society for Heart and

² Appendix D.2: Designated Transplant Program Requirement, Organ Procurement and Transplantation (OPTN) Bylaws

Lung Transplantation (ISHLT), requesting their feedback on fundamental questions for structuring the proposal. The Committee sought input on how to define a pediatric program and how to set appropriate case volume requirements. Case volume requirements have been, and remain, the most controversial aspect of this proposal and refer to the number of pediatric transplants the primary surgeon must have performed in order to demonstrate minimal expertise. Respondents to the Committee's memo generally expressed support for pediatric requirements for all programs that perform any pediatric transplants. They supported caseload requirements stratified by age, size, and other clinically-relevant factors within each organ program to reflect the diversity of pediatric transplant surgery.

After reviewing the responses, the Committee convened organ-specific working groups, comprised of both surgeons and physicians, to develop initial requirements. Endorsed by the full Committee, these initial requirements were similar to the current proposal with the exception of the transplant caseload requirements. Consistent with the feedback it received, the Committee proposed organ-specific caseload requirements for the primary pediatric surgeon that was stratified by age, size, and other clinically-relevant factors (for example, 6 kidney transplants in patients weighing 20 kilograms or less at time of transplant or 9 liver transplants in patients less than 12 years old and five technical variants, including split, reduced, or living donor liver transplants). The surgeon had to achieve the required caseload within a recent five-year period. The Committee shared this initial proposal in a memo to stakeholders that had provided feedback.

In the fall of 2013, the Committee presented the initial requirements at the regional meetings to solicit community feedback. Generally, attendees requested that the Committee consider modifications to the proposed requirements to preserve access to pediatric transplantation. As anticipated, they expressed concern that existing programs would not meet the proposed transplant caseload requirements. Some suggested that programs that perform transplants in adolescent patients be excluded from the pediatric requirements. Others recommended that the OPTN permit programs without an approved pediatric component to perform pediatric transplant in an emergency, such as acute fulminant liver failure.

In an effort to preserve access to transplantation while maintaining quality of care, the Committee has modified the key personnel requirements. In this proposal, the transplant caseload of patients less than 18 years old is not stratified by age, size, or any other clinical factor. Key personnel can achieve the required caseload over a lifetime instead of five years, so long as they demonstrate currency of pediatric transplant experience (within the last 2 years). In addition, with the support of the Thoracic Organ Transplantation Committee, thoracic caseloads have been reduced to accommodate the relative rarity of pediatric heart and lung transplantation. In the spring of 2014, the Committee shared the modified requirements in an update at the regional meetings.

However, the Committee has decided not to restrict the pediatric component requirements to programs that perform transplants in young pediatric and infant patients. Although physiologically similar to adults, adolescent patients have complex medical and psychosocial needs that are best met at programs with an approved pediatric component.^{3,4} In considering alternatives to defining

³ Kaufman, M. E. Shemesh, T. Benton. "The Adolescent Transplant Recipient." *Pediatric Clinics of North America* 57 (2010): 575-592.

⁴ Lochridge, J., J. Wolff, M. Oliva, J. O'Sullivan-Oliveira. "Perceptions of Solid Organ Transplant Recipients Regarding Self-Care Management and Transitioning." *Pediatric Nursing* 39 (2013): 81-9.

a pediatric patient, the Committee chose to retain the National Organ Transplant Act's definition of a child as less than 18 years old.⁵

The Committee also discussed but ultimately did not support an exception that would allow programs without a pediatric component to perform a pediatric transplant in an emergency, such as acute fulminant liver failure. An emergency exception was first suggested at the fall 2013 regional meetings out of concern for access to qualified programs and would require that the MPSC retrospectively review any instance in which a program without an approved pediatric component registers or transplants a patient less than 18 years old. Such an exception would represent a departure from the current standard that OPTN members must fully meet program and program component requirements in order to perform transplants. In these exceedingly rare emergencies, the Committee believes that the community is well-prepared to transport patients to qualified programs where these critical patients will be best served. Therefore, the Committee proposes that a program must have an approved pediatric component in order to register or transplant pediatric patients.

In recent months, the Committee has worked especially closely with the American Society of Transplant Surgeons (ASTS) to understand and address their concerns regarding this project. In June 2014, the Committee leadership met with the ASTS Executive Committee to discuss the proposal. The ASTS decided to convene a task force to review the proposed requirements for the primary pediatric surgeons and make specific recommendations. Committee leadership agreed not to proceed to public comment until they had considered the task force's recommendations, which the ASTS President presented to the Committee in August 2014. While the task force did not provide specific recommendations, it expressed concern regarding a lack of evidence to support a patient safety concern and a lack of data to support proposed requirements, especially transplant caseloads. The Committee chose to proceed with the current proposal despite these reservations. It believes the need for establishing a standard of quality in pediatric transplantation exists regardless of irrefutable evidence of a patient safety concern. The Committee has also since reviewed data that provides evidence of improved graft and patient survival outcomes for programs that meet the proposed case volume requirements (see "Supporting Evidence").

On December 10, 2014, the MPSC reviewed this proposal and voted to approve this proposal for public comment (24-Support, 12-Oppose, 0-Abstentions). Those opposed voiced concerns similar to those that have been raised throughout the Bylaw development process and that the Committee has systematically worked through. These concerns included the definition of a pediatric patient as less than 18 years old, access to pediatric transplantation, and quality of evidence to support either a patient safety concern or the proposed transplant caseload requirements. Those in support said that this proposal is the best progress made toward developing pediatric requirements in 20 years. The Chair encouraged the MPSC to allow this proposal to receive the benefit of broader consideration and feedback in public comment. On December 17, 2014, the Pediatric Transplantation Committee considered the feedback from the MPSC and voted to approve this proposal (12-Support, 0-Oppose, 0-Abstentions).

⁵ 42 USC Sec. 274 (b)(2)(O).

Supporting Evidence

The required number of transplants the primary surgeon must perform in order to demonstrate pediatric expertise has been, and remains, the most controversial aspect of this proposal. While the association between center case volume and recipient and graft outcomes is well-documented in the literature, the data does not provide evidence for minimal case volume requirements for individual key personnel.^{6,7,8,9} The Committee attempted to collect such data in 2002 when it surveyed 257 transplant programs, which represented 82% of the total pediatric transplants performed from 1998 to 2001. While valuable as the first census of programs performing pediatric transplants, the results did not yield significant, program-related predictors of good transplant outcomes. Therefore, as with most OPTN membership requirements involving case volume, these pediatric component requirements have been developed through clinical consensus. The Committee has intentionally limited the scope of the requirements to key personnel, including the primary pediatric surgeon and primary pediatric physician, in an effort to build consensus for these minimal criteria.

While the Committee shares the desire of others for more stringent pediatric program requirements, this proposal defines, for the first time, a standard of quality and safety in pediatric transplantation. In fact, a descriptive analysis of OPTN data showed significantly better unadjusted Kaplan-Meier graft and patient survival for pediatric transplants performed at high versus low volume kidney, liver, and heart programs from 1995-2010 ([Exhibits A-C](#)). High volume programs were determined using the proposed case volume requirements for each organ, i.e., at least 12 kidney transplants, 18 liver transplants, 8 heart transplants, and 4 lung transplants. While high-volume lung transplant programs also experienced better patient survival outcomes, the difference was not statistically significant ([Exhibit D](#)).

The Committee is also satisfied that the modifications made to the proposal as a result of the Fall 2013 regional meetings have better balanced the competing interests of quality of care and access to transplantation. Of the 383 programs that performed at least one pediatric kidney, liver, heart, or lung transplant from January 1, 2005 to July 31, 2014, 61% (235) met the case volume requirement ([Exhibit E](#)). This assumes that the primary pediatric surgeon performed the transplant or served as the first assistant and is likely an underestimate of the number of programs that would currently qualify, since historically having performed a pediatric transplant does not indicate current practice. In general, programs that do not currently meet the case volume requirement are also located in proximity to those that do, ensuring equitable access geographically to pediatric transplantation ([Exhibits F-I](#)).

Expected Impact on Living Donors or Living Donation:

Only pediatric programs with a pediatric component will be able to transplant a living donor organ into a recipient less than 18 years old. Otherwise, no expected impact on living donors or living donation.

⁶ Schurman, S.J., D.M. Stablein, S.A. Perlman, B.A. Warady. "Center volume effects in pediatric renal transplantation." *Pediatric Nephrology* 13 (1999): 373-378.

⁷ Edwards, E.B., J.P. Roberts, M.A. McBride, et al. "The effect of the volume of procedures at transplantation center on mortality after liver transplantation." *NEJM* 341 (1999): 2049-2053.

⁸ Shuhaiber, J.H., J. Moore, D.B. Dyke. "The effect of transplant center volume on survival after heart transplantation: a multicenter study." *Journal of Thoracic and Cardiovascular Surgery* 139 (2010): 1064-1069.

⁹ Kilic, A., T.J. George, C.A. Beaty, et al. "The effect of center volume on the incidence of postoperative complications and their impact on survival after lung transplantation." *Journal of Thoracic and Cardiovascular Surgery* 144 (2012): 1502-1509.

Expected Impact on Specific Patient Populations:

By establishing pediatric training and experience requirements for key personnel, this proposal seeks to promote safety and quality of care for pediatric candidates and recipients.

Expected Impact on Program Goals, Strategic Plan, and Adherence to OPTN Final Rule:

In 2012, the Board of Directors included developing separate program requirements for pediatric programs as a key initiative under Goal 4: Promote Patient Safety of the OPTN/UNOS Strategic Plan. The Board has charged the Pediatric Committee with developing a Bylaws proposal that fulfills this key initiative.

Plan for Evaluating the Proposal:

The submission of applications and the successful designation and approval of pediatric program components at member transplant hospitals will be the basis for evaluating this proposal.

- The number of approved pediatric components will be monitored by organ periodically during the 3-year delayed implementation period and at 3-6 months following full implementation of the policy
- The number of pediatric transplants will be tabulated by center and organ periodically during the 3-year delayed implementation period and at 6-12 months following full implementation of the policy, and compared to the number of transplants prior to the implementation of the policy.

Additional Data Collection:

Pediatric component application forms will be similar to existing transplant program application forms and will require Office of Management and Budget (OMB) approval. New information collection will be limited to the training and experience qualifications of the pediatric key personnel, as detailed in this proposal.

Expected Implementation Plan:

If public comment is favorable, this proposal will be reviewed by the Board of Directors at their meeting in June 2015. If approved, these proposed Bylaws will be implemented pending programming and notice to members. Upon implementation, only transplant programs with an approved pediatric component will be permitted to register and transplant patients younger than 18 years of age. To assure that members have adequate time to prepare for these changes, these Bylaws will be implemented no sooner than three years after the OPTN/UNOS Board of Directors' adoption of these proposed changes. During this time, UNOS will provide updates on the pending implementation date and educational opportunities to help prepare for the implementation of these Bylaws.

Implementing these Bylaws will require substantial programming changes to UNetSM and the UNOS membership database. Following completion of the programming changes, there will be a 90-day period for members to submit OPTN transplant program pediatric component applications. The proposed Bylaws will then be slated for implementation 18 months after the conclusion of the 90-day pediatric component application submission period. During these 18 months, UNOS and the MPSC will process each application received before the pediatric component application deadline. Members will be alerted of the status of all processed applications before the

implementation date. Specifically, applying hospitals will be told that the MPSC will recommend that the Board of Directors approve their pediatric component (and that they may register and transplant pediatric patients upon the implementation of these Bylaws), or that their application has been rejected and the reason why.

Every application received during the 90-day pediatric component application submission period will be acted on prior to the implementation of these proposed Bylaws. Pediatric component applications submitted after the deadline will be processed in the order they are received. UNOS and the MPSC will strive to act on every application it receives before the proposed Bylaws' implementation date; however, applications received after the established deadline may not be processed before the implementation date of these proposed Bylaws. Timely submission of a transplant program's pediatric component application will be critical in obtaining pediatric component approval before the implementation of these proposed Bylaws.

UNOS will notify members as the necessary programming changes near completion. This notification will also detail when the 90-day pediatric component application submission period will occur. At this time, every member transplant program that has had at least one pediatric patient on their waiting list in the previous five years will receive an OPTN transplant program pediatric component application. OPTN transplant program pediatric component applications will be structured similarly to current transplant program application forms, also incorporating the additional pediatric key personnel elements established by these proposed Bylaws. Transplant programs that receive this packet will be asked to complete all requisite information to apply for a pediatric component, and submit the application before the conclusion of the 90-day pediatric component application period. Transplant programs that receive this packet but do not intend to apply for a pediatric component will be asked to document this in writing and submit that to UNOS. Transplant programs that do not receive this packet but wish to apply for a pediatric component should contact the UNOS Membership Analyst for their region to obtain an application and the necessary instructions, once the 90-day pediatric component application period is announced.

Upon implementation, any program without pediatric component approval that has pediatric patients on its waitlist must follow the transition plan described in OPTN Bylaws Appendix K.5 (Transition Plan during Long-term Inactivity, Termination, or Withdrawal) for the pediatric patients on its list.

Communication and Education Plan:

The OPTN will follow established protocols to inform members of the public comment period and educate them on any policy changes through Policy Notices. The OPTN plans to advertise instructional webinars on its family of websites. It will also host breakout sessions at professional conferences to educate transplant programs on the pediatric component application process. Finally, the OPTN will communicate when the pediatric component applications are released and due, as well as release System Notices before and on implementation day.

This proposal will be monitored for potential instructional opportunities, in order to give members, professionals and the transplant community an avenue to gain information, ask questions, and modify processes, if necessary. This proposal will continue to be monitored for instructional needs based on any process changes (i.e. application submission) or additional resources (i.e. work instructions or guidance).

Compliance Monitoring:

The MPSC will review the initial pediatric component applications to determine compliance with these proposed Bylaws. Upon implementation, the OPTN Contractor will facilitate the key personnel change process and the MPSC will review key personnel change applications to ensure ongoing compliance with the Bylaws when changes to a transplant program's primary pediatric surgeon or primary pediatric physician occur.

Also upon implementation, the OPTN Contractor will monitor any transplant program that does not have an approved pediatric component but has pediatric candidates on its waiting list to verify that the program is complying with patient notification and transition plan requirements specified in OPTN Bylaws Appendix K. Monitoring of the transition plans will include:

- Reviewing the written notice sent to pediatric candidates and pediatric potential candidates
- Reviewing routine reports documenting the program's progress in transferring pediatric candidates and pediatric potential candidates to transplant programs approved to perform pediatric transplants

The OPTN Contractor will refer a transplant program to the MPSC for further review of its transition plan if the program fails to:

- Notify its pediatric candidates and potential candidates in the time and manner required
- Submit required information to the OPTN Contractor in the time and manner required

The proposed language will not change the current routine site surveys of OPTN members. Any data entered in UNetSM may be subject to OPTN review, and members are required to provide documentation as requested.

Bylaw Proposal:

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

~~C. Alternative Pathway for Predominantly Pediatric Programs~~

~~If a surgeon does not meet the requirements for primary kidney transplant surgeon through either the transplant fellowship pathway or clinical experience pathway as described above, transplant programs that serve predominantly pediatric patients may petition the MPSC in writing to consider the surgeon for primary transplant surgeon if the program can demonstrate that the following conditions are met:~~

- ~~1. The surgeon's kidney transplant training or experience is equivalent to the fellowship or clinical experience pathways as described in Sections E.2.A or E.2.B above.~~

2. ~~The surgeon has maintained a current working knowledge of all aspects of kidney transplantation and patient care, defined as direct involvement in kidney transplant patient care within the last 2 years.~~
3. ~~The surgeon submits a letter of recommendation from the primary surgeon and transplant program director of the fellowship training program or transplant program last served by the surgeon outlining the surgeon's overall qualifications to act as a primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.~~
4. ~~The hospital participates in an informal discussion with the MPSC.~~

~~The MPSC or an Ad Hoc Subcommittee of at least 4 MPSC members appointed by the MPSC Chair is authorized to conduct the informal discussion and make an interim determination. Interim determinations are:~~

- ~~■ Advisory to the MPSC, Board of Directors, or both, who have the final authority to grant approval of a designated transplant program.~~
- ~~■ Effective temporarily, pending final decision by the MPSC or Board of Directors.~~

~~Any application recommended for rejection by the MPSC or the Board of Directors may entitle the applicant to due process as specified in *Appendix L: Reviews, Actions, and Due Process* of these Bylaws.~~

E.3 Primary Kidney Transplant Physician Requirements

F. ~~Alternative Pathway for Predominantly Pediatric Programs~~

~~If a physician does not meet the requirements for primary physician through any of the transplant fellowship or clinical experience pathways as described above, transplant programs that serve predominantly pediatric patients may petition the MPSC in writing to consider the physician for primary transplant physician if the program can demonstrate that the following conditions are met:~~

1. ~~That the physician's kidney transplant training or experience is equivalent to the fellowship or clinical experience pathways as described in *Sections E.3.A through E.3.E* above.~~
2. ~~The physician has maintained a current working knowledge of all aspects of kidney transplantation, defined as direct involvement in kidney transplant patient care within the last 2 years.~~
3. ~~The physician receives a letter of recommendation from the primary physician and transplant program director of 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 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.~~
4. ~~The hospital participates in an informal discussion with the MPSC.~~

~~The MPSC or an Ad Hoc Subcommittee of at least 4 MPSC members appointed by the MPSC Chair is authorized to conduct the informal discussion and make an interim determination. Interim decisions are:~~

- ~~▪ Advisory to the MPSC, Board of Directors, or both, which has the final authority to grant approval of a designated transplant program.~~
- ~~▪ Effective temporarily, pending final decision by the MPSC or Board.~~

~~Any application recommended for rejection by the MPSC or the Board of Directors may entitle the applicant to due process as specified in *Appendix L: Reviews, Actions, and Due Process* of these Bylaws.~~

G.F. Conditional Approval for Primary Transplant Physician

E.5 Kidney Transplant Programs that Perform Transplants in Patients Less than 18 Years Old

A designated kidney transplant program that performs transplants in patients less than 18 years old must have an approved pediatric component. To be approved for a pediatric component, the designated kidney transplant program must identify a qualified primary pediatric kidney transplant surgeon and a qualified primary pediatric kidney transplant physician, as described below.

A. Primary Pediatric Kidney Transplant Surgeon Requirements

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

1. The surgeon meets *all* of the requirements described in *Section E.2: Primary Kidney Transplant Surgeon Requirements*, including completion of at least *one* of the following training or experience pathways:
 - The formal 2-year transplant fellowship pathway as described in *Section E.2.A: Formal 2-year Transplant Fellowship Pathway*
 - The kidney transplant program clinical experience pathway, as described in *Section E.2.B: Clinical Experience Pathway*
2. The surgeon has performed at least 12 kidney transplants, as the primary surgeon or first assistant, in patients less than 18 years old. These transplants must have been performed during or after fellowship, or across both periods. 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.
3. The surgeon has maintained a current working knowledge of pediatric kidney transplantation, defined as direct involvement in pediatric kidney transplant patient care in the last two years. This includes the management of pediatric patients with end stage renal disease, the selection of appropriate pediatric recipients for transplantation, donor selection, HLA 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.

B. Primary Pediatric Kidney Transplant Physician Requirements

A pediatric component at a designated kidney transplant program must have a primary pediatric physician who meets all of the requirements described in Section E.3: Primary Kidney Transplant Physician Requirements. In addition, the primary pediatric transplant physician must have completed at least one of the training or experience pathways listed below:

- The 3-year pediatric nephrology fellowship pathway, as described in Section E.3.C: Three-year Pediatric Nephrology Fellowship Pathway
- The 12-month pediatric transplant nephrology fellowship pathway, as described in Section E.3.D: Twelve-month Pediatric Transplant Nephrology Fellowship Pathway
- The combined pediatric nephrology training and experience pathway, as described in Section E.3.E: Combined Pediatric Nephrology Training and Experience Pathway

C. Conditional Approval for a Pediatric Component

A designated kidney transplant program can obtain conditional approval for a pediatric component if either of the following conditions is met:

1. The program has a qualified primary pediatric kidney physician who meets all of the requirements described in Section E.5.B: Primary Pediatric Kidney Transplant Physician Requirements and a surgeon who meets all of the following requirements:
 - a. The surgeon meets all of the requirements described in Section E.2: Primary Kidney Transplant Surgeon Requirements, including completion of at least one of the following training or experience pathways:
 - i. The formal 2-year transplant fellowship pathway as described in Section E.2.A: Formal 2-year Transplant Fellowship Pathway
 - ii. The kidney transplant program clinical experience pathway, as described in Section E.2.B: Clinical Experience Pathway
 - b. The surgeon has performed at least 6 kidney transplants, as the primary surgeon or first assistant, in patients less than 18 years old. These transplants must have been performed during or after fellowship, or across both periods. 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.
 - c. The surgeon has maintained a current working knowledge of pediatric kidney transplantation, defined as direct involvement in pediatric kidney transplant patient care in the last two 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 HLA typing, performing the pediatric 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.
2. The program has a qualified primary pediatric kidney surgeon who meets all of the requirements described in Section E.5.A: Primary Pediatric Kidney Transplant Surgeon Requirements and a physician who meets all of the following requirements:
 - a. 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.
 - b. The physician gained a minimum of 2 years of experience during or after fellowship, or

- accumulated during both periods, at a kidney transplant program.
- c. During the 2 or more years of accumulated experience, the physician was directly involved in the primary care of 5 or more newly transplanted kidney recipients and followed 15 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.
 - d. The physician has maintained a current working knowledge of pediatric 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 HLA 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 recipients 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.
 - e. The physician should have observed at least 3 organ procurements and 3 pediatric kidney transplants. The physician should also have observed the evaluation, the donation process, and management of at least 3 multiple organ donors who donated a kidney. If the physician has completed these observations, they must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
 - f. The following letters are submitted directly to the OPTN Contractor:
 - i. A letter from the supervising qualified transplant physician and surgeon who were directly involved with the physician documenting the physician's experience and competence.
 - ii. 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 pediatric surgeon, Director, or others affiliated with any transplant program previously served by the physician, at its discretion.
 - iii. A letter from the physician that details the training and experience the physician has gained in kidney transplantation.

A designated kidney transplant program's conditional approval for a pediatric component is valid for a maximum of 24 months.

D. Full Approval for a Pediatric Component following Conditional Approval

The conditional approval period begins on the first approval date granted to the pediatric component application, whether it is interim approval granted by the MPSC subcommittee, or approval granted by the full MPSC. The conditional approval period ends 24 months after first approval date of the pediatric component application.

The MPSC can consider granting a 24-month conditional approval extension to the designated kidney transplant for its pediatric component if the program provides substantial evidence of progress toward fulfilling the requirements, but is unable to complete *all* of the requirements within the initial 24-month period.

Once the designated kidney transplant program has met the full approval requirements for the pediatric component, the program may petition the OPTN Contractor for full approval.

If the designated kidney transplant program is unable to demonstrate that it has both a pediatric primary kidney surgeon onsite that meets *all* of the requirements as described in *Section E.5.A: Primary Pediatric Kidney Transplant Surgeon Requirements* and a pediatric primary kidney physician onsite that meets *all* of the requirements as described in *Section E.5.B: Primary Pediatric Kidney Transplant Physician Requirements* at the end of the 24-month conditional approval period, it must inactivate its pediatric component as described in *Appendix K: Transplant Program Inactivity, Withdrawal, and Termination*.

E.56 Kidney Transplant Programs that Perform Living Donor Recovery

Appendix F: Membership and Personnel Requirements for Liver Transplant Programs

F.2 Primary Liver Transplant Surgeon Requirements

C. ~~Alternative Pathway for Predominantly Pediatric Programs~~

~~If a surgeon does not meet the requirements for primary liver transplant surgeon through either the 2-year transplant fellowship pathway or clinical experience pathway as described above, transplant programs that serve predominantly pediatric patients may petition the MPSC in writing to consider the surgeon for primary transplant surgeon if the program can demonstrate that the following conditions are met:~~

- ~~1. The surgeon's liver transplant training or experience is equivalent to the fellowship or clinical experience pathways as described in *Sections F.2.A or F.2.B* above.~~
- ~~2. The surgeon has maintained a current working knowledge of all aspects of liver transplantation and patient care, defined as direct involvement in liver transplant patient care within the last 2 years.~~
- ~~3. The surgeon submits a letter of recommendation from the primary surgeon and transplant program director at the fellowship training program or transplant program last served by the surgeon outlining the surgeon's overall qualifications to act as a primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.~~
- ~~4. The hospital participates in an informal discussion with the MPSC.~~

~~The MPSC or an Ad Hoc Subcommittee of at least 4 MPSC members appointed by the MPSC Chair is authorized to conduct the informal discussion and make an interim determination. Interim determinations are:~~

- ~~▪—Advisory to the MPSC, Board of Directors, or both, who have the final authority to grant approval of a designated transplant program.~~
- ~~▪—Effective temporarily, pending final decision by the MPSC or Board.~~

~~Any application recommended for rejection by the MPSC or the Board of Directors may entitle the applicant to due process as specified in *Appendix L: Reviews, Actions, and Due Process* of these Bylaws.~~

F.3 Primary Liver Transplant Physician Requirements

~~F. Alternative Pathway for Predominantly Pediatric Programs~~

~~If a physician does not meet the requirements for primary physician through any of the transplant fellowship or clinical experience pathways as described above, transplant programs that serve predominantly pediatric patients may petition the MPSC in writing to consider the physician for primary transplant physician if the program can demonstrate that the following conditions are met:~~

- ~~1.—That the physician’s liver transplant training or experience is equivalent to the fellowship or clinical experience pathways as described in *Sections F.3.A through F.3.E* above.~~
- ~~2.—The physician has maintained a current working knowledge of all aspects of liver transplantation, defined as direct involvement in liver transplant patient care within the last 2 years.~~
- ~~3.—The physician submits 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.~~
- ~~4.—The hospital participates in an informal discussion with the MPSC.~~

~~The MPSC or an Ad Hoc Subcommittee of at least 4 MPSC members appointed by the MPSC Chair is authorized to conduct the informal discussion and make an interim determination. Interim decisions are:~~

- ~~▪—Advisory to the MPSC, Board of Directors, or both, which has the final authority to grant approval of a designated transplant program.~~
- ~~▪—Effective temporarily, pending final decision by the MPSC or Board.~~

~~Any application recommended for rejection by the MPSC or the Board of Directors may entitle the applicant to due process as specified in *Appendix L: Reviews, Actions, and Due Process* of these Bylaws.~~

G.F. Conditional Approval for Primary Transplant Physician

F.6 Liver Transplant Programs that Perform Transplants in Patients Less than 18 Years Old

A designated liver transplant program that performs transplants in patients less than 18 years old must have an approved pediatric component. To be approved for a pediatric component, the designated liver transplant program must identify a qualified primary pediatric liver transplant surgeon and a qualified primary pediatric liver transplant physician, as described below.

A. Primary Pediatric Liver Transplant Surgeon Requirements

A pediatric component at a designated liver transplant program must have a primary pediatric surgeon who meets all of the following requirements:

1. The surgeon meets all of the requirements described in Section F.2: Primary Liver Transplant Surgeon Requirements, including completion of at least one of the following training or experience pathways:
 - The formal 2-year transplant fellowship pathway as described in Section F.2.A: Formal 2-year Transplant Fellowship Pathway
 - The liver transplant program clinical experience pathway, as described in Section F.2.B: Clinical Experience Pathway
2. The surgeon has performed at least 18 liver transplants, as the primary surgeon or first assistant, in patients less than 18 years old. These transplants must have been performed during or after fellowship, or across both periods. 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.
3. The surgeon has maintained a current working knowledge of pediatric liver transplantation, defined as direct involvement in pediatric 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 HLA typing, performing the pediatric 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.

B. Primary Pediatric Liver Transplant Physician Requirements

A pediatric component at a designated liver transplant program must have a primary pediatric physician who meets all of the requirements described in Section F.3: Primary Liver Transplant Physician Requirements. In addition, the primary pediatric transplant physician must have completed at least one of the training or experience pathways listed below:

- The 3-year pediatric gastroenterology fellowship pathway, as described in Section F.3.C: Three-year Pediatric Gastroenterology Fellowship Pathway
- The 12-month pediatric transplant hepatology fellowship pathway, as described in Section F.3.D: Pediatric Transplant Hepatology Fellowship Pathway
- The combined pediatric gastroenterology or transplant hepatology training and experience pathway, as described in Section F.3.E: Combined Pediatric Gastroenterology/Transplant Hepatology Training and Experience Pathway

C. Conditional Approval for a Pediatric Component

A designated liver transplant program can obtain conditional approval for a pediatric component if either of the following conditions is met:

1. The program has a qualified primary pediatric liver physician who meets all of the requirements described in Section F.6.B: Primary Pediatric Liver Transplant Physician Requirements and a surgeon who meets all of the following requirements:
 - a. The surgeon meets all of the requirements described in Section F.2: Primary Liver Transplant Surgeon Requirements, including completion of at least one of the following training or experience pathways:
 - i. The formal 2-year transplant fellowship pathway as described in Section F.2.A: Formal 2-year Transplant Fellowship Pathway
 - ii. The liver transplant program clinical experience pathway, as described in Section F.2.B: Clinical Experience Pathway
 - a. The surgeon has performed at least 9 liver transplants, as the primary surgeon or first assistant, in patients less than 18 years old. These transplants must have been performed during or after fellowship, or across both periods. 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.
 - b. The surgeon has maintained a current working knowledge of pediatric liver transplantation, defined as direct involvement in pediatric 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 HLA 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.
2. The program has a qualified primary pediatric liver surgeon who meets all of the requirements described in Section F.6.A: Primary Pediatric Liver Transplant Surgeon Requirements and a physician who meets all of the following requirements:
 - a. 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.
 - b. The physician gained a minimum of 2 years of experience during or after fellowship, or accumulated during both periods, at a liver transplant program.
 - c. During the 2 or more years of accumulated experience, the physician was directly involved in the primary care of 5 or more newly transplanted pediatric liver recipients and followed 10 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 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.
 - d. The individual has maintained a current working knowledge of pediatric liver transplantation, defined as direct involvement in pediatric 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.
- e. The physician should have observed at least 3 organ procurements and 3 liver transplants. In addition, the physician should have observed the evaluation of donor, the donation process, and the management of at least 3 multiple organ donors who donated a liver. If the physician has completed these observations, they must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
 - f. The following letters are submitted directly to the OPTN Contractor:
 - i. 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.
 - ii. 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.
 - iii. A letter from the physician that details the training and experience the physician gained in liver transplantation.

A designated liver transplant program's conditional approval for a pediatric component is valid for a maximum of 24 months.

D. Full Approval for a Pediatric Component following Conditional Approval

The conditional approval period begins on the first approval date granted to the pediatric component application, whether it is interim approval granted by the MPSC subcommittee, or approval granted by the full MPSC. The conditional approval period ends 24 months after first approval date of the pediatric component application.

The MPSC may consider granting a 24-month conditional approval extension to the designated liver transplant for its pediatric component if the program provides substantial evidence of progress toward fulfilling the requirements, but is unable to complete *all* of the requirements within the initial 24-month period.

Once the designated liver transplant program has met the full approval requirements for the pediatric component, the program may petition the OPTN Contractor for full approval.

If the designated liver transplant program is unable to demonstrate that it has both a pediatric primary liver surgeon onsite that meets *all* of the requirements as described in *Section F.6.A: Pediatric Primary Liver Transplant Surgeon Requirements* and a pediatric primary liver physician onsite that meets *all* of the requirements as described in *Section F.6.B: Pediatric Primary Liver Transplant Physician Requirements* at the end of the 24-month conditional approval period, it must inactivate its pediatric component as described in *Appendix K: Transplant Program Inactivity, Withdrawal, and Termination*.

F.67 Liver Transplant Programs that Perform Living Donor Recovery

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

G.2 Primary Pancreas Transplant Surgeon Requirements

C. ~~Alternate Pathway for Predominantly Pediatric Programs~~

~~If a surgeon does not meet the requirements for primary pancreas transplant surgeon through either the 2-year transplant fellowship pathway or clinical experience pathway as described above, transplant programs that serve predominantly pediatric patients may petition the MPSC in writing to consider the surgeon for primary transplant surgeon if the program can demonstrate that the following conditions are met:~~

- ~~1. The surgeon's pancreas transplant training or experience is equivalent to the fellowship or clinical experience pathways as described in Sections G.2.A or G.2.B above.~~
- ~~2. The surgeon has maintained a current working knowledge of all aspects of pancreas transplantation and patient care, defined as direct involvement in pancreas transplant patient care within the last 2 years.~~
- ~~3. The surgeon submits a letter of recommendation from the training program's primary surgeon and director at the fellowship training program or transplant program last served by the surgeon outlining the surgeon's overall qualifications to act as a primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.~~
4. The hospital participates in an informal discussion with the MPSC.

~~The MPSC or an Ad Hoc Subcommittee of at least 4 MPSC members appointed by the MPSC Chair is authorized to conduct the informal discussion and make an interim determination. Interim determinations are:~~

- ~~▪ Advisory to the MPSC, Board of Directors, or both, who have the final authority to grant approval of a designated transplant program.~~
- ~~▪ Effective temporarily, pending final decision by the MPSC or Board.~~

~~Any application recommended for rejection by the MPSC or the Board of Directors may entitle the applicant to due process as specified in Appendix L: Reviews, Actions, and Due Process of these Bylaws.~~

G.3 Primary Pancreas Transplant Physician Requirements

~~C. Alternative Pathway for Predominantly Pediatric Programs~~

~~If a physician does not meet the requirements for primary physician through the transplant fellowship or clinical experience pathways as described above, transplant programs that serve predominantly pediatric patients may petition the MPSC in writing to consider the physician for primary transplant physician if the program can demonstrate that the following conditions are met:~~

- ~~1. That the physician's pancreas transplant training or experience is equivalent to the fellowship or clinical experience pathways as described in Sections G.3.A and G.3.B above.~~
- ~~2. The physician has maintained a current working knowledge of all aspects of pancreas transplantation, defined as direct involvement in pancreas transplant patient care within the last 2 years.~~
- ~~3. The physician submits a letter of recommendation from the primary physician and transplant program director at the fellowship 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.~~
- ~~4. The hospital participates in an informal discussion with the MPSC.~~

~~The MPSC or an Ad Hoc Subcommittee of at least 4 MPSC members appointed by the MPSC Chair is authorized to conduct the informal discussion and make an interim determination. Interim decisions are:~~

- ~~▪ Advisory to the MPSC, Board of Directors, or both, which has the final authority to grant approval of a designated transplant program.~~
- ~~▪ Effective temporarily, pending final decision by the MPSC or Board.~~

~~Any application recommended for rejection by the MPSC or the Board of Directors may entitle the applicant to due process as specified in Appendix L: Reviews, Actions, and Due Process of these Bylaws.~~

D.C. Conditional Approval for Primary Transplant Physician

G.8 Pancreas Transplant Programs that Perform Transplants in Patients Less than 18 Years Old

A designated pancreas transplant program that performs transplants in patients less than 18 years old must have an approved pediatric component. To be approved for a pediatric component, the designated pancreas transplant program must identify a qualified primary pediatric pancreas transplant surgeon and a qualified primary pediatric pancreas transplant physician, as described below.

A. Primary Pediatric Pancreas Transplant Surgeon Requirements

A pediatric component at a designated pancreas transplant program must have a primary pediatric surgeon who meets all of the requirements described in Section G.2: Primary Pancreas Transplant Surgeon Requirements.

B. Primary Pediatric Pancreas Transplant Physician Requirements

A pediatric component at a designated pancreas transplant program must have a primary pediatric physician who meets all of the requirements described in Section G.3: Primary Pancreas Transplant Physician Requirements.

Appendix H: Membership and Personnel Requirements for Heart Transplant Programs

H.2 Primary Heart Transplant Surgeon Requirements

~~D. Alternative Pathway for Predominantly Pediatric Programs~~

~~If a surgeon does not meet the requirements for primary heart transplant surgeon through either the training or clinical experience pathways described above, hospitals that serve predominantly pediatric patients may petition the MPSC in writing to consider the surgeon for primary transplant surgeon if the program can demonstrate that the following conditions are met:~~

- ~~1. The surgeon's heart transplant training or experience is equivalent to the residency, fellowship, or clinical experience pathways as described in Sections H.2.A through H.2.C above.~~
- ~~2. The surgeon has maintained a current working knowledge of all aspects of heart transplantation and patient care, defined as direct involvement in heart transplant patient care within the last 2 years.~~
- ~~3. The surgeon submits a letter of recommendation from the primary surgeon and transplant program director at the training program or transplant program last served by the surgeon outlining the surgeon's overall qualifications to act as a primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.~~
- ~~4. The hospital participates in an informal discussion with the MPSC.~~

~~The MPSC or an Ad Hoc Subcommittee of at least 4 MPSC members appointed by the MPSC Chair is authorized to conduct the informal discussion and make an interim determination. Interim determinations are:~~

- ~~■ Advisory to the MPSC, Board of Directors, or both, who have the final authority to grant approval of a designated transplant program.~~
- ~~■ Effective temporarily, pending final decision by the MPSC or Board.~~

~~Any application recommended for rejection by the MPSC or the Board of Directors may entitle the applicant to due process as specified in Appendix L: Reviews, Actions, and Due Process of these Bylaws.~~

H.3 Primary Heart Transplant Physician Requirements

~~C. Alternative Pathway for Predominantly Pediatric Programs~~

~~If a physician does not meet the requirements for primary physician through any of the transplant fellowship or clinical experience pathways as described above, hospitals that serve predominantly pediatric patients may petition the MPSC in writing to consider the physician for primary transplant physician if the program can demonstrate that the following conditions are met:~~

- ~~1. That the physician's heart transplant training or experience is equivalent to the fellowship or clinical experience pathways as described in Sections H.3.A and H.3.B above.~~
- ~~2. The physician has maintained a current working knowledge of all aspects of heart transplantation, defined as direct involvement in heart transplant patient care within the last 2 years.~~
- ~~3. The physician submits a letter of recommendation from the primary physician and transplant program director of 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 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.~~
- ~~4. The hospital participates in an informal discussion with the MPSC.~~

~~The MPSC or an Ad Hoc Subcommittee of at least 4 MPSC members appointed by the MPSC Chair is authorized to conduct the informal discussion and make an interim determination. Interim decisions are:~~

- ~~■ Advisory to the MPSC, Board of Directors, or both, which has the final authority to grant approval of a designated transplant program.~~
- ~~■ Effective temporarily, pending final decision by the MPSC or Board.~~

~~Any application recommended for rejection by the MPSC or the Board of Directors may entitle the applicant to due process as specified in Appendix L: Reviews, Actions, and Due Process of these Bylaws.~~

~~D.C. Conditional Approval for Primary Transplant Physician~~

H.4 Heart Transplant Programs that Perform Transplants in Patients Less than 18 Years Old

A designated heart transplant program that performs transplants in patients less than 18 years old must have an approved pediatric component. To be approved for a pediatric component, the designated heart transplant program must identify a qualified primary pediatric heart transplant surgeon and a qualified primary pediatric heart transplant physician, as described below.

A. Primary Pediatric Heart Transplant Surgeon Requirements

A pediatric component at a designated heart transplant program must have a primary pediatric surgeon who meets all of the following requirements:

1. The surgeon meets all of the requirements described in *Section H.2: Primary Heart Transplant Surgeon Requirements*.
2. The surgeon has performed at least 8 heart transplants, as the primary surgeon or first assistant, in patients less than 18 years old. These transplants must have been performed during or after fellowship, or across both periods. 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.
3. The surgeon has maintained a current working knowledge of all aspects of pediatric heart transplantation, defined as a direct involvement in pediatric heart transplant patient care within the last 2 years. This includes performing the pediatric transplant operation, donor selection, use of mechanical assist devices, pediatric recipient selection, post-operative hemodynamic care, post-operative immunosuppressive therapy, and outpatient follow up.

B. Primary Pediatric Heart Transplant Physician Requirements

A pediatric component at a designated heart transplant program must have a primary pediatric physician who meets all of the following requirements:

1. The physician meets all of the requirements described in *Section H.3: Primary Heart Transplant Physician Requirements* and has current certification in pediatric cardiology by the American Board of Pediatrics.
2. The physician has been directly involved in the primary care of at least 8 heart transplant patients less than 18 years old. These transplants must have been performed during or after fellowship, or across both periods. 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.

C. Conditional Approval for a Pediatric Component

A designated heart transplant program can obtain conditional approval for a pediatric component if either of the following conditions is met:

1. The program has a qualified primary pediatric heart physician who meets all of the requirements described in *Section H.4.B: Primary Pediatric Heart Transplant Physician Requirements* and a surgeon who meets all of the following requirements:
 - a. The surgeon meets all of the requirements described in *Section H.2: Primary Heart Transplant Surgeon Requirements*, including completion of at least one of the following training or experience pathways:
 - i. The formal cardiopathic surgery residency pathway, as described in *Section H.2.A: Cardiothoracic Surgery Residency Pathway*
 - ii. The 12-month heart transplant fellowship pathway, as described in *Section H.2.B: Twelve-month Heart Transplant Fellowship Pathway*
 - iii. The heart transplant program clinical experience pathway, as described in *Section H.2.C: Clinical Experience Pathway*
 - b. The surgeon has performed at least 4 heart transplants, as the primary surgeon or first assistant, in patients less than 18 years old. These transplants must have been performed during or after fellowship, or across both periods. 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.
- c. The surgeon maintained a current working knowledge of all aspects of pediatric heart transplantation, defined as a direct involvement in pediatric heart transplant patient care within the last 2 years. This includes performing the transplant operation, donor selection, use of mechanical assist devices, pediatric recipient selection, post-operative hemodynamic care, post-operative immunosuppressive therapy, and outpatient follow up.
2. The program has a qualified primary pediatric heart surgeon who meets all of the requirements described in *Section H.4.A: Primary Pediatric Heart Transplant Surgeon Requirements* and a physician who meets all of the following requirements:
 - a. The physician meets all of the requirements described in *Section H.3: Primary Heart Transplant Physician Requirements* and has current certification in pediatric cardiology by the American Board of Pediatrics.
 - b. The physician has been directly involved in the primary care of at least 4 heart transplant patients less than 18 years old. These transplants must have been performed during or after fellowship, or across both periods. 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.

A designated heart transplant program's conditional approval for a pediatric component is valid for a maximum of 24 months.

D. Full Approval for a Pediatric Component following Conditional Approval

The conditional approval period begins on the first approval date granted to the pediatric component application, whether it is interim approval granted by the MPSC subcommittee, or approval granted by the full MPSC. The conditional approval period ends 24 months after first approval date of the pediatric component application.

The MPSC may consider granting a 24-month conditional approval extension to the designated heart transplant for its pediatric component if the program provides substantial evidence of progress toward fulfilling the requirements, but is unable to complete all of the requirements within the initial 24-month period.

Once the designated heart transplant program has met the full approval requirements for the pediatric component, the program may petition the OPTN Contractor for full approval.

If the designated heart transplant program is unable to demonstrate that it has both a primary pediatric heart surgeon onsite that meets all of the requirements as described in *Section H.4.A: Primary Pediatric Heart Transplant Surgeon Requirements* and a primary pediatric heart physician onsite that meets all of the requirements as described in *Section H.4.B: Primary Pediatric Heart Transplant Physician Requirements* at the end of the 24-month conditional approval period, it must inactivate its pediatric component as described in *Appendix K: Transplant Program Inactivity, Withdrawal, and Termination*.

Appendix I: Membership and Personnel Requirements for Lung Transplant Programs

I.2 Primary Lung Transplant Surgeon Requirements

~~D. Alternative Pathway for Predominantly Pediatric Programs~~

~~If a surgeon does not meet the requirements for primary lung transplant surgeon through either the training or clinical experience pathways described above, hospitals that serve predominantly pediatric patients may petition the MPSC in writing to consider the surgeon for primary transplant surgeon if the program can demonstrate that the following conditions are met:~~

- ~~1. The surgeon's lung transplant training or experience is equivalent to the residency, fellowship, or clinical experience pathways as described in Sections 1.2.A through 1.2.C above.~~
- ~~2. The surgeon has maintained a current working knowledge of all aspects of lung transplantation and patient care, defined as direct involvement in lung transplant patient care within the last 2 years.~~
- ~~3. The surgeon submits a letter of recommendation from the primary surgeon and transplant program director of the fellowship training program or transplant program last served by the surgeon outlining the surgeon's overall qualifications to act as a primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.~~
- ~~4. The hospital participates in an informal discussion with the MPSC.~~

~~The MPSC or an Ad Hoc Subcommittee of at least 4 MPSC members appointed by the MPSC Chair is authorized to conduct the informal discussion and make an interim determination. Interim determinations are:~~

- ~~■ Advisory to the MPSC, Board of Directors, or both, who have the final authority to grant approval of a designated transplant program.~~
- ~~■ Effective temporarily, pending final decision by the MPSC or Board.~~

~~Any application recommended for rejection by the MPSC or the Board of Directors may entitle the applicant to due process as specified in Appendix L: Reviews, Actions, and Due Process of these Bylaws.~~

I.3 Primary Lung Transplant Physician Requirements

~~C. Alternative Pathway for Predominantly Pediatric Programs~~

~~If a physician does not meet the requirements for primary physician through any of the transplant fellowship or clinical experience pathways as described above, hospitals that serve predominantly pediatric patients may petition the MPSC in writing to consider the physician for primary transplant physician if the program can demonstrate that the following conditions are met:~~

- ~~1. That the physician's lung transplant training or experience is equivalent to the fellowship or clinical experience pathways as described in Sections 1.3.A and 1.3.B above.~~

- ~~2. The physician has maintained a current working knowledge of all aspects of lung transplantation, defined as direct involvement in lung transplant patient care within the last 2 years.~~
- ~~3. The physician submits a letter of recommendation from the primary physician and transplant program director of 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.~~
- ~~4. The hospital participates in an informal discussion with the MPSC.~~

~~The MPSC or an Ad Hoc Subcommittee of at least 4 MPSC members appointed by the MPSC Chair is authorized to conduct the informal discussion and make an interim determination. Interim decisions are:~~

- ~~▪ Advisory to the MPSC, Board of Directors, or both, which has the final authority to grant approval of a designated transplant program.~~
- ~~▪ Effective temporarily, pending final decision by the MPSC or Board of Directors.~~

~~Any application recommended for rejection by the MPSC or the Board of Directors may entitle the applicant to due process as specified in *Appendix L: Reviews, Actions, and Due Process* of these Bylaws.~~

D.C. Conditional Approval for Primary Transplant Physician

I.4 Lung Transplant Programs that Perform Transplants in Patients Less than 18 Years Old

A designated lung transplant program that performs transplants in patients less than 18 years old must have an approved pediatric component. To be approved for a pediatric component, the designated lung transplant program must identify a qualified primary pediatric lung transplant surgeon and a qualified primary pediatric lung transplant physician, as described below.

A. Primary Pediatric Lung Transplant Surgeon Requirements

A pediatric component at a designated lung transplant program must have a primary pediatric surgeon who meets *all* of the following requirements:

1. The surgeon meets *all* of the requirements described in *Section I.2: Primary Lung Transplant Surgeon Requirements*.
2. The surgeon has performed at least 4 lung transplants, as the primary surgeon or first assistant, in patients less than 18 years old. These transplants must have been performed during or after fellowship, or across both periods. 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.

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

B. Primary Pediatric Lung Transplant Physician Requirements

A pediatric component at a designated lung transplant program must have a primary pediatric physician who meets all of the requirements described in Section I.3: Primary Lung Transplant Physician Requirements, and either this individual or another member of the lung transplant program must have current board certification in pediatric pulmonary medicine, or be approved to take the qualifying exam, by the American Board of Pediatrics.

C. Conditional Approval for a Pediatric Component

A designated lung transplant program can obtain conditional approval for a pediatric component if either of the following conditions is met:

1. The program has a qualified primary pediatric lung physician who meets all of the requirements described in Section I.4.B: Primary Pediatric Lung Transplant Physician Requirements and a surgeon who meets all of the following requirements:
 - a. The surgeon meets all of the requirements described in Section I.2: Primary Lung Transplant Surgeon Requirements.
 - b. The surgeon has performed at least 2 lung transplants, as the primary surgeon or first assistant, in patients less than 18 years old. These transplants must have been performed during or after fellowship, or across both periods. 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.
 - c. The surgeon has maintained a current working knowledge of all aspects of pediatric lung transplantation, defined as direct involvement in pediatric lung transplant patient care within the last 2 years. This includes the care of acute and chronic lung failure, cardiopulmonary bypass, donor selection, pediatric recipient selection, pre- and post-operative ventilator care, post-operative immunosuppressive therapy, histological interpretation and grading of lung biopsies for rejection, and long-term outpatient follow up.
2. The program has a qualified primary pediatric lung surgeon who meets all of the requirements described in Section I.4.A: Primary Pediatric Lung Transplant Surgeon Requirements and a physician who meets all of the requirements as described in Section I.3.D: Conditional Approval for the Primary Transplant Physician, and either this physician or another member of the lung transplant team has current board certification in pediatric pulmonary medicine, or be approved to take the qualifying exam, by the American Board of Pediatrics.

A designated lung transplant program's conditional approval for a pediatric component is valid for maximum of 24 months.

D. Full Approval for a Pediatric Component following Conditional Approval

The conditional approval period begins on the first approval date granted to the pediatric

component application, whether it is interim approval granted by the MPSC subcommittee, or approval granted by the full MPSC. The conditional approval period ends 24 months after first approval date of the pediatric component application.

The MPSC may consider granting a 24-month conditional approval extension to the designated heart transplant for its pediatric component if the program provides substantial evidence of progress toward fulfilling the requirements, but is unable to complete *all* of the requirements within the initial 24-month period.

Once the designated lung transplant program has met the full approval requirements for the pediatric component, the program may petition the OPTN Contractor for full approval.

If the designated lung transplant program is unable to demonstrate that it has both a primary pediatric lung surgeon onsite that meets *all* of the requirements as described in *Section 1.4.A: Primary Pediatric Lung Transplant Surgeon Requirements* and a primary pediatric lung physician onsite that meets *all* of the requirements as described in *Section 1.4.B: Primary Pediatric Lung Transplant Physician Requirements* at the end of the 24-month conditional approval period, it must inactivate its pediatric component as described in *Appendix K: Transplant Program Inactivity, Withdrawal, and Termination*.